

FEDERAL RESPONSE TO AIDS

HEARINGS
BEFORE A
SUBCOMMITTEE OF THE
COMMITTEE ON
GOVERNMENT OPERATIONS
HOUSE OF REPRESENTATIVES
NINETY-EIGHTH CONGRESS
FIRST SESSION

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AUGUST 1 AND 2, 1983
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FEDERAL RESPONSE TO AIDS

MONDAY, AUGUST 1, 1983

HOUSE OF REPRESENTATIVES,
INTERGOVERNMENTAL RELATIONS
AND HUMAN RESOURCES SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Ted Weiss (chairman of the subcommittee) presiding.

Present: Representatives Ted Weiss, Sander M. Levin, Robert S. Walker, Alfred A. (Al) McCandless, and Larry E. Craig.

Also present: Representative Barbara Boxer.

Staff present: James R. Gottlieb, staff director; Susan Steinmetz, professional staff member; James F. Michie, chief investigator; Gwendolyn S. Black, secretary, and Hugh Coffman, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN WEISS

Mr. WEISS. Good morning.

The subcommittee will come to order.

Let the record show that a quorum was present. We have Mr. Walker, who is the ranking minority member on the committee to my immediate right, Larry Craig at the end of the table on my right, and Barbara Boxer on my immediate left.

I would like to begin this hearing by extending my appreciation to the many witnesses who have traveled here from across the country to express their concerns about acquired immune deficiency syndrome [AIDS] and the Federal Government's response to this public health emergency.

The AIDS epidemic continues its cruel relentless pace. The most recent data from the Centers for Disease Control reveals almost 2,000 reported cases and 730 fatalities in this country alone. The number of cases is still doubling every 6 months. The young age of the victims and the debilitating nature of the disorder deepens the human tragedy of AIDS. And there is little sign that researchers are close to unraveling the mystery of the epidemic.

For far too long our collective response, societal as well as governmental, to the crisis was haphazard and inexcusably slow. But within the last few months, the consensus for urgent and exhaustive action has solidified. The Federal Government, in fulfilling its duty to protect the Nation's health and safety, must mobilize its enormous resources to meet this challenge as quickly as possible. Moreover, Congress, the administration, and the Public Health

Service must act aggressively to provide care and compassion to the victims with respect to their right to confidentiality.

This forum will enable representatives from many groups involved with AIDS to share their concerns and insights about the epidemic with Federal officials. At the same time, it will afford the administration an opportunity to describe its activities and respond to concerns that may be raised. I believe that such an exchange will increase Government responsiveness to those affected by its decisions. In this situation, the quality of these decisions may determine whether people live or die.

As part of this subcommittee's oversight responsibilities, we have initiated an inquiry into the Department of Health and Human Services' efforts to extinguish the epidemic. Unfortunately, the refusal of the Department to provide full access to its staff and records has seriously hampered our oversight work. However, during our preliminary inquiry, many issues have emerged which will be addressed during these hearings. These include:

Are adequate resources available for research, treatment, and prevention?

How comprehensive are the research and surveillance activities?

Has the Government's response been timely?

What is the extent of coordination in the efforts to fight the epidemic?

What is the scope of public education and how effective is it?

How accessible is health care for persons with AIDS?

Is the confidentiality of those who suffer from AIDS being protected?

In the course of our preliminary oversight work, CDC has suggested that their unwillingness to cooperate with this subcommittee was based largely on confidentiality. There is no justification for this excuse to deny Congress complete access to information on the agency's AIDS activities.

I want to make it unquestionably clear, as I have to the Department, that the subcommittee has no interest or intention of collecting names or other identifying information regarding individual patients. There is serious concern whether CDC should even have this information as long as there are alternative procedures in place to assure adequate research. It is my understanding that CDC is in the process of developing such a system so that it will no longer be necessary for any agency at the Federal level to maintain such records.

I believe that there is a strong need to assure that the confidentiality of all patients and research participants is preserved, and I am exploring several possible legislative remedies, similar to the provisions already contained in the Federal law to protect participants in drug abuse and prevention activities.

The growing sense of national emergency that has catapulted AIDS into the headlines has also intensified the fight against the epidemic. Unfortunately, at the same time rumors and misconceptions have unleashed a public panic that diverts attention from the real needs. The epidemic has even been used as an excuse to malign gays and Haitians and to disregard their fundamental human rights. The best way to counter the hysteria and prejudice is to provide the public with accurate and timely information. I am

confident that this hearing will help disseminate this needed information.

Before we ask our first set of witnesses to testify, I would like to ask the other members, starting with Mr. Walker, for whatever opening statements they would care to make.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. Chairman, acquired immune deficiency syndrome, commonly known as AIDS, is a serious public health problem. Determined systematic research, accurate communication and intense cooperation between Government, private citizens, scientists, and community groups will be necessary to insure a timely resolution of the AIDS threat.

I am hopeful, Mr. Chairman, that during the next 2 days of hearings, we can help focus attention on what has been done to discover the cause of AIDS and what can be done to eradicate this unfortunate condition. It is important that we strive to avoid engaging in hysteria and harangues that serve only to scare the public.

There seems to have been a tendency to speak out first about AIDS and check the facts later. Jay Winsten, director of the Office of Health Policy Information at the Harvard School of Public Health, has written:

"Public health information—and misinformation—has a powerful effect on society, and the few highly inflammatory news reports on AIDS has done considerable damage."

Winsten adds:

"The absence of concrete information on AIDS, its cause, its mode of transmission and the extent to which it might spread, permits public fears to grow unrestrained."

For a variety of reasons the homosexual community and the popular media chose to focus extraordinary attention on AIDS. Unfortunately, the resultant hysterical reaction in some segments of our society has been an undesirable and unneeded result.

We should not lose sight of a simple fact. With the knowledge they have now, medical researchers will readily state that most people are not going to get AIDS. Homosexual males, particularly those with very high numbers of sexual liaisons, intravenous drug abusers and users, hemophiliacs, and Haitians are the groups at risk. Let me emphasize that we need to protect these people, we need to help them, but AIDS is not spreading widely on a geographic or demographic basis.

We want an AIDS cure; we need AIDS prevention. If counselors, sensitive to the affected communities, must speak to lifestyle issues to help prevent AIDS, I urge them to do it. Topics like sexual activity or drug abuse are never comfortably discussed but doctors, mental health officials, and community counselors must be prepared to do so if it can mean one less person with AIDS.

I spoke of a cure, and I believe we will eventually solve this medical mystery. It will be done, most likely, by painstaking research and through an accumulation of knowledge. We should be careful to avoid the inevitable push for more money as if dollars are a magic potion.

Let's let our scientists work. We can prod them, but let us allow for the time needed to get all the facts; let us have the necessary peer review and let us have the studies and exchange of informa-

tion that will eliminate this awful problem. More money may be needed but let us use our resources wisely.

Attention has certainly been focused on AIDS. Research is underway within Federal agencies and in university and private laboratories. Let us maintain our perspective, deal in facts, and hope for the earliest possible resolution of this unfortunate problem.

Thank you, Mr. Chairman.

Mr. WEISS. Thank you very much, Mr. Walker.

Before we proceed, I indicated previously that Mrs. Boxer, who is a member of the full committee, is with us. We have also been joined by Mrs. Burton of California. We may have other members join us during the course of these hearings today and tomorrow.

Without objection, I would like permission from the subcommittee to allow any members on the full committee or Members of the House to join with us and to participate to the extent that their time permits. Without objection, it is so directed.

Let me ask at this point Mr. Craig if he has any comments to make.

Mr. CRAIG. I compliment you on holding these hearings. I think that Mr. Walker has stated both the obvious and the necessary as it relates to this most critical national problem. I hope that this hearing, and those who attend and participate in this hearing over the next couple of days, will focus not only on what we are currently doing, but what must be done to bring this problem within the bounds of control, and hopefully to find a solution and a cure to this disease.

From what I have heard and am now aware of, there appears to be a growing national hysteria that need not continue if the kind of information that can go forth from this hearing is allowed to go forth and is responsibly reported in the press. It cannot be treated in that way if we are to bring it to a conclusion and allow the agencies of this Government, who are now pouring millions of dollars into the necessary and appropriate research for this problem, are allowed to address it in the only way they can, as it relates to medical science and the proper procedures for bringing this problem to a conclusion.

I hope that is the goal of this hearing. If it is handled and conducted in a responsible fashion, that certainly can be the outcome, and we can be direct participants in solving this most important national problem, Mr. Chairman.

Thank you.

Mr. WEISS. Thank you, Mr. Craig.

Mrs. Boxer?

Mrs. BOXER. Thank you.

I want to thank the members of the committee for allowing me to participate in this particular subcommittee hearing on a subject that is very close to my heart and to my congressional district. I want to thank the chairman for holding these hearings and for the leadership he has shown in fighting this disease, and I have worked with him on many bills.

The tragedy of AIDS disease is very well known, as I said, to my congressional district. But only with the understanding of Members of Congress from all over this country will we be able to win this fight.

Recently the Congress appropriated \$12 million for AIDS research. We need to do more. Dollars will have to fund this research just as dollars funded research for all other baffling disease.

These hearings give us an opportunity to examine how well our Government is responding, and what more we can do to ease the pain and ease the fears of the American people and, above all, help to find the cause and cure of AIDS.

Thank you, Mr. Chairman.

Mr. WEISS. Thank you, Mrs. Boxer.

We have just been joined by one of the more active members of the subcommittee, Mr. McCandless.

Would you care to make an opening comment?

Mr. McCANDLESS. Thank you very much, Mr. Chairman.

I have no statement at this time.

Mr. WEISS. Thank you.

I think we are ready to proceed at this point with the hearing.

I think the best place to begin is to hear from witnesses who are struggling each day with the terrifying prognosis of AIDS, the names and faces behind the statistics announced each week. They are here to share their personal and unique experiences, to help the Government become more responsive and sensitive to their needs, and to participate in the decisionmaking that affects their survival.

We are an oversight and investigative committee. We administer an oath or affirmation to each of our witnesses.

So first let me introduce the three of you: Michael Callen of New York, Roger Lyon of San Francisco, and Anthony Ferrara of Washington, D.C.

We want to welcome each of you on behalf of the subcommittee. We very much appreciate your willingness to come before this subcommittee and share with us your personal experiences and thoughts regarding this epidemic.

I would appreciate if you would all stand at this point, raise your right hands.

Do you affirm to tell the truth, the whole truth, and nothing but the truth?

Let the record indicate each of the witnesses has nodded affirmatively.

Thank you.

We have asked you, instead of submitting prepared statements, as is the usual course, if you would simply each briefly recount your own story of being diagnosed and describe the emotional and physical dimensions of the change in your life. If we may, let us begin with you, Mr. Callen.

STATEMENT OF MICHAEL CALLEN, NEW YORK CITY

Mr. CALLEN. In December of 1981 I had some blood testing done by my private physician, and those tests indicated that I was immune deficient. In December of 1981 there was very little known about this disease, but there was in the gay press beginning to be reports of increased instances of very unusual diseases, and they outlined some of the symptoms. I was very concerned because I had some of these symptoms—fevers, night sweats, general lymphade-

nopathy, swelling of the lymph nodes, malaise, fatigue. So I had myself tested and, as I indicated, in December of 1981 I was told I was immune deficient.

The effect of being told that I was immune deficient was devastating. I called my parents and said "I am going to die." I was not hospitalized until the summer of 1982, when I was diagnosed with cryptosporidiosis, which is one of the qualifying opportunistic infections according to the CDC definition of this syndrome.

I was hospitalized for over a week with what is known as the wasting syndrome. It was the lowest point of my life. I was convinced from everything I read and heard that I was going to die. But I recovered from that specific infection, and I was rehospitalized in the fall of 1982. They suspected pneumocystis pneumonia. I had a bronchoscopy performed and other tests. It turned out to be bronchitis. But my story really illustrates one of the consistent stories for people who have this syndrome. So little is known.

When my doctor indicated to me in December of 1981 that I was immune deficient I said, "What does that mean?" And he said, "We don't know." So now a lot of people who are being told they are immune deficient are simply waiting, waiting for the next infection.

Now, I have come to believe that I am going to beat this disease. I no longer think that I am going to die. But it is very difficult when you pick up newspapers or turn on the television and you hear that no one has fully recovered from this syndrome, and that 80 percent of those diagnosed with the syndrome are dead after 2 years.

So I guess that is my story—waiting around for infections, checking myself every morning for Kaposi's sarcoma lesions and waiting for information about this disease to be forthcoming.

Mr. WEISS. Thank you very much, Mr. Callen.

Mr. Lyon.

STATEMENT OF ROGER LYON, SAN FRANCISCO, CALIF.

Mr. LYON. Thank you, Mr. Chairman.

I was diagnosed with Kaposi sarcoma on February 3 of this year. Prior to that time I was having absolutely no AIDS-related symptoms whatsoever. On physical exam at that time three lesions were found internally. Prior to that I was being treated for an amoebic disorder, no real symptoms of AIDS.

February 3, basically 100, I think more exactly 180 days ago, I became aware I had a life-threatening disease. February 4 I entered UC, I went to University of California without an appointment, at the suggestion of my doctor, and started what is called their staging process—a battery of tests to determine the extent of this disease. At that time I was basically numb. I had no feeling. I was just moving. UC has been—they have been very kind and helpful.

One of the tests that is used to determine the extent of a disease today diagnosed as pneumocystis pneumonia, which my doctor was 100 percent sure I had, was a bronchoscopy.

On February 28 I went in for a bronchoscopy, which is basically an invasive procedure, a lung biopsy. At that time the doctors took

six biopsies. One of the biopsies, unfortunately, gave me a pneumothorax, collapsed my lung, and at that time I was hospitalized for 4 days. Also, at this time my family was visiting, they had no idea of what was going on, did not at that time even know that I was gay. So the first time they saw me was in the hospital with chest tubes, and they were quite concerned. Fortunately for me, they took everything as well as—better than I could ever expect. They were wonderful.

Since then I have gone through the staging process, upper and lower endoscopies, other invasive procedures. They wanted to do lymph node biopsies to determine whether it is in the lymph nodes but I refused. Fortunately, I have been very lucky. The disease, the Kaposi's sarcoma, has not spread. There were three lesions, one was biopsied. The remaining two appear to have disappeared, gone into remission. That does not mean I do not have AIDS. Basically that means I do not have symptoms of Kaposi's sarcoma at this time. But my immune system is still very suppressed and extremely susceptible to many opportunistic infections.

Since that time, in late April I came down with a very severe shortness of breath. The doctor again thought I had pneumocystis pneumonia. Fortunately, he was only 80 percent sure at this time. I was convinced that it was not. They did another bronchoscopy and they found cytomegalovirus. That was all. Since then, that has cleared up, and I have been very fortunate that no other symptoms have appeared.

However, it is a matter of day-to-day waiting, waiting for something to happen, living in constant fear that I am going to wake up one morning to find lesions, waking up finding that I have some other opportunistic infection, cryptosporidiosis, possibly pneumocystis pneumonia.

At this time I am basically living in fear of what is to come. Other than that, it is a day-to-day wait-and-see process.

Mr. WEISS. How old are you?

Mr. LYON. 34.

Mr. WEISS. Mr. Callen, how old are you?

Mr. CALLEN. 28.

Mr. WEISS. Mr. Ferrara?

Mr. FERRARA. 30.

Mr. WEISS. If you will respond to the question that we asked.

STATEMENT OF ANTHONY FERRARA, WASHINGTON, D.C.

Mr. FERRARA. The first idea there was something wrong with me was last summer. I had lymphadenopathy, swollen lymph glands especially around the jaws and throat and under the arms. That continued for a few months, but the whole time I felt quite good. I continued to run and jog and I experienced no fatigue, no night sweats, no fevers. In fact, in November, I finished the Marine Corps marathon, when I was supposedly very, very ill.

The lymphadenopathy went away. So I thought nothing further of it. But all along, I had been reading about AIDS, and of course, as every conscious gay man should be, was very worried about it.

In February, I saw two small purple lesions, one on the inner aspect of each of my lower thighs, and I knew what they were, or I

knew what they could be, and I said I would wait a month and if they were still there in a month I would seek treatment or seek a diagnosis. Well, in the beginning of March they were still there.

I belong to the George Washington University HMO. I went there and told them that they really should biopsy one of these lesions to see what it was, gave them my sexual history and told them that there was a good chance I did have AIDS. They biopsied it, and the diagnosis was Kaposi's sarcoma. That was March 8.

Obviously the first day I was very, very upset, and I went into a deep depression for about a month. I came home that night and my significant other held me in his arms, and I said to him, "Why do I feel like Ali McGraw, it is just like a movie, it is really terrible, it is the most horrible thing that ever happened."

My depression lasted a month, and I decided if there was any chance I was going to get over this, if I had any chance of surviving at all, I would have to have a more positive attitude and just continue on, live my life as best I can, and try to not worry about it too much.

I was very lucky. I had the choice of being treated at GW by a very good cancer specialist there, who instilled a great deal of confidence in me, or I had the choice of being treated at the National Institutes of Health. I think it was an easy choice, because I think—NIH wanted me because I was so healthy at that point. I was a good specimen for research I think. And also, I felt that if I have the disease and no one knows anything about it, the best place to be treated would be where they are doing the research.

The choices were being treated at GW, with a mild form of chemotherapy called VP-16, which now is thought doesn't have much effect on Kaposi's sarcoma, or being treated with interferon at NIH. So I have been on and off at NIH since then. I have gone through two protocols, one was alpha interferon, and the second was gamma interferon. Both are made from blood cells, one is made—the gamma interferon is made from the immune blood cells themselves, that is my understanding.

I am going to go back. In fact when I leave here today I am going back there and probably going to spend the next 6 weeks doing a third protocol, 2 to 3 weeks of plasma pheresis, and then interleukin 2, which has been getting a lot of press lately. And that brings me to today.

Mr. WEISS. Thank you very much.

Because I know that all of my colleagues on the panel will have numerous questions and because we have a large number of witnesses, I am going to defer further questions on my part and begin the 5-minute questioning phase. At the end of the questioning, if there are still areas that you feel we have not touched on, I will give you an opportunity to come back and fill in whatever gaps exist.

With that, if I may, let me ask Mr. Walker if he has questions.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. Ferrara, what has been the attitude of the nurses, the technicians, and the officials at NIH toward you and the other persons with AIDS who are under treatment at NIH?

Mr. FERRARA. I think the nurses and the doctors that deal with us the most, those in the Institute of Allergies and Infectious Dis-

eases and in the National Cancer Institute, are invariably compassionate and helpful. The nurses and doctors take the minimal precautions possible.

When the nurses may come into contact with our blood, for example when they give us an IV, or they give us a shot, they will wear gloves. Other than that, very few precautions are taken, except handwashing when entering and leaving the room. The doctors very often do not use gloves to examine us.

The doctors of course are researchers. So sometimes, because they are researchers, they are not really schooled in the best bedside manner, but I think generally they are extremely compassionate. They are working very hard, many of the doctors are there from morning until late at night. They are as desperate to find a solution to this problem as we are.

Mr. WALKER. Some critics of the Federal response to AIDS have criticized the use of interferon, which you said you have been treated with, and the potential of interleuken 2. I understand that you are going to undergo treatment with interleuken 2. Could you tell the subcommittee how you feel about the treatment that you have had with interferon, and then also whether you are optimistic or pessimistic about your upcoming treatment with interleuken 2?

Mr. FERRARA. The first type of interferon, the alpha interferon, which I believe is being used elsewhere in the country, I felt had some effect. I felt that it stopped the spread of the Kaposi's. I felt that there was some remission.

The doctors, however, felt that the response was not good enough to continue. They would like to see a 50 percent remission before they would continue with a particular drug.

I think the problem with interferons is that there is very little known. They are still being experimented with. It is like penicillin when it was first discovered, they didn't know what dosage to give, they didn't know how to give it. I think that is the problem the doctors are experiencing with the interferon. I think there is hope there.

The second type of interferon, whether it was the dosage or whether it was for other reasons, whether the drug itself simply did not work, there was a spread in my Kaposi's lesions. I felt that the gamma interferon had no effect at all.

Obviously I am very, very hopeful for interleuken 2. Every AIDS patient clings to hope. And the laboratory results for interleuken 2 are extremely good. The doctors feel it has the potential, although the results at this point are inconclusive—it has the potential of restoring the immune system to near normal.

My layman's understanding of what it does, and this might be more beneficial to you than what the doctors tell you, is that it essentially bypasses the T-4 cells, the helper cells, and it is the substance that the T-4 cells emit to tell the other body cells to fight disease. An analogy would be insulin for diabetics. It would bypass the T-4 cells and have the effect that those cells would have on their own.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. WEISS. Thank you, Mr. Walker.

I want to take note of the fact that we have just been joined by another outstanding Member of the House on our committee, Mr. Levin of Michigan. Welcome.

Mrs. Boxer.

Mrs. BOXER. Thank you, Mr. Chairman.

I wanted to ask the panel, if anyone can address this, if you feel that you are given enough information about the disease, and then the second part, do you think that the gay communities throughout the country, from your knowledge, are being given enough information so that they can perhaps make some changes in their life to try and avoid it.

Would you comment on that?

Mr. CALLEN. Well, I am still using the same information that I knew in early 1982 when people asked me questions about the disease. As far as I can tell, there hasn't been much new information at all. Some members of my community appear to be numb, because there hasn't been much new about the disease coming out from research centers. A lot of people just don't want to hear about it any more, and they say "when you have the cure, let us know."

I think that certainly in New York City the gay community has been straining to make what little information there is available in a way that is accessible to the community, and organizations like the Gay Men's Health Crisis have done an outstanding job disseminating what little information exists.

Mrs. BOXER. Mr. Lyon.

Mr. LYON. In San Francisco it is very much the same experience as New York. There is no new information. Every bit of information that has come out has been very widely disseminated. People are hungry for information. The city government, the public health officials, the city of San Francisco have, as far as I am concerned, gone overboard and made information available. Public forums have been held. Many of the health care facilities have asked patients and health care officials to come and explain, "tell us everything you know, give us the information in order that we can dispel many of the fears."

The main problem is there is no new information. It is a rehash over and over and over again of the same information.

Mr. FERRARA. I agree with Mr. Lyon. I believe the problem is more misinformation than lack of information.

I do my best to do as much as I can to dispel misconceptions about the disease. People don't have to be afraid to be in the same room with us, people don't have to be afraid to swim in the same swimming pool. I believe that gay organizations across the country should be given more information concerning guidelines that can be disseminated to the gay community in terms of—in terms of ways that gay men can protect themselves from the disease, rather than causing the paranoia and hysteria that the information that has been disseminated so far has caused.

Mrs. BOXER. Do I have time for one last question?

Do you find that you have a support system out in your communities to help you get through this experience?

Mr. FERRARA. Shall I start?

Yes. Personally, my support system is quite good. I have a lover who has been very supportive and very loving. I have good friends

who help me a great deal. No one has shunned me. My employers have been very good to me. They have given me a parking space downtown so I won't have to ride on the Metro.

I believe the gay community can do more to provide support services for people who are stricken with the disease. I think part of the problem there is again a lack of information.

The gay groups in Washington are having great difficulty finding out who needs help. I think there must be more coordination between the hospitals who treat AIDS patients and the gay community support services. There is a problem there of course with doctor-patient confidentiality. But I believe that can be gotten around by having the hospitals involved and the doctors involved make the patients aware that these support services are available.

For example, the doctors and the nurses at NIH are very compassionate and very supportive. But they are not gay. They don't understand the special psychological needs of gay people. The gay community can help there, and I believe that many of the hospitals who are treating AIDS patients are hindering those efforts.

I believe that information can be disseminated and without breaching the doctor-patient confidentiality problem.

Mr. CALLEN. I cofounded a support group called Gay Men With AIDS, which is run by those of us gay men who have been diagnosed with the syndrome. It has made the difference for me. It is really what relieved some of the fear on a day-to-day basis. I saw other people fighting for their lives. We share information, we talk about doctors, hospitals, and treatments. For me AIDS was another closet, was another coming out.

When I was first diagnosed there wasn't the terrible stigma that is attached to being diagnosed with AIDS now. So it never occurred to me not to identify myself to my friends as having the disease. But since that time, because of a lot of the misinformation and often hysterical coverage in the media, I know a number of people who refuse to identify themselves to their community, even to their family, as having the syndrome, because there is such tremendous stigma and isolation attached to it.

But my support group meets in my living room, because there isn't any other space. I know in New York City we are trying to get a community center, but apparently we are going to have to raise \$2 million to purchase it.

I am a member of another support group which meets in the cramped offices of the National Gay Task Force. I am really glad they have made this space available. But it interrupts their activities. We sit in the room where their hotline is. And people come and go.

I think that there is a need for government to support the community-based efforts in the various cities, to make support services available to people who need it.

Mr. LYON. My support system is primarily all private. Friends, I have a fantastic group of friends who have been behind me, in every decision that I have made all the way through. My family is right there also.

There are also some other private groups. One I will mention, the Shanty Group, the AIDS-KS Foundation. Information? There are phone lines available if you want to call someone, if you want

to talk any time of the day, they are there. Primarily personal support groups. Nothing that anyone else, including the Federal Government, has set up. It is all personal. And I think those are the best support groups.

Mrs. BOXER. Thank you, Mr. Chairman.

Mr. WEISS. Thank you very much.

Mr. McCandless.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

Gentlemen, the Department of Health and Human Services has supplied us with statistics. I find them interesting and wish to throw them out for whatever value it may be.

If you wish to comment, it might be of assistance to us, and particularly me, in understanding the circumstances a little better.

According to these statistics, the total cases reported, both United States and foreign, are approximately 2,100. Of these two-thirds are in the States of New York and California, with the greatest percentage in the metropolitan areas of New York City, San Francisco, and Los Angeles.

Can you comment on why there is a concentration of cases in these areas with respect to the total figures, and the rest of the United States?

Mr. CALLEN. Well, I am not an epidemiologist. I think it indicates there are many, many unusual features about this syndrome. It indicates the need for really high quality epidemiological research to explain the unusual pattern of this disease. And to date, none of the epidemiology has been published.

One hears rumors that the epidemiology of the CDC was poorly constructed and poorly written. I don't know what the reason is, but I understand that they have had some difficulty finding a medical journal to publish the study.

The question of epidemiology and why the disease seems to be clustered in large urban centers will tell us a lot about who gets this disease and who doesn't and why. And so I don't have any more answers than anybody else. But I am very, very eager for the epidemiology to be done and done right and done quickly.

Mr. WEISS. May I indicate, although obviously the question is absolutely appropriate to these witnesses, there will be additional witnesses in panels later on who can address some of the expert areas.

Mr. MCCANDLESS. Thank you.

That is all I have at this time, Mr. Chairman.

Mr. WEISS. Thank you, Mr. McCandless.

Mr. Levin.

Mr. LEVIN. I don't have any questions.

Thank you for your testimony.

Mr. Craig.

Mr. CRAIG. Thank you very much.

To all of you on the panel, thank you for your openness, your honesty and forthrightness in your testimony. It is critically important that you are willing to come forward and discuss this serious problem in the way you have—if we are to be participants here in helping.

I have a couple of questions, I think reflective of how the gay community is responding. You mentioned earlier, some fears and concerns on your part and the community's part.

Has there been, or is there now, because of the fear of this disease, an exodus if you will, from the areas or the communities Mr. McCandless talked about, New York and San Francisco specifically where the larger number of cases are reported. In places where it seems to be relatively well understood that there are large populations in the gay community—have people left the community out of fear? Are they leaving?

Would any of you respond to that, as best you can?

Mr. FERRARA. Well, first of all, I think it is impossible to leave the gay community. You are either a member of the community or not.

Mr. CRAIG. OK. That is a valid statement.

What I am saying is, are the gays leaving the area in which they resided because of fear?

Mr. FERRARA. I see. No, I don't think so. I think we are being much more careful about—they are much more worried. But I don't think there is a mass exodus from large urban areas.

Mr. LYON. I haven't seen or even considered the fact that there has been an exodus from any area. I think what we are finding within the gay community is a very strong bonding, a coming together, a recognition of a problem. I think that it is strengthening the gay community. I don't see anyone leaving because of the fear of AIDS.

Mr. CALLEN. Many of us go into these specific cities to escape the prejudice that we experience as gay and lesbian people. So, where else are we going to go? Also, as was mentioned, our support systems are in these cities—our jobs, where we will get our insurance. For most people there is not the option to go anywhere else. If you are an openly gay person—you have to—most gay people I know tend to congregate in large urban centers, because there is perceived to be greater tolerance.

Mr. CRAIG. With those responses in mind, you say there is a growing bond, if you will, toward support and assistance within the community. Does the gay community view themselves as a direct participant in assisting in getting this problem under control? Because—one of you made some comments earlier that there seems to be a reaction on the part of some—I don't want to hear any more about it, tell me when there is a cure, or tell me when there is new information, but until that point don't bother me.

My reaction to that comment was that that would be very negative to any assistance that a cooperative effort on the part of medical science and the community working towards a solution to the problem. Is that a prevalent attitude in the community, or was it a reaction that is now turning about toward cooperation?

Mr. CALLEN. I think there has been unprecedented cooperation from the community. If money were available for screening, I think you would have the entire community available.

When I made the comment that there are some people who don't want to hear, the reason they don't want to hear is because there is no new information. They have already absorbed the old information, and they don't like to be beat over the head with the same old information. They have already made whatever adjustments that they plan to make to protect themselves from the disease, and

a lot of people are very, very tired of dwelling on the tragedy of this disease.

Mr. CRAIG. Thank you, Mr. Chairman.

Mr. WEISS. Thank you, Mr. Craig.

We have touched on the emotional and medical aspects of the disorder and your reactions to it.

I wonder if we could touch just a bit on your professional or occupational background—how the syndrome has affected that, what kind of insurance coverage you have and who pays for the costs of your medical care.

We know, Mr. Ferrara, that you are at NIH. But I wonder, Mr. Lyon and Mr. Callen, how you and others in your situation are coping with this particular aspect of the problem.

Mr. CALLEN. Well, at the time I was initially diagnosed, I was a paralegal, and I had just changed jobs 3 months prior to my diagnosis. I have about \$6,000 in hospital bills that the insurance company has declined to pay. They are claiming preexisting condition. It is unclear to me exactly why: whether they just are doing that to do it—as I understand some insurance companies do—or whether because the etiology of AIDS is so mysterious, they are going to claim that I had the syndrome at some point in the past. I am being chased by the hospitals for about \$6,000. I don't know how I am going to pay it.

Mr. WEISS. Mr. Lyon?

Mr. LYON. I work for a large leasing company. I am a sales representative. I am fortunate in the fact that I am still able to work. Many of the patients, many of my friends are totally unable to work. They are lucky if they can get up in the morning, shower, and go on about their daily activities.

As far as the costs, to date my medical bills have run in excess of \$11,000. And I am not on any treatment whatsoever, not antibiotics, nothing. It is all diagnostic. Fortunately, my insurance, private medical insurance, has paid approximately 80 percent of that. That still leaves somewhere in the neighborhood of \$2,500, \$3,000 that I am responsible for.

Many of the patients, I think far, far more of the patients, do not have the benefit of private medical insurance. Many are on disability. Many are now seeking social security which, thank God, has become available. It is, however, a very lengthy time-consuming process. So much of the costs to many of the patients is thrown back on the community as a whole. Many people are just indigent in this area.

Mr. WEISS. Mr. Ferrara?

Mr. FERRARA. I am also very lucky to be able to continue working. I am a Federal employee. As I said before, I belong to the GWHMO. So it was—I was very lucky in the sense that either choice, either being treated by the HMO, which would cover all costs, or being treated at NIH would be for free. I haven't had to pay anything up to this point, except for a few dollars that the HMO didn't cover.

However, I think part of the problem is the drugs involved are so extremely expensive, the experimental drugs. If any of them work, what my fear is is that, one, it is going to be too expensive to be

widely disseminated, and two, the experimental status of the drugs may cause insurance companies to avoid paying for them.

Mr. WEISS. Has anyone at NIH indicated to you what your costs would be for the treatment and medication if in fact you were able to and had to secure care through private sources?

Mr. FERRARA. If I had to pay for the drugs I receive at NIH, at this point—I am not sure about this, but from indications that I received, the cost of the drugs would have already exceeded half a million dollars.

Mr. WEISS. Because of the experimental nature?

Mr. FERRARA. Because of the experimental nature, and because the drugs very often at this point cannot be genetically engineered through the recombinant DNA method which is cheaper than creating them by essentially having all these blood cells and cooking up the drug and letting the cells create the drug themselves. So that the processes to create these drugs now are extremely expensive.

Mr. CALLEN. I think one can anticipate this problem of experimental treatment as being rejected for insurance coverage. I know of one instance where a friend of mine went for plasmapheresis. His insurance declined to cover that with the justification that any treatment for this disease is experimental because it is thought to be new. So there are no treatments of any proven efficacy.

I think we can anticipate that increasingly insurance companies are going to decline paying for any treatment with the justification that it is all experimental.

Mr. WEISS. Given the parameters of our hearing and the time-frame in which we are operating, that completes the questions that we have specifically directed toward you.

However, I don't want you to go without giving each of you the opportunity to fill in whatever gaps you think we have left. If there is anything that you want this committee or the Congress or the American people to know about AIDS generally or a particular situation, now is the time to do it. Any and all of you are welcome at this point to make closing comments.

Mr. Lyon?

Mr. LYON. I came here today with the hope that this subcommittee would be able to do everything possible to halt the spread of this disease. AIDS has been called the number one health priority of the Nation. It certainly is my No. 1 priority.

I came here today with the hope that this administration would do everything possible, make every resource available—there is no reason this disease cannot be conquered. We do not need infighting, this is not a political issue. This is a health issue. This is not a gay issue. This is a human issue. And I do not intend to be defeated by it. I came here today in the hope that my epitaph would not read that I died of redtape.

Mr. WEISS. Thank you, Mr. Lyon.

Mr. Ferrara?

Mr. FERRARA. I think I would just like to say that there is probably a limit to how much money the research community can spend on research for the disease. I think there are just so many minds that can go around and do so many experiments and spend so much money to try to find a cause, a cure, or a control.

Beyond research, I think if more funds are to be made available, a place where they can do a lot of good is in screening programs—moneys given directly to the gay community or organizations within the gay community that can set up this sort of thing, screening programs, to try and find out just how many people there are out there with the disease, and in that way halt the spread of the disease.

Mr. WEISS. Thank you.

Mr. Callen?

Mr. CALLEN. Well, as a person with AIDS, I suffer in two basic ways. I suffer from the disease itself, and I suffer from the stigma attached to being diagnosed with this disease. The end to both aspects of this suffering will come only if the vast resources of the Federal Government are turned on this problem.

We need answers to the pressing questions of cause, cure, and contagion. And so the bottom line is, as it almost always is, money. But in order to make that money accomplish something, it has to be well spent. And I think that one of the things that is encouraging to me about this committee is that you have requested access to information from the governmental agencies dealing with this problem.

I have yet to see a comprehensive plan of attack emerge from the Government. What do they plan to do, in what order? Is there a master plan for research which is guiding their funding requests? Are they developing an animal model? What treatment options are being pursued? Which have been discarded? Why?

So the first priority is money. The second is that the money be well spent, and that will require that there be a very clear master plan. There needs to be some sort of accountability, which is what this committee is all about.

I would also like to speak briefly to the issue of confidentiality, which is beginning to be mentioned more frequently in the context of AIDS research, and to clarify, because I think that the issue is often misunderstood.

The issue of confidentiality is really two issues. As you know, the information being collected by the Centers for Disease Control involves basically very sensitive personal information. So there exists the potential for the political abuse of information collected in the context of surveillance.

But the other more important issue of confidentiality, as I see it, is that we need to remove any and all obstacles to collecting accurate information. And the basic scenario is this: A representative of the Federal Government, a CDC representative, shows up at the bed of a person who has just been diagnosed with a life-threatening illness, and asks that person to admit to illegal acts—for example, drug abuse, sexual acts which are illegal in most States, acts of prostitution. Assuming for a moment that those questions are necessary to elucidate the etiology of this disease, one needs to create a situation where patients are likely to give truthful responses to be forthcoming with detailed information.

And so the issue of confidentiality, as I see it, is simply reassuring communities which, as far as I can tell, have no reason to trust the Government blindly. We need to be reassured that the confidentiality of this very sensitive information is being protected. So I

view whatever measures have to be taken to insure confidentiality as justified in a cost-benefit sense.

If you can assure people that the sensitive information being collected is being protected—that it cannot be used against them—you will encourage them to give more truthful responses; and truthful responses in turn will be more useful to researchers in terms of resolving the mystery of AIDS.

So to reiterate, money; money that is well spent; and sensitivity to the issues of confidentiality. I guess that is basically what I would like to see.

Mr. WEISS. Thank you very much.

I want to thank all of you on behalf of the subcommittee, the full committee, and the House.

As Mr. Craig indicated before, we have nothing but admiration for your determination, perseverance, and courage, both in fighting the syndrome itself and in sharing your knowledge and experience with the rest of us.

Thank you all very, very much.

Our second panel consists of representatives from affected communities: Virginia Apuzzo, executive director, National Gay Task Force; Stephen Endean, executive director, Gay Rights National Lobby; Dr. Jean-Claude Compas, vice president, Haitian Medical Association Abroad, and Alan Brownstein, executive director, National Hemophilia Foundation.

We will hold off questions until the witnesses have all completed their testimony. I know that you all have prepared written statements, and those will be entered into the record without objection, in their entirety. If you wish to highlight or summarize your remarks, please feel free to do so.

Again, if you will stand for the affirmation.

Do you affirm that you will tell the truth, the whole truth, and nothing but the truth?

Ms. APUZZO. I do.

Mr. ENDEAN. I do.

Dr. COMPAS. I do.

Mr. BROWNSTEIN. I do.

Mr. WEISS. We will begin with Ms. Apuzzo, then Mr. Endean, Dr. Compas, and Mr. Brownstein.

STATEMENT OF VIRGINIA M. APUZZO, EXECUTIVE DIRECTOR, NATIONAL GAY TASK FORCE

Ms. APUZZO. My name is Virginia Apuzzo.

I am grateful for the opportunity to testify today. But I am saddened and, yes, I am angered by the necessity, a necessity brought on by what we perceive to be the Federal Government's policy of gestures and not actions.

Quite simply, from our point of view, Mr. Chairman, the Federal Government's response to the AIDS epidemic reveals that the health care system of the wealthiest country in the world is not equipped to meet the needs of its citizens in an emergency, however brief or extended that emergency might be.

Further, if we take a look at the Federal Government's response to the AIDS crisis it leads unavoidably to the conclusion that

within this administration, there is a sharp contrast between the rhetoric of concern and the reality of response. That failure is underscored when one looks at the record of the lesbian and gay community in filling the gap.

I was pleased to hear the number of questions posed about this. Perhaps I can add additional specifics to the extent to which the gay and lesbian community has indeed responded.

The National Gay Task Force survey of community voluntary organizations found that \$2.3 million was budgeted for AIDS projects in 1983 for the gay and lesbian community, with another \$6.8 million being projected and budgeted for 1984 in the gay and lesbian community. These figures do not include local and State government grants to these groups, nor do they include the value of hundreds of thousands of voluntary hours in these programs.

Indeed, the National Gay Task Force last October opened up a crisis line, an 800 number, that would enable members of the community and the public at large to seek information about AIDS. We are getting in excess of 3,000 calls a day that we cannot respond to. And we are open 8 hours a day, 5 days a week, until 9 o'clock at night, so that we can take care of the concerns and the questions from the Western part of the country.

Our community, is proud of this response. But our experience in the front lines tells us that we cannot be expected to solve this crisis on our own. Our Government must respond to our needs.

We have found the administration has been out of touch with the magnitude of the crisis. It has been following, not leading the general public and the affected communities. In hearings before Congressman Waxman's subcommittee, Dr. Brandt admitted that the fiscal 1984 budget which showed less money for AIDS work than in 1983 was "prepared before we understood in fact how much money it would require."

That belated recognition is shocking enough. What is inconceivable is that the administration has yet to adjust its 1984 budget request.

More than 2 years after this medical crisis became generally recognized, the administration still has not presented a comprehensive plan of attack. Mr. Callen said it as eloquently as it could be said.

More than 2 months ago I wrote a letter to Secretary Heckler asking her to set forth just such a plan. She has been unable or unwilling to do so.

My written testimony submitted to your committee details the failures of the Federal Government's response in, first, setting out requests for research projects to study AIDS, second, in funding those projects which pass its review programs, and third, in even identifying such crucial study areas as the cause or etiology of AIDS, now set for funding for the first time, Mr. Chairman, in October of 1983.

When you look at how NIH is handling the funding of research, what is driven home time and time again is that we lack the resources to do the job, even if you accept the administration's more limited view of what needs to be done.

In point of fact, there are now more requests for applications out than money appropriated to fund them. Even the NIH bureaucracy recognizes a greater need than the budget cutters at OMB. \$9.6

million was appropriated for NIH for basic research on AIDS, in fiscal 1983. State and local governments along with the private sector are coming close to matching that figure on their own. That is a very sad commentary on the Federal Government's response, and what we have come to expect as an appropriate response.

You must know from our standpoint that the Government's timetable has been simply unacceptable. We count not in months or weeks or in days, sir; we count in lives. We count in terms of lives that may very well be lost as a result of a lethargic response.

Because of its mysterious nature, and I submit, because of the groups associated with it, AIDS has generated something just short of a public panic. A good deal of that panic has been fostered by homophobes bent on turning a public health crisis into an opportunity to attack the gay and lesbian community.

Recently we could not ask for a more forthright response in the personal statements of PHS officials like Dr. Brandt, their sincere and willing effort to be out front in reassuring the general public about unwarranted concerns of casual contact with persons with AIDS and members of high risk groups. Unfortunately, the programmatic efforts backing up those statements seem to be very weak, leaving us open to the calculated abuses that we have witnessed in this community.

The hysteria created by those ill-intentioned people cannot be handled by the limited public health education efforts the Federal Government has put into effect; leaving us again very vulnerable. The Federal AIDS hotline, which started with only three lines and now fortunately has added five more, is still capable of handling only a fraction of the 10,000 calls that attempt to get through to it daily, and none of the calls after 5 p.m. eastern daylight savings time, when the hotline is shut down.

Federal public education efforts such as there are concentrate on the general public. That is good. But education about AIDS must also reach affected groups, persons with AIDS, and those who work in very close contact with persons who are from high-risk groups.

We have heard much about health care workers, about morticians, police officers, and others who are fearful of close contact. Most of those fears are unjustified. But it is hard to blame people who have not received clear-cut guidelines and concrete information to assure them. The Public Health Service should be taking a much stronger, a vitally needed lead role in this area.

Perhaps the one issue that is most inciting of hysteria has been concern about our Nation's blood supply. Let me restate the gay community's position on the issue of blood donations. At every possible forum, we have urged that those in our community who feel they might be at risk to AIDS or feel unwell to refrain from donating blood. We have felt that that is the responsible position. Recent reports about dangerously low blood supplies directly result from the Government's failure to investigate the transmissibility of AIDS through blood, to develop a marker for AIDS in blood, to test surrogate markers, or to study the safety of the blood supply and giving blood.

The negative effect of this has been that blood donations seem to have endangered more lives by virtue of the lack of blood supply than AIDS itself.

From Secretary Heckler on down, the Health and Human Services Department has of late done an excellent public relations job, reassuring the public that there are not risks in giving blood, and that the dangers of receiving AIDS from a transfusion are minimal at worst. But where were they, sir, a year ago when this issue first surfaced and the overreaction could have been addressed? And why have they still not done the research needed to garner scientific support for that position, a position that the public wants to be assured about?

In another vital area, the particular concerns of groups at risk to AIDS are reflected most clearly in the issue of confidentiality, an issue I know that is quite controversial and of considerable importance to you, Mr. Chairman.

This issue has been used in what we consider to be unscrupulous ways, to paint the gay and lesbian community as irresponsible and unwilling to cooperate with CDC in the fight against AIDS.

At the very same time, we see that CDC has failed utterly to recognize the most basic patient rights of confidentiality and privacy. It is used as an excuse, sir, to deny this committee access to information vital to the legitimate performance of the oversight function.

I want to state unequivocally our position on confidentiality, and to offer some legislative proposals to provide strong and lasting protection for the privacy and confidentiality of persons with AIDS.

When we ask what steps have been taken to protect the confidentiality of the information CDC has already gathered, we are told, I have been personally told "Trust us." But trust requires a history of credibility, and that is conspicuously lacking.

Some of the most basic social science research precautions for protecting confidentiality have not been observed.

Now, let me make one statement very clear. No community could be more concerned about hearing all the necessary information to find an answer to AIDS. It is our community that is being ravaged by this disease. We can and we must legitimately ask whether collecting full identification information along with sexual histories is an essential ingredient to epidemiological research.

The National Gay Task Force and LAMDA Legal Defense and Education Fund are proposing today that the Congress adopt legislation to extend to all persons who are part of a federally-funded research or surveillance program the same confidentiality protection others already have under Federal law. The Drug Abuse Office and Treatment Act of 1972, for example, provides that medical records may be disclosed "only in accordance with the prior written consent of the patient," except in rare cases.

Similar language covers alcohol abuse programs.

We propose that Congress enact legislation extending this protection to the privacy of medical surveillance and research documents to persons with AIDS, both in Federal agencies and those local jurisdictions receiving Federal funds.

With such legislation in hand, the concerns of our community would be addressed, and another precedent for privacy in patient rights would be established.

Mr. Chairman, there is a conclusion that my community is drawing—and the conclusion is that who is being struck with this dis-

ease is part of why we haven't found an answer to that disease. We live with this condition in our lives every moment.

It is vital that you, sir, that your committee, that the Congress understand basic aspects of our lives. We are part of a society that has for the most part treated us as outlaws. We have lived as outlaws in our own society. To ask for trust without guidelines, to ask that we endure what appears to be an interminable time lapse between the identification of a problem and the pursuit of a resolution of that problem is asking, too much of this community.

Thank you.

Mr. WEISS. Thank you very much.

[The prepared statement of Ms. Apuzzo follows:]

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TESTIMONY

VIRGINIA M. APUZZO

Executive Director

August 1, 1983

Subcommittee on Intergovernmental Relations & Human Resources
U.S. House of Representatives

Member: Leadership Conference on Civil Rights

Mr. Chairperson, I want to thank you for calling these hearings today. They address an issue critical for millions of Americans. We must give hope to those who are worried about Acquired Immune Deficiency Syndrome--hope that the government will finally respond adequately to this crisis.

Mr. Chairperson, what you will learn from today's hearings is startling. The federal government's response to the AIDS epidemic has demonstrated that the health care system of the wealthiest country in the world is, quite simply, not equipped to meet the medical needs of its citizens in an emergency or an extended crisis. That should be a source of deep concern to all Americans--not just the 20 million gay and lesbian Americans the National Gay Task Force represents.

Before going into detail, let me point out some of the more shocking instances of the federal government conducting business as usual--and thereby threatening the well-being of its citizens.

- Two years after the federal government, belatedly, recognized that AIDS was indeed a public health problem, the National Institutes of Health have still not funded research into the etiology--the cause--of AIDS. The first research to be funded begins in October 1983. This delay is unconscionable. It does not take a medical degree to realize that unless you are looking into the cause of a disease, you aren't likely to find a cure. The process of funding NIH research is generally too slow, too cumbersome, and the mechanism for setting priorities is obviously askew.

- The Centers for Disease Control have been forced to beg, borrow, and steal from other vital programs to support their work on AIDS. The medical detectives who Secretary Heckler says have adequate funding to do their job have shut down their hepatitis control program and cut back on VD control and childhood immunization to divert resources to AIDS work that is inadequate at best. Surveillance activities are minimal and not providing the basic information we need. And support services to local governments are only beginning to come forth well into the crisis.

- We are all painfully aware of the hysteria about AIDS that is sweeping many parts of the country. The federal government has responded with public education efforts that, while sincere and responsible, were initiated after the hysteria struck. And even these efforts are woefully underfunded, and lacking in personnel and resources.

- Perhaps the one issue that has most incited this hysteria has been the concern about our nation's blood supply. Unwarranted fears about the safety of giving and receiving blood could have been avoided had the government responded properly. The Public Health Service has recently done a good job of reassuring the public about the blood supply--but it has not initiated basic research regarding the safety of blood, and whether screening out high-risk groups is indeed necessary. In the meantime, because of diminished supplies, the lives of all Americans are being placed in jeopardy.

- This public health crisis has struck minorities who have traditionally been the victims of officially sanctioned discrimination, and democracy has not been applied in the policy-making or decision-making process. Affected groups like gays and Haitians have not been part of the process. In the health care system generally, patients' needs are not necessarily being addressed--though they are the ones with the most at stake.

- The particular concerns of groups at risk to AIDS are reflected most clearly in the issue of confidentiality--an issue I know is quite controversial and of considerable importance to you, Mr. Chairperson. The government agencies with which we have been dealing, most particularly the Centers for Disease Control, have failed miserably to recognize the most basic rights of patients and research subjects: that of confidentiality and privacy. This seeming inability to address the issue forthrightly and sensitively has undercut the effectiveness of what little epidemiologic research the government is doing--because those most affected simply don't trust the government to protect their rights. The confidentiality issue can and must be addressed in such a way that the rights of patients are protected without compromising larger public health needs.

- The tremendous outpouring of support for voluntary efforts within the gay/lesbian community has been in sharp contrast to the federal government's response. Existing organizations are expanding their work to include issues related to AIDS, and new service groups are being formed to meet the crisis.

An NGTF survey of voluntary organizations in the gay/lesbian community found that in 1983, more than \$2.5 million has been budgeted, with another \$6.8 million projected for 1984. These figures do not include local and state government grants to these groups, nor do they include the value of millions of volunteer hours that sustain these organizations.

This work is a source of tremendous pride for my community. It is banding together as a community should. But we cannot be expected to do the job alone. The government must help. It must be part of the solution as well. At the federal level there has been no effort to include these voluntary organizations in planning and coordinating. The PHS sees fit to hold special briefings for science editors, but none for those doing the most important science work during this crisis. This administration claims to be committed to rekindling the volunteer spirit in America. My community has responded to an unprecedented degree. Where is the federal government's recognition of and support for these efforts?

• Mr. Chairperson, there is a conclusion we can draw about this government's response to medical crises that will make some people very uncomfortable. The record on AIDS shows--and I submit would prove the same in other instances--that the government's slow response on AIDS is directly related to who is affected by this disease as much as what the disease is. The groups most affected--gay men, Haitians, IV drug users--are traditionally victims of discrimination, often officially sanctioned. And among those who have AIDS, over 40 percent are persons of color. As the author of the national gay/lesbian rights bill, Mr. Chairperson, you are fully aware of the continuing official and unofficial discrimination facing the gay/lesbian community. If one is black and gay, or black and an immigrant who doesn't speak English--the discrimination is even greater. A certain lack of speed in the government's response is apparent, especially in comparison to that for Legionnaire's disease, which affected a very different sociological cross-section. The implications of this are shocking, but unavoidable--and unacceptable. Because they are gay, Haitian, or IV drug users, these people's lives are thought to be expendable. The lesson to be learned is that if you are part of a minority, don't expect the government to respond to your needs without a fight. Institutional neglect and resistance are more likely to be the norm.

A detailed look at the federal government's response to the AIDS crisis leads to the unavoidable conclusion that in this Administration, there is a sharp contrast between the rhetoric of concern and the reality of response.

The Administration has been out of touch with the magnitude of this crisis. It has been following, not leading, the general public and the affected communities. In hearings before Cong. Waxman's subcommittee, Dr. Brandt admitted that the

fiscal year 1984 budget request--which showed less money for AIDS work at CDC than in 1983--was prepared "before we understood in fact how much money it would require." That belated recognition is shocking enough from an agency with a mandate to protect the public health; what is inconceivable is that the Administration has yet to adjust its fiscal year 1984 request to reflect its newfound wisdom.

More than two years after this medical crisis became generally recognized, the Administration still has not presented to the public a comprehensive plan of attack. More than two months ago, I wrote Secretary Heckler, asking her to set forth just such a plan. She has been unable or unwilling to do so--even after declaring AIDS to be the nation's number one health priority. CDC, NIH, and other agencies are engaged in detective work that is uncoordinated and unplanned. Without a centrally devised approach to research, public and private efforts cannot be coordinated and a clearcut assessment of what needs to be done and how much it costs cannot be made. As long as a comprehensive plan is not forthcoming, the public will legitimately wonder and worry how seriously the Administration is taking this issue.

An understanding of the magnitude of the AIDS problem is essential to developing a policy. The CDC is charged with surveillance which could give us some sense of the scope of the epidemic. Yet, after all this time, we still don't have accurate statistics on the number of cases, partly because CDC's programs suffer from inadequate staffing and insufficient funding. Dr. Richard Selig of CDC told USA Today (July 21, 1983) that CDC statistics probably represented only one-half of the actual number of AIDS cases.

In 1981, the same year the AIDS epidemic was beginning to get attention, CDC's budget was slashed by 20 percent. It is understandable, therefore, though unacceptable, that CDC has had difficulties meeting its responsibilities in this crisis.

To compensate for insufficient funds, CDC has diverted resources from existing programs, thus jeopardizing important medical work in other areas. The hepatitis control program has been shut down, and the venereal disease control and childhood immunization programs have suffered. These are ongoing concerns, not luxuries that can be cut back when a more pressing crisis arrives on the scene.

The problem of diverting resources also arose when the Administration sought to reprogram \$12 million for AIDS work throughout the Public Health Service, rather than seek the supplemental budget preferred by Congress. There is no

excuse for the United States government, faced with medical emergencies, to force choices between groups who need help. The protection of the public health should not be a zero sum game.

Here are some more examples of insufficient resources undermining CDC's efforts:

- It was only two months ago that CDC was able to send public health advisors to San Francisco, Los Angeles, and Miami to assist with AIDS studies. New York City was assigned an advisor just a few months earlier. It had been well known for some time that these cities were the most affected. (And the CDC still has not provided local jurisdictions with special technical assistance in public education as they have with other diseases.)

- Tracing of cases--getting more detailed case histories and medical information--is important to the epidemiologic research that may give us clues to the source of AIDS. It is our understanding that routine risk groups are not being traced; only anomalies are being studied in depth. While that may provide reassuring information to quell public hysteria, from an epidemiologic standpoint it is the patterns in high-risk groups that might provide us with an answer.

- Epidemiologic work is further hampered by inconsistencies in reporting systems about AIDS. Only a few jurisdictions have made AIDS a reportable disease. With no consistent national policy to deal with information gathering, it will remain impossible to have accurate statistics on how quickly this epidemic is growing.

The question of accurate reporting and surveillance inevitably raises the issue of confidentiality. This issue has been used in unscrupulous ways to paint the gay/lesbian community as irresponsible and unwilling to cooperate with the CDC in the fight against AIDS. And at the very same time, our concerns--which have been so studiously rejected by CDC--have been used as an excuse to deny this committee access to information vital to the legitimate performance of its oversight function.

I want to state unequivocally the gay/lesbian community's position on confidentiality--so no one in the CDC or elsewhere can misunderstand just what will and won't be acceptable to us--and also to offer some legislative proposals to take this issue out of the hands of bureaucrats and provide some strong and lasting protection for the privacy and confidentiality of persons with AIDS.

To understand my community's position on confidentiality, the position of the gay/lesbian community in American society must first be understood. The gay/lesbian community is a disenfranchised minority. In all but one state and the District of Columbia, you can still lose your job simply because you are gay or lesbian. In half the states, our expressions of love make us criminals. Many jurisdictions deny us the right to raise our children or teach those of others. The federal government still bars us from military service and employment in key sections of the civil service; it subjects others of us to harassment by investigations into our lifestyles. Given this context, you can better understand why there is suspicion within our community about any surveillance activity that can place our names and sexual orientation together in a government computer. Yet, that is what the CDC is blithely asking for.

When we ask what steps have been taken to protect the confidentiality of the information the CDC has already gathered, we are told, "trust us." But to trust requires a history of credibility--and that is conspicuously lacking. Some of the most basic social science research precautions for protecting confidentiality have not been observed.

Now let's make one thing unmistakably clear: no community could be more concerned about gathering all the necessary information to find an answer to AIDS. It is our community that is being ravaged by this disease. But we can legitimately ask whether collecting full identification information along with sexual histories is an essential ingredient of epidemiologic research.

There are two purposes for collecting identification information: to avoid duplication of case histories and to be able to make follow-up contacts. After much discussion within the community, with groups such as the New York AIDS Network, Persons with AIDS, and the Lambda Legal Defense and Education Fund, the following compromise procedure has been suggested: initials only, date of birth, city of residence, mother's maiden name, and attending physician should be collected. The statistical odds of all that information being identical are quite low. The possibility of follow-up contact is assured through the attending physician. And we also avoid the possibility of lists of gay men falling into the hands of the wrong people. It should be noted that a version of this model is already in use in Washington, D.C.

With the glaring exception of the CDC, this approach strikes all we have dealt with--from public health officers in major cities to medical researchers--as reasonable. Yet, we cannot even get the CDC to sit down with us and negotiate

this matter in a professional way. But the CDC and all others must understand: unless and until these concerns about confidentiality are resolved, the accurate reporting and epidemiologic research we all desire will be incomplete and inaccurate--because patients and physicians with legitimate fears about how this information will be handled will resist cooperating with CDC.

The procedures outlined above provide a good interim model. But a firmer basis of trust ultimately needs to be established. Therefore, the National Gay Task Force and Lambda Legal Defense and Education Fund are proposing today that the Congress adopt legislation to extend to all persons who are part of a federally funded research or surveillance program the same confidentiality protections others already have under federal law.

The Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1175), for example, provides that medical records may be disclosed "only in accordance with the prior written consent of the patient," except in rare emergencies. Similar language covers alcohol abuse programs.

We propose that Congress enact legislation extending this protection of the privacy of medical, surveillance, and research documents both in federal agencies and those local jurisdictions receiving federal funds. With such legislation in hand, the concerns of our community would be addressed, and another precedent for privacy and patient rights would be established.

Our concerns for confidentiality, Mr. Chairperson, do not in any way diminish our support for the work of this committee and its vital oversight function. The sudden concerns of the CDC about confidentiality are a red herring. They are an excuse to deny this committee access to CDC files. What we are witnessing from CDC is an attempt to stonewall--and that implies that CDC has something to hide.

In their dealings with the gay/lesbian community, the CDC has been taken aback that we--the consumers--might have the audacity to question how they carry out their mandate. That mandate, CDC needs to be reminded, comes from the Congress and the people. It is for us, not them, to determine what is in our best interests.

Given the performance of CDC during this crisis, oversight by this committee is essential. The concerns expressed by CDC regarding confidentiality might be taken more seriously if CDC had been more responsive when we discussed this issue in terms of their surveillance work. Further, the fact that names are part of any records this committee might be seeking is proof of the CDC's failure to protect confidentiality. Names should never have been allowed in those documents in the first place.

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Now that the names are included, it is important to be sure that, in conducting your investigation, appropriate safeguards are taken. To that end, I seek this committee's commitment to continued work with the gay/lesbian community so that guidelines that are workable and acceptable to you and to us can be adopted. I am confident that can be achieved.

The general public, and most certainly the gay/lesbian community, are looking impatiently to biomedical researchers to find the answers we so desperately seek to this disease. Much of the biomedical research is performed and/or funded by the National Institutes of Health. Here, too, poor planning, poor procedures and poor funding are undermining efforts.

Money alone won't find a cause or a cure for AIDS. Research that is funded should address the right questions and must be of high quality. But these criteria do not necessarily dictate delay. The etiology and the question of transmissibility through blood are basic, clearly definable issues. Yet they are just beginning to be addressed.

Research into the etiology of AIDS will not be funded until October 1983. The first Request for Applications (RFA) for work to find an infectious agent in this epidemic was issued in May 1983--again, about two fiscal years after AIDS became a clearly recognized threat.

Similarly, the question of researching transmissibility of AIDS and finding markers for AIDS in the blood supply is still in the future--at least as far as government-sponsored research is concerned. (The American Red Cross is spending \$200,000 to investigate the relationship of transmission of AIDS to blood transfusions.)

This is part of a pattern of lethargy at NIH that may have bureaucratic justifications under normal circumstances but has no place during a crisis. AIDS was identified as a disease in 1981. It was not until August 1982 that the first RFA was issued by NIH and funds did not begin to flow until May 1983--and this under an allegedly expedited process!

One of the explanations for the delay in issuing grants is the need for peer review. We certainly do not want money wasted on unworthy projects. But there is no reason why peer review committees cannot meet on an emergency basis to deal with an emergency situation.

Above all, when you look at how NIH is handling the funding of research, what is driven home again and again is that we lack the resources to do the job, even if you accept the Administration's more limited view of what needs to be done. In point of fact, there are now more RFA's out than money appropriated

to fund them. Even the NIH bureaucracy recognizes a greater need than the budget cutters at OMB.

\$9.6 million was appropriated for NIH to deal with AIDS in fiscal year 1983. That is the sum total of federally sponsored basic research on AIDS. States and local governments, along with the private sector, are coming close to matching that figure on their own: New York State has appropriated \$4.5 million for research, the University of California has been given \$2.9 million; the Cancer Research Institute, for example, is spending \$350,000; and gay community-based organizations have budgeted about \$300,000. This is to make up for the federal government's deficiencies--a very sad commentary on the state of NIH's response.

The NIH should issue a general call for research on AIDS--one that does not restrict the approaches to be considered. With sufficient resources clearly behind it, such an effort will attract the best scientists in the country. I will leave it to those scientists to discuss specific research projects. But let me outline some of the basic work that needs to be done: viral and immunological research; study of simian AIDS; monitoring what has been called "prodromal" AIDS; monitoring the U.S. armed forces and also blood recipients for incursion of AIDS; early diagnosis of AIDS and related treatment; screening tests for blood donation ("surrogate markers"); and African swine fever virus tests.

In order even to begin the long process of systematically identifying the transmissible agent for AIDS--critically important to developing a cure or preventive measure--we first must find an experimental animal species that is susceptible to AIDS. This has not yet been accomplished. We must test as many different primate species as possible in the hope of finding one which is susceptible. In humans, AIDS incubates close to two years. If this is true in other primates, research will be slow and very costly.

Rhesus monkeys and chimpanzees, for example, cost about \$100 per day to house and care for. To intravenously expose 25 animals in each of six species of primates with blood from AIDS patients, and house them for two years, comes to \$10,950,000. To test just five other body fluids and tissues would bring the bill to \$65,700,000. By adding routine intraperitoneal and intramuscular exposure, the cost soars to \$197,000,000--all this just to discover a susceptible animal so that real research can begin.

How has NIH tackled this basic problem? It is spending \$56,000 to determine if AIDS can be transmitted to two chimpanzees by infusing the animals with plasma from AIDS patients.

The level of research outlined here seems costly. But is it really...in terms of the lives saved...in terms of the knowledge gained...and if those aren't worthy enough goals, in terms of money saved on health care costs? At an estimated \$100,000 per case, we have already spent over \$170 million on health care costs--and that figure may rise to \$4.8 billion by the end of 1985 if AIDS cases continue to rise at current rates.

The public must be reassured that serious research is being done or their faith that this epidemic will not get out of hand may evaporate. They must see real work and real progress--not announcements of ostensibly new discoveries that in fact are not new. Such was the case last month with interleukin-2, which only cured AIDS in six test tubes, but was presented with such fanfare as to give perhaps unreasonable hope. Or was the announcement timed to coincide with Congressional action on AIDS funding--to give the Congress the impression more money was not needed?

We have seen a good deal of hysteria on the subject of AIDS--above all on the question of blood. Let me restate the gay community's position on the issue of blood donations. At every possible forum available to us, we have urged those in our community who feel they might be at risk to AIDS or feel unwell, to voluntarily refrain from donating blood. That is the responsible approach and the right approach--as we wait for the government to take more definitive steps.

Recent reports about dangerously low blood supplies in many metropolitan areas directly result from the government's failure to investigate the transmissibility of AIDS through the blood, to develop a marker for AIDS in blood, to test surrogate markers, or to study the safety of the blood supply and giving blood.

The negative effect this has had on blood donations has endangered more lives than the threat of AIDS itself. I fear that soon we are going to hear of someone dying during an operation for lack of a transfusion, because of the public perception that the blood supply and giving blood are unsafe.

From Secretary Heckler on down, the Health and Human Services Department has, of late, done an excellent public relations job reassuring the public that there are not risks in giving blood, and that the dangers of receiving AIDS from a transfusion are minimal at worst. But where were they one year ago when

this issue first surfaced and the overreaction could have been prevented? And why have they still not done the research needed to garner scientific support for their position?

In the meantime, because we have no markers and no conclusive research on blood, attempts are being made to screen all homosexual men from donating blood, making gay men as a class unfairly bear the discriminatory effect of the government's inaction on AIDS--while blood supplies continue to drop.

I have alluded to public hysteria over AIDS in discussing the blood question. Far from preventing this hysteria, early statements by federal officials, such as Dr. Anthony Fauci of NIH, who wrote an article implying that casual contact could spread the disease, actually helped to ignite it. AIDS has--because of its mysterious nature and, I repeat, because of the groups associated with it--generated something just short of public panic. A good deal of that panic has been fostered by homophobes bent on turning a public health crisis into yet another opportunity to attack the gay/lesbian community.

Whatever the cause, AIDS has resulted in a need for public education that, while belated, has been marked recently in the PHS by good will and energetic attempts to make the best of limited resources. There are really four audiences for education efforts, requiring very different approaches: the general public with vague fears that are easily calmed; affected or high-risk groups in need of more detailed response; persons with AIDS; and those people who work in very close contact with high-risk groups who have legitimate concerns that must be addressed.

One could not ask for more in the personal statements of PHS officials such as Dr. Brandt. They are sincere and willing to be out front in reassuring the public about unwarranted concerns of casual contact with persons with AIDS and members of high-risk groups. Unfortunately, the programmatic efforts backing up those statements are very weak--so weak that they leave the PHS open to charges of tokenism and suggestions that these efforts are designed to appease critics rather than confront the problem.

The centerpiece of the public education effort is the federal AIDS hotline. It is clear from the response--some 10,000 attempted calls a day--that this is at least trying to meet a need. But the process becomes a sham for the public, and an unfair burden on those assigned to work on the hotline, when you realize that the hotline started with only three lines and now, with an additional five, is capable of meeting only a fraction of the demand. Once more, despite public relations hype, the government is not willing to devote new resources to the job.

Further, those staffing the hotline have been drawn from other public affairs positions. They are not specially trained for this kind of work, they are not experts on AIDS, and they have not been sensitized to the special concerns of the high-risk groups most likely to call.

The National Gay Task Force can speak with some expertise about hotlines. Since October 1982, we have been operating an AIDS crisisline. Over 3,600 people daily have attempted to call us. The volunteers who answer these phones have undergone at least 20 hours of training--about the subject matter, crisis intervention, and general sensitivity to the special needs of their callers. There is no less of a need for such training for the federal hotline.

The NGTF Crisisline, while available to the general public, does focus on the needs of one high-risk group. Federal public education efforts concentrate on the concerns of the general public. But it is essential that education about AIDS reach the most affected groups in particular. It might not be appropriate for the federal government to mount such a campaign, if only because suspicion of the government is so high among these groups. But at the least, federal funds should be available to assist community-based organizations carrying on education programs.

There is one more group of people for whom education efforts are sorely needed and desperately lacking. We have heard much about health care workers, morticians, police officers, and others who are fearful of contact with persons with AIDS or members of high-risk groups. Most of those fears are unjustified. But it is hard to blame people who have not received clear-cut guidelines to reassure them about their contacts. This is definitely a government responsibility--and the PHS should be taking a stronger lead in this regard.

The cost of medical care for persons with AIDS is one of the more staggering aspects of this crisis. While there are no hard figures available, the common estimate is \$100,000 per patient. Many AIDS patients spend long periods in the hospital, often in intensive care units. The cost can skyrocket if experimental treatments are used; for example, interleukin-2 treatments are estimated to run \$125,000 per patient.

To obtain a sense of how the cost of health care affects patients, and how that in turn impedes their recovery, let me quote from a letter published in JAMA (July 8, 1983) from a group of physicians at the University of Medicine and Dentistry of New Jersey, New Jersey Medical School, Newark:

We find that a large portion of our AIDS population is indigent and unable to obtain the requisite out-patient care. In an ongoing investigation at our institution, many patients studied thus far have shown evidence of protein-calorie malnutrition and multiple vitamin deficiencies. Once discharged, they can neither eat well enough to bolster their deficient nutritional state nor afford the many drugs required for their multiple infections.

AIDS has placed, so far, a \$170 million burden on our health care system, which has fallen disproportionately on cities (through Medicaid and city hospitals) and individuals. The only federal response has been to make persons with AIDS eligible for Social Security disability. This move, while positive, is only a small step toward dealing with the problem--and it adds to the false assumption that persons with AIDS are totally disabled. Many continue to lead productive lives for long periods of time...but this does not eliminate their medical expenses.

Mr. Chairperson, we appreciate the leadership you have shown in offering legislative solutions to this problem. Your bill to eliminate the waiting period before Medicare coverage can be extended to those with AIDS deals with part of the problem. And your Public Health Emergency Treatment Fund, which would provide up to \$60 million for cities and states overwhelmed by the costs of caring for patients during a health emergency, will provide some much needed relief. In the meantime, the federal government must make certain that all possible existing benefits for which they are eligible are extended to persons with AIDS.

The overview I have just presented on the AIDS crisis leads to some important general observations. It tells us some things about our nation's health care system that are distressing to an outside observer and alarming to any person or group in the grips of a health care emergency.

First, the system simply takes too long to respond to a new crisis. Two years to begin research into the etiology of a disease. Two years to begin dealing with threats to the blood supply. A way must be found to gear up, to pump up the system faster. Cong. Waxman's Public Health Emergency Act, which sets aside \$30 million a year to deal with new crises such as AIDS, is an important first step toward making the health care system more responsive, but even that must still be appropriated.

But more is needed. Standard mechanisms must be in place to expedite approval procedures for new research. Ways to beef up the staffs and functions of agencies

such as CDC, so that a new crisis will not mean shutting down or impairing work. In other important areas must be found.

Above all, the government must learn to plan in a comprehensive and systematic manner. The Administration's defense for its poor performance on AIDS is often that money alone does not solve problems. We can see that: the money currently appropriated is not being spent as effectively as it might because there has been no planning. It seems so obvious--but it just hasn't been done. No one has convened the best minds in and out of government to determine what needs to be done, how much it costs, and how it can all be accomplished. Perhaps it is time to create an independent health care planning commission to deal with this issue--a blue-ribbon commission comprised of the best medical minds as well as health care professionals and consumer representatives, a commission that is insulated from bureaucratic interests and in-fighting that can tell us as objectively as possible what needs to be done. Then we can hold the politicians and bureaucrats responsible for implementing the proposals.

Another concern we must address is the quality of response offered by the government's medical establishment. I do not doubt for one instant the dedication of those working for NIH and CDC, but serious questions can and must be raised about the quality of work being done at institutions such as NIH. As the White House Science Council recently reported, the quality of the work at NIH is seriously jeopardized by its inability to attract top-flight medical researchers. Government medical service must be made an attractive option for the best researchers if there is to be any credibility to our government's claim that CDC and NIH are the medical detectives of the world.

We in America pride ourselves on our democratic system. It should mean that we have a fundamental right to participate in decisions that affect our lives. But instead, the medical establishment, hiding behind medical degrees and impressive titles, keeps us out of the decision-making process. This is true on an individual basis, as patients' rights to choose are ignored or trampled upon during treatment or research at all levels of the health care system. And it is true on a broader basis as a crisis disproportionately affects particular groups. This often has social as well as medical implications--yet these groups are only allowed audiences with decisionmakers after several years of banging on the door--or when the crisis becomes so great that it is expedient for the powers that be to at least appear to include us in the process. When

one baby needs a liver transplant, the crisis gets presidential attention. When 1700 people are fighting for their lives, the Administration often seems deaf at the highest levels.

Another issue that the AIDS crisis has brought home to the gay/lesbian community in letters writ large in dollar bills, is the cost of health care in the United States. Catastrophic illnesses bring catastrophic costs. Well over \$170 million has been spent on health care alone for persons with AIDS. For patients or consumers, hospitals, and local governments, AIDS is just one more example of a need to deal forthrightly and thoroughly with the issues of health care costs and the need to provide insurance for all Americans facing catastrophic illnesses.

Mr. Chairperson, I want to thank you again for holding this hearing. It has provided a service to my community--in airing our specific concerns about the federal response to AIDS--and an important service to the general public, all of whom are potential consumers in the American health care system. For the gay/lesbian community, this crisis has forced us to focus our attention on our nation's medical establishment in ways we would never have imagined.

The immediate future does not look bright on the issue of AIDS. We have a great deal of suffering and many battles--emotional, medical, and political--ahead of us. But the gay/lesbian community will emerge stronger from this crisis--stronger because of the greater sense of community and new activism that this epidemic has generated. When the AIDS crisis is finally over, we will not forget what we have learned about health care in the United States. We will use our growing strength to return to the halls of Congress and of the Executive Branch again and again until the deficiencies revealed to us over the past few years are remedied for all Americans.

Thank you very much.

Mr. WEISS. Mr. Endean.

**STATEMENT OF STEPHEN R. ENDEAN, EXECUTIVE DIRECTOR,
GAY RIGHTS NATIONAL LOBBY**

Mr. ENDEAN. Good morning, Mr. Chairman, members of the subcommittee.

My name is Stephen Endean. I am the executive director of the Gay Rights National Lobby. As you know, Mr. Chairman, Gay Rights National Lobby is the only full-time lobby at Congress on gay issues and, until recently, our primary focus has been on insuring civil rights and equal justice for gay and lesbian Americans. But increasingly our focus has necessarily turned to the AIDS crisis. We appreciate your invitation for us to join you this morning.

It would be an extreme understatement to say that this Nation's gay community, which numbers over 22 million Americans, is not deeply concerned about the AIDS crisis. The gay community is alarmed by both the slow and insufficient response of the Federal Government. In the last 3 years, not only gay men but Haitians, hemophiliacs, women and children have come down with the syndrome. People are dying from a disease which medical science knows almost nothing about.

Secretary Heckler has named AIDS the number one public health priority. Dr. William Foege, the director of the Centers for Disease Control, has said "AIDS is the most complex epidemic we've ever had to deal with." But while the press and the public have heard that this crisis is the No. 1 priority, it appears that the administration has failed to communicate a similar message to its budget offices or to the Appropriations Committees.

Quite frankly, the Federal Government's response to the AIDS crisis thus far remains a cruel joke. Since fiscal year 1981, when AIDS was first identified as an epidemic, the National Institutes of Health, which is the largest medical research organization in the world, has spent only \$12 million on AIDS research to date. And yet NIH has spent \$11.2 billion on other medical research since fiscal year 1981. In other words, only one-tenth of 1 percent of the NIH research budget has been spent on AIDS. Whether the reason, or excuse, is the inherent bureaucratic delays in responding to public health emergencies or it is another example of a far too common institutional homophobia by the Federal Government, the response to date by the Federal Government has been inexcusable.

By contrast, State and local governments, which normally do not even fund significant medical research which has traditionally been a Federal responsibility, have committed about \$8 million to AIDS research this year, almost as much as the Federal Government estimates it will spend on basic AIDS research in 1983.

Recently, both Houses of Congress overwhelmingly voted to include \$12 million for AIDS research in the 1983 supplemental appropriations bill. That \$12 million would nearly double Federal funding for AIDS research. Shortly the bill will go to President Reagan and, unfortunately, he has threatened to veto it. We sincerely hope he does not, because even with the additional \$12 mil-

lion, researchers will only be able to begin the massive effort necessary to discover the cause of AIDS and how it can be stopped.

A moment ago, I alluded to not only too little but too late. It is shocking that it has taken 3 years for the Federal Government to begin to take action, shocking in view of the mortality rate, shocking in view of the media attention the AIDS crisis has received, shocking in view of not only the deep concern but near hysteria of the American public.

Gay Rights National Lobby congratulates the Congress for the decision to create a public health emergency research fund to more expeditiously disburse Federal research dollars to combat public health crises such as AIDS. Representative Waxman, Senators Kennedy and Cranston, and others who worked to establish this fund certainly deserve our thanks.

It is important to remember that AIDS is the only infectious disease which can attack and destroy the body's immune system. Because of this unique characteristic, scientists believe that if they conquer AIDS, they will better understand the immune system. Top medical experts consider AIDS one of the great research challenges and opportunities in medical history.

But of course AIDS is more than just a research opportunity, especially to the more than 1,200 Americans who have the disease. No one with AIDS has lived longer than 3 years after being diagnosed, and no one has recovered from the underlying syndrome. Five to six new cases are reported every day, and the total number of cases doubles every 6 months.

Unfortunately, having a critical illness is only part of the burden persons with AIDS must carry. The ignorance and discrimination they face is incredible. I applaud you, Mr. Chairman, for including in these hearings persons with AIDS themselves. No one could presume to speak for them or share their experiences so eloquently.

One area of concern is the staggering medical bills that persons with AIDS must face. Many are forced to give up all their property and rely on medicaid and public hospitals to provide the highly complex and usually experimental treatment they need. Medicaid and public hospitals simply cannot provide this care.

Congressman Weiss, we applaud you for introducing a bill last week that would provide \$60 million for treatment and prevention activities required to combat public health emergencies such as AIDS. The Congress simply must address the medical care needs of persons with AIDS, and other victims of epidemics.

Your bill is particularly significant in that it addresses not only the medical care problems caused by AIDS, but also the public health and prevention problems, which have become critical. Hysteria is rampant. People are combining their fear of the disease, their homophobia and their racism, and using that combination to justify bigotry and discrimination against gays and against Haitians. They are punishing persons with AIDS by firing them from their jobs, by denying them housing, by denying them fundamental human rights.

And what has our Federal Government done to quell this hysteria and stop the backlash? Far too little.

Thus far no money has been budgeted or appropriated for public education on the AIDS epidemic. HHS has prepared a one-page

factsheet on AIDS, which is available if you call the national AIDS hotline. But good luck. It's estimated that 50 percent of the callers who attempt to get through on this hotline don't. If one gets through, one can't expect highly trained experts on the subject to answer questions. Public relations employees with no medical or public health training give standard replies.

While we can take some consolation that Secretary Heckler and the administration have not embraced Reverend Falwell's un-Christian views of the AIDS crisis, views that are little more than justifications for bigotry and discrimination toward gay people, HHS education efforts thus far remain woefully inadequate. A real and substantive education program, not media hype, is needed.

The appropriations process for fiscal year 1984 is now underway. While no figures are yet available from the Appropriations Subcommittee, we are deeply concerned that none of the figures speculated about approach the real need. Not only the administration but the Congress, that is charged with representing all the people, people who live in great fear of AIDS, must face the fact that funds must be increased dramatically and immediately.

The Gay Rights National Lobby, in cooperation with the newly created AIDS Federation, with the National Gay Task Force, and with others both gay and nongay, has pledged to continue to actively advocate such dramatically increased Federal funds for research, patient care, and education on the AIDS crisis. However, it remains more than a little ironic that lobbying initiatives are even necessary in the face of such a serious crisis and statements that it is the No. 1 public health priority.

Mr. Chairman, let nothing that I have said here today be misconstrued to make light of the considerable efforts and real concern of many Members of Congress. Without those efforts, much of what has been done probably would not have been. But Federal efforts to this point remain too little, too late, and too much business as usual.

Mr. Chairman, members of the subcommittee, I congratulate you on your hearings and ongoing oversight efforts. I hope they will assist this Congress in getting to a more effective and expeditious response to this public health crisis.

I believe that Representative Waxman, who has worked on health policy for many years and most effectively, is correct when he said, "There is no doubt in my mind that if the same disease had appeared among Americans of Norwegian descent, or among tennis players rather than among gay males, the response of both the government and the medical community would have been different."

Thank you, Mr. Chairman and members of the subcommittee, for the opportunity to discuss this matter today.

Mr. WEISS. Thank you for your testimony.

Dr. Compas.

**STATEMENT OF DR. JEAN-CLAUDE COMPAS, VICE PRESIDENT,
HAITIAN MEDICAL ASSOCIATION ABROAD**

Dr. COMPAS. Thank you, Mr. Chairman. Thank you, members of the committee, to invite the Haitian groups to come here and speak about the question of AIDS.

In the United States, where the incidences of AIDS and its fatality rate have been most impressive, scientists began investigating the disease more than 3 years ago. However, causative factors and mechanisms of transmission have not yet been definitively determined. Despite the lack of a conclusive scientific data base and, as Haitian AIDS patients have repeatedly and persistently denied any history of homosexuality, drug abuse or hemophilia, U.S. health authorities declared Haitians a high-risk group.

In an effort to rationalize this arbitrary classification, several theories have emerged. At the outset, it was suggested that AIDS might have originated in Haiti as a result of the voodoo practices. It was then suggested that Haitians may be genetically predisposed to the disease. As neither of these hypotheses could be scientifically substantiated, the so-called Haitian connection was more recently explained by establishing a liaison between the African swine fever, which had struck Haiti in 1978, and the deadly new syndrome, through the alleged consumption of undercooked pork by Haitians, followed by homosexual relations between Haitian male prostitutes and homosexual American tourists—Newsweek, May 16, 1983. The latest one states that there must be some tropical factors in the Haitian connection.

The most elementary analysis of these theories indicates that there was a great deal of unfounded speculation by the CDC and other U.S. AIDS-related groups. To date, no epidemiologic survey has ever been conducted among the Haitian population in the United States. Most of the data used by the CDC and other health authorities were gathered by hospital-based physicians with no knowledge of French or Haitian Creole and who, in addition, have admitted to a complete ignorance of the intricacies of Haitian culture.

Sociologists have established that diseases such as tuberculosis, syphilis, epilepsy, and behaviors such as homosexuality and drug abuse are strongly stigmatized and taboo in highly religious and non-Western societies such as Haiti. No Haitian should therefore be expected to ever admit, let alone confess to a stranger, having had at any time engaged in these so-called deviant practices.

In addition, most of the Haitian AIDS victims are uneducated, do not speak English or French and, having no legal status in the United States, live in constant fear of being deported. The credibility of their responses to any American interviewer should certainly be considered questionable, at best.

In an attempt to investigate the African swine fever connection, the serum of Haitian AIDS patients in Haiti was tested for the presence of antibodies to African swine fever virus—The Lancet, July 9, 1983, page 110. These antibodies were not detected.

Haitian physicians investigating in Haiti and in the United States, though working with far less sophisticated technical facilities and more modest financial means than researchers from the

CDC, have established that more than 30 percent of the Haitian AIDS population have actually admitted to homosexual experience. This points to the necessity of utilizing Haitian personnel in research activities.

As a result of their separate classification, a Haitian phobia rapidly developed in U.S. communities. Haitians across the country were being evicted from their jobs.

Children were not spared. Haitian pupils were harassed by their schoolmates. Mothers forbade their children to play with Haitian children. In an elementary public school in Brooklyn, a teacher refused to resume her classroom activities, stating that there were too many Haitians on the premises.

THE MEDICAL ENVIRONMENT

Haitian AIDS victims are mostly recent undocumented immigrants without any legal status. In the hospital, they suffer the same discriminatory treatment as other AIDS patients. However, upon discharge from those facilities, they face additional insults. They are not eligible for social services or any type of public assistance such as medicaid. Even the victims who are legal immigrants are newcomers to the country and are therefore unaware of available resources.

HAITIANS' RESPONSE TO AIDS

Since the beginning of this ordeal, Haitian communities across the country have set up special AIDS task forces. In New York, for example, we have organized a scientific committee for research purposes and have founded, in cooperation with the community, the Haitian Coalition on AIDS. Immunologic studies which we have performed in collaboration with Downstate Medical Center have demonstrated that there is no immunodeficiency in the Haitian population.

From a sociological perspective, we have had to deal with three major problems. These include the growing fear and frustration of the Haitian community, the detrimental relations between the Haitian community and its neighbors and the social problems encountered by the victims of AIDS.

In most communities, the Haitian Coalition on AIDS has done its best to overcome these three problems. We have employed a multimedia approach in attempting to educate the population. We have been faced with the necessity of sheltering some of the victims; we have had to provide food and money to buy their expensive medications. We must see to it that they are educated so that they can understand what is being told to them in the hospitals. We must also provide some form of counseling for relatives and close friends whose confusion and frustrations are multiplied because of the language barrier. All of these activities are being carried out without the help of any local or Federal agencies.

Regarding relations with the American community, we think that at this stage it is imperative to inform Americans that Haitians were erroneously classified as a high-risk group. As of July 28, 1983, New York City no longer lists Haitians as a high-risk group.

We appreciate Dr. David Sencer's courageous and scientific stand. However, it is not enough that categorization remain in the Federal list. The CDC argue that the total Haitian case is very high compared to the Haitian population here, 103-to-1 million—but what if we were to designate their 1922 cases according to national origins. Let us ponder about this statement.

While we are aware that the CDC is currently launching an epidemiologic study of the Haitian community, we emphasize that it will not be valid unless it utilizes professionals and questionnaires adequately adopted to our Haitian culture.

On the social front, we must develop a program to repair the damage caused by this unscientific classification of Haitians by the CDC. To accomplish this vast task, we will need cooperation by the various public health authorities and the media as well as substantial resources. We need educational and counseling programs; we need halfway houses for our patients. In addition, we need to develop some type of financial relief for victims of AIDS which will apply to all victims, regardless of their immigration status.

Again, our resources are severely limited. As recent immigrants in this country, we do not have the connections or the means to make our voices heard. Even if we do succeed in telling the truth, the public, we will still have to deal with the subtle, yet malignant, fear that people carry within themselves when they are faced with ignorance and misinformation.

We deeply appreciate the opportunity you have given us to present our case before this subcommittee. We have all gratefully received the moral support of various community groups and politicians. This support has been vital to us and to our efforts. Unfortunately, the support which we have received falls far short of our necessities. The task before us is of tremendous magnitude and will require substantial Federal funding. We urge you to consider our plight and to act accordingly.

Thank you.

[The prepared statement of Dr. Compas follows:]

PREPARED STATEMENT OF DR. JEAN-CLAUDE COMPAS, VICE PRESIDENT, HAITIAN MEDICAL ASSOCIATION ABROAD, NEW YORK CHAPTER, CHAIRMAN, HAITIAN COALITION ON AIDS

INTRODUCTION

As is well known, the disease now identified as the Acquired Immuno-Deficiency Syndrome, or AIDS seems to have erupted simultaneously in more than 17 countries throughout the world during the past four years. In four of these countries, namely, the Zaire and the Congo in Africa, and the United States and Haiti in the Western Hemisphere, it has taken, in the past twelve months, the form and the virulence of an epidemic.

In the United States, where the incidence of AIDS and its fatality rate have been most impressive, scientists, including specialists in immunology and epidemiology began investigating the disease more than three years ago. However, causative factors and mechanisms of transmission have not yet been definitively determined. Despite the lack of conclusive scientific data base, a high-risk group categorization was established by the Center for Disease Control (CDC) in late 1982 based solely upon the incidence of the disease in the New York area. As a result, three social/medical groups, homosexuals, intravenous drug abusers and hemophiliacs, and one ethno-national community, Haitian immigrants, were labelled as being responsible for the eruption and the spread of the AIDS outbreak. For the first time in history, a disease was being attributed to a nationality without clear epidemiologic or scientific justification.

THE FACTS

In 1981, a few Haitians residing in the United States were diagnosed with Pneumocystis Carinii Pneumonia - a lung infection caused by a parasite - and Kaposi's Sarcoma - a rare form of tumor or cancer of the blood vessel walls; two infections that were identified as being most commonly associated with the AIDS syndrome. During the same period, the same pathological conditions were diagnosed in much greater numbers among homosexuals, intravenous drug abusers and hemophiliacs.

In 1983, the number of AIDS victims in the United States rose to 1552, and the social profile of the disease displayed the following pattern according to a July 27, CDC report:

	<u>%</u>	<u>CASES</u>
Homosexuals or Bisexuals	71.3%	1901
IV Drug Abusers	17.1	266
Haitians	5.0	101
Hemophiliacs	0.8	13
Unknown	5.8	90

As Haitian AIDS patients have repeatedly and persistently denied any history of homosexuality, drug abuse or hemophilia, United States health authorities, for statistical purposes, declared them a separate high-risk group.

In an effort to rationalize this arbitrary classification, three theories have emerged. At the outset, it was suggested that AIDS might have originated in Haiti as a result of the Voodoo practices. It was then suggested that Haitians may be genetically predisposed to the disease. As neither of these hypotheses could be scientifically substantiated, the so-called Haitian connection was more recently explained by establishing a liaison between the African Swine Fever - which had struck Haiti in 1978 - and the deadly new syndrome, through the alleged consumption of undercooked pork by Haitians followed by homosexual relations between Haitian male prostitutes and homosexual American tourists (Newsweek, May 16, 1983).

The most elementary analysis of these theories indicates that there was a great deal of unfounded speculation by the CDC and other U.S. AIDS-related groups.

To date, no epidemiologic survey has ever been conducted among the Haitian population in the United States. Most of the data used by the CDC and other health authorities were gathered by hospital-based physicians with no knowledge of French or Haitian Creole and who, in addition, have admitted a complete ignorance of the intricacies of Haitian culture. Sociologists have established that diseases such as tuberculosis, syphilis, epilepsy, and behaviors such as homosexuality and drug abuse are strongly stigmatized in highly religious and non-western societies such as Haiti. Those Haitians who have been victimized by AIDS have originated primarily

from the lower socioeconomic strata where such practices are particularly taboo. No Haitian should therefore be expected to ever admit, let alone confess to a stranger, having had at any time engaged in these 'deviant practices.

In addition, most of the Haitian AIDS victims are uneducated, do not speak English or French and, having no legal status in the U.S. live in constant fear of being deported. The credibility of their responses to any American interviewer should certainly be considered questionable at best.

Furthermore, the Haitian diaspora is not limited to the U.S. Approximately one-third of the population of the Bahamas is composed of Haitians. There are some 300,000 Haitians in the Dominican Republic, 15-20,000 in French Guyana and 8-10,000 in the French Antilles. Yet, no occurrence of AIDS has been reported in these territories.

On the other hand, Haitian physicians investigating in Haiti and their colleagues of the Haitian Doctors Association (AMHE) operating in the U.S., though working with far less sophisticated technical facilities and more modest financial means than researchers from the CDC, have established that more than 30% of the Haitian AIDS population have actually admitted to a homosexual experience.

In an attempt to investigate the African Swine Fever connection, the serum of Haitian AIDS patients in Haiti was tested for the presence of antibodies to African Swine Fever (ASFV) by immunoelectro-osmophoresis and by indirect immuno-fluorescence (The Lancet, July 9, 1983, p. 110). These antibodies were not detected. Investigations on necropsy or biopsy materials were also unsuccessful (ibid. loc).

THE SOCIAL ENVIRONMENT

As a result of their separate high-risk classification, other high-risk groups began to use the Haitians as scapegoats, blaming their miseries on the imaginary Haitian connection. The media also capitalized on the issue. As a spawned population, because of their immigrant and low socioeconomic status, Haitians had no access to U.S. media. It was simple to turn the anger of an already panicking population against black, poor, illegal immigrants. A New York magazine correctly noted that every Haitian had become an object of dread.

A Haitian phobia rapidly developed in U.S. communities. As a result, Haitians across the country were being evicted from their jobs. Restaurants, hotels and parking areas were firing their Haitian personnel. Haitian home attendants and housekeepers were ejected from their employment. In one particular instance, a Haitian maid presented herself to work on a Monday morning, only to find all of her belongings in the street and to be told through a closed door that as all Haitians were sick she would not receive her salary directly but by mail. Haitian applicants were advised by Home Services Agencies not to reveal their Haitian identity if they wanted to be accepted by the clients. The New York Times, Channel ABC and other prominent media confirmed these horror stories.

Children were not spared. Haitian pupils were harrassed by their schoolmates. Mothers forbade their children to play with Haitian children. In an elementary public school in Brooklyn, a teacher refused to resume her classroom activities stating that there were too many Haitians on the premises. In some apartment houses, leaflets were circulated urging parents not to let their children mingle for any purpose with their Haitian counterparts.

THE MEDICAL ENVIRONMENT

Haitian patients have been receiving minimal care in hospitals because of fear of physical contact by health care workers and professionals. The incidence of psychosomatic diseases such as headaches, acute ulcers, impotence, generalized itching and stress related diseases such as hypertension have been increasing in the Haitian community. The pride and self-esteem of the Haitian population has also been damaged immeasurably. The management of this crisis by the American Public Health Community has made it extremely difficult and painful for most Haitians to admit their identity.

Haitian AIDS victims are mostly recent undocumented immigrants without any legal status. In the hospital, they suffer the same discriminatory treatment as other AIDS patients. However, upon discharge from those facilities, they face additional insults. Many of them, being recent immigrants, have no families. Others are rejected by their families and friends. They have no place to live and cannot find rooms. They are not eligible for social services such as Medicaid. Even the victims who are legal immigrants are newcomers to the country and are therefore unaware of

available resources. The stress experienced by these AIDS victims upon release from the hospital could contribute to the higher mortality rate suffered among the Haitian AIDS population.

HAITIAN RESPONSE TO AIDS

Since the beginning of this ordeal, every substantially sized Haitian community across the country has set up special AIDS Task Forces. In New York, for example, we have organized a scientific committee for research purposes and have founded, in cooperation with the community, a Haitian Coalition on AIDS. Immunologic studies which we have performed in collaboration with Downstate Medical Center have demonstrated by random blood sampling from the Haitian population, that there is no immunodeficiency in the Haitian population at large, nor is there a tendency among Haitians to develop AIDS.

We have been debating with the CDC the potential for an extensive epidemiologic study which would investigate all centers of heavy Haitian immigration. We have stipulated in our discussions that Haitian scientists and professionals should be involved in these studies. So far, no official answer has been received.

On the social aspect of the AIDS issue we have had to deal with three major problems. These include the growing fear and frustration of the Haitian community, the detrimental relations between the Haitian community and its neighbors and the social problems encountered by the victims of AIDS.

In most communities, the Haitian Coalition on AIDS has done its best to overcome these three problems. We have employed a multimedia approach in attempting to educate the population. However, our efforts are hampered by severe financial constraints.

No study has yet been done to evaluate the long term effect of the AIDS propaganda on the Haitian community. We have established an information hotline and have tried to provide counseling for the families of the victims.

Regarding relations with the American community, we think that at this stage, it is necessary to tell the public the truth about the transmissibility of the disease and to inform Americans that Haitians were erroneously classified as a high-risk group.

Again, our resources are very limited. As recent immigrants in this country, we do not have the connections or the means to make our voices heard. Even if we do succeed in telling the truth to the public, we will still have to deal with the subtle fear that people carry within themselves when they are faced with ignorance and misinformation.

We have been faced with the necessity of sheltering some of the victims as well as their families. We have had to provide food and money to buy their expensive medications. As already mentioned, many of these patients are undocumented aliens and have been denied social benefits. We must see to it that they are educated so that they can understand what is being told to them in the hospitals. We must also provide some form of counseling for relatives and close friends whose confusion and frustrations are multiplied because of the language barrier. All of these activities have been and are being carried out without the help of any local or federal agencies.

We deeply appreciate the opportunity you have given us to present our case before this Subcommittee. We warmly thank Congressman Major Owens for his help in the Brooklyn area. We have all gratefully received the moral support of groups such as the National Council of Churches, 1199 and DC37, the Bedford Stuyvesant Family Health Center and Downstate Medical Center. This support has been vital to us. Unfortunately, the support which we have received falls far short of our necessities.

OUR NEEDS

On the scientific front, an adequate epidemiologic study including proper interviewers and questionnaires adequately adapted to our Haitian culture should be the priority. We do know that the CDC is launching such a study. However, we emphasize that in order to be successful, it must use professionals who are familiar with the Haitian culture. The study will not be valid otherwise. In addition, we need a broader spectrum of immunologic research studies.

On the social front, we must develop a program to repair the damage caused by this unscientific classification of Haitians by the CDC. We need programs to educate our people as well as the American community and to do counseling for the family members of the victims. We need halfway houses for the patients with no housing in order to alleviate their suffering and prevent the dissemination of AIDS. The task is indeed of tremendous magnitude and requires substantial federal funding.

Mr. WEISS. Mr. Brownstein.

**STATEMENT OF ALAN P. BROWNSTEIN, EXECUTIVE DIRECTOR,
NATIONAL HEMOPHILIA FOUNDATION**

Mr. BROWNSTEIN. Thank you very much.

The National Hemophilia Foundation is most grateful for the support that Congress has provided over the years for much needed hemophilia research and care. This support has facilitated a revolution in hemophilia treatment over the last 10 years.

Plasma clotting factor concentrates have become widely available and home infusion therapy has freed these patients from hospital care and emergency room visits.

The committee report accompanying the Omnibus Budget Reconciliation Act of 1981 concluded, "Hemophilia treatment is one of the biomedical and medical successes of the decade." This statement is based on clear-cut documentation of progress in hemophilia treatment. And I ask you to consider the following 1981 data as compared with 1975.

The number of patients on home care has nearly quadrupled. Hospital utilization is down, more than 80 percent; average hospital days per year reduced from 9.4 to 1.8. The percent of unemployed adults dropped from 36 percent to 12.8 percent. These important human benefits are coupled with significant economic savings. Careful studies have documented a 62-percent reduction in total health costs per patient for the 9,500 hemophiliacs enrolled in Federal subsidized comprehensive care centers. This is down from \$15,800 in 1975 to \$5,932 per person in 1981.

Clearly the advances in hemophilia care have enabled hemophiliacs for the first time in history to lead nearly normal full and productive lives.

Now we are faced with the frightening specter of AIDS. Although in absolute terms the number of hemophiliacs, 16, who have become afflicted with AIDS may seem small, the risk of contracting AIDS is far greater among hemophiliacs than any other risk group. Today, of the 20,000 hemophiliacs, one out of 1,250 has contracted AIDS.

Further, if you consider that there are approximately 7,500 hemophiliacs who are classified as severe, that is those who are far more dependent upon blood products, the risk is much greater, one out of every 500 hemophiliacs. It is indeed ironic that the very substance that has served to liberate hemophiliacs from the disabling aspects of their disease is now highly suspect as the source of AIDS.

The fear of AIDS among hemophiliacs has been exacerbated by extensive and in some instances distorted reporting by the media. Some patients have abandoned appropriate use of blood products because they fear contracting AIDS. This is documented by reported reductions in blood clotting factor sales. These are reports from industry as well as from treatment centers that are reporting reduced use of the much needed clotting factor.

This is an inappropriate response and the foundation is now making major efforts to urge hemophiliacs to maintain use of the clotting factor in the treatment of hemorrhagic episodes.

The risk of not treating exceeds the risk of contracting AIDS, because uncontrolled bleeding is the leading cause of death among hemophiliacs, not to mention the potential of serious orthopedic complications and crippling if bleeding episodes are untreated.

The fear of AIDS has other tragic implications. No longer are flu symptoms or fever passed off as trivial problems. Some family members have questioned whether physical closeness with hemophilic children may be dangerous. Similarly, sexual partners wonder whether intercourse should be avoided. Many physicians and treatment centers are deluged with calls from apprehensive patients and families seeking information, and of course reassurance. Many patients are fearful that their treatment may be changed. And this is a threat to the autonomy they have gained through home therapy. And this represents a potential of being set back two decades to the old sense of helplessness and dependence upon others.

As you can see, the incidence of AIDS among hemophiliacs is of serious concern. But of even greater concern is the profound impact of the threat of AIDS.

We are most grateful for the support of Congress and the Federal agencies involved with AIDS. All of the Federal agencies involved with AIDS and hemophilia have worked closely with the National Hemophilia Foundation during this difficult period.

CDC has kept us informed of all new cases and hemophilia-related developments in a timely way so we have ample time to communicate to treatment centers, chapters, and patients throughout the country. This has helped a great deal to reduce undue alarm that results from misunderstanding of media reports about the disease. The CDC has involved the input of our medical expertise and is working in collaboration with the foundation on two major studies.

The NIH as well has worked closely with the foundation and has relied heavily upon the input of our medical experts. In response to the urgency of AIDS, NHLBI has provided increased funding support for AIDS research and has successfully compressed the peer review process without sacrificing quality in order to get new research activity moving as quickly as possible.

For example, a study of blood product use in genetic and immunologic factors that may contribute to the development of AIDS was approved in a very short time. This is also true of two other important studies that are just getting off the ground that will begin in early 1984, which is much shorter than the usual review process.

One of the problems regarding research, according to our medical advisers, is related to the very complexities of the disease itself. Because of the many unknowns, it has been difficult for the scientific community to develop a well-focused research strategy which is needed.

Last January the National Hemophilia Foundation's Medical and Scientific Advisory Council issued a series of recommendations. These recommendations included urging that those who might transmit AIDS should be excluded from blood donation. And here again the Public Health Service, with the involvement of CDC and the Food and Drug Administration, used a series of recommendations directed at discouraging blood donation from high-risk groups.

Last, the Office of Maternal and Child Health, which has responsibility for the Federal Hemophilia Treatment Center program, has been supportive of all of our efforts concerning AIDS.

In summary, we are pleased with the support, sensitivity, and sense of urgency demonstrated by the various branches of the Public Health Service.

But the needs that have been created by the AIDS crisis in our view will require much more Federal support in the years ahead. The National Hemophilia Foundation considers research in this area to be a matter of highest priority. We urge you to give this problem your most serious consideration.

Adequate funding should be provided to the CDC to expand its epidemiologic investigation and laboratory studies of AIDS, and major increase in allocations to the NIH are needed to study the etiology of AIDS.

Basic research is fundamental in helping us to learn more about this disease. In addition, the special urgency represented by AIDS requires specific funding support. The recently-enacted Public Health Emergency Research Act should be fully funded at the \$30 million level, so that funding will be available as new developments unfold with AIDS.

The AIDS crisis has created a need for comprehensive care for hemophiliacs that is greater than ever before. An informal sampling revealed a 25-35 percent increase in patient encounters at many comprehensive centers throughout the country due to AIDS. Physicians and nurses are seeing patients more frequently as patients are being examined and tested for AIDS type symptoms. Patients require more education concerning their risks and fears as well as the treatment of actual AIDS cases. This increased demand for care is most difficult because most of these treatment centers are operating on a shoestring budget as it is.

We urge an additional \$2 million of new funding to be earmarked for the Hemophilia Treatment Center program for a total of \$4.6 million for fiscal 1984. This additional funding is essential to the increase in new AIDS-induced demand for services.

Because there is so much misunderstanding about AIDS and hemophilia, it is important that funding be provided to expand the flow of accurate information to physicians and patients throughout the country in order to improve patient care and to coordinate hemophilia-related research activity. Currently, the National Hemophilia Foundation is partially addressing this need through its scarce resources and we would be supportive of any government initiative in this area.

In closing, I would like to express our appreciation to this committee for the focus you are providing on this disease. We need your help to respond to this new and devastating problem.

The recognition that AIDS appears to be transmitted through clothing factor concentrates has had a profound effect on the hemophiliacs and their families. Indeed, AIDS is a cloud over the entire hemophiliac community.

I thank you for providing us with the opportunity to share our views with you today. Thank you very much.

[The prepared statement of Mr. Brownstein follows:]



**THE NATIONAL
HEMOPHILIA FOUNDATION**

**TESTIMONY SUBMITTED TO THE HOUSE OF REPRESENTATIVES
INTERGOVERNMENTAL RELATIONS AND HUMAN RESOURCES SUBCOMMITTEE
OF THE
COMMITTEE ON GOVERNMENTAL OPERATIONS**

HEMOPHILIA AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS): THE FEDERAL RESPONSE

Statement by: The National Hemophilia Foundation

Alan P. Brownstein, M.P.H., M.S.W.

Executive Director

The National Hemophilia Foundation

August 1, 1983

I am Alan P. Brownstein, the Executive Director of The National Hemophilia Foundation. The National Hemophilia Foundation is made up of 48 chapters throughout the country and is the only national organization in the United States that is exclusively devoted to improving the health and welfare of the 20,000 persons with hemophilia and other related bleeding disorders. (Attached to the testimony is a brochure that briefly describes hemophilia and the work of the Foundation.)

The Foundation is most grateful for the support that Congress has provided over the years for much needed hemophilia research and care. As you are aware, this support has facilitated a revolution in hemophilia treatment over the last ten years. Plasma clotting factor concentrates have become widely available and home infusion therapy has freed these patients from hospital care and emergency room visits. The Committee report accompanying the Budget Omnibus Reconciliation Act of 1981 (H.R.3982) concluded "... hemophilia treatment is one of the biomedical and medical success stories of the decade." This statement is based on clear cut documentation of progress in hemophilia treatment over the past eight years. I ask you to consider the following 1981 data as compared with 1975:

- the number of patients receiving comprehensive care increased more than 350%;
- the number of patients on home care nearly quadrupled;
- hospital utilization is down more than 80% (average hospital days per year reduced from 9.4 to 1.8);
- the percent of unemployed adults dropped from 35% to 12.8%; and
- there has been a 75% reduction in the number of days lost from work or school each year.

These important human benefits are coupled with significant economic savings - careful studies have documented a 62% reduction in total health cost per patient (\$15,800 per year in 1975; \$5,932 per year in 1981) for the 9,500 hemophiliacs enrolled in federally subsidized comprehensive care centers.

Clearly, the advances in hemophilia care (i.e., availability of AHF concentrates, comprehensive care and home therapy) have enabled hemophiliacs, for the first time in history, to lead nearly normal, full and productive lives - a truly dramatic turnaround from the early 1970's.

The Impact of AIDS

Now we are faced with the frightening specter of AIDS as it has appeared in the hemophilia population. Although in absolute terms the number of hemophiliacs (16) who have become afflicted with AIDS may seem small, the risk of contracting AIDS is far greater among hemophiliacs than any other risk group. Today, of the 20,000 hemophiliacs, one out of 1,250 has contracted AIDS. Further, if you consider that there are approximately 7,500 hemophiliacs who are classified as severe, who are far more dependent on blood clotting products, the risk is much greater - 1 in 500. It is indeed ironic that the very substance that has served to liberate hemophiliacs from the disabling aspects of their disease is now highly suspect as the source of AIDS infection. To those with hemophilia, AIDS represents the makings of a nightmare - a lethal threat from a mysterious source. Blood clotting factor replacement, the source of their newly found freedom from pain and disability, has changed overnight from a life sustaining substance to a possible threat to their survival. The progress of two decades suddenly became a "mixed blessing".

The fear of AIDS among hemophiliacs has been exacerbated by extensive and in some instances distorted reporting by the media. In many respects, excess fear of AIDS among some hemophiliacs has presented more risk of death and disability than AIDS itself. Some patients have abandoned appropriate use of blood products because they fear contracting AIDS. This is based on anecdotal reports from patients and physicians, particularly orthopedists, who have reported increased joint damage resulting from inadequately treated bleeding episodes. This concern is further documented by reported reductions in blood clotting factor sales from industry and reduced blood clotting factor use from treatment centers. This is an inappropriate response and the Foundation is now making major efforts to urge hemophiliacs to maintain use of clotting factor in the

treatment of hemorrhagic episodes. The risks of not treating exceed the risks of contracting AIDS because uncontrolled bleeding is the leading cause of death among hemophiliacs not to mention the potential of serious orthopedic complications if bleeding episodes are untreated.

The fear of AIDS has other tragic implications. No longer are flu symptoms or fever passed off as trivial problems. Some family members have questioned whether physical closeness with their hemophilic children may be dangerous. Similarly, sexual partners wonder whether intercourse should be avoided. How sad it was the other day when I learned from one of our chapters that their hemophilia camp enrollment was down 75% this year because parents of hemophilic children had fear of their children being exposed to other children with hemophilia. We are now beginning to get reports of instances in the workplace where fear of contracting AIDS is expressed by those working side by side with hemophiliacs.

Many physicians and treatment centers are deluged with calls from apprehensive patients and families seeking information and, of course, reassurance. A number of physicians themselves are concerned and disagreement exists among experts as to whether or not treatment should be modified. Some have suggested that the potential for reducing the risk of AIDS would be increased if cryoprecipitate, which is derived from smaller donor pools was used instead of the dominant replacement therapy now in use - AHF concentrates, which are derived from much larger donor pools. Yet, there is serious question raised as to whether or not this would represent a safer alternative and, of course, the patients are caught in between as the uncertainty among physicians compounds the distress. Many patients are fearful that their treatment may be changed - a perceived threat to autonomy gained from home therapy and the potential of being set back two decades to the old sense of helplessness and dependence upon others.

As you can see, the incidence of AIDS among hemophiliacs is of serious concern, but of even greater concern is the profound impact of the threat of AIDS for all hemophiliacs throughout the country. Because it is suspected that this dreadful disease is caused by a transmissible agent that can be spread through blood products, we urge that the public sector continue and expand its efforts to learn more about the spread and etiology of this disease.

The Federal Response to AIDS: Current

We are most grateful for the support of Congress and the federal agencies involved with AIDS. All of the federal agencies involved with AIDS and hemophilia have worked closely with The National Hemophilia Foundation during this difficult period.

The Centers For Disease Control (CDC) has kept us informed of all new AIDS cases and hemophilia related developments. They have been sensitive to the needs of our constituents by providing background information in a timely way so that we have ample time to communicate to treatment centers, chapters and patients. This has enabled us to establish the Foundation as the major source of information for the hemophilia community. This has helped a great deal to reduce undue alarm that results from misunderstanding of media reports about the disease. The CDC has served as an always available source of information which has helped to control many unfounded rumours (and there have been many). The CDC has heavily involved the input of our medical expertise and is working in collaboration with the Foundation on two major studies.

The National Institutes of Health (NIH) as well has worked closely with the Foundation and has relied heavily upon the input of our medical experts.

In response to the urgency of AIDS, the National Heart, Lung and Blood Institute (NHLBI) has provided increased funding support for AIDS research and has successfully compressed the peer review process, without sacrificing quality, in order to get new research activity moving as quickly as possible. For example, a study of blood product use and genetic and immunologic factors that may contribute to the development of AIDS was approved (pending final determination of funds needed) in a short time.

NHLBI has also issued an RFA on July 15 to develop new tests for determining the AIDS carrier state. And, at this time, an RFP is being prepared for a prospective epidemiologic study on hemophilia and other diseases requiring blood product use. It is expected that both of these studies will be operational within seven months of

issuance of the RFA/RFP. We are impressed with this responsiveness because, as you know, the peer review process usually takes much longer. It is clear to us the NHLBI has been active in generating ideas as well as committing resources to seeking new scientific thinking.

One of the problems regarding research, according to our medical advisors, is directly related to the complexities of this disease. Because of the many unknowns, it has been difficult for the scientific community to develop a well focused research strategy.

Last January, The National Hemophilia Foundation's Medical and Scientific Advisory Council issued a series of recommendations (full text of January 14, 1983 recommendations attached) to prevent AIDS in patients with hemophilia. One of those recommendations urged as a precautionary measure that those who might transmit AIDS should be excluded from blood donation. The Public Health Service (PHS), with the involvement of CDC and the Food and Drug Administration (FDA) issued a series of recommendations directed at discouraging blood donation from high risk groups. And, most recently, the FDA's Office of Biologics held a meeting on July 19 to discuss the safety and purity of plasma products with specific attention directed at recall of plasma derivatives in situations where a donor is identified as an AIDS patient or has symptoms of AIDS. There was agreement about having ongoing discussion concerning newly reported cases of suspect donors.

And lastly, the Office of Maternal and Child Health (OMCH), which has responsibility for the federal hemophilia treatment center program, has been supportive of all of our efforts concerning AIDS. OMCH was very helpful in assisting us in our collaborative survey with CDC of all treatment centers in the nation. Further, efforts are being made to identify resources to bring treatment center directors together in the Fall to discuss AIDS and its impact on treatment.

In summary, we are pleased with the support, sensitivity and sense of urgency demonstrated by the various branches of the PHS.

The Federal Response to AIDS: Future

The needs that have been created by the AIDS crisis, in our view, will require more federal support in the years ahead. Because hemophiliacs require blood products for their very survival and because these blood products have the potential for AIDS, the hemophiliac has a special interest in efforts to understand and control this disease.

A. Research - The National Hemophilia Foundation considers research in this area to be a matter of highest priority and we urge you to give this problem your most serious consideration:

- adequate funding should be provided to the CDC to expand its epidemiologic investigation and laboratory studies of AIDS; and
- major increases in allocations to the NIH are needed to study the etiology of AIDS.

In recent years, NIH funding has not kept pace with inflation. Basic research is fundamental in helping us to learn more about this disease. In addition, the special urgency represented by AIDS requires specific funding support. The recent enactment of the Public Health Emergency Research Act (H.R.2713) provides up to \$30 million for the purposes of having the financial reserve capacity to address public health emergencies such as AIDS. We urge that appropriations be made at the \$30 million level, so that funding will be available as new research direction is defined for AIDS. We also urge that efforts continue to review research proposals as rapidly as possible without undermining the quality of the peer review process.

B. Treatment Center Funding - The AIDS crisis has created a need for comprehensive care that is greater than ever before. An informal sampling has revealed a 25% to 35% increase in patient encounters at many comprehensive care centers and this is specifically due to concern about AIDS. Physicians and nurses are seeing patients much more frequently as patients are being more carefully examined and tested for AIDS type symptoms; patients require more education concerning the risks and their fears; as well as treatment of actual AIDS cases. This increased demand for care is most difficult because most of these treatment centers are

operating on a shoestring budget after being cut back 22% last year.

We urge an additional \$2 million of new funding to be earmarked for the hemophilia treatment center program for a total of \$4.6 million for fiscal year 1984. This additional funding is essential if we are to adequately address this new AIDS-induced need for services for those who are currently enrolled in comprehensive care centers. This would also provide a modest expansion of comprehensive care to those states that are not currently part of the federal treatment center network.

C. Patient and Provider Education - Because there is so much misunderstanding about AIDS and hemophilia, it is important that funding be provided to expand the flow of accurate information to physicians and patients throughout the country in order to improve patient care and to coordinate research activity. Such an information network would also serve to collect hemophilia specific AIDS related data, survey and disseminate information concerning product use and new forms of treatment. Currently, The National Hemophilia Foundation is partially addressing this need through its scarce resources. The National Hemophilia Foundation would be supportive to any government initiative in this area. Active discussion is currently underway with the OMCH for potential funding in this area.

In closing, I would like to express our appreciation to this Committee for the focus you are providing on this disease. We need your help to respond to this new and potentially devastating problem.

The recognition that AIDS appears to be transmitted through clotting factor concentrates has had a profound effect on hemophiliacs and their families throughout the country. AIDS is a cloud over the entire hemophilia community.

Thank you for providing us with the opportunity to share our views with you today.

August 1, 1983

What You Should Know About Hemophilia



The boy on the cover is infusing himself with clotting factor concentrate at school. This will temporarily allow his blood to clot normally. This treatment, though very expensive, prevents crippling caused by repeated bleeding into joints.

WHAT DOES THE NATIONAL HEMOPHILIA FOUNDATION DO?

The National Hemophilia Foundation (NHF) is the only organization in the United States which is exclusively devoted to improving the health and welfare of persons with hemophilia. Von Willebrand's disease and other clotting factor deficiencies. NHF was founded in 1948 by Robert Lee Henry.

Today the NHF coordinates the activities of more than fifty local chapters which provide services directly to hemophiliacs and their families throughout the United States.

NHF and its local chapters provide the following services and activities:

- Support of Specialized, Comprehensive Hemophilia Care Centers
- Patient, Public and Professional Education
- Research
- Emergency Financial Assistance
- Promote the Safety, Efficacy and Equitable Distribution of Blood Products
- Camperships
- Air Lifts for Specialized Treatment
- Information and Referral to Other Community Services
- Insurance Information
- Maintaining a Hemophilia Data Base and Information Clearinghouse



**THE NATIONAL
HEMOPHILIA FOUNDATION**

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The National Hemophilia Foundation is a voluntary, non-profit national health agency, complying with all statutes relating to charitable solicitations. NHF is a member of the World Federation of Hemophilia, the National Health Council, and is a founding member of the American Blood Commission.

ARE NHF SERVICES FOR PATIENTS AND FAMILIES ONLY?

No! The National Hemophilia Foundation and its chapters provide research grants to scientists studying hemophilia sponsor educational programs for professionals serving the hemophiliac and his family, promote public policies benefiting the hemophiliac, advise governmental agencies and legislatures on the needs of hemophiliacs, and provide public information services to keep the public informed about hemophilia.

As a chronic and genetic disease, much of the research done on hemophilia has contributed to advancements in many other diseases.

Through the efforts of the National Hemophilia Foundation, a federal program for the creation of Comprehensive Hemophilia Diagnostic and Treatment Centers has been put in place. Today, there are more than 20 comprehensive care centers with over 60 affiliated treatment programs across the United States. In addition, through the efforts of the NHF and its chapters, many states have passed legislation to help underwrite comprehensive hemophilia treatment programs. These centers provide optimal care through a range of comprehensive services delivered by a multi-disciplinary team. With proper treatment and the growth of these comprehensive care centers, hemophiliacs may now look forward to a normal lifespan and a full, productive life.

HOW CAN YOU HELP?

- MAKE A CONTRIBUTION to The National Hemophilia Foundation or your local chapter
- DONATE YOUR TIME AND SERVICES to your local NHF chapter
- DONATE BLOOD either on an individual basis or as a part of a group or corporate blood drive. Contact your local NHF chapter for details.
- EDUCATE YOUR FRIENDS AND FAMILY about the true nature of hemophilia.



NHF wishes to thank the American Legion Chad Welfare Foundation, Inc. whose generous support helped make this brochure possible.

What You Should Know About Hemophilia

WHAT IS HEMOPHILIA?

Hemophilia is a hereditary blood clotting disorder which affects males almost exclusively. Although most of the time it is inherited, hemophilia can occur in families without a known history of the disease.

Hemophilia is caused by the inactivity of one of the blood proteins necessary for clotting. Scientists continue to direct their research toward determining the cause of this inactivity.

Hemophilia is classified by its level of severity: mild, moderate, and severe. Severity is determined by the percentage of active clotting factor in the blood. Persons with severe hemophilia have less than 1% of the normal levels of active clotting factor present in their blood. By definition, normal levels can vary between 50% and 150%.

Our definition of hemophilia includes Hemophilia A (Classical Hemophilia, Factor VIII deficiency), and Hemophilia B (Christmas disease, Factor IX deficiency). Von Willebrand's disease (which also affects females) and other rare clotting disorders may have similar symptoms, but are not usually termed hemophilia. Nonetheless, these disorders are included within the purposes and program of the National Hemophilia Foundation.

WHO GETS HEMOPHILIA?

Hemophilia can occur in any family, even one without a known history of the disease.

Hemophilia equally affects people of all races, nationalities, and economic levels.

Hemophilia occurs most often in males, but a few females have the disorder. Von Willebrand's disease occurs in both males and females.

HOW DOES HEMOPHILIA OCCUR?

Hemophilia is a genetic disease. Mothers with apparently normal clotting ability may, nonetheless, pass hemophilia on to their sons. In most instances, there is a known family history of hemophilia, however, up to 1/3 of newly discovered cases occur in families without a history of this disorder. Daughters may carry the gene for hemophilia, but rarely have symptoms of the disease.

A hemophilic male cannot pass the disease on to his sons. However, all of his daughters will be genetic carriers of the

disease and they can pass hemophilia on to succeeding generations. Von Willebrand's disease and other clotting disorders have different patterns of inheritance.

HOW MANY PEOPLE HAVE HEMOPHILIA?

There are at least 20,000 males in the United States that have hemophilia. This estimate does not include the many mild cases, who remain undiagnosed until after major trauma or surgery.

With hemophilia occurring in one out of every 4,000 live male births, this population is expected to continue to grow, as medical advances have enabled the hemophiliac to approach a normal life expectancy.

The prevalence of Von Willebrand's disease and other clotting disorders may be as high as that for hemophilia.

WHAT HAPPENS WHEN A HEMOPHILIAC BLEEDS?

A hemophiliac does not bleed faster than anyone else, but he may bleed for a longer period of time.

Contrary to the common conception, hemophiliacs do not bleed to death from minor external wounds. Minor cuts are easily treated, much as they are with the non-hemophiliac.

The major problem for the hemophiliac is uncontrolled internal bleeding which can begin spontaneously without apparent cause. If internal bleeding is not quickly stopped with appropriate treatment, it will result in pain and swelling. Over a period of time bleeding into joints and muscles can cause permanent damage and chronic pain.

HOW IS HEMOPHILIA TREATED?

The hemophiliac is treated by infusing a clotting factor, derived from human blood, which remains active in his blood for a short period of time. Each time internal bleeding occurs, additional clotting factor is needed. It is important to administer clotting factor as soon as internal bleeding begins in order to reduce the chances of permanent damage.

Although there are effective controls, there is no cure for hemophilia. A child born with the disease will have it all of his life.

HOW MUCH DOES HEMOPHILIA CARE COST?

The treatment of hemophilia is extremely expensive. Because hemophiliacs have a virtually normal lifespan, they must bear the catastrophic costs for a lifetime. The cost of blood products and other hemophilia-related medical expenses will vary from person to person. Studies have shown that the average cost to an individual is approximately \$10,000 a year. On occasion, complications of hemophilia have caused annual medical expenses to exceed \$100,000.

WHAT ADVANCES HAVE BEEN MADE IN THE TREATMENT OF HEMOPHILIA?

The treatment of hemophilia has radically changed since the 1960's due to the availability of plasma clotting factors in concentrated form. As a result, the quality of hemophiliacs' lives has improved dramatically. Hemophiliacs and their families are being taught to administer clotting factor concentrate at home, at work, and at school (see photograph on cover). Home therapy enables early treatment and frees the patient and his family from complete dependency on the hospital. With adequate clotting factor and careful management, most hemophiliacs may safely undergo complex dental procedures and major surgery.

Counseling and educational services have substantially enhanced the potential for hemophiliacs to lead independent lives. Of particular note is the expansion in genetic counseling due to recent advances in genetic testing (e.g. detection of carriers and prenatal tests).

WHAT NEEDS TO BE DONE?

- Find a cure for hemophilia through research.
- Provide optimal health care to all hemophiliacs.
- Reduce the prohibitive cost of treatment.
- Improve employment opportunities.
- Improve availability of health and life insurance.
- Educate the public about hemophilia.



Recommendations of
the Medical and Scientific
Advisory Council submitted
to the NHF Board of Directors

THE NATIONAL
HEMOPHILIA FOUNDATION

THE NATIONAL HEMOPHILIA FOUNDATION
MEDICAL AND SCIENTIFIC ADVISORY COUNCIL

January 14, 1983

RECOMMENDATIONS TO PREVENT AIDS IN PATIENTS WITH HEMOPHILIA

- I. Recommendations for physicians treating patients with hemophilia.
- A. It is recommended that cryoprecipitate be used to treat patients in the following groups except when there is an overriding medical indication:
- newborn infants and children under 4;
 - newly identified patients never treated with factor VIII concentrate;
 - patients with clinically mild hemophilia who require infrequent treatment.
- Similar guidelines should be applied to factor IX deficiency patients where fresh frozen plasma can be used instead of concentrate.
- B. The potential advantages and disadvantages of cryoprecipitate versus factor VIII concentrate therapy for severe hemophilia A are not clear at the present time and are controversial. The Medical and Scientific Advisory Council does not offer a specific recommendation at this time, but will continue to review the data.
- C. DDAVP should be used whenever possible in patients with mild or moderate hemophilia A.
- D. All elective surgical procedures should be evaluated with respect to the possible advantages or disadvantages of a delay.
- II. Recommendations to factor VIII concentrate manufacturers:
- A. Serious efforts should be made to exclude donors that might transmit AIDS. These should include:
1. Identification, by direct questioning, individuals who belong to groups at high risk of transmitting AIDS, specifically male homosexuals; intravenous drug users; and those who have recently resided in Haiti.
 2. Evaluation and implementation (if verified) of surrogate laboratory tests that would identify individuals at high risk of AIDS transmission.
 3. In addition, the manufacturers should cease using plasma obtained from donor centers that draw from population groups in which there is a significant AIDS incidence. It is clear from the epidemiologic data that the pool of individuals at risk for AIDS transmission is not uniform throughout the country and that a great deal could be achieved by excluding donors from the "hot spots".
- B. Efforts should be continued to expedite the development of processing methods that will inactivate viruses potentially present in factor VIII concentrates.

- over -

- C. There should be an evaluation of the possibility that the yield of factor VIII in pheresis donors could be increased using DDAVP or exercise to maximize yield. This would permit a reduction in the size of the donor pool and would compensate for losses in plasma that might occur due to steps rec'd above.
 - D. There should be an evaluation of the feasibility of fractionating and processing plasma so that lyophilized small pool products are available. While this will certainly be more costly, it may be the only way to break out of the present dilemma without going to an all-cryoprecipitate effort.
 - E. Concentrate manufacturers should immediately cease purchase of recovered plasma for factor VIII concentrate from blood centers that do not meet the criteria listed in II A above. These criteria should also apply to the production of cryoprecipitate.
 - F. Manufacturers should accelerate efforts towards the production of coagulation factor concentrates by recombinant DNA technology.
- III. Recommendations to regional and community blood centers:
- A. Those centers that are in regions in which there is a very low incidence of AIDS should increase capacity for cryoprecipitate production to be used locally and in other regions.
 - B. These centers should evaluate the feasibility of preparing small pool lyophilized cryoprecipitate for hemophilia treatment.
 - C. The production of cryoprecipitate should also adhere to criteria detailed in II A, above.



THE NATIONAL
HEMOPHILIA FOUNDATION

HEMOPHILIA AND ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
FACT SHEET

FEDERAL SUPPORT NEEDS

- FULL FUNDING FOR EPIDEMIOLOGIC INVESTIGATION AND LABORATORIES STUDIES (CDC);
- FULL FUNDING OR BASIC BIOMEDICAL RESEARCH, AIDS-SPECIFIC FUNDING AND \$30 MILLION APPROPRIATION FOR THE PUBLIC HEALTH EMERGENCY ACT (NIH);
- \$4.6 MILLION (\$2 MILLION NEW FUNDING) TO SUPPORT HEMOPHILIA TREATMENT CENTER PROGRAM TO MEET THE INCREASED DEMAND FOR SERVICES DUE TO AIDS (OMCH); AND
- FUNDING FOR PATIENT AND PROVIDER EDUCATION RELATED TO AIDS.

I. HEMOPHILIA - WHAT IT IS - Hemophilia is a lifelong, hereditary blood clotting disorder which affects males almost exclusively. Hemophiliacs' blood does not clot due to the inactivity of a plasma protein in their blood. Hemophiliacs may experience uncontrolled, painful bleeding and hemorrhaging. Chronic joint bleeding results in progressive joint damage and crippling without adequate treatment.

II. INCIDENCE OF AIDS - Sixteen cases of AIDS confirmed, nine deceased. This represents a rate of one out of 1,250 hemophiliacs with AIDS. Among hemophiliacs who are classified as severe, the rate is one in 500.

III. IMPACT OF AIDS - Since the early 1970's, the advances in hemophilia care have enabled hemophiliacs, for the first time in history, to lead nearly normal, full and productive lives. Now this population is faced with the frightening specter of AIDS. Blood clotting factor replacement, the source of their newly found freedom from pain and disability, has changed overnight from a life sustaining substance to a possible threat to their survival. The fear of AIDS has tragic implications. Some hemophiliacs have abandoned use of blood products even though the risks of not treating exceed the risks of contracting AIDS because uncontrolled bleeding is the leading cause of death among hemophiliacs, which is compounded by the potential of serious orthopedic implications if bleeding episodes are not treated.

IV. RESEARCH, HEMOPHILIA, AND AIDS - Because hemophiliacs depend upon a factor derived from blood plasma, they are vulnerable to anything that may contaminate blood products. More research and epidemiologic work needs to be done to reduce the spread of AIDS and, in the long run, to reduce other risks of blood infectivity in the future. Such research will benefit the general public as well as hemophiliacs.

V. HEMOPHILIA TREATMENT AND AIDS - Due to AIDS, the need for comprehensive care is greater than ever before. Physicians and nurses are seeing patients much more frequently and the need for psychosocial intervention has greatly increased.

VI. PATIENT/PROVIDER EDUCATION AND AIDS - Because there is so much misunderstanding about AIDS and hemophilia, it is important that funding be provided to expand the flow of accurate information to physicians and patients.

August, 1983

Mr. WEISS. I want to thank all of you for your testimony. It has been very effective, eloquent, and factual.

I also want to thank each of you for summarizing and highlighting your testimony. Your prepared statements will all be entered into the record. I hope that not only members of this committee, but Members of the House and the general public will take occasion to read those full statements because they are filled with a wealth of factual information and analysis that go far beyond the summaries which we asked you to make in the interests of saving time.

We will again adhere to the 5-minute rule and go around as many times as is necessary to cover all the questions that members have.

Ms. Apuzzo, in the course of your testimony you stressed, as did some of the witnesses prior to your testimony, the issue of confidentiality. And as you may know, for some 8 to 10 weeks this subcommittee has been attempting to get access to factual information from the Centers for Disease Control and other component agencies of HHS. HHS has repeatedly raised the issue of confidentiality, claiming they were not confident that the subcommittee would adhere to the requirements of confidentiality.

We have taken great pains, as I said in my opening statement, to assure and reassure the Department that, in fact, we had no interest in learning the names of people afflicted with AIDS. They were not necessary for our oversight work. Indeed the last thing that we did was to provide a detailed system for CDC to excise whatever names may be in those files and to assure that our people would never get to see them.

We still have not gotten access to the files, incidentally.

I give you all that background because I really had not known until I read your testimony the extent to which CDC has been using the other side of the argument in refusing to recognize the concerns that the community at risk, which you represent, had about questions of confidentiality.

I find that to be the height of cynicism; in the one instance to be using the confidentiality argument to obstruct the work of their oversight subcommittee and, at the same time, to refuse to recognize the legitimate confidentiality concern which you have expressed.

Would you go into some greater detail as to what efforts you have made to work out the confidentiality issue with CDC?

Ms. APUZZO. Yes, Mr. Chairman.

It is necessary to provide you with some sense of what our communities are dealing with in their various locales. In New York, early on confidentiality became an issue of enormous concern to us, an issue relating to the blood question, and in the context of epidemiology.

We have attempted in our own networks to raise the consciousness of our community about the necessity of being as cooperative as possible in reaching a resolution of AIDS. But again and again, as Mr. Callen pointed out, the community has had to acknowledge that there was no premise, no substance, no basis upon which to provide information to a government that in fact denies us job security—in 24 States we are illegal, sir—denies us the opportunity

to serve in the military, denies us the opportunity to raise our own children, denies us an opportunity to teach other people's children.

You must understand the reality of our lives. When that Government—CDC, NIH, any other Government institution—comes to us, asks us questions that in fact represent illegalities in I believe 24 States—you must understand that it is not paranoia. It is the very real fear of our lives that has raised our concerns here.

We have worked in locales and then had an opportunity in Denver to come together at a gay lesbian health conference, where I chaired a public policy seminar. At that particular seminar, we had paradigms, constructions, that we had worked out with Lambda legal defense to demonstrate that we would be willing to provide all the information essential, providing confidentiality would be assured, that providing that CDC and Government would enter into an agreement to assure us that in fact this information would not be used to sabotage our lives in the future.

We have not been able to get to first base in our negotiating with CDC to utilize this kind of a system. And so it is only as a last resort that we come requesting that legislation be considered that would guarantee not only thoroughness in that vital area of epidemiology, but the security needed so that persons could respond to questions and could guarantee integrity about that data that we so desperately need. That has been just a bit of our experience.

Mr. WEISS. Thank you very much.

Dr. COMPAS, in the course of your testimony, you indicated that in New York City the Department of Health has now removed Haitians as a special category of communities or groups at risk. You have indicated that has not yet happened with CDC at the national level.

Have you engaged in any discussions or are there discussions ongoing regarding CDC following through on a similar kind of determination?

Dr. COMPAS. Yes. In fact, we have started to discuss with CDC more than a year ago. Two or three weeks ago we have met with Dr. Joyce Johnson, who is supposed to be the chief epidemiologist for epidemiological research in the Haitian community. We told her what we consider as a weakness in those studies upon which the classification is done.

What we have found is that, as I have said in my testimony, most of the patients were interviewed by Americans, who don't know the Haitian culture, don't speak Creole, don't speak French at all. Those patients are undocumented, what they call "illegal aliens."

They came to their bed, asking questions like: are you homosexual, drug addicts, all things that are supposed to be illegal. The answer was always no. What we have told the CDC is that the interviewers should be Haitians, people who do understand the culture of the patients and who can communicate properly with the patients.

In New York City, Dr. Sencer understood what we have told him, he is a very scientific man. On the basis of what we have found in New York, he decided to remove the Haitians from the high-risk group. The CDC, in their article in the New York Times yesterday,

said that they are not going to remove the Haitians on their list, and also they are not going to use any Haitian interviewers.

In fact, somebody said, Dr. Fishee I think from Miami, she said she doesn't believe that Haitians should interview Haitians, which is in our opinion totally unscientific. If you are dealing with people who are in a different category, have a different culture, you have to use agents who know this culture.

I feel in the gay community here, the people who are interviewers were Americans, they share the same culture as the gay community, they have some differences—but basically the cultural background is the same. And we do feel it should be the same for Haitians.

Mr. WEISS. Thank you very much.

Mr. Walker?

Mr. WALKER. Thank you, Mr Chairman.

Ms. Apuzzo, I understand from the chairman now that your written record, your written remarks have been submitted for the record.

Ms. APUZZO. Yes, sir.

Mr. WALKER. And I assume, then, that questions about those written remarks are in order as well as what you delivered.

Ms. APUZZO. To the best of my ability I will attempt to, sir.

Mr. WALKER. Fine, thank you.

On page 3, you make the allegation or the suggestion that discrimination, either racial or otherwise, is being pursued against people with AIDS. And you suggest rather vividly that someone in the Government thinks that AIDS victims are expendable.

Those charges are pretty sensational, and they are pretty serious. What I would ask you, since they are on the record, is if you could provide us with the names of any Government officials who you think are guilty of such acts, and if you could give specific incidents that have led you to make such serious allegations.

Ms. APUZZO. Yes, sir.

Let me say that I will provide you with additional data. But let me say this, sir: In the last year the blood issue, as we have heard from our representative from the hemophilia community, this last year the gay community and other communities, the Haitian community, have been essentially standing out there on a limb where the blood issue has been concerned.

If you will, sir, it was 1 year ago, that Dr. Curran came to New York and identified the blood issue as a very volatile issue.

There is no need to demonstrate to you, I think, the amount of stigmatization associated with the term "gay blood, bad blood." I think it pretty much speaks for itself.

In that year, we have headline after headline after headline that suggested that the blood supply in this country was being contaminated by homosexuals. The homosexual community has responded with what I consider to be unprecedented force and unprecedented commitment, to educate itself, educate itself long before the media took up the question of AIDS.

If you look back at the publications in this community over the last 2 to 3 years, you will find that each publication, many of which are circulated free of charge, have made every attempt to bring to the gay community the latest information, attempting to get the

gay community politicized, to be able to apply pressure, and beyond that, in light of this blood crisis, attempting to demonstrate to our community a responsible response to what was being told to us.

In that 12-month period, sir, we have been left hanging out on a limb.

Increasingly, headlines have alleged that we were simply looking to be obstreperous or failing to cooperate with a life and death situation.

I maintain, sir, that the lethargy with which the Federal Government has responded has made many of us victims of redtape, as we heard earlier.

That kind of vulnerability to a community that is already vulnerable, has resulted in outbreaks of violence against gay people, which I can document and give you names.

I don't know the facts about how much research is actually going on, despite the fact that I have asked for it consistently. I don't know today what programs are going on where.

I have information to the fact that in this 1-year period, despite the fact that Dr. Curran came to us a year ago and identified the volatile issue of blood, there is now \$56,000 in one program seeking to find a resolution of the blood issue, which has left us very vulnerable.

Mr. WALKER. I thank you, and I hope you will provide us for the record with the specific incidents to which you refer.

If I understand, though, in your testimony, I did not hear the names of any Government officials specified here. You were evidently indicating or expressing the attitude that AIDS victims are expendable.

There are such Government officials?

Ms. APUZZO. Sir, when a government fails to respond to an issue that is resulting in the loss of life, it is convenient not to be able to find a single individual.

It is convenient to blame it on a system, but that system, in fact, has been something less than just lethargic in responding to our need, something less than just lethargic to responding to our cry for assistance, and what I would consider to be an attempt to cooperate. This community has approached the Government consistently, attempting to cooperate and be a part of the process with the Government. Rarely has that offer been accepted.

Mr. WALKER. I was going to ask you to go beyond the systemic problem and identify the specifics.

Ms. APUZZO. I think, sir, when fully 6 months ago I asked Dr. Curran, in the company of representatives from the Lambda Legal Defense, over the telephone, for a report that would demonstrate to us exactly what programs were in effect, what their costs were, what professional personnel were assigned, and what the clerical support were for each of those programs, and I did not get an answer; and 2 months later I wrote a letter to Dr. Brandt; 2 months ago, I wrote to Secretary Heckler and still do not have an answer. That is a 6-months' lag, and if we don't know what the Government is actually doing, how can we responsibly know what it is to ask for?

Mr. WALKER. You mentioned on three occasions, Dr. Curran. Are you accusing Dr. Curran of engaging in racial or other—

Ms. APUZZO. The issue has to do with the fact that the victims of AIDS, 40 percent of the victims of AIDS, are people of color.

The longer the situation is allowed to persist, the more vulnerable the population is.

Mr. WALKER. OK. I am trying to get to some specifics here, though.

Are you accusing Dr. Curran of engaging in discrimination or in treating the problem as though AIDS victims are expendable?

Ms. APUZZO. I am accusing the entire system, sir, of failing to respond with the same speed and the same commitment that might have been its motivation, if those persons who were vulnerable to AIDS were, in fact, a member of another sociological group.

Mr. WEISS. If the gentleman will allow, 7 minutes have elapsed. We will come back for a second round.

Mrs. Boxer?

Mrs. BOXER. Mr. Brownstein, do you feel that there should be a way to develop a test so we can tell from a blood sample if it carries AIDS disease?

Mr. BROWNSTEIN. Absolutely; yes. We have supported that as being the best way of preventing AIDS until we learn more about how this disease is spread, and what it is; there should be some sort of a test.

Mrs. BOXER. Do you know at this time whether such research is going on in the Federal Government?

Mr. BROWNSTEIN. Yes, it is. The Centers for Disease Control is exploring different types of tests, and also an RFA has been issued by NHLBI to determine, to learn more about the AIDS carrier state, and should be operational at the beginning of 1984, and hopefully this will provide new information about what kind of testing should be applied to the blood.

Mrs. BOXER. What does the Government, if you know this, spend on research on hemophilia?

Mr. BROWNSTEIN. OK.

Mrs. BOXER. What did it spend in the height of the research effort?

Mr. BROWNSTEIN. I cannot answer that specifically. One of the problems is that there are so many areas that are related to hemophilia; much of genetic research is related to hemophilia, as is much of the research related to joint diseases, and so on; so it is difficult to pinpoint a specific number, but we do receive printouts from the various Institutes of the NIH, so that the Foundation and its medical research advisory group can keep tabs on what is going on in different places, and I would be glad to share that information with you after this hearing.

Mrs. BOXER. You can't give me a ballpark figure as to how much research money is spent specifically through the Hemophilia Foundation, so we can try to get a handle on that kind of information?

Mr. BROWNSTEIN. Specifically, through The National Hemophilia Foundation, there is about \$100,000 of research.

NHF is a small foundation. That is private nongovernmental funds supplemented by about \$30,000 of Government funds.

Mrs. BOXER. So you feel, I would assume, above and beyond that, we would need to put more funds into the testing of blood to pick up the AIDS disease?

Mr. BROWNSTEIN. Absolutely.

Mrs. BOXER. Have you quantified how many dollars it would take just on that research effort alone? Any ideas on that?

Mr. BROWNSTEIN. No, but we can furnish that information to this committee, should it be desirable.

Mrs. BOXER. I would appreciate that.

[The information follows:]



THE NATIONAL
HEMOPHILIA FOUNDATION

September 7, 1983

Honorable Barbara Boxer
U.S. House of Representatives
1517 Longworth House Office Building
Washington, DC 20515

Dear Ms. Boxer:

I am most pleased with the interest you have taken concerning the serious matter of Acquired Immune Deficiency Syndrome (AIDS) and your participation in the hearing that was conducted on August 1-2 by the House Intergovernmental Relations Subcommittee.

Mr. Alan P. Brownstein, Executive Director of the National Hemophilia Foundation, requested that I respond to a question that you had asked concerning the development of a blood test to detect the AIDS carrier state. As I am sure you can appreciate, there are many variables (including chance) that would affect the amount of time and funding support that would be required to develop a test that was sufficiently specific and sensitive to detect AIDS or markers for AIDS in individuals who were asymptomatic but whose blood was potentially infectious. In my opinion, the first step would be to develop a collection of white cells and plasma from a large number of individuals at high risk for the development of AIDS and analyze these stored samples when AIDS develops in those who donated these blood samples. Given the long incubation period associated with AIDS, this would require at least 2 - 4 years and a \$2 - 5 million investment. The specific cost of such a study would depend upon how many individuals were included in the sample, how frequently they had samples taken, and where the study was conducted--clearly, high risk areas would be more likely to provide useful information.

Another more broadly based approach depends upon a better understanding of the immune deficiency in AIDS through basic research. This would also help in developing a suitable blood test.

I wish I could be more specific about such an effort, but our level of understanding of AIDS limits our ability to provide a definite answer at this time.

Once again, I am most appreciative of your commitment to help us learn more about the etiology of AIDS and its treatment.

see How To Use Us

Sincerely yours,

Leon W. Hoyer, M.D., Chairman
NHF Medical and Scientific Advisory Council

cc: A.P. Brownstein

19 WEST 34th STREET • SUITE 1204 • NEW YORK, NEW YORK 10018 (212) 583-0211

Mrs. BOXER. Dr. Compas, I was rather shocked by what I am concluding as a result of your testimony. It appears to me that the Haitian community was branded as an entire community before it should have been, and that because we used sloppy techniques in interviewing the patients, that it is your conclusion that the Haitian people who have AIDS are the same high-risk population as the American population, if you will, and that, at this point, you say in your testimony on page 5 that you have received no official answer from CDC on discussing this problem.

My concern is, if, in fact, it turns out that you are correct, and they were wrong, and they had sloppy information, that you have a stigma on your community, and if that should be the case, do you think it would be incumbent upon HHS and this Government to really clear the name of the Haitian community in terms of its not being any different than any other community? And should that be done, if this proves to be the case, with a massive public education effort?

Dr. COMPAS. Yes; definitely.

We did not receive any help from any agency, Federal or local, for education in our community.

It isn't true that the community did not do any good work, and the classification was totally premature.

Mrs. BOXER. I understand, but would it be your desire, should this prove true, that there should be a massive public information campaign to make the truth known, because it seems to me from what you say there is great prejudice against children, hiring people. It seems that we have caused a lot of pain and suffering to an entire group here.

Dr. COMPAS. Yes, because all Haitians in general have been classified as a high-risk group, and people, let's say professionals, lay people, people working as maids, or whatever type of work they are doing, were stigmatized or fired from their jobs, and definitely, if the truth comes to light, the American Government has to do a great deal of education to the American public to make them known what is the truth about the Haitian community.

Mrs. BOXER. In other words, if we have been wrong, we better admit our mistake because an entire community has been stigmatized.

I want to move on to Ms. Apuzzo here. I have had a very similar experience, as you have had, in dealing with Dr. Curran, and given the fact that I am a Member of Congress, it has been a little bit frustrating for me in trying to set up meetings and get information and data.

Do you know of any other health crisis in the country where the Congress has had to really push the health officials? In other words, it seems to me from my experience as an elected official, and although I have only been in the Congress a short time—I have been in local government—that it is the health people that have come before us elected officials and tried to really fight for funds, money. In this case, I see a very reverse type of situation, where it is the Members of Congress that are really pushing, and I wonder that in your research you might want to comment on whether this seems to be a different kind of attack.

Ms. APUZZO. It certainly has raised suspicions in our minds, Congresswoman Boxer.

We only have to look at an instance like Legionnaires' disease, where I don't believe the public health officials had to come to you to say, don't push us; we are doing a great job. I believe they were serious and directed, and very above board in pursuing a rapid response, and they should have been.

I believe that we make a terrible error when we pit groups in need against each other.

My own response, and Mr. Endean certainly can share his, is that we have virtually had to tug every inch of the way, and I venture to say that neglect is never benign.

If I have suggested that the neglect has been malignant, I mean to suggest precisely that. I believe if we have left the Haitian community, the gay community, if we have left the I.V. drug users standing by to be consistently vulnerable to a life-threatening disease, then we cannot call that benign neglect.

Mr. ENDEAN. Congresswoman, we faced enormous difficulties in this process. On the one hand, the administration and many public persons say, don't throw money at a problem.

On the other hand, as Ms. Apuzzo has alluded to, we have had incredible difficulty in finding out what is being done, and what could be done that is not being done.

We have seen a consistent pattern here that leaves us at a very significant disadvantage. When the supplemental appropriation was being marked up before the House subcommittee, the administration made clear time and time again that we did not have need for AIDS money, and at the very same time as that was being marked up, Dr. Brandt was testifying before Congressman Waxman's subcommittee, and on significant probing, it was discovered that they were not sure whether they did or did not, and they might have to ask for an emergency supplemental, and in the final situation, \$12 million was put in the supplemental, and we are very pleased with that, but it is not enough, but there has been a consistent pattern here that leaves many of us that are attempting to advocate for increased funds at a significant disadvantage, and you are quite right: For a public health emergency of this sort, I think many of us are baffled as to why we have to be pushing as hard as we do.

Mr. WEISS. Thank you very much.

Mr. McCandless?

Mr. MCCANDLESS. Before I ask my questions, I would like to start by saying I am not an insensitive person. You are here before us, so that we may try to find solutions to problems. If my questions tend to take on some kind of a connotation, it is not intended.

I would also like to comment that this is a number-one public health priority, Ms. Apuzzo, and I certainly don't mean to place it in a second-rate position, but for those of us who have had loved ones die of cancer, we may find it a little difficult to accept this as the No. 1 priority for public moneys.

If I had the disease, I would probably think entirely different. The area that I have some problems with is the information that the staff gave to me as a basis for participation.

It indicates that there are certain personal habits completely separate from homosexuality that have a direct bearing upon the possibility of acquiring the disease.

For example, a report indicates that 90 percent of the patients involved have used nitrate inhalers, an intravenous drug. I would compare this to a person having a problem with his liver and being subjected to a cirrhosis type of indication, and continuing to drink alcohol. Certainly the cirrhosis of the liver is going to get worse rather than moderate itself.

What I would like to know, Ms. Apuzzo, is have you or and your organizations produced anything in the way of a self-awareness program on the lifestyle of individuals and what they might or might not do in order to prevent the disease?

Ms. APUZZO. Sir, I appreciate your refutatory comment. I appreciate an opportunity to address the question, because it is a difficult question, and difficult questions don't have simple answers.

I would say to you parallel to your question, sir, that there is a high correlation between smoking and lung cancer, and yet we continue to pour, appropriately, money into the cure of that dread disease. There is a correlation between other behaviors and other diseases, and we continue to seek the answers to those diseases.

More specifically to your point, what you raised is a question that we have faced every day since we have had to deal with AIDS, and the question basically is the distinction between diagnosis and judgment.

Each time we have had to deal with the issue of diagnosis, there has been attendant to that diagnosis a judgment.

I submit, sir, that it is not the purpose of government to judge in the face of a crisis. It is the purpose of government to solve that crisis.

But let me go one step further.

You could raise a variety of specific instances, I am sure, that would not be easy questions to answer, but I would beg you, to take some cognizance of what is the oppression of a gay male or a lesbian in this country. Not as an excuse, but symptomatic of that oppression, there is a style of life that might not be the style of life, if we were not unable to share domiciles together in many States. One cannot live together. There is, in an attempt to take a shortcut, there is a series of circumstances that mitigate against gay people simply growing up and living their lives minding their own business.

You don't need me to tell you that. I would submit that just anyone from this community coming up here could tell you that.

In terms of the amyl nitrates and butyl nitrates, those questions should be addressed, as I am sure they are, in the testimonies that I have read by Dr. Bruce Voeller.

Mr. McCANDLESS. I understand that, but my question was, shouldn't you, as executive director of the National Gay Task Force, and Mr. Endean of the Gay Rights National Lobby, and as leaders in the communities you represent, make certain awareness programs available.

Ms. APUZZO. Absolutely.

Mr. McCANDLESS. I got a dialog completely separate from that. If I want to continue to drink Scotch, it is self-induced—

Ms. APUZZO. Let me assure you, sir, that the hotline that we have, every line is filled and has to be filled, every person requesting information gets information, and we alert the person as to the risks of what has commonly been called "fast lane."

We have invested an immense sum of money in public health education literature that has gone out, and every organization in the gay community that has been involved over the course of these last 2 or 3 years has produced literature advising our community about what constitutes at-risk, and what behaviors put persons in the category of at-risk, and have urged people to consider very strongly their personal lifestyles and the necessity to address those lifestyles in a manner that will bring them into well being as opposed to illness.

Mr. McCANDLESS. Thank you, Mr. Chairman. I have nothing else.

Mr. WEISS. Thank you, Mr. McCandless.

Mr. LEVIN?

Mr. LEVIN. Thank you.

Let me, if I might converse with you, Mr. Brownstein, because I found that there is a somewhat different experience that you had in your organization, in dealing with the Government, than was the flavor in the testimony of the other witnesses. And thank you for all of your testimony.

I think it has been most helpful.

How do you react—I don't want to put you too much on the spot, but you have had a lot of experience in a field dealing with the Government, and a lot of experience obviously in the public health field dealing with perhaps one sector, but, as you have testified, it relates to others.

What is your comment, forgetting about motivation for a moment, as important as that is, what reaction do you have to the experience in this battle with the Federal Government?

Mr. Endeane testified about the slow and inefficient response of the Federal Government, and the testimony of Ms. Apuzzo, that the Government responded with lack of speed, especially in comparison to that for Legionnaire's disease.

Mr. BROWNSTEIN. I have two responses to your question, which I think is a very good one. First of all, it was not until July of 1982 that CDC first announced three cases of AIDS among hemophiliacs; that is quite some time after AIDS had been identified in the gay community; so I think that in relative terms, the hemophiliac community were newcomers to this.

So, in a way, we have had the benefit of the most recent increase in public awareness, so we are at the eclipse of the awareness that comes from the Government, from the Congress, and we are seeing increased activity going on.

Quite frankly, we went to our medical community, and we asked, what needs to be done, not just for this hearing, but for numerous meetings that we have had over the past year due to this crisis, and we have identified certain areas, and we have reason to believe, that these areas are being addressed and the timetables for reviewing research grants have been compressed to the point practical.

That is part one.

Part two is that surely everything is too slow. It is much too slow when you consider that 1 out of every 500 severe hemophiliacs has contracted the AIDS problem to this very date. We want a cure tomorrow.

Daily, myself, and chapters, and our medical people throughout the country, are in daily contact with hemophiliacs, mothers who call up and say, I infused my child last night, and I am afraid that that infusion had AIDS in it, but we know that that is not possible to determine, knowing the incubation period, but these are very real fears, so it is too slow! Yes, it is, and our frustration calls out for a cure.

I cannot comment to your question as it relates to the Government's response 2-3 years ago, when it became apparent that this was a major problem, but, as we are seeing it now, we see the administration and Congress, we see all this activity, and all of this contributes to increased awareness and support, so the slowness will become, hopefully, more rapid. That is my response.

Mr. LEVIN. Let me ask Ms. Apuzzo or Mr. Endean, have either of your organizations tried to put together what a more comprehensive plan might look like?

I know it is very difficult for you to do that, but the prime focus of these hearings will be on that question, or it is at least one of the major areas of attention, with the human tragedies beyond description, and—I hope—I think all of us are deeply troubled by it.

We also want to try to embody that in some kind of response here that makes sense.

Do you have any guidelines for us that you would like to throw out at this point? Perhaps it would only provide some useful material for us to consider before we talk with the Government witnesses.

Mr. ENDEAN. The Gay Rights National Lobby has lobbied Congress for a number of years now. A primary focus until recently has been on securing civil rights and equal justice for gays and lesbians.

Our focus has changed dramatically to look at the AIDS issue. However, we are a small organization, and we face, as I suspect the task force and other organizations face, enormous difficulty in getting the facts about what is and is not being spent, what is and is not needed.

So I have some difficulties, frankly, giving you the guidance as to all of the details of what should be done that is not being done.

It seems to me that administration and public health officials who know from the various institute heads, for instance, what they believe would be needed, have, when they come up to Capitol Hill, been gagged. OMB does not let them spell out what is and what is not needed except within the confines of the budget that they choose to dictate, so I am at somewhat of a loss to really give you the guidance that I think you need.

It is my hope that these hearings will play a major role in getting a clear handle on what is needed. Clearly, we have not even scratched the surface at the present.

Ms. APUZZO. If I may just add to that, sir, and I know Dr. Voeller and Dr. Conant will be much more specific in their recommendations to you as a result of their expertise, but I would say from one

lay person to another, where this is concerned, we need animal models and we need them rapidly. They are very expensive. We probably ought to look at each and every body fluid, and probably over a 2-year period of time, because that is what is being hypothesized as the incubation period. I don't know what the parameters are in terms of the number of animals, but I have seen models that suggest over a 2-year period of time in each of the six body fluids that one could spend \$193 million. That does not take into consideration a beefed-up epidemiological program that really takes confidentiality seriously and provides data we can have confidence in. That does not take into consideration public health information, which has to educate fast, and that does not take into consideration a real partnership with the affected groups, so we can, in fact, work together to get to the bottom of this, and it does not take into consideration patient care. I am sure I have left some things out, but I think, if we continue to think in terms of \$10 million, \$25 million, and think that those sums seem very large, that they will solve the problem, then I think we are foot dragging.

It appears to me, and I said before Mr. Natcher's committee sometime ago, that we have a National Academy of Science and the best minds available, if CDC and NIH cannot come up with a program that says, this is what is needed over this much period of time, and this is what it will cost. Again, to gain our confidence in that program, perhaps it is time to go to another body that I understand was put into effect to apprise Congress of scientific issues when they needed to call upon it.

Perhaps it is time that we look to another group of experts to assist us in putting together something that frankly all of us can have some confidence in.

Mr. WEISS. Thank you.

Mr. Craig?

Mr. CRAIG. Thank you very much, Mr. Chairman, and special thanks to all of the panelists.

I am at a point of being confused as to what questions to ask, because I see a variety of accusations and immediate contradictions flying in the whole testimony of the panel. Let me address, first of all, the issue of discrimination.

My reaction to that issue as it relates to the testimony I have heard this morning is, if you were here testifying on the issue of cancer, as we now know it today, the issue of discrimination would never arise, because it is a nondiscriminatory disease.

It appears from the evidence that is available today on AIDS, that it is apparently discriminatory to a point. If you are to talk of the disease based on the information that is available today, then by the knowledge of that information, you have to speak about certain groups of people and certain communities or lifestyles, and in so speaking of the disease, the accusation can be made that in speaking of it, you are discriminatory.

I question, then, the accusation that is made, based on that kind of logic which I don't find too faulty, as it relates to blood, and a person who is on the threshold of studying this problem recognizing that it is blood related. Then if we are to speak of blood, and you have to in the confines of this disease, and you speak of communities with which the disease seems to be prevalent, you, by

that relationship, develop a problem. I remember Government research officials in the early stages of other areas of research making statements that were later found to be totally faulty. But, based on the early information, they thought they were being responsible in making those statements.

If I could be so crass as to say cyclomates are carcinogenic—now it is questionable whether they are at all, but we went through that era, and we have that problem. I think that Mr. Brownstein mentioned today in his testimony the tremendous complication involved in the intricacy of what we believe to be involved with this disease.

You would not be here today, Ms. Apuzzo, if it were not for all that has transpired since 1981.

You would not have been here in 1981, because this hearing would never have been called. We simply did not have even the preliminary research we have today which is beginning to identify the extensiveness of the problem. So I look at the record, and I am not saying you should not be a prophet of action, and hopefully this committee can respond in a reasonable sense as it relates to dollars and a course of direction in assisting with CDC and NIH, but from 1982 to 1984 this Government has spent \$37 million, excluding the supplemental twelve. Look at legionnaires: we spent \$18.5, and yet you say, that was an immediate call to action, and the timeframe was 1976 to 1984 for the expenditure of those dollars.

I will agree that when you look at the report, there were 2,700 in that timeframe that were identified as having contracted legionnaires with an 18-percent death rate in a much shorter timeframe, but only because the research has gone on and the collection data has been brought about.

We are now able to determine some 2,000-plus cases, with nearly a death rate of 38 percent.

If you look at toxic shock syndrome, \$8.2 million to date was spent by the Federal Government.

We have now appropriated and/or spent over \$40 million to date, and obviously a great deal more will now be spent or else the Secretary of HHS would not have called it the No. 1 medical problem in this country today.

Based on the research I have read, I think we are beginning to respond with a great deal more urgency, and they will respond with a great deal more urgency since it is now recognized to be a specific emergency.

I believe that if you would look at the past, the present, and what we perceive we must now do in the future, that I could find selected areas of criticism. However, the record bears rather clearly that this Government, based on its knowledge, this administration, on history and the record, is beginning to respond faster than they have ever responded to anything else. It is beginning to respond in an appropriate fashion, and it will be this committee and your assistance that will bring that kind of response at a much more rapid rate than we have seen in the past.

Mr. WEISS. Although your time has expired, I think it is only fair to allow the panel to respond hopefully ever so briefly.

Mr. CRAIG. Thank you, Mr. Chairman.

Mr. ENDEAN. Congressman, I am glad you raised the issue, because since Secretary Heckler proclaimed AIDS the No. 1 priority, the administration has not modified its initial 1984 budget proposals. Those are woefully inadequate. The administration proposals for fiscal year 1984 are less than already has been spent. With all due respect, I think we are seeing a rapid speedup in rhetoric.

I grant that. I think that the administration has spoken out forcefully. It has not spoken out forcefully to its budget offices, to the appropriations committees, subcommittees, or to the Congress.

Without that kind of action, it remains, in my view, so many words.

Ms. APUZZO. I think it is difficult to acknowledge perhaps, from your perspective, that the Government could, in fact, be discriminating against any group of people in this country. From my perspective, it has been a part of my life. From the perspective of those who are persons with AIDS, ask them.

When you say that the administration is now speeding up, I can respond to that; I can have hope in that, and I can be willing to continue to work and encourage my community to continue to work, but I have to say to you, sir, we now have upward of 1,902 cases in this country as of a couple of days ago. That is a long time waiting, and it is very, very costly waiting, sir.

Thank you.

Mr. CRAIG. Thank you, Mr. Chairman. Recognizing the time limit, let me conclude on the discrimination issue that Ms. Apuzzo talked to—

Mr. WEISS. You have taken twice your allotted time.

Mr. CRAIG. I appreciate that, Mr. Chairman—and I will make it very brief—I don't think anyone in this Government chooses to discriminate.

There may be exceptions, but I do recognize that when you single out a problem that may address a select group of people, depending on your sensitivity to the problem and the group, that can be, and oftentimes is, construed as being discriminatory.

Mr. WEISS. If members have other questions, of course, we will provide the time for addressing them to the panel.

If not, however, we do have a group of medical people, doctors and researchers, who will comprise the next panel.

I would like to move on to them.

Mr. Walker?

Mr. WALKER. On page 3 of your prepared testimony, you suggest that other high-risk groups have used the Haitians as scapegoats, Dr. Compas.

Would you elaborate on that comment a little bit for me, please?

Dr. COMPAS. A few gay people have been trying, in some newspaper articles, I don't remember which one exactly—to relate the disease to the swine fever virus and has been saying that we, Haitians, are bringing the diseases here. Some gay community leaders have rejected those accusations and defended the Haitians.

Mr. WALKER. OK. Could you provide for the record some of the documentation that you have.

Dr. COMPAS. Yes.

[The articles referred to follow:]

D'ERAMO

Continued from preceding page

of factor VIII included in blood products such as factor VIII that hemophiliacs receive.

Dr. Gordon stated, however, that the intravenous administration of factor VIII concentrates concentrated from many different sources itself induces a mild disorder resembling Kaposi's sarcoma in the absence of the other opportunistic infections. Dr. Gordon suggests that this mild immunosuppression predisposes hemophiliacs to a more severe infection; this may be the mechanism by which hemophiliacs develop AIDS. This suggests that an investigation of the geographic location of AIDS cases and the source of factor VIII concentrates used by the *Lancet* group would be helpful.

Dr. Gordon's statement from Dr. G. M. Kessler, who has been successful in supporting the hypothesis that exposure to factor VIII concentrates obtained from AIDS cases (human T-cell leukemia virus A) had been associated with the development of AIDS, supports Dr. Gordon's hypothesis. Dr. Kessler reported that exposure to factor VIII concentrates obtained from AIDS cases predisposed hemophiliacs to the development of AIDS. These results suggest that exposure to factor VIII concentrates predisposes hemophiliacs to the acquisition of AIDS.

A Married Haitian Couple in Paris Dies of AIDS

Dr. J. Dournon *et al.* reported in a letter to the *Lancet* (May 7, page 1040) that a Haitian couple living in Paris died of opportunistic infections most probably resulting from AIDS. The 31-year-old wife had lived in Paris since 1979, and was first admitted to a hospital there in 1981. She died in February 1982. She had also lived in Newark, New Jersey, from March to September 1980, during which time she had sexual relations with another Haitian (male). Her American sexual partner died of AIDS in January 1983.

Her 38-year-old husband never visited the U.S. He arrived in Paris in October 1981 and was first admitted to a hospital there in October 1981. He died four months later. This report seems to give more weight to the notion that AIDS has originated in Haiti, and has been spread to the U.S. and Europe from there.

Gay Men and Anorectal Cancer

In a letter to the *Journal of the American Medical Association* (May 13, page 2459), Bruce Voeller, Ph.D., cites medi-

anal intercourse. Other studies should include gay men who act exclusively as anal penetrators, and gay men who act exclusively as anal recipients who use oil lubricants, and recipients who use water-soluble, non-oil lubricants.

Interferon Therapy for KS

Interferon is a small protein produced by a living cell in response to infection by a virus. Interferon may go on to cause resistance to another infection by the virus or even infection by a different virus. Interferons, either naturally formed or produced in laboratories, have been shown to be occasionally capable of inhibiting the growth of certain kinds of tumors. Interferon may also modify the course of viral infections in humans, including hepatitis B and cytomegalovirus (CMV) infection. Persistent CMV infections in gay men have been considered as a possible cause of AIDS, and have been associated with KS as well.

The effects of a particular kind of interferon on immunosystemic disease with KS were presented at the *Lancet* (see *British Medical Journal* (May 10, page 1071) by Susan E. Krown and her colleagues. Dr. Krown administered interferon to 15 AIDS patients who had KS. Five demonstrated a major positive response, and three had a minor temporary response. These data suggest that interferon may prove useful in treating KS in AIDS victims, and also that interferon may restore at least some aspects of cell-mediated (T-cell) immune functions. Some chemotherapeutic agents used to treat KS have an immunosuppressive effect. Interferon may be particularly advantageous because it does not produce these untoward immunosuppressive effects, a factor of great importance in treating AIDS victims.

Wear Condoms—Reduce Your Risk of Contracting AIDS

Research papers and comments appearing in the medical literature imply that wearing condoms to prevent semen from entering one's partner's body may have a role in preventing AIDS. Sexual practices by which semen is received orally or anally have, of course, commonly occurred throughout the history of human sexuality. For the present, however, the risk of getting AIDS requires certain precautions in sexual practices that involve exposure to semen, urine, feces, and blood. If there is a causative agent of AIDS, like a virus,

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ABC NEWS

20/20

May 19, 1983

HUGH DOWNS: Good evening. I'm Hugh Downs. And this is 20/20.

ANNOUNCER: On the ABC Newsmagazine, 20/20, tonight:

AIDS — an incurable disease.

Dr. MARCUS CONANT: I think it's naive to believe that the AIDS epidemic is going to remain confined to one small segment of the population. I think this is a problem for the entire American public.

ANNOUNCER: The most frightening epidemic since polio; 80 percent of its victims die, and reported cases are doubling every six months. First identified in the the homosexual community, now it's in 35 states, and the nation's blood supply may be threatened. Did moralistic attitudes delay the medical counterattack? Did prejudice give AIDS a fatal head start? Geraldo Rivera, with a report on the mysterious killer called "AIDS."

Bette Midler — what drove her to the top?

AARON RUSSO: She thought for about three seconds, four seconds, and said, "I want to be a legend." And when she said that to me, it made everything very clear. You know, I knew exactly what my job was.

ANNOUNCER: His job was to make her a national star. Bette Midler — abrasive, provocative, often outrageous on stage, offstage she's been called a shy and private person.

BETTE MIDLER: I should have been something just a little more conventional, like a teacher or a— and I would have been a wonderful teacher.

ANNOUNCER: Steve Fox, with the story of the Divine Miss M — "Bette Midler."

LESLIE GEIGER: When I would look in the mirror when I had a pair of shorts on, I would cringe. My whole body image was tied up in my thighs.

ANNOUNCER: Cellulite — the warm weather embarrassment. Women work to lose it, and they spend millions of dollars to do it. They're slapped, steamed, wrapped and bagged — but does it do them any good? John Stossel reports on the treatments of "Cellulite: Fad, Fact or Fantasy?"

DOWNS: Up front tonight, A-I-D-S, AIDS, the most frightening initials in America today. They stand for Acquired Immune Deficiency Syndrome, a medical mystery that destroys the immune system, and leaves our bodies defenseless against unusual and deadly infections. And yet, wide publicity and public funding for an attack on this dangerous disease have only recently begun. Why the delay? Here is Geraldo Rivera. Geraldo?

Note
GERALDO RIVERA: Why the delay especially, Hugh, when you consider the fact that AIDS has already killed more people than the Legionnaire's Disease outbreak and the toxic shock syndrome combined. It is the most frightening medical mystery of our times. AIDS has spread worldwide, but apparently it began in equatorial Africa and somehow spread to Haiti, and from Haiti to the United States. Why? Nobody knows: specialists at the Centers for Disease Control, the CDC, think AIDS may be caused by some new virus, but so far they have had absolutely no success in tracking it down, even though AIDS has been killing people in this country since 1979.

[clip of memorial march for AIDS victims]

MAN: Fighting for our lives... too little is being done too late...

RIVERA (voice-over): There is an epidemic loose in the land. This memorial march is in honor of the past and future victims of AIDS, a so far incurable disease which kills its victims in stages.

BILL BURKE, AIDS patient: I'm tired of losing people that I love and I care about.

RIVERA (voice-over): The doctors believe that Bill Burke and these other men have it.

[interviewing] Every day you hear about more people.

Mr. BURKE: Yeah, a friend of mine's going for biopsies today. Another friend of mine died two weeks ago. And every week, somebody else comes down with it, or somebody I know goes into the hospital who had been doing well. And it's heartbreaking. It's heartbreaking.

RIVERA *[voice-over]*: Heartbreaking and terrifying. Bill and these other men seem to be doing pretty well, but all of them know that 80 percent of all AIDS victims are dead within just two years. This is easily the worst epidemic since polio. The story of the birth and malignant spread of the killer disease may seem like a scenario from some horror movie, but this is real life.

KEN RAMSAUR, AIDS patient: Before I got Kaposi's, I thought I was a pretty good-looking guy — average, but happy — and now it's — I actually see myself fading away.

RIVERA *[voice-over]*: Twenty-seven-year-old Ken Ramsaur's case is, unfortunately, typical. Diagnosed just last summer, AIDS has already stripped his body of its ability to fight off other diseases and infections. Left unprotected, he's contracted Kaposi's sarcoma, up to now a rare form of cancer.

Mr. RAMSAUR: Everything that I used to be able to do by myself, I now need lots of help with, and it's just scary — it's scary the way I'm not what I was.

RIVERA *[voice-over]*: And Ken is not the only one who is scared — but let's trace this killer disease back to its beginnings.

MAN: Free AIDS literature — please, learn about the symptoms.

RIVERA *[voice-over]*: In 1979, this is where the first cases came to light, in New York's Greenwich Village and within male homosexual communities in San Francisco and Los Angeles.

BOB CECCHI, AIDS patient: I was going out and meeting people, and trying to find a lover, and making love to people who interested me. I didn't know that, you know, that there were things out there so secretly hidden that it was going to destroy my life.

RIVERA *[voice-over]*: Because it was first thought limited to this one group, it was known then as "the gay cancer," and later, "the gay plague." However, those derogatory labels soon become obsolete.

Dr. MARCUS CONANT, University of California at San Francisco Medical Center: I think it's naive to believe that the AIDS epidemic is going to remain confined to one small segment of the population. I think this is a problem for the entire American public.

RIVERA *[voice-over]*: When the disease was identified in mainlining drug users, the researchers were fairly convinced that it was like hepatitis — either sexually transmitted or blood-borne. But then, in the fall of 1981, the mystery became even more ominous, when the disease was also diagnosed in otherwise healthy immigrants from Haiti, men who were neither homosexual nor drug users. Then it spread to the women who were the sexual partners of those at risk.

Dr. CONANT: If research funds are not brought to bear on this problem quickly, the problem is going to spread throughout the entire country and be a major health problem for us.

RIVERA *[voice-over]*: Like ink spreading on a blotter, AIDS continues to claim different types of victims. As an example, eight infants born of high-risk parents seem to have contracted the disease. Four have died. And just last summer, AIDS began turning up in hemophiliacs, and other people who had received transfusions of blood. Some estimate there will be 20,000 AIDS cases reported by the end of next year. *[on camera]* And so the evil genie is out of the bottle. With reported cases doubling every six months, AIDS has now been identified in over 35 states and 16 foreign countries. Of course, the counterattack has also begun. Scores of medical researchers and scientists are studying the problem. The epidemic has also received a great deal of recent attention in the news media, but one charge we hear really raises a question for all of us: whether our prevailing social and political

attitudes — put more bluntly, whether our negative attitudes about homosexuals — allowed this killer epidemic a bizarre and deadly head start.

LARRY KRAMER, Gay Men's Health Crisis: We're into this two years, and you are finally doing a story — *Time* and *Newsweek* are finally doing a story. There are a thousand—1,600 cases, there are 800 dead people. How many does it take before somebody pays attention to it?

RIVERA [voice-over]: Larry Kramer, a co-founder of the Gay Men's Health Crisis, is especially critical of the newspaper of record, the *New York Times*.

Mr. KRAMER [on telephone]: The *New York Times* is being socially irresponsible by not relating to one million members of its community what is affecting them.

RIVERA [voice-over]: Although New York has about half the reported cases in the nation, with about 250 dead so far, Kramer points out that in its coverage the *Times* has never put the AIDS story on its front page. Contrast that with the front-page prominence given a recent herpes outbreak that killed 30 dancing horses in Austria. The management of the *New York Times*, on the other hand, told us they feel they have adequately covered the story. In any case, now that AIDS poses a threat to the nation's blood supply, society and the media are finally paying attention.

Rep. HENRY WAXMAN, (D) California: Public officials are very influenced by public opinion, and public opinion is very much influenced by what the media does.

RIVERA [voice-over]: Henry Waxman has also been critical of the government's handling of the epidemic. He should know: he's chairman of the House Subcommittee on Health and the Environment.

Rep. WAXMAN: We saw when Legionnaire's Disease came into the public awareness that there was immediate clamor for action. Had this disease afflicted children or members of the Chamber of Commerce, I'm sure the Reagan administration would have been breaking down all doors in order to push the government on all fronts to deal with it.

RIVERA: Has it been bigotry, bureaucracy or budget cuts that have slowed the response to this terrible problem?

Rep. WAXMAN: I think all three of those factors have meant that the government did not respond as we should have to this public health crisis.

Rep. WAXMAN [to House Subcommittee on Health and Environment, May 9, 1983]: CDC first identified the disorder in June of 1981. According to your testimony, the first NIH grants were made 15 months later, and then for only \$165,000.

RIVERA [voice-over]: Bothered by the apparently slow initial response to the AIDS epidemic, both Waxman of California and Senator Moynihan of New York have introduced legislation requesting \$40 million a year for public health emergencies like AIDS. But Dr. Edward Brandt, the assistant secretary of Health, is opposed.

Dr. EDWARD BRANDT, assistant secretary of Health: I oppose those measures because they're not needed.

RIVERA [voice-over]: And Dr. Brandt is the Reagan administration official to whom all public health agencies report. [to Dr. Brandt] It's given the fact that the disease is so complex and the ramifications so awful, the mortality rate so high, that critics say the federal government should have done more sooner, more money, more people, more research — isn't this the prototypical case where emergency funding and emergency measures should have been taken by the federal government?

Dr. BRANDT: The issue is, what would you have done different?

RIVERA [voice-over]: What might have been done differently? Example: with more federal money, researchers and scientists at the Centers for Disease Control, the CDC, might have been able to keep a closer watch on the spread of this killer disease.

Mr. KRAMER: The gay community has been trying for nine months to get the CDC to

reinstitute active, serious, in-depth surveillance, interviewing the victims to see who they had slept with, what they had done — figuring out the patterns. No one is doing that.

RIVERA *[voice-over]*: Example: case reporting to public health officials is required for all of the following diseases: gonorrhea, hepatitis, German measles, and mumps. Case reporting is not required of AIDS. *[to Dr. Brandt]* Wouldn't it be logical, then, to have mandatory case reporting so your experts here in Washington or at the CDC in Atlanta will know exactly where the disease is going, and presumably can use that as one factor in the evidence suggesting where it came from.

Dr. BRANDT: At the present time, with the heightened awareness in the professional community that we have created through articles, through other things, we believe we're getting virtually all the cases reported to us.

RIVERA *[voice-over]*: But are they getting all the cases? Example: according to the CDC, there are only 27 AIDS cases in all of the state of Texas. But 20/20 has learned that in the city of Houston alone there are an estimated 100 AIDS cases.

MAN *[addressing meeting in Houston]*: I am an internist in private practice here in Houston who is now seeing at least weekly one patient with AIDS, or some depression of their immune system.

RIVERA *[voice-over]*: When information on AIDS was first published in April of 1981, there were five reported cases nationwide and two deaths. By that summer, it was recognized as a serious public health problem: there were 108 cases, 43 were dead. In the summer of 1982, there were 593 cases; 243 were dead. The latest figures: there are over 1,400 reported AIDS cases; 541 are dead — and that is just the official body count.

Dr. LINDA LAUBENSTEIN, New York University Medical Center: Things are getting worse. There's more patients, more complexity to the situation, more hysteria and no easy answers.

RIVERA *[voice-over]*: In March, Dr. Linda Laubenstein sponsored this international AIDS conference at New York University Medical Center. Since this is ground zero for this frightening medical mystery, the other nations affected are looking to the United States for research leadership. So far, they say, they are disappointed.

Dr. ROEL COUTINHO, Dutch virologist: I think I'm a bit amazed that not more research has been done, because there are so many cases, there are so many opportunities to study it.

RIVERA: In fairness, the federal government does claim to have spent almost \$15 million in the fight against this epidemic, but most critics maintain that, up until now at least, the federal government has not done enough fast enough. Example: it was not until the summer of 1982, after it became clear that AIDS posed a threat to the nation's blood supply, that the National Institutes of Health, the major source of research funding, even issued their request for grant applications on the subject of AIDS. As of today, just 18 percent of those research requests have been granted. *[voice-over]* Aside from the classic problems associated with catastrophic illness, like inability to work and inadequate medical insurance, AIDS victims must also deal with the trauma of being both a patient and a pariah, even in the hospital.

Mr. RAMSAUR: And one night I heard two of, I believe they were the nurse's aides, not the actual nurses, standing outside my door sort of laughing and I would almost say placing bets on, now, how long is this one gonna last?

RIVERA: What did they say, exactly?

Mr. RAMSAUR: "I wonder how long the faggot in 208 is gonna last."

Dr. ANTHONY FAUCI, National Institutes of Health: There's no question and no denying that there is a feeling among members of any of a number of professions, or just the general population, that patients with AIDS, many of whom are homosexual, are a little bit different. I think that that has probably, at least early on, led to a little bit of a complacency about the approach towards this disease.

RIVERA [voice-over]: Dr. Anthony Fauci is a top government researcher. The attitudes he is talking about almost lost him the chance to work with the very patient who is the focus of his current research.

RON RESIO, AIDS patient: I was refused at this hospital . . .

RIVERA [voice-over]: Thirty-six-year-old Ron Resio was refused admission to the Clinical Research Center at the National Institutes of Health, despite the fact that he had been receiving treatment here as an outpatient.

Mr. RESIO: I had double pneumonia, confirmed by x-rays, and a temperature of over 103. I was interviewed, or I should say inquisitioned, by a doctor who kept calling it "the gay plague."

RIVERA [voice-over]: The official reason for the refusal was the feeling that his case did not fit into the facility's long-range research plans. *[to Mr. Resio]* How did you get into this hospital then, finally?

Mr. RESIO: When they found out I had a twin.

RIVERA [voice-over]: The attitude toward Ron changed dramatically, when government researchers discovered he had a healthy identical twin brother, providing them a textbook opportunity to search for a cure. Brother Don flies into Washington for two days every three weeks from his home in Vicksburg, Mississippi, where he lives with his wife and children. It is Don's healthy white blood cells that are being used to boost Ron's immune system, but it is not easy for either man.

DON RESIO, brother of AIDS patient: It's very frustrating to come up here every three weeks and watch parts of my brother disintegrate — watch him have trouble with his eyes one time, problem with his lungs, Kaposi's, different things — and you just keep asking yourself, how long can that go on?

[clip of memorial march for AIDS victims]

RIVERA: Whatever your personal feelings about the homosexual community, the basic complaint of these candlelight demonstrators rings true: until it was discovered that this disease posed a threat to the nation's blood supply and began claiming other less controversial victims, we all paid a lot less attention than we should have in the beginning. *[to Ron Resio]* Do you ever feel like just giving up?

Mr. RESIO: Not very often. I think one of the things that makes me a good patient is that I am a fighter, and I have decided that I'll be the first one to make it, the first one to get over this.

HUGH DOWNS: We can hope he does. It's a terrible situation. What are the symptoms of AIDS?

RIVERA: There are several symptoms. Hugh, I guess the first most obvious one is swollen glands. Then those bruise-like markings on the skin you saw in the piece itself; weight loss; persistent fever; night sweats; persistent dry cough; persistent unexplained diarrhea. Those are the most common symptoms.

DOWNS: Just today there were some reports of some new cases — women who had been the wives or lovers of AIDS victims, and a sanitation worker who doesn't fit the AIDS profile.

RIVERA: First of all, the doctors aren't sure that all of those are suspected AIDS cases, although they are showing the early symptoms. The point is, there is no evidence whatsoever that just casual contact with an AIDS victim will get you the disease; the best evidence of that is the fact that no medical personnel — doctors, nurses — have caught it from their patients over the last four years. One way we know you can get it, though, is by blood transfusions — getting contaminated blood from an AIDS victim. And that'll be the focus of our next report. That's the real threat to most of the rest of us.

DOWNS: We'll be watching that next week. Thank you, Geraldo.

Later in the broadcast, the evolution of a legend. Steve Fox profiles the explosive Bette Midler. But next, summer is almost on us, and people are paying attention to their figures. John Stossel pays attention to cellulite, that embarrassing fat, right after this.

[commercial break]

DOWNS: Summertime is coming, time to get into shorts and swimsuits, and time for millions of women to worry about how they look in a bikini, because of something called cellulite [CELL-u-leet] — or do you call it cellulite [CELL-u-light], since it seems to be spelled that way? Here is our consumer correspondent, John Stossel. John?

JOHN STOSSEL: It's pronounced both ways, actually. Cellulite is that lumpy or dimply-looking fat that gathers in the hips and thighs of some women. We asked people about it on a beach, and got strong reactions. *[on camera]* What do you think of cellulite?

1st WOMAN: I think it's gross.

2nd WOMAN: It's really ugly.

3rd WOMAN: Ah, it's what you dread!

STOSSEL: What's it look like?

4th WOMAN: Orange peels.

5th WOMAN: Wrinkly and bumpy.

6th WOMAN: Jello.

7th WOMAN: Not smooth.

8th WOMAN: Yucky.

MAN: Big flabby thighs on girls, I don't know. I like, you know, lean woman, you know?

STOSSEL *[voice-over]:* Lean is in today.

[clip from Richard Simmons Show]

RICHARD SIMMONS: How many of you have cellulite? *[audience yells]* I don't think I'd shout about it!

STOSSEL *[voice-over]:* There's lots of advice about how to get rid of it.

WOMAN *[to Richard Simmons]:* I try exercising.

Mr. SIMMONS: And what happens?

WOMAN: I get discouraged, because it doesn't go away.

Mr. SIMMONS: It's not going to go away right away, but if you continue to exercise, it will.

[to exercise class] Come on, get rid of that cellulite!

STOSSEL *[voice-over]:* In fact, exercise may not help. That's one of the weird things about cellulite — exercise doesn't always take it away. Even some athletes and dancers who exercise all the time still have cellulite. And many thin women have it; just visit this cellulite salon. *[to woman in salon]* I don't get it — you're thin, you're five-eight? You weigh...

WOMAN: One-fifteen.

STOSSEL: And you're worried about cellulite? Why?

WOMAN: I don't think it matters how thin you are whether you have cellulite or not. It's just a very ugly skin condition, and I have it right here. I'm afraid to turn around half the time.

STOSSEL *[voice-over]:* Yet many doctors say there's no such thing as cellulite.

Dr. LAWRENCE SIEFERT, California Society of Plastic Surgeons: Cellulite, along with some other products from France, is an import, but in this case it doesn't mean anything. It's a media hype term that is a fancy name for fat. It's fat in Paris, fat in Pomona, it's the same fat.

STOSSEL *[voice-over]:* It is true that when scientists look at fat cells from dimply thighs

Virus: Part II

by James E. D'Eramo, Ph.D.

NOTE Commentary

The theory that Haitian ASFV may be related to AIDS poses a brilliant potential model for approaching the AIDS epidemic. But the significance of Dr. Teas' theory lies not only in its plausibility, but also in the disturbing manner with which it has so far been received by American medical and research institutions. Dr. Teas initially submitted her letter to the *New England Journal of Medicine*, which rejected it. It was subsequently published in Great Britain by the *Lancet* (a non-establishment medical journal). When corresponding with chiefs of departments of various American research institutions, she often received no more than a cold shoulder and a curt "thank you" in response to her theory. The CDC in Atlanta responded to her letters in a manner which seems particularly unworthy of such a prestigious institution. The *New York Native* has since learned that the CDC in Atlanta has contacted researchers at Plum Island for specific materials (distinctive slides and coverslips) necessary for investigations of ASFV. This seems to have occurred after Dr. Teas' letter was published in the *Lancet* and the lay media became interested.

Dr. Teas has had a much more positive response from Dr. P.J. Wilkinson of London, and initially from Dr. Farouk Hamdy of Haiti, both of whom have expressed an interest in her theory and in collaborating with her on specific research projects.

The cool reception and dismissal of scientific theories that originate from so-called "outside" scientists—such as Dr. Teas—by governmental funding institutions and research centers is at best an unfortunate comment on the state of "establishment" science and research in America today. This attitude connotes an alarming, selfish, dark side of some aspects of institutional and governmental scientific research.

For many researchers, scientists, and physicians, the meaning of science is inherently based in the discovery of truth. For others, the emergence of a new disease is regarded as a mere vehicle for advancing their personal careers. There are many fine, diligent, scientific researchers who have the backing and funding of "establishment" science in America, but there are also many worthy scientists whose theories and proposals—which may have a better and more direct approach to solving AIDS—are often simply ignored by the establishment because these

April 26, 1983

Jane Teas, Ph.D.
Research Fellow at Large
Harvard School of Public Health
665 Huntington Avenue
Boston, Massachusetts 02115

Dear Dr. Teas:

Many thanks for your letter of April 14 regarding the possible association between African swine fever virus and AIDS. I have showed and discussed your letter and your thoughts with Dr. James Curran who is Director of the Task Force on AIDS here at CDC. I have also shared it with Dr. John Bennett, Assistant Director for Medical Science of the Center for Infectious Diseases. They both appreciate your obvious interest and concern about this possible association. Rest assured that if they and other members of the senior staff here feel that more effort should be directed to uncover any real association between the two diseases, it will be done.

As I believe I implied in our telephone conversation, it is relatively difficult for outside scientists such as yourself to impact directly on research programs within a center such as CDC. Quite frankly, perhaps the best you can expect is an acknowledgement with thanks.

Nevertheless, I do wish to convey to you my personal thanks for your obvious interest and encouragement. As you stated, the power of the pen should not be underestimated.

Best wishes.

Sincerely yours,
Michael B. Gregg, M.D.
Deputy Director

is also interested in testing AIDS blood samples for ASFV. Dr. Jonathan Gold (Sloan-Kettering, NYC) has offered his collection of AIDS blood for such purposes. Dr. Michael Lange and Dr. Klein at St. Luke's/Roosevelt, NYC are interested in developing experiments to test her theory, as is Dr. Kenneth Mayer (Fenway Community Health, Boston). Drs. Richard Wardley, Philip Wilkinson, and R.F. Sellers (Animal Virus Research Institute, England) have said they will conduct investigations of Dr. Teas' theory. Dr. James Larrick (physician, San Francisco) and Dr. Ronn Rucker (medical sociologist, Cincinnati) wish to begin studies as well.

Researchers at the National Cancer Institute, who have worked with Actinomycin-D—a drug used for only experimental purposes in virology research—have visited Haiti and are interested in the AIDS problem there. Dr. Krause, of the National Institutes of Health, has recently visited Haiti, where he has attempted to establish lines of communication between American researchers and scientists there to investigate AIDS cases in Haiti.

As Dr. Teas' theory gains the interest of experts (it received coverage on Boston's Channel 7 on May 17, and in *New Scientist* in their April 28 issue), it is hoped that another important lead to the resolution of AIDS etiology will be illuminated. It is much too early to discount or verify her theory. It is known that certain viruses can cause immunosuppression and leukemia in animals and possibly humans. Dr. Teas' theory that ASFV may be related to AIDS is charac-

science is inherently based in the discovery of truth. For others, the recognition of a new disease is regarded as a mere vehicle for advancing their personal careers. There are many fine, diligent, scientific researchers who have the backing and funding of "establishment" science in America, but there are also many worthy scientists whose theories and proposals—which may have a better and more direct approach to solving AIDS—are often simply ignored by the establishment because these scientists are regarded as "outside" the system.

It seems possible that some of the researchers who are studying AIDS may not be individuals who want to cure the disease quickly. In the academic and research world, one's future is married to working on an interesting problem; if the problem is solved, the academic mileage it may have provided a researcher is removed.

For example, the AIDS epidemic is much like the gold rush of the 1800s. One wants to stake a claim on some aspect of the issue. This becomes tragically apparent when scientists refuse to share their findings with colleagues or with the lay press until their data is published in a medical journal. In some arenas, AIDS research now seems to be at the mercy of scientific egos—a situation above which even our most respected institutions, like the NIH and CDC, may not always necessarily rise.

Dr. Jane Teas has been without funding since December 1982 because she does research which is not popular with funding institutions and government foundations; she is not a member of the scientific "in crowd." Her situation and the funding predicament of many more researchers point directly to the need for separate funding organizations to help establishment science combat AIDS. It is evident, now more than ever, that the gay community must bear substantial responsibility for the founding and operating of new funding organizations for AIDS research.

James E. D'Erano, Ph.D.

ine, has encouraged Dr Teas and recommended that she communicate her theory to Dr. F Hamdy of Haiti (an ASFV expert). Dr Hamdy has written and met with Dr Teas. Dr. J.J Callis, Director of the USDA Plum Island Animal Disease Center off Long Island, has entered into discussion with Dr. Teas about the possible relationship between ASFV and AIDS. Dr. C Mebus and Dr. W Hess, also of Plum Island, have encouraged Dr Teas and outlined several experiments that would be useful in further investigating her theory. Researchers in Australia have contacted Dr Teas as well, and are very interested in following up her theory, but

their research facilities will not be ready for another eighteen months. Dr. F Mulhern, who has worked as a veterinarian in an official capacity with the U.S. government for ten years, has advised Dr. Teas that her theory is of great importance and has promised to help obtain funds for research projects related to it. Dr. Noble, Head of Virology at the CDC, has communicated with Dr. Teas and may be interested in investigating her theory. On the other hand, Dr. Michael B Gregg, Deputy Director of the Epidemiology Program Office at the CDC, has given Dr Teas' theory only a very cool and polite review

interest and encouragement. As you stated, the power of the pen should not be underestimated.

Best wishes

Sincerely yours,
Michael B Gregg, M.D.

Deputy Director
Epidemiology Program Office

cc
Dr. James Curran
Dr. John Bennett
Dr. Nicholas Fiumara

Dr. E. Vinuela, Center for Molecular Biology, Madrid, has agreed (at the request of the World Health Organization) to investigate AIDS blood for the presence of ASFV. Dr. Larry Falk, of the New England Regional Primate Center—where monkeys have an AIDS-like disease—has encouraged and assisted Dr. Teas. Dr. Fred Siegal (Mount Sinai Hospital, NYC)

the resolution of AIDS has not been illuminated. It is much too early to go count or verify her theory. It is known that certain viruses can cause immunosuppression and leukemia in animals and possibly humans. Dr. Teas' theory that ASFV may be related to AIDS is enhanced by astute observation and distinct plausibility. The ASFV theory and other plausible theories of AIDS etiology merit the serious attention of the scientific community and official government health agencies.

Jane Teas invites any scientific discussion of her theory to be communicated in writing to the following address:

*Jane Teas, Ph.D.
Interdisciplinary Programs in Health
Harvard School of Public Health
665 Huntington Avenue
Boston, MA 02115*

The CIA-ASFV Connection

On January 9, 1977, the *Boston Globe* published an article by Drew Fetherston and John Cummings connecting the CIA to the outbreak of African Swine Fever Virus in Cuba in 1971. According to the writers, "A U.S. intelligence source said in an interview that he was given the virus in a sealed, unmarked container at an Army base and CIA training ground in the Panama Canal Zone with instructions to turn it over to the anti-Castro group." The reporters detail how the virus was moved from Ft. Gulick (an Army base in the Panama Canal Zone) to a fishing trawler off the Panamanian coast. The trawler then carried the virus to Navassa Island, a tiny, deserted U.S.-owned island between Jamaica and Haiti. From there, it was taken to a Navy base at Guantanamo Bay. Havana is 500 miles northwest of Guantanamo. How the virus got from Guantanamo to Cuba is not stated in the article.

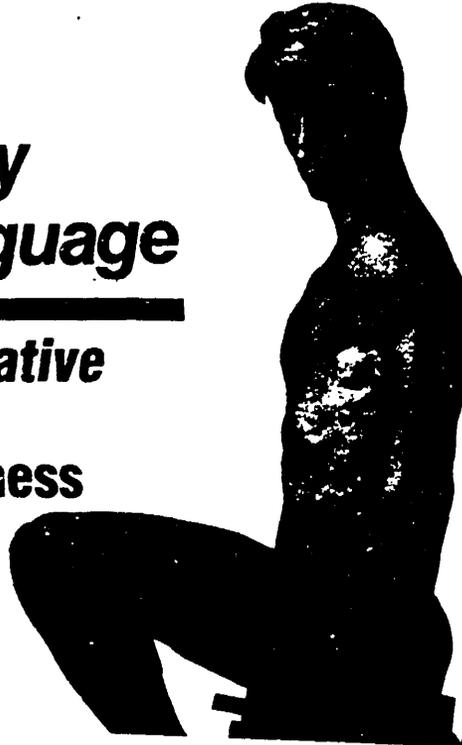
According to the reporters, "A paper prepared by the Cubans for a scientific conference in Mexico City said the first sick pigs were found about May 6 (1971), but no precise location was given. A non-Soviet-bloc agricultural technician then in Cuba said the disease easily could have gone undetected for months. The virus can be transmitted rapidly through food or the water supply."

At the time, the only remark from the CIA was, "We don't comment on information from unnamed and, at best, obscure sources."

The reporters could get no additional information from Congressional sources who had access to some CIA records. They point out that "Congress's efforts to probe CIA activities in chemical and biological warfare have been frustrated."

Body
Language

The Native
Side
Fitness



Is African Swine Fever Virus the Cause?

by James E. D'Eramo, Ph.D.

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A most uncommon, exciting, and plausible theory has surfaced on the chaotic horizon of the AIDS mystery. Dr. Jane Tass of the Harvard School of Public Health has proposed in a letter to the *Lancet* (April 23, page 923) that a strain of the deadly African Swine Fever Virus (ASFV), present in the pig populations of Haiti, may be linked to the cause of AIDS. Dr. Tass has drawn a striking parallel between the first cases of AIDS diagnosed in Haiti in 1978 and the first confirmed appearance of ASFV in the Haitian pig population in 1978. The symptoms displayed by pigs with ASFV and those of AIDS victims have extraordinary similarities: fever, hypergammaglobulinemia (excess antibodies), loss of appetite, and hyperplasia of the lymph nodes—possibly analogous to the lymphadenopathy (swollen glands) seen in AIDS victims.

The ASFV-infected pigs become immunosuppressed and susceptible to other infections as well: 50 percent of the pigs die of pneumonia, and some pigs develop skin lesions (purplish spots) which resemble Kaposi's sarcoma in AIDS victims. Dr. Tass suggests that ASFV was accidentally introduced into the Haitian human population by eating undercooked ASFV-infected pork. ASFV has been shown to be present and stable in the blood, urine, semen, and feces of pigs. Persons who ate the infected pork and who were also immunosuppressed could be infected through ulcerations or tears in the mucosal linings of their alimentary canal. These persons could then transmit the virus sexually to partners who had rips in their mucosal linings and who were already immunosuppressed. Dr. Tass' theory that ASFV is linked to AIDS may hold the answers to many of the questions that pertain to the etiology, development, and transmission of AIDS, but as

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(Continued from page 1)
cial agencies and institutions.
Linking AIDS to ASFV

Jane Teas, 26, earned a Ph.D. in pathology from Johns Hopkins, her special expertise is in breast cancer research. The possible connections between ASFV and AIDS that Dr. Teas has proposed evolved over a period of months during which she debated her ideas in informal discussions with her colleagues at Harvard, while making a diligent search of the scientific literature—both medical and veterinary. In conversations with various groups of American researchers working in Haiti, she found out that the Canadian, Mexican, and U.S. governments are in the process of destroying the pig population of Haiti in an attempt to control the current ASFV infection, with the United States footing the 18 million dollar bill.

percent as chronic carriers of the ASFV agent. (Pigs do not form neutralizing antibodies to ASFV.)

ASFV

Until 1909, when it decimated the pig population of Kenya, ASFV* was a disease of wild African Wari Hogs and certain ticks. ASFV is a member of the arbovirus group—that is, viruses which are transmitted via certain ticks to warm-blooded animals and vice versa. The ticks transmit the virus while feeding on the blood of the animals, and the virus may then be transmitted from animal to animal as well. ASFV is also transmitted between ticks sexually, and from one generation of tick to the next. ASFV is the only DNA-containing arbovirus. This characteristic makes the virus particularly dangerous because when it infects a particular cell it

shown to infect the macrophage cells of chickens as well. Different strains of ASFV may be found circulating in the bloodstream of infected animals at different stages of the infection, occasionally the virus cannot be found in infected animals at all. In pigs, ASFV causes high mortality rates ranging from 80 to 100 percent in some outbreaks, and 30 to 60 percent in others. For this reason, ASFV is a highly feared virus. Obviously, there are profound economic implications for the pig industry and related agricultural industries.

In Haiti, ASFV infection of the pig populations has taken a significantly different course. Initially, ASFV killed 90 to 100 percent of the pigs in a given location, but as it spread from one pig feeding lot to another the mortality rate of the pigs decreased to a mere 3 percent. This means that a high percentage of the Haitian pigs are now chronic carriers of the virus, and a reservoir of possible transmission to pig populations in other countries and possibly even to other species—like humans who consume undercooked pork.

Transmission of ASFV

When the Haitian boat people arrived as refugees in Cuba in 1980, within six months 500,000 Cuban pigs died of ASFV. (The remaining pig population

sion) could therefore provide a possible route of transmission for ASFV to humans. Although ASFV has not been known to infect humans, the situation in Haiti has made such infections and modes of transmission possible. After consuming infected pork, ASFV could possibly enter the human bloodstream through an ulceration or break in some mucosal lining of the alimentary canal. Once the virus has established an infection and is circulating in the bloodstream, it could then be transmitted through sexual contact or various other means to other persons via the blood, urine, semen, or feces of ASFV infected persons.

The Possible AIDS Connection

NOTE
According to Dr. Teas, the pivotal point for the linkage of ASFV to the development of AIDS in gay American men would be the transmission of the virus from an infected Haitian to an American through a sexual contact which would cause infected blood, urine, semen, or feces to encounter a break in the mucosal lining of the sexual partner. According to Dr. Teas, the sexual partner of the infected Haitian would also have to be in an immunosuppressed state. Many studies now indicate that the average sexually active gay American male is exposed to several immunosuppressive agents, including cytomegalovirus (CMV) and semen itself.

A History of Major ASFV Outbreaks in Pigs

1909	Kenya
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ASFV Outbreaks in Pigs

Year	Location
1939	Orange Province (S. Africa)
1949	Algeria
1957	Portugal
1959	Senegal
1960	Spain
1964	France
1966	Madeira
1967	Italy
1971	Cuba
1978	Sardinia
1978	Dominican Republic
1979	Haiti
1980	Cuba

The nutritional and general health status of many Haitians is poor; Haiti is in fact the poorest country in the Western Hemisphere. Haiti also has the highest unexplained mortality rate in the hemisphere for persons between the ages of 15 and 45 years of age. Health officials in Haiti attribute many of these deaths to a disease that is called simply "fever." Given the implications of Dr. Teas' theory, there is a distinct possibility that this "fever" may be AIDS. This particular notion gains some degree of credibility due to the adaptability of ASFV to different host species and due to the fact that ASFV infections of pigs have taken a course in Haiti heretofore unseen in other countries, where the virus normally kills a much larger percentage of the pig population. According to Dr. Teas, a large percentage of the Haitian pig population is infected with ASFV. The pigs are currently dying at a rate of 3 percent, leaving 97

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becomes involved with important functions of the cell's DNA (genetic make-up), thereby altering the way the cell normally functions. In pigs, ASFV infects many kinds of cells, including cells of the immune system (T-cell lymphocytes, macrophages, monocytes) and causes a deficiency in the essential interaction of these cells which precipitates a "breaking down" of the proper functioning of the immune system. This process closely parallels the kinds of immune cellular deficiencies which are a hallmark of AIDS victims.

An important characteristic of ASFV is that it is an actively changing virus which develops different strains readily, even within the same animal. This adaptive characteristic may account for the ease with which the virus "jumps" from one animal species into another. In Spain during the 1950s, ASFV infected populations of cattle and sheep, and it has been

*Not to be confused with Swine Flu.

pork.

Transmission of ASFV

When the Haitian boat people arrived as refugees in Cuba in 1980, within six months 500,000 Cuban pigs died of ASFV. (The remaining pig population was subsequently killed.) It is suspected that the Haitian refugees brought the ASFV with them in undercooked pork. Pigs eat (and are fed) offal—the uncooked internal organs of animals. ASFV may spread in the pig population by feeding infected offal from slaughtered pigs to other pigs.

According to Dr. Teas, a high percentage of the Haitian pigs are infected with ASFV; the consumption of undercooked pork by immunosuppressed Haitians (malnutrition often causes immunosuppres-

sion) becomes a means of the spreading of the sexual partner. According to Dr. Teas, the sexual partner of the infected Haitian would also have to be in an immunosuppressed state. Many studies now indicate that the average sexually active gay American male is exposed to several immunosuppressive agents, including cytomegalovirus (CMV) and semen itself. There is a distinct possibility that an immunosuppressed gay American visiting Haiti would contract ASFV infection through sexual contact with an infected Haitian.

To recapitulate, in order for ASFV to spread via sexual contact from an infected person to a sexual partner, three elements would be necessary: the ASFV would have to be currently circulating in the bloodstream of the infected person or present in his urine, semen, or sweat. The sexual partner would have to be immunosup-

Pigs and Kaposi's Sarcoma

At Ohio State University in Columbus, Dr. C. Prakash has reported that pig immunosuppression is a potential animal model for human Kaposi's sarcoma. He has noted that some male pigs display homosexual activity, especially when housed together in groups. Some of these pigs have developed skin lesions which are similar in many ways to the appearance of KS in humans. The pigs engaged in anal intercourse and were observed to consume semen spilled on the floor of the pig pens. A biopsy performed on one pig did not heal for five months, although healing in pigs is normally rapid.

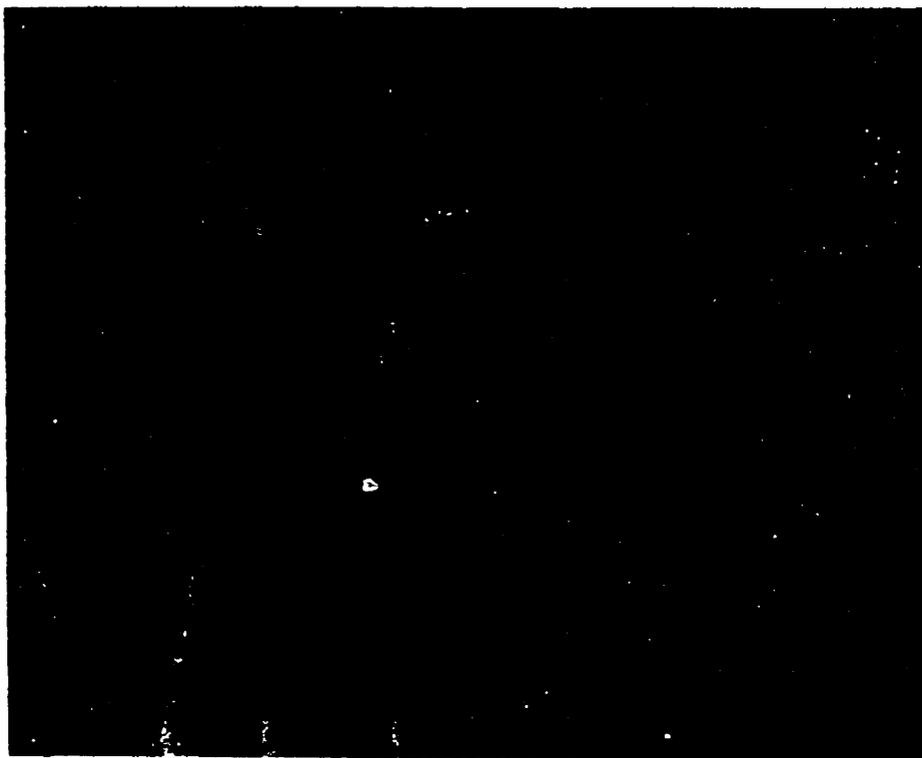
These findings may indicate that immunosuppression is immunosuppressive for pigs—a finding now confirmed by several studies in humans. Although these results are clearly unrelated to African Swine Fever Virus—so far—they seem to enhance the case for some general similarities in human and pig immunologic responses.

Also in Columbus, John Hughes of Children's Hospital Research Foundation has been awarded a grant by the National Institutes of Health to determine whether human semen suppresses immune functions in animals.

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Dr. Jane Teas

Photo by Jim D'Ermo.

tion: The immunosuppression would facilitate the process by which ASFV may infect human T-cell lymphocytes and macrophages, thus leading to a more profound immune deficiency—typical of

infections; it is also known that stress has an untoward effect on the immune system in general.

It seems apparent that many of the immunosuppressed, and a break in the

It is more than interesting that Dr. Teas' theory creates a kind of marriage between the two most predominant theories of AIDS etiology: "the immunologic overload" and the "kindle seed virus"

when examining human macrophages infected with ASFV, certain cytoplasmic inclusion structures were found, but that these did not resemble any virus-related structures. On April 7, 1983, E.P. Ewing, et al., reported in the *New England Journal of Medicine* that they had found structures they termed "vesicular rosettes" in the lymphoid cells of AIDS-related patients when examined by EM. These two accounts bear a striking resemblance.

Dr. Teas suggests that the AIDS-like disease reported in certain American monkey colonies may have a relationship to ASFV as well. Stanford University set up a monkey colony on an island off the north central coast of Mexico. In 1975, all the pigs on the island died of unexplained "fever"—possibly ASFV. The possibility exists that researchers who were studying the monkeys could have independently carried the ASFV to American monkey colonies. There are reports that the ASFV may be transmitted from one pig population to another by workers and/or by agricultural implements.

Examining the tonsils of pigs has proved to be a diagnostic tool for determining whether a pig has ASFV or a disease called hog cholera. ASFV is found in the tonsils of all pigs with the disease. Some veterinarians suggest that the many convolutions of the tonsils harbor the ASFV, thus affording a longer exposure to the infectious agent when it is consumed in contaminated foods. The tonsils of humans may provide a similar extended exposure to ASFV if the virus is contracted orally either by eating or having sexual contact with infected substances. It may be of interest to determine what percentage of AIDS victims have tonsils.

Possible Investigations with ASFV

According to Dr. Teas, there are several experiments which may be useful in ascertaining whether a relationship exists

An epidemic of myths and misperceptions.

THE HISTORY OF AN EPIDEMIC

BY ROBERT BAZELL

I STEPPED OFF a plane from Port-au-Prince the other day, and the immigration officer at Kennedy Airport refused to touch my passport. Because I had been to Haiti, he was afraid he might catch AIDS from me.

In *A Distant Mirror*, Barbara Tuchman notes that even though the Black Death of 1348-50 killed one third of the population living between India and Iceland, the disorders of the time could not be attributed to that cause alone. There were many other problems which "existed prior to the Black Death and continued after the period of the plague was over."

The effects of AIDS cannot be understood without considering the preexisting problems of certain groups—not only the homosexuals, drug addicts, hemophiliacs, and Haitians to whom AIDS is a plague, but also the medical research establishment and the mass media. The immigration officer's reaction is part of a hysteria afflicting many people in recent months, especially on the East and West Coasts: AIDS SHOCKER AT BELLEVUE, screams a headline in the *New York Post*. "One thing we do know for sure," shouts Geraldo Rivera, "this dreadful disease has spread well beyond its original bounds." Suddenly a lot of people fear that they and their families might suddenly catch some mysterious, fatal illness which until now has been confined to society's outcasts.

This is indeed a dreadful disease, a horrible epidemic that will kill thousands before it is over. It is certainly the most serious public health emergency in the United States since polio was controlled. The cause is unknown, and there is no cure. But AIDS is not going to kill your grandmother.

In 1981, when the first cases were identified, AIDS had no name. Doctors in New York and San Francisco suddenly saw relatively large numbers of patients with rare diseases—particularly a cancer called Kaposi's sarcoma and pneumonia caused by the bacterium *Pneumocystis carinii*. All of the victims were young homosexual men. Doctors quickly learned that the victims were contracting these rare diseases because part of their immune system—certain white blood cells crucial to the body's defense against infection—had been destroyed. It was not until last summer that someone (there is

confusion about who) thought of the name Acquired Immune Deficiency Syndrome. Later, when investigators from the federal government's Centers for Disease Control (C.D.C.) searched their records, they realized the disease had first appeared in New York in 1978, and that there had been at least seven cases in 1979.

When the doctors in New York and San Francisco first recognized the syndrome, they contacted the C.D.C. in Atlanta. The C.D.C. tracks down the causes of unexplained outbreaks of illness. It is staffed by physicians and scientists who are highly competent, usually young, and invariably willing to work for less money than they could make on the outside. They enjoy the role of medical detective. Often their tasks are relatively trivial: finding the tainted macaroni salad which gave diarrhea to dozens at a crowded picnic. Sometimes the challenge is much greater, as when C.D.C. scientists identified the bacterium responsible for Legionnaires Disease, and turned a mystery killer into a treatable ailment.

Much has been said and written about the allegation that because AIDS primarily affects homosexuals and drug addicts, the federal government was lax in responding to it. I cannot say that more researchers and case workers would not have been assigned if this were a fatal affliction of investment bankers. But it would be difficult to make a case that the C.D.C. could have accomplished more than it did in the initial phases of the investigation.

The science of epidemiology concentrates on finding the one exposure shared by those infected by an ailment and not by those unaffected by it. "At the picnic did you eat the potato salad or the macaroni salad?" In the early stages of the investigation in 1981, the C.D.C. scientists exhaustively interviewed every AIDS victim they could find. They tested samples of the victims' blood, urine, saliva, and feces for every known bacterium, virus, and parasite. Many theories were put forward: that the amyl nitrate stimulants known as "poppers" were the cause, that certain bathhouses or bars might be involved. The laboratory tests found nothing. The only fact that emerged from the interview was that many of the victims were having a lot of sex with a lot of other men. Many had had hundreds of sex partners a year, and some had had more than a thousand.

Ironically, the investigation moved faster at the beginning stages precisely because the disease was affecting primarily people whom most of society and the mass me-

Robert Bazell, who studied immunology at the University of California at Berkeley, is the science correspondent for NBC News.

die tend to ignore. During those first months C.D.C. scientists did not have to contend with hysterical inquires from citizens and public officials. They did not have to spend much time answering reporters' questions, because reporters weren't calling.

Between 1979 and the end of 1981, 280 cases had been diagnosed and reported to the C.D.C., 225 in 1981 alone. The number seemed to be increasing exponentially, doubling every six months. The investigators saw that AIDS had spread to drug addicts, to Haitians, to hemophiliacs, and to children. They realized that 75 percent of the victims who had had the disease for a year and a half or more were dead. And most important, it became increasingly clear that what was causing the disease was something "new": not the familiar bacterium waiting to be found in the macaroni salad, but an agent to which human beings had never previously been exposed. At this point it was obvious that traditional epidemiology and the resources of the C.D.C. were not enough. A lot of basic research was needed. And here there was a lag.

The National Institutes of Health dominates medical research in the United States. The N.I.H. is not set up as the C.D.C. is to respond quickly to emergencies. It funds research and researchers to pursue long-term goals that are established by Congress and, indirectly, by the lobbying groups that influence Congress. That is why the largest part of the N.I.H. budget pays for studies of diseases which might kill a 68-year-old white male Senator. Not surprisingly, the top scientists follow the money. Most spend their time on problems such as cancer and heart disease. The N.I.H. offered no money for AIDS research in 1982. But even if it had, few top scientists would have jumped in. From the outside it seemed the C.D.C. still might come up with a quick, easy explanation, and few big-time scientists would have been willing to switch to research that might prove a waste of time.

As a result the gap was filled by scientists who, like Dr. James Oleske of the New Jersey School of Medicine and

Dentistry in Newark, stand below the top rung. Dr. Oleske, among the first to study AIDS in children, set off much of the current panic about AIDS.

The mothers of most of the children who have AIDS are drug addicts, and other researchers had assumed that the children contracted the disease from their mother's blood in the womb. But Dr. Oleske announced at a press conference, in dozens of media interviews, and, months later, in a paper in the *Journal of the American Medical Association* that AIDS seemed to be spreading in the families by casual contact, by inhaling the breath of a victim or by kissing. Several other scientists say Dr. Oleske's work is flawed. (As Dr. Arye Rubenstein, Professor of Pediatrics and Director of N.I.H. research on AIDS at the Albert Einstein College of Medicine in the Bronx, diplomatically put it, "My feeling was that the information included in his *JAMA* paper does not yet justify the far-reaching conclusion that there is an intrafamilial spread through casual contact.") They contend he did not check thoroughly enough whether the mothers had a history of drug use or bisexual lovers. Some of the cases, they say, might not have even been AIDS, and some were investigated after the victims had died. He was the first—and to my knowledge he remains the only—scientist to claim that AIDS can be spread by casual contact. But a lot of reporters picked up on that story. Soon hospital workers, prison guards, undertakers, and many others were regarding AIDS victims as lepers.

No group has suffered more from bad science than Haitian immigrants. When the first cases appeared, American doc-

tors interviewed the victims. The doctors spoke mostly English. Occasionally they found someone who could ask the questions in French. But the recent immigrants understand only a little French, and even less English. None of the original interviews was conducted in their native Creole. Nor did the doctors bother to learn much about the Haitian culture. They simply asked, "Are you a homosexual? Do you shoot drugs?" When the answer to both ques-



BY HARRY PINCUS FOR THE NEW REPUBLIC

tions was no, the doctors declared that Haitians were susceptible to AIDS for some mysterious reason.

Suddenly there was a popular notion—and it seemed ever so logical—that AIDS had originated in Haiti. What better place for a deadly new disease to spring up than the land of voodoo and poverty? And who better to blame than Haitian immigrants? Poor, black, and speaking little English, they were already facing more discrimination than almost any other group in America. So why not blame them for AIDS too? My experience at the airport illustrates the attitude about Haitians. About eighty Haitians in the United States—out of four hundred thousand—have AIDS. But because of the fear of AIDS, hundreds of immigrants have lost their jobs or have been told they will not get one.

There is simply no evidence to support the so-called "Haitian connection." When Haitian doctors interviewed the victims, they learned that at least one quarter had worked as male prostitutes meeting foreign gay men, mostly Americans, in bars in Port-au-Prince and in the resort areas of Cap-Haitien. These Haitian men did not consider themselves homosexual. In fact, there is a strong cultural taboo against homosexuality in Haiti. Many of these men were married with families. They had sold themselves in order to survive.

In Haiti I learned that AIDS is a growing problem there. At least one hundred fifty cases have been diagnosed. But there is no evidence that AIDS began there. It probably came from the United States. In Haiti many victims, like the victims among the immigrants to the United States, worked as male prostitutes. Others are their wives and girlfriends. Folk doctors, who provide much of the poor Haitians' medical care, often inject several patients with the same hypodermic needle without cleaning it. This practice may be spreading AIDS among Haitians the way it is spread among drug addicts in the U.S. Still, there is no reason to say that AIDS is a Haitian disease or that Haitians get it for reasons that are different from everyone else's.

Some gay organizations and gay publications have repeated the allegation that AIDS originated in Haiti. One story has it that during voodoo rituals Haitians drink pigs' blood, and can contract an African swine virus which infects Haitian pigs. There is no evidence whatsoever to support this tale. Although gays have protested vociferously about the discrimination they have suffered because of AIDS, some elements of the gay community seem to have no qualms about abetting discrimination against others. There is a strong desire among some gays to say that AIDS came from somewhere—anywhere—else.

It is unlikely we will ever learn where AIDS originated. Within a year or two scientists will probably identify a virus that causes it. But no one will be able to say where that virus underwent the genetic mutation that enables it to infect humans and destroy white blood cells. We can say that once the virus appeared, one of the main reasons it became such a public health problem was the promiscuity of many gay men.

Homosexuality, it has often been noted in the discus-

sions of AIDS, is as old as mankind. Some people have always had sex with a lot of other people. But the emergence of homosexuality as an accepted culture in the last decade enabled thousands of gay men to indulge in the age-old male fantasy of having sex with whomever you want as often as you want. A network where thousands of people are interacting sexually is as rich an environment for the dissemination of disease as one could possibly imagine. This is particularly so when much of the sex is anal, with tiny sores in the rectum allowing for the mixing of semen and blood and often the blood of one sex partner with the blood of the other.

Before AIDS appeared, many gay men were already victim to dozens of bacterial, viral, and parasitic infections which had been rare until recently. When a fatal disease found its way into the network, its rapid spread was inevitable—first among the most promiscuous, then throughout the gay community. Whenever it started, AIDS quickly became a disease of male homosexuals. More than 70 percent of the victims are gay men. The evidence suggests that from the homosexual matrix it spread to i.v. drug users, and then to the few dozen people who have gotten it from transfusions and to the few dozen hemophiliacs who have gotten it from Factor 8, a product made from blood which they must inject to make their own blood clot. Women who have contracted AIDS (the C.D.C. knows of 110 female victims in the United States) got it either from bisexual lovers or from dirty needles. The few dozen child victims almost certainly got it from their mother's blood while in the womb and not from any casual contact.

FACED with the possibility of contracting a fatal illness, many gay men have thought hard about their lifestyle. The issue has been raised frequently in gay publications. But even though gays have criticized government officials, most officials dealing with AIDS have tried not to sit in judgment on people's behavior—no matter how much that behavior may have been responsible for the spread of the disease. If AIDS were magically to disappear and many gay men were to resume widespread promiscuity, there is a good chance that some other horrible disease would find its way into the gay population and then spread to others. One need not be a Moral Majority moralist to raise questions about the fast life; there are powerful medical reasons for doing so, and for heterosexuals as well as homosexuals. (On July 2 Jay Mathews of *The Washington Post*, citing C.D.C. figures, reported significant declines in the numbers of cases of syphilis and gonorrhea since the beginning of the year. Several health officials speculate that the recent herpes scare has contributed to the decline.)

In the past few months the N.I.H. has responded. It has awarded millions of dollars in research grants, and some very good scientists have turned their attention to AIDS. It is now certain that glory awaits the one who discovers the cause of or cure for the disease. Scientists are using medicine's most complex and modern technologies. It

may take a few years, but it is a good bet they will succeed.

But based on what is already known, and based on the behavior of viruses, particularly hepatitis B that affects the same groups, it is possible to sort some things out now.

—Despite the hysteria, AIDS is not highly contagious. All the evidence indicates it can be transmitted only by sexual contact or mixing of blood; even then it requires repeated exposures. AIDS has been around long enough that if it could be caught by breathing the air or in some other casual way, there would be many cases. There are none. Thousands of gay men have had sex with AIDS victims and have not gotten it. A lot of people are waiting anxiously because the disease can appear six months to two years after exposure, but AIDS is certainly not anywhere nearly as contagious as the Black Death of the Middle Ages.

—There are more than seventeen hundred cases now, and there will be more than thirty-four hundred six months from now. But it is not likely there will be sixty-eight hundred a year from now. Almost certainly, the number of cases is not going to double every six months as it has since the onset of the epidemic. At some point the disease will have swept through the susceptible populations and the number of new cases will level off.

—It is unlikely that everyone who is infected will get the

fatal disease. Most viruses affect people to different degrees. It would be surprising if AIDS were different. Some people might get a "mild case" and act as carriers but not suffer the complete immune deficiency.

—Another factor limiting the spread of AIDS is that while men can transmit it to women through sexual contact, there is little evidence that women can give it to men. Thus it will not spread like syphilis or gonorrhea.

—Finally, as long as AIDS receives close attention from the media there will be reports of people who contracted it through some route other than through sex, blood, or blood-contaminated needles. It is not easy to get honest answers about peoples' sex lives and drug-taking habits.

At the end of *The Plague*, Camus notes that the bacillus never really disappears, and reflects gloomily that "perhaps the day would come when it would rouse up its rats again and send them forth to die in a happy city." His warning might apply equally well to AIDS, because a mutant variant of the AIDS virus or some new organism could appear anytime. Even if interferon, recombinant D.N.A., or one of the other wonders of modern medicine provides a cure for AIDS or a vaccine to prevent it, health authorities and gay men would do well to remember the dangers to gays and others that a return to the old pattern of massive promiscuity would create.

Mr. WALKER. Mr. Brownstein, I gather from your responses to some of the questions, and also what you said in your testimony, you see no evidence within the Public Health Service that there is a feeling among the CDC or the NIH scientists that hemophiliacs are expendable.

Mr. BROWNSTEIN. No, but I would like to answer that more than yes or no.

There was a comment made earlier about if this happened to Norwegians or tennis players, there would be a different response.

Quite frankly, hemophiliacs do not represent any particular group that has been stigmatized or against which there has been discrimination; so we have received a very positive response from all the organizations we are dealing with.

I am hearing, and I have heard, these other comments from other groups, from the other groups identified as being as high risk, and it has not been my experience, but, you know, there has never been discrimination on that basis, against hemophiliacs. There has been discrimination against hemophiliacs with respect to employment, and so on and so forth, being labeled as disabled, and so on, but not quite in the same regard.

Mr. WALKER. I appreciate your statement on that.

Mr. Endean, you said it took the Federal Government 3 years to act on AIDS. Isn't it true that HHS officials dispatched epidemiologists to New York City and California immediately after the first five cases were reported in Los Angeles in June of 1981?

Mr. ENDEAN. I can't speak to Los Angeles.

I am not sure. My impression was that the epidemiological efforts that were underway were in New York City and not elsewhere around the country.

Certainly all of us would have to agree that the epidemiological efforts to this point have been utterly and totally insufficient.

Mr. WALKER. Well, I am asking you to confirm the facts here. In other words, you don't have knowledge of the fact that the epidemiologists did begin acting after the first five cases were discussed. You don't have knowledge of that.

Mr. ENDEAN. Yes.

Mr. WALKER. Isn't it true the first AIDS victim was admitted to NIH in mid-1981?

Mr. ENDEAN. I can't speak to that.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. WEISS. Thank you very much, Mr. Walker. I want to thank our panelists for excellent testimony.

Mr. CRAIG. The question of confidentiality is a very valid question. How are we to get the kind of information and material necessary. This question just came to mind, as you talk about national legislation to assure confidentiality and to gain the confidence of the people that that information would have to be sought from.

Is there a problem with a national law versus State laws that say, certain types of behavior that these communities might be engaged in is an illegal type of behavior within the State confines, and therefore, the search for information, although the Federal law might blanket, they would run into the problem of violating State law? Is that a problem that anyone in this area has discussed?

Ms. APUZZO. Sir, we are going to hear testimony from Lambda Legal Defense, which has coproposed this, and it sounds like one of those questions that we might best leave to the attorneys to define the parameters of.

Mr. CRAIG. Thank you. Probably a valid suggestion.

Mr. WEISS. Mr. Craig, thank you.

Mr. McCandless?

Mr. McCANDLESS. In May of 1983, the French Government announced its decision to ban the importation of American blood because of its possible contamination with AIDS.

We learned earlier that there is no test to determine whether or not blood has been donated by someone with AIDS before it is given as a transfusion. Is that correct?

Mr. BROWNSTEIN. That is correct, and, in fact, at this point it has not been definitively established scientifically that it is a transmissible agent through the blood.

Mr. McCANDLESS. Is there any parallel between this and the problems we have had with hepatitis being transmitted through blood transfusions?

Mr. BROWNSTEIN. I would defer to Dr. Bove, who will be testifying later this afternoon.

Mr. McCANDLESS. Do you know if we import blood for the purpose of creating the necessary activities to help the hemophiliacs?

Mr. BROWNSTEIN. No, we do not import blood for that purpose.

Most of the blood fractionation is done in the United States by four major pharmaceutical companies. In some small amounts, blood does come from European concerns.

For the most part, the blood products that are used by hemophiliacs are exported to other countries, and, in fact, the notion of bans on blood from the United States are somewhat overstated.

I have just returned from the Congress of the World Federation of Hemophilia in Stockholm, and some of these reports are exaggerated, and I would be pleased to elaborate more on that at some other time, if you wish.

Mr. McCANDLESS. Thank you, Mr. Chairman.

Mr. WALKER. Mr. Chairman, since there do seem to be some questions for the panelists, could we have permission to submit questions in writing to the witnesses, so we could have those to flesh out the record where some questions may still remain?

Mr. WEISS. I am sure the panelists would have no objection to responding to questions submitted in writing.

Without objection, we will leave the record open for the 10 days after the close of the hearings for that purpose.

Thank you all very much for very, very effective testimony.

What has been demonstrated not just in your panel, but in the hearings up to this point, is that there is a tremendous lack of hard information about the Government's AIDS activities. That is what we are all struggling with.

Thank you very, very much.

The next panel includes professionals from the medical and research communities who have played critical roles in moving us closer to unraveling the puzzles of this devastating affliction.

I would like to call to the witness table Dr. Frederick Siegal, Dr. Mathilde Krim, Dr. Marcus Conant, Dr. Joseph Bove, and Dr. Bruce Voeller.

While they are approaching the witness table, let me begin by introducing the panel.

Dr. Marcus Conant, professor of dermatology at the University of California Medical Center at San Francisco, and president of the board of directors of the National AIDS-KS Foundation;

Dr. Frederick Siegal, chief of the division of clinical immunology, at the Mount Sinai School of Medicine and City University of New York;

Dr. Mathilde Krim, head of the Interferon Laboratory at Memorial Sloan-Kettering Cancer Center in New York, and chairperson of the board of trustees of the AIDS Medical Foundation in New York;

Dr. Bruce Voeller, biologist, head of the Mariposa Foundation in Los Angeles. Dr. Voeller has held professorships at the Rockefeller Institute, Hunter College, and Harvard University; and

Dr. Joseph Bove, professor of laboratory medicine, and director, blood transfusion service at Yale New Haven Hospital. Dr. Bove will be addressing the issue of AIDS and blood.

I would appreciate it if you would stand at this point. Do you affirm to tell the truth, the whole truth, and nothing but the truth?

Dr. CONANT. I do.

Dr. SIEGAL. I do.

Dr. VOELLER. I do.

Dr. KRIM. I do.

Dr. BOVE. I do.

Mr. WEISS. Again, may I suggest that for the sake of time limitations, that you summarize your prepared statements. Of course, the entire text of your statement will be entered into the record.

We will begin with Dr. Conant and proceed to Dr. Siegal, Dr. Krim, Dr. Voeller, and Dr. Bove.

STATEMENT OF DR. MARCUS CONANT, PROFESSOR OF DERMATOLOGY, UNIVERSITY OF CALIFORNIA MEDICAL CENTER, SAN FRANCISCO, CALIF.

Dr. CONANT. Thank you, Mr. Chairman.

Mr. WEISS. May I indicate for the benefit of the observers that we will take a brief break after this panel concludes its testimony and before questioning begins.

Dr. CONANT. I am Marcus Conant, codirector of the Kaposi Sarcoma Clinic in San Francisco.

We would like to thank you and the members of the committee for convening this hearing, and my complete testimony, as you indicated, has been submitted to your staff.

I would like to, in my brief comments, focus in on just three aspects of the problem as we see it as medical researchers involved with this problem in a community that has more per capita gay men than any other community in the United States.

Researchers who are in a major medical center right at the edge of that community, medical researchers who are seeing daily new cases of patients admitted with Kaposi sarcoma and pneumocystis.

The failure to respond to this epidemic now borders on a national scandal.

The second point is that this body, Congress, and indeed the American people, have been misled about the response.

We have been led to believe that the response has been timely and that the response has been appropriate, and I would suggest to you that that is not correct.

Finally, I would like to spend a few minutes from my perspective suggesting to you what needs to be done immediately, if we are not going to face a catastrophe of undeniably unbelievable proportions.

First, the issue of failure to respond: I think that has created two major epidemics. The first epidemic is the epidemic of AIDS as we now know it, and the second is the epidemic of fear sweeping our country.

There are now 1,900 cases of AIDS in this country, and 900 of those young people are dead.

The epidemic is now doubling every 6 months.

We hear that changes in lifestyle may make the problem go away. I would suggest to you that many members of the gay community that I see as patients have clearly changed their lifestyles.

If you were confronted by a disease that has a mortality rate approaching 100 percent, it does not take much medical persuading to convince that patient to substantially alter his behavior, but I would further submit that to think that any individual is going to totally deny his sexuality, a basic human function, is naive and extreme.

Gay men will continue to have sexual contacts. They will continue, even though they know the risk that they are placing themselves at; they will continue to be human.

For us to suspect that they will cease to be human is naive.

At this time 1 year ago, there were 300 cases of AIDS in the United States. We now have 300 cases of AIDS in San Francisco alone.

By the time the current administration finishes its term of office 1½ years from now, there will be 12,800 cases of AIDS in this country, and, as I have told you, 80 percent at least of those patients will die.

No one who has acquired pneumocystis pneumonia has survived for more than 2 years.

Those brave young men that you saw testify are looking to you to help us to come up with treatments to try to prolong their lives, but at the present time no one with pneumocystis has lived for more than 2 years after that diagnosis was made.

If nothing is done by the time the next administration finishes its term of office, there may be as many as 3,300,000 cases of this disease in the land.

I spoke of the epidemic of fear. In San Francisco, we now have the hysteria of policemen unwilling to go into certain areas without wearing masks, the ridiculous situation where a bus operator refused to take a transfer from someone he assumed might be gay, because he was afraid he would acquire the disease.

Clearly, we are failing in public education. The incredible situation where nurses are refusing to care for dying patients because they don't understand enough about the disease, and they are fearful of acquiring the disease, themselves.

We are failing in educating our medical community as well as the entire citizenry; and then we had a situation last week where young men were running through the streets of Seattle with ball bats, beating up on people who they think might be spreading a disease. These self-appointed public health officials out there spreading fear and anger, why? Because they are hearing this fear and anger from their parents and their peers, and it is our job to try to dispel some of that, and we can only do it with coordinated education at the highest levels.

As a second point, I suggested that you have been misled; that we have all been misled.

We heard a moment ago that the Government had only recently become aware of this problem.

I was invited to attend the first meeting held at Bethesda, National Institutes of Health, in the fall of 1981.

Everyone attending those meetings knew at that time what we were facing. We knew the type of disease we thought this was, a transmissible agent, probably blood-borne.

We knew that the numbers were doubling at an incredible rate. We were terrified of the implications of this epidemic. We were at that time able to draw an epidemic coverage.

By May 1982, we were predicting 300 cases by the end of 1982. And the prediction of that upswing was perfectly correct. We were just naive in terms of the numbers. There were not 300 cases by the end of 1982, there were 900 cases.

The delay in funding research has been unconscionable and has resulted in loss of lives. As a medical researcher I can tell you that we have lost much valuable information: Individuals who we could have questioned epidemiologically about who they had contact with are now dead. There is no way to do retrospective epidemiology on individuals who have died. By losing them we are losing information vital to understanding how this disease is transmitted.

We know there are not enough projects yet being submitted by researchers across the country. And yet from our own institution, the full grant that we submitted was not fully funded. Many portions were completely approved. It went through the peer review process and we were told yes, indeed, this appears to be good work but there is not enough money to fund it.

It would seem that the NIH does not have the money to fully fund all of the projects that have already been submitted, many of which are necessary and worthy.

And I would suggest that there is a double accounting process going on. In terms that we have received in response to inquiries to the National Institutes of Health, we have been told that large amounts of money are being used to study and investigate the AIDS epidemic. And yet when we look at this, we find that these were moneys appropriated to study cancer, clearly appropriate studies that should go forward, but that were appropriated 4 and 6 years ago. But they are now being lumped into the accounting for the moneys being spent for AIDS, deceiving, if you will, those read-

ing it into believing that this large amount of money is being spent on AIDS, when in fact there is nothing more than moneys that had been there all along for other important research activities.

I would also like to focus on a misconception that we hear commonly, that this is a problem often referred to similar to cancer where we may be in for the long haul. Let me remind this committee that there are two aspects of this disease, and I think it is important that all of us keep this clear.

The first aspect is that we are dealing with a new sexually-transmitted blood-borne agent, probably a retrovirus, and that we have at our disposal the intellect, the abilities, the capabilities of isolating a virus, producing a vaccine and protecting a population not yet exposed who are at risk.

The second component of the disease is that in some way this agent mysteriously cuts off the immune system of its victims and places them at great risk for developing some opportunistic infection, such as pneumocystis pneumonia, or Kaposi's sarcoma.

While it may take many, many years to unravel all of the immunological complications of the disease, and by the time we have a vaccine we may have hundreds of thousands of people who have AIDS, who need that research to save their lives. Funds applied today to look for the agent may in fact break this chain of transmission. But the job is not easy. The incubation period of this disease is 18 months. So if I put a vaccine in front of you today and we began to vaccinate individuals, that would have no impact on the incidence of this disease at all until 1985.

Said another way, every case that is going to appear next year is already in the pipeline, and we have no way of stopping it.

Namely, let me suggest some things at least from our perspective that could be done immediately and indeed must be done if we are going to prevent this disaster.

First, new Federal funds need to be committed to attack specifically this problem. Throughout this epidemic, some funds have been shifted from one agency over to another, a little bit of money has been found here, a small amount of money has been found there. The amounts of money for the type of problem we have here is just not adequate.

I would suggest that you gentlemen view this like a national disaster, and if this city were devastated by a hurricane tomorrow, you certainly would not say, well, the sewage department is still working, the light departments are out there working, we are going to get the problem taken care of. The city would have been struck by a new disaster. And it takes new resources to deal with that disaster.

This country has been struck by a new disaster. None of us expected a new infectious disease to appear at the end of the 20th century which has a mortality rate greater than smallpox. We need new extensive funding to attack the problem.

The second is that all of the worthy grants that have been reviewed should be fully funded immediately, so that researchers can go to work to try to elucidate what the causative agent is and how it cuts off the immune system of its victims.

The next thing is that the NIH should solicit grants frequently from the research community. There should be every 3 to 4 months

calls for new research papers to stimulate thought in the medical community and to continue to have new grants to review.

The problem is changing rapidly. We need new information rapidly.

We need a task force in the executive branch of Government to attempt to coordinate the educational activities, the physician education activities, the community needs that you had eloquently expressed by the panel that preceded me.

And finally, and probably the most important from the perspective of a medical researcher, is we need an ad hoc peer review committee, probably under the National Institutes of Health, which can expedite the peer review process.

As a scientist, I can tell you that the peer review process is time-honored and worthy, and should not be tampered with except in the case of a national emergency. We have such an emergency today. Eminent scientists could be picked, they could review projects, and they could recommend funding immediately.

If the Jonas Salk of this epidemic were to appear today with a proposal that all of us felt was worthy, it would take him 18 months to 2 years to get his first test tube paid for.

For those of us from the west coast, we don't get back to Washington very often. I was lucky enough to arrive 2 days ago, park and walk up the Mall, look at some of the national monuments that we don't get to see, and walked into the National Archives Building to see the Declaration of Independence. And one is struck that 207 years ago, when Jefferson penned that document, he said that we as citizens had three inalienable rights, and I don't think it is by accident that he said that the first of those was life. And he pointed out that to secure those rights, governments are instituted among men. And as I read that, it was his interpretation that the purpose of government, the mandate of government is to insure the life and lives of its citizens.

We are in the beginning, not the midst—we are in the beginning of a national and indeed worldwide epidemic that is going to threaten the lives of hundreds of thousands of individuals. It would seem clear that the mandate of this Government is to respond and to respond immediately.

Thank you, Mr. Chairman.

Mr. WEISS. Thank you.

[The prepared statement of Dr. Conant follows.]

My name is Marcus A. Conant. I am a physician at the University of California at San Francisco and the co-director of its Kaposi Sarcoma Clinic. I wish to thank Representative Weiss for calling this hearing.

Some time three or four years ago, in a manner that will probably forever remain unknown, a new and terrifying illness was introduced into the human population. At first, we did not even know that it had arrived. Instead, it was thought that for some bizarre reason there was an epidemic of a rare skin cancer called Kaposi Sarcoma among homosexual men in a few large cities. At about the same time, it was also noted that others in the same population group were coming down with a lethal form of pneumonia in unusually large numbers. It was not until several months later that public health officials realized that the illnesses they were seeing were actually only the symptoms of a much more fearsome disease, the phenomenon we have come to call Acquired Immune Deficiency Syndrome. AIDS has since become America's most feared acronym. The statistics on its proliferation have become numbing, but they bear repeating here. Last year, there were a few hundred persons with AIDS. Now there are 1,800. The number of AIDS victims currently doubles every six months, and by the end of the year, more than 3,000 people will have it. As the number of persons with AIDS grows, the growth rate of the disease itself also increases, with the AIDS population expected to be doubling first every four months, and then every two. The number of people with AIDS could easily reach the tens of thousands in the very near future. Because the incubation period for AIDS is so long- we believe it to be 18 months- even if a

vaccine were found today, the number of victims would continue to grow until at least 1985. The final statistic in this grim litany is that nearly 60 percent of the people who contract AIDS die from it. The disease, quite simply, is the most lethal infectious killer known to modern medicine, and it is on a rampage in this country.

In the face of this appalling specter, one would expect the government of the United States, the world's most affluent and technically advanced nation, to be sparing no resource in its fight to stop AIDS. But as a physician and researcher who has worked with this problem from the beginning, I have to characterize the federal response to AIDS as bordering on the negligent. I see in my office every day young men who should be in the prime of life but who instead are wasting away towards an early, pointless but once-preventable death. They regularly ask me why their own government does not seem to care if they live or die. The question is not a rhetorical one. I have no answer for it.

I would like in my testimony to explain briefly how the federal response has been inadequate, and then to propose what I think we as a nation should be doing.

Recently, the administration announced that conquering AIDS is, in the words of the Secretary of Health and Welfare, the nation's number one health priority. We welcome this verbal support, especially after such a long period of official silence. However, I wish it was being backed up with financial support as well. The record clearly shows that it is not.

We often hear that from the National Institute of Health that it has all of the money it needs to deal with AIDS. However, my every experience with AIDS contradicts that. I can, with no effort at all, think of two dozen research projects that could be crucial to the fight against AIDS that aren't being carried out for the simple lack of grant money. I know of any number of colleagues who, instead of staying in their laboratories doing vital research, have to spend their time chasing funds. Compared to the enormity of the problem, the federal funding response has been, relatively speaking, a pittance. The failure of the federal government and the NIH to respond promptly and forcefully to this crisis is a national disgrace. It has helped the spread of two epidemics, one of a deadly disease, the other of public hysteria. I cannot help but conclude that federal officials who say that enough money is being spent on AIDS are simply mouthing some required political line that has nothing to do with reality. I wish they could be with me in my office every day as I have to face yet another patient who will likely die because a major federal commitment to fighting AIDS was not made sooner.

I would also question whether the federal government has actually committed as much money to this fight as it says it has. I believe that the NIH has been less than candid in describing the amount it is spending on AIDS. For example, the NIH includes in its figures monies it was spending on projects that have nothing directly to do with AIDS; projects that were underway before the AIDS epidemic even began. I also know that the National Cancer Institute has not released some of the

monies for research projects that it has already approved through its laborious peer review process. It is almost as though dubious accounting methods are being used to inflate the federal government's purported AIDS budget in order to create the appearance of a major effort being undertaken, when in fact that is not the case.

The United States can be proud that its research establishment is the ablest in the world. It stands ready to be unleashed against AIDS; all that is needed is the backing of the federal government. The tremendous intellectual resources of the public sector, including private industries and the universities of America, must be utilized in solving this problem. This can only be accomplished if Congress appropriates enough money to stimulate research outside of the NIH and the Center for Disease Control. I am sure we all have different opinions about how active the federal government should be in matters of social welfare. But no matter what your notion of the proper federal role is, it has to include taking the lead in a fight against a disease that has struck citizens in every state of the union; a fight that only the federal government has the resources to undertake.

There is one point I would like to address here briefly before moving on. Most of my patients with AIDS are gay, and almost to a man, they tell me that they believe the federal government would have acted against AIDS with a vengeance had it only struck a segment of the population that was in better standing at the moment in the nation's capitol. While gay men are by no means the only persons afflicted by AIDS, it is clear they have suffered from it more than any other group. I personally find it hard to believe that any member of Congress would

deny funds for research into an disease because they did not approve of certain aspects of the lifestyles of most of the people contracting it. AIDS is a medical problem, and questions of the legitimacy or illegitimacy of the modern gay movement must be left to some other forum. But if anyone is reluctant to fund the fight against AIDS because most of its victims happen to be gay, let me lead them to the crib of a newborn child who has AIDS, so they can watch as the infant screams with pain. There alone they will find reason enough to want to halt this killer.

One misconception frequently heard from funding agencies is that AIDS is such a complex, enigmatic pathological phenomenon that providing funds for research would be like throwing money down a bottomless hole. The analogy is sometimes drawn to cancer, where a final cure is probably still many years away. This is a grievously mistaken assumption, which if not corrected, could spell the deaths of tens of thousands of Americans.

AIDS is a baffling medical mystery. But it is a solvable medical mystery. AIDS is a new infectious disease agent, and all available evidence indicates that it is some form of virus. Fortunately, at this point in the twentieth century, (thanks in no small part to the support for scientific research provided in the past by the Congress) we have the knowledge and tools at our disposal to isolate a virus. We can then proceed to sequence the genetic information in the virus; to produce a vaccine that will protect people from acquiring the virus without incurring the disease; to clone that genetic material; and to

then produce large amounts of the vaccine for public distribution. We are hopeful that, given the proper support, we can accomplish all of this reasonably quickly, and thus break the chain of transmission of this disease.

But even with that achieved, there would remain another enormous medical and social problem connected with AIDS. By the time a vaccine is developed, there will likely be tens or hundreds of thousands of persons already afflicted with AIDS. In those cases, a vaccine would be useless, since the virus is already present in their bodies and wreaking havoc with their immune systems. We therefore need to continue, at fever pitch, research into the exact mechanism by which AIDS does its work. This is so we can save the lives of those already with the disease, and the many more we know will be contracting it before the vaccine is available.

These, then, are the two ultimate goals of AIDS research-- creating a vaccine for the well and finding a course of treatment for the ill. How do we accomplish all of this?

I would like to put forward the proposal that AIDS is such an unparalleled threat to the American people that an emergency task force be created at the very highest level of government. The task force would be headed by an emergency coordinator whose job it would be to act as steward while we, as a nation, join together to fight this threat. The group would report directly to the President or to the Secretary of Health and Welfare.

There are dedicated men and women throughout the country making heroic efforts every day to solve the AIDS mystery. I have nothing but respect for my research colleagues at the NIH and the CDC. Without them, we would be crippled in this effort. But the work of those scientists, along with those at research centers throughout the country, is not being coordinated; it is as though they are along the rim of a wheel that has no center. A task force would be that center of the wheel. This is not some symbolic action or hollow public relations gesture, but a desperate need. Today, with no one group overseeing the entire AIDS effort, it is easy for research to be duplicated; for vital scientific findings not to be passed along to those needing them; for researchers in one part of the country to pursue leads already discredited somewhere else. As you can well guess, any of those scenarios can be deadly in such a time of crisis. Equally deadly is the business-as-usual attitude of federal health officials in the timetables they use to approve funds for research studies. We desperately need to expedite the funding of worthy projects. If the Jonas Salk of AIDS were to come to Washington today with a research proposal, he would probably be told to come back in two years after his papers had been reviewed.

The National Conference of Mayors, at its recent annual conference, passed a resolution asking the Congress to appropriate \$50 million a year to combat the AIDS threat. I think that is an acceptable minimum amount. In considering the question of funding, the Congress must understand that AIDS is a new disease being visited on the population, and therefore new monies must be made available to deal with

it. Some have suggested that AIDS research be funded by diverting money from other public health projects. But it makes no more sense to do that than it does to find the money for Social Security payments for a new retiree by cutting off payments to someone already in the system. The public health concerns towards which those earlier funds were appropriated are still with us even with AIDS, and they deserve continued federal support. As a researcher, I would also wish to point out that it would be extremely shortsighted to fund AIDS by cutting money that was earmarked for other, more basic, research. We would be helpless in the fight against AIDS-- or in any other battle in medicine-- had it not been for the basic research done in years past. Continuing that research is part of our commitment to the future.

I would like to make one additional observation about money. I think it demeans this body to suggest that it would only make a judgement on matters of life and death because of economics. The main reason we must vanquish AIDS is because it is the only moral choice presented to us. But should anyone need further persuading, consider the simple dollars and cents of the matter. It now costs about \$70,000 to provide care for a patient with AIDS. Thousands have, or will get, the disease. Simple multiplication makes it clear that it is cheaper for us to cure AIDS than to treat it.

I have already spelled out the ultimate goals of AIDS research, and asked you to commit federal resources to help us achieve those goals. But there are a number of other steps we must take in the interim.

*1) While everything possible must be done to disseminate information about AIDS to all interested researchers, this must be done in such a way that patient confidentiality is preserved at the same time. Growing millions of Americans are completely comfortable with their homosexuality and do not regard it as any source of embarrassment. But there are, of course, many others who are unwilling to be publicly identified as being gay. As a result, a firm federal policy on patient confidentiality would be a boon to research, since it would make closeted homosexuals much more willing to fully and candidly discuss their AIDS problems and related issues with their doctors. Such a policy would also respect the right to privacy that every American cherishes.

*2) We need to greatly expand the extramural research being done into the epidemiology of AIDS. The disease baffles us on a number of fronts, not the least of which is the networks by which it is transmitted. Some examples of the questions we would like answered- San Francisco has a very large Asian population, yet there are only four Asian-Americans there with AIDS, while most other ethnic groups have the illness in proportion to their percentage of the population. Why is this so? In the first sets of studies on AIDS patients, they were revealed frequently to be highly promiscuous gay men. This is not at all the case today. Why the change? Among the Haitian males who have AIDS, nearly 100 have described themselves as heterosexuals. How did the disease spread to them? The questions go on and on.

*3) Fundings for research proposals are generally reviewed through

the peer review process of the National Institute of Health. This is a time-honored procedure, and one that all scientists, including myself, regard as the very cornerstone of our work. Truth flourishes and science advances only in an atmosphere of skepticism, questioning and caution. I think we must also remember, though, that we are in the middle of a public health emergency unlike any other of our generation, and that, as I indicated earlier, the slow, deliberative evaluations that in less critical times are the lifeblood of research could, in this instance, quite literally spell the death of untold thousands of Americans. In the average case, the time that elapses between a proposal being put before the NIH and the funds for the project being released is 18 months to two years. As I think you can appreciate, that is close to an eternity when it comes to the current AIDS crisis. The NIH needs to very quickly establish an ad hoc review committee made up of able, dedicated experts who can review proposals for AIDS research on an emergency basis. These scientists would bring with them both their expertise as researchers as well as their recognition that a grave public health crisis exists that demands prompt action.

*) I also think it is important for the NIH to issue a general call for research proposals dealing with AIDS. This would send a signal from the federal government to the scientific community that it is genuinely serious about AIDS. I know of a number of able scientists who currently will not even bother spending the time putting together an AIDS-related proposal because they feel it will not be seriously considering by the authorities in Washington.

*) Every American has an interest in seeing to it that the nation's blood supply is protected. Efforts must be made to develop a reliable, scientific method of screening that supply for infectious agents such as AIDS. In recent months, as it has become suspected that AIDS may be transmitted through blood transfusions, the vast majority of gay men have taken themselves out of the pool of blood donors for the duration of this health emergency. Most blood banks have also cut back on blood drives in gay neighborhoods. But a policy of protecting the blood supply by screening donors, rather than blood, is ultimately shortsighted and ineffective. It is easy to imagine, for example, an office blood bank drive where a closeted gay man, and a potential AIDS carrier, wishes to "prove" his heterosexuality to his co-workers by going along with the others and donating blood. No amount of pre-donation screening or questioning can prevent a person like that from donating blood. And a massive screening effort to determine who is, and who is not, a homosexual (or, for that matter, an intravenous drug user or a Haitian or a hemophiliac) is a social policy that is, at very best, of questionable wisdom, and at worst Orwellian. As far as the nation's blood supply is concerned, the emphasis must therefore shift from the donor to the blood.

*) There needs to be increased federal support for persons actually afflicted with AIDS. The cost of AIDS treatment is staggering, and is simply beyond the financial resources of most Americans. In the case of kidney dialysis, the federal government long ago realized that it was not befitting a civilized nation for its citizens to die because they could not afford the cost of medical

care. The situation is much the same today with AIDS, and I believe the federal response should be the same.

*) Six months ago, those of us doing research into AIDS were frightened by two things- the disease itself, and the complete lack of awareness of it outside of the gay community. Now, we have the opposite problem. There are, in fact, now two AIDS epidemics; one involving immunology, the other involving fear. There are any number of horror stories in this regard; one of the most appalling has to do with a San Francisco bus driver who, out of a fear of contracting AIDS from a tattered slip of paper, refused to take a bus transfer from a man he presumed to be a homosexual. I also hear too-frequent reports of hospital workers refusing to care for AIDS patients. It is a sad time indeed when members of the healing professions no longer wish to care for the sick.

I don't wish to belittle the fear of AIDS; no one knows more than myself what a truly fearsome medical phenomenon it is. But I think there is a considerable public education project ahead of us to tell the public who is, and who is not, at risk. It cannot be repeated too often that there is no evidence that AIDS is transmitted through casual social contact. Common sense alone would lead one to that conclusion. If AIDS were easily transmitted, then by now millions of Americans would have it, not 1,800, most of whom are gay men.

In several ways, this fear of AIDS is a public health problem in its own right. The health and welfare department's new toll-free phone

line is a small step in the right direction. (I would point out, though, that the phone lines are receiving up to 10,000 calls a day-- testimony indeed to the concerns Americans have about AIDS.) There are also grave questions of social justice in this regard. I have heard too many stories of persons with AIDS being fired from their jobs or evicted from their homes once their condition became known. There are also economic aspects to the AIDS hysteria. My businessmen friends back in San Francisco have started to worry about the effect of the fear of AIDS on tourism in that city. They also say that friends in other big cities have started to echo the same concern. There is even the worry that foreign tourism to the U.S. could begin to suffer because of the world-wide attention given to AIDS. All of these AIDS-related fears are, of course, groundless. A high-level task force could do much towards re-assuring the public of that fact.

*) The definition of AIDS must be broadened by the Social Security Administration for the purposes of providing benefits. Currently, the Social Security use the definition provided by the Center for Disease Control, which defines as AIDS patients as a person under 60 with either Kaposi Sarcoma or pneumocystis pneumonia, and a few other disease. However, we have recently see a number of new infectiuous agents take hold in AIDS patients. These people are just as disabled, just as in need of Social Security help, as a person with KS. Yet they are currently denied that help because of an outdated definition of the problem.

*) Due to the publicity AIDS has received in large cities with substantial gay populations, most physicians and other health care

workers are now familiar with the clinical manifestations of AIDS, as well as the appropriate treatment protocols. But this awareness of AIDS must be spread to doctors all over the country, so that persons suffering from the disease are diagnosed correctly, and from the very start receive appropriate medical care. This will help save the lives of these patients; it will also help curb the spread of the disease.

In closing, I would like to point out that last week alone, my home city of San Francisco buried four of its sons; young men who only months ago were in the prime of their lives. At a time such as this, one can't help but recall that it is the right to life that is the first of the three unalienable rights set forth in our Declaration of Independence; and that, as Jefferson wrote 207 years ago, that it is to secure those rights that governments are instituted among men. Any government has no higher purpose than to protect the lives of its citizens, and the citizens of the United States today face no greater public health threat than they do from AIDS. We have the profound moral obligation to take every step necessary to conquer it as rapidly as is humanly possible.

Thank you.

Mr. WEISS. Dr. Siegal.

STATEMENT OF DR. FREDERICK P. SIEGAL, CHIEF, DIVISION OF CLINICAL IMMUNOLOGY, MOUNT SINAI SCHOOL OF MEDICINE AND CITY UNIVERSITY OF NEW YORK

Dr. SIEGAL. Mr. Chairman, I was asked to comment today on the response of the Federal Government to the public health emergency presented by AIDS. I realized when thinking about this question that by virtue of existing NIH support, that I and many other investigators like me do in fact represent a part, albeit small, of that response, and that to some extent my professional history and current work exemplifies some of what the Federal Government can do and is doing about AIDS.

From my medical student days, through my house staff training, I learned in an environment heavily endowed one way or another by public support. But, and this is important, it was a time in which students and trainees were actively encouraged to enter a research career. The U.S. Army taught me practical public health and preventive medicine and Federal funds made possible the functioning of the immunology research laboratories in which I did my post-doctoral fellowship.

Since 1973 I have been engaged in clinical investigation into the somewhat arcane and certainly obscure field of immune deficiencies of adults, funded almost continuously out of Federal moneys, first at Memorial Sloan-Kettering Cancer Center and then Mount Sinai School of Medicine.

It was not an endeavor that could have supported a private practice. Yet from my relatively few patients with these rare diseases, I was able to have an impact chiefly because of my special research and rather unique background.

I could not have predicted nor could anyone else that that kind of background developed first in 1970 could have had an importance or usefulness to a major public health problem in 1983.

At several other centers in New York City, as well as in Los Angeles, San Francisco, Atlanta, and Miami, physicians with similar backgrounds were also trying to figure out obscure immunodeficiencies. We were doing this for a variety of reasons, none of which obviously had anything to do with the coming epidemic, to help those few patients, to expand our own knowledge of those diseases, and to improve through those experiments of nature the understanding of human immune deficiency infection. So we happened to be in the path of AIDS when it appeared and we were ready in effect to deal with the problem.

Had the disease hit other cities in the United States, there are federally trained and supported clinical investigators who could also have promptly become involved.

But given the present climate of opinion, we are concerned that 10 years from now there won't be the same kind of background population available to study a similar epidemic.

It might be useful to look back at the time of the outbreak of AIDS and the mechanisms that we did use to respond to it.

In June 1980, the first of our cases appeared at Mount Sinai. He was then just an unusual case of immune deficiency, and we

turned our NIH-funded laboratory to his investigation. Because he had unremitting herpes simplex infection, we turned for help to colleagues at Memorial Sloan-Kettering, who had somewhat different and specialized backgrounds.

Carlos Lopez, Ph. D., whose training in herpes viruses and the host defense was also supported by Federal grants, was also brought to bear on the problem as were many other investigators. Without realizing it, we had begun a prospective study of AIDS with our very first patient.

[Article relating to study follows:]

SEVERE ACQUIRED IMMUNODEFICIENCY IN MALE HOMOSEXUALS, MANIFESTED BY CHRONIC PERIANAL ULCERATIVE HERPES SIMPLEX LESIONS

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Abstract Four homosexual men presented with gradually enlarging perianal ulcers, from which herpes simplex virus was cultured. Each patient had a prolonged course characterized by weight loss, fever, and evidence of infection by other opportunistic microorganisms including cytomegalovirus, *Pneumocystis carinii*, and *Candida albicans*. Three patients died; Kaposi's sarcoma developed in the fourth. All were found to have depressed cell-mediated immuni-

ty, as evidenced by skin anergy, lymphopenia, and poor or absent responses to plant lectins and antigens in vitro. Natural-killer-cell activity directed against target cells infected with herpes simplex virus was depressed in all patients. The absence of a history of recurrent infections or of histologic evidence of lymphoproliferative or other neoplastic diseases suggests that the immune defects were acquired. (N Engl J Med. 1981; 305:1439-44.)

CHRONIC ulcerating lesions caused by herpes simplex viruses (HSV) are unusual even in patients with severe immunologic defects. These lesions occur in advanced lymphoproliferative disease, after immunosuppression for organ transplantation, during treatment with high doses of corticosteroids, and in certain primary immunodeficiency disorders.¹⁻⁴ In four previously healthy homosexual men we found chronic perianal ulcers infected with HSV. Immunologic evaluation confirmed the presence of apparently acquired cellular immunodeficiency. The course in these patients was characterized by severe, unrelenting opportunistic infections, leading to death in three patients.

METHODS

Subjects

The four patients were referred to Mount Sinai Hospital or to Memorial Hospital for diagnosis or treatment. Controls were normal male and female volunteers 20 to 50 years old.

Immunologic Studies

Mononuclear cells were obtained from heparinized venous blood and characterized by cell markers as previously described.⁵ Hybridoma-derived reagents defining Leu-1, present on all normal human T lymphocytes, and Leu-2a, characteristic of a suppressor/cytotoxic subset, were kindly provided by Dr. Robert L. Evans.⁶ Responses to phytohemagglutinin, concanavalin A, pokeweed mitogen, and antigens from microbial pathogens were measured by cellular DNA synthesis.¹¹ Natural-killer-cell function was determined by comparing the cells' cytotoxicity among uninfected ⁵¹Cr-labeled human foreskin fibroblasts with their cytotoxicity among HSV-infected fibroblasts.¹² Delayed skin hypersensitivity was tested with recall antigens that usually elicited a response in normal adults (*Candida albicans*, streptokinase-streptodornase, mumps, and tetanus toxoid). Immune complexes were detected with a modification of the Raji-cell assay for Patient 1¹³ and precipitation with 3.5 per cent polyethylene glycol for the other three

patients.¹⁴ Specimens for viral culture were transported in Hanks' salts and incubated with a panel of cell types. Cytopathic effects in human embryonic kidney were observed within 24 to 48 hours when a specimen was positive for HSV. Commercial antisera were used to characterize direct immunofluorescence for HSV in biopsy specimens.

PATIENTS

Patient 1

A 26-year-old white homosexual man first noted perianal pain and vesiculation in January 1980. During the following spring, ulcerations gradually developed and fever and weight loss began. At presentation elsewhere the patient was anemic. Results of marrow and liver biopsies were negative. Antibiotics were administered. A large perianal ulcer had formed by July, and hepatosplenomegaly and generalized lymphadenopathy were observed when he was admitted to Memorial Hospital. Cultures taken from the ulcer bed indicated HSV Type 2; sigmoidoscopy revealed proctitis and an anterior anal ulcer. Chest x-ray films showed an infiltrate of the right upper lobe. Skin anergy was noted. Further evaluation for suspected inflammatory bowel disease or lymphoma was negative. By August, the patient had lost approximately half his original weight, and fever and perianal ulceration continued. Exploratory laparotomy with splenectomy and biopsies of the liver, small intestine, and lymph nodes showed only lymphocyte depletion. Satellite ulcers appeared on the buttocks. Parenteral nutritional supplements, transfusions, and antibiotics were given, but without benefit. In October, the chest films were unchanged. Persistently positive cultures for HSV, abnormal liver-function tests, and an enlarging ulcer led to a trial of an experimental antiviral compound 2'-fluoro,5-iodo-aracytosine (FIAC). Rectal bleeding developed; colonoscopy revealed vesicles and ulcers, but biopsies were nondiagnostic and cultures were negative for HSV and other pathogens. Human-leukocyte interferon, broad-spectrum antibiotics, and trimethoprim-sulfamethoxazole (TMP-SMZ) were given for increasing dyspnea with bilateral pulmonary infiltrates. Renal failure and encephalopathy developed, and the patient died in October.

Autopsy revealed herpetic proctitis and colitis, with viral dissemination to the posterior columns of the spinal cord. *Pneumocystis carinii* was present in the lungs. Intranuclear and intracytoplasmic inclusions typical of cytomegalovirus were present in the adrenals, lungs, colonic smooth muscle, and endothelium underlying the ulcerations. Electron microscopy (kindly performed by Dr. Robert A. Erlanson) showed inclusions compatible with either HSV or cytomegalovirus.

Patient 2

A 32-year-old Hispanic homosexual man had perianal vesicular lesions in July 1979; biopsy suggested cytomegalovirus infection. In November, he began to have fever, anorexia, gradual weight loss,

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abdominal pain, and hematochezia. In March 1980, rectal bleeding was severe enough to require transfusion of eight units of blood. Ulceration of the perianal lesion and diffuse lymphadenopathy were noted. The cause of these conditions was not revealed by sigmoidoscopy, gastrointestinal barium studies, examination of stools for bacteria and parasites, abdominal computerized tomography, sonography, or serologic studies; on the basis of inclusions found on rectal biopsy, which suggested lymphogranuloma venereum, tetracycline was given, without effect.

The patient was transferred to the Mount Sinai Hospital in May because of continued fevers and cachexia. He had oral candidiasis, generalized shotty lymphadenopathy, and abdominal tenderness in the left lower quadrant. The perianal ulcer had enlarged to 12 cm. Anemia and leukopenia were noted. Culture and immunofluorescence testing of the ulcer showed only HSV Type 2. Evaluation for lues, gonorrhea, lymphogranuloma venereum, and other pathogens was negative. A biopsy suggested that HSV and cytomegalovirus coexisted in the ulcer. Lymph-node biopsy indicated the absence of germinal centers. Treatment with vidarabine for five days had no effect, nor did a four-day trial of acyclovir (kindly provided by Burroughs-Wellcome). Spiking fevers, rectal bleeding, progressive wasting and lymphopenia did not respond to broad-spectrum antibiotics and transfusions. Terminally, the patient appeared to have a generalized cardiomyopathy; he died on August 8, 1980. Permission for autopsy was denied.

Patient 3

A 28-year-old Colombian homosexual man reported dull pain in the left lower abdominal quadrant and rectal bleeding in May 1980. He was treated surgically for presumed perianal abscess. Postoperative rectal bleeding necessitated transfusions. In June fever (temperature to 40°C) and weight loss began. After additional anal surgery, a perianal ulcer developed and gradually spread. Tetracycline and prednisone were given. However, unrelenting fever, perianal ulceration, and a 12-kg weight loss prompted an extensive but unrevealing evaluation, which included colonoscopy, gastrointestinal contrast studies, marrow biopsy, gallium and liver/spleen scans, abdominal sonography, and standard cultures.

The patient was transferred to the Mount Sinai Hospital in February 1981 because of cachexia and a 20-cm perianal ulcer (Fig. 1). Repeat evaluation for inflammatory bowel disease and lymphoma included exploratory laparotomy and construction of a diverting colostomy. No specific pathologic process was found; node-biopsy specimens were normal. Cultures of the ulcer grew HSV Type 2, which was confirmed by immunofluorescence testing and typical morphologic appearance. Vidarabine was given until central-nervous-system toxicity developed. In April, the patient was transferred to Memorial Hospital for further treatment with interferon and FIAC; however, the ulcer did not regress and cultures remained positive. Bilateral interstitial pneumonitis and encephalopathy led to his death in June.

At autopsy, necrotizing, hemorrhagic bronchopneumonia, hemorrhagic colitis, and cholelithiasis were found. Post-mortem cultures from lung, liver, spleen, lymph nodes, and heart were negative, but herpetic intranuclear inclusions suggestive of cytomegalovirus were seen in the colon, adrenals, stomach, and lungs.

Patient 4

A 22-year-old Hispanic homosexual man had fever (38.5°C) and night sweats in July 1980. Gradual weight loss began. Oral candidiasis was noted in September. By December, an 8-kg weight loss, generalized lymphadenopathy, splenomegaly, anemia, and leukopenia were observed. Chest films showed an infiltrate in the right upper lobe. Evaluation for underlying disease, including gastrointestinal roentgenography, liver biopsy, gallium scanning, abdominal sonography, and colonic and lymph-node biopsies, gave non-specific or normal results. In January 1981, perianal vesicular lesions first appeared; cultures showed HSV Type 2. Spiking fever, lethargy, anorexia, and weight loss continued, and the perianal lesions formed a gradually enlarging ulcer; ulcerative lesions, from which HSV was cultured, also appeared on the nasolabial fold (Fig. 24). By April, the patient had lost 22 kg and had severe oral candidiasis. Treatment with amphotericin led to some reduction in the

candidal infection; klebsiella bacteremia resolved with antibiotics. Treatment with vidarabine for two weeks did not affect the lesions or other symptoms, but in May acyclovir (Burroughs-Wellcome) given for 10 days led to defecescence and gradual healing of the ulcers (Fig. 2B). The marked lymphopenia and lymphoid dysfunction that had characterized the disease (see Results) were not altered. TMP-SMZ was given in low doses to prevent pneumocystosis. In July, the ulcers recurred and HSV was again cultured. During successful retreatment with acyclovir, bluish nodules on the back and penile shaft were noted. On biopsy, a diagnosis of Kaposi's sarcoma was made.

RESULTS

Serologic data are summarized in Table 1. Patient 1 never had detectable complement-fixing antibodies against HSV, Patients 2 and 4 had unchanging titers, and Patient 3 had a fourfold increment in titer. Serologic evidence of active cytomegalovirus infection was present only in Patient 2. Patient 4 had complement-fixing antibody titers of 1:8 and less than 1:8. There was no evidence of acute or recent infection with varicella-zoster or Epstein-Barr viruses, lymphogranuloma venereum, or toxoplasmosis. Antibody to hepatitis B virus was present in two patients, and hepatitis B surface antigenemia developed late in Patient 1. Other serologic studies, particularly in Patient 1, failed to



Figure 1. Perianal Ulceration of Patient 3, before Therapy with Vidarabine.

The appearance of the lesion did not change during or after this treatment.

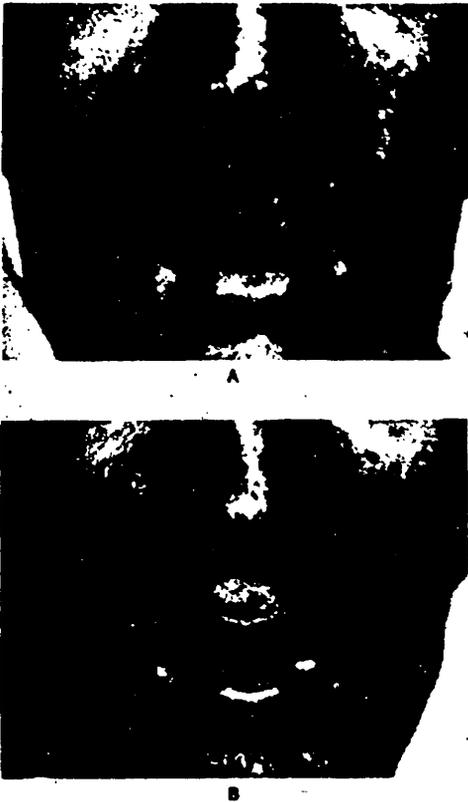


Figure 2. Nasolabial Lesion of Patient 4.

Panel A shows lesion (completely obstructing both nares) before therapy with acyclovir, and Panel B shows healing three days after treatment.

suggest infection with legionella species, cryptococcosis, histoplasmosis, *Entamoeba histolytica*, toxoplasma, respiratory syncytial viruses, or rubella virus. Serologic testing for syphilis was negative in all patients.

Skin anergy to recall antigens was present in all subjects (Table 2). Total lymphocyte counts were regularly depressed. Except for a single determination (Patient 1, July 1980), counts did not exceed 1000 and averaged from 200 to 600. The severe lymphopenia limited the studies that could be done. The proportion of cells with T-cell characteristics ranged from normal to depressed in various determinations. The proportion of sheep rosettes tended to be lower than the proportion of cells demonstrable with use of hybridoma-derived antibodies to T cells (anti-Leu-1). Although this finding suggests that a serum inhibitor of rosette formation was present, none was found in Patients 3 or 4. The proportion of T cells exhibiting a

suppressor/cytotoxic cell phenotype (Leu-2a) was increased in Patient 3 but not in Patients 2 or 4. Lymphocyte responses to plant lectins were moderately diminished in Patient 1, more severely so in Patients 2 and 3, and progressively depressed in Patient 4. Only Patient 4 had a response to phytohemagglutinin that was within the normal range when he was first studied. Responses to pokeweed mitogen were relatively preserved. In Patient 1, despite only moderate depression of mitogen-induced proliferation, transformation responses to all antigens tested, including HSV and cytomegalovirus, were absent.

Measurements of serum immunoglobulin and immunoelectrophoresis indicated polyclonal hyperimmunoglobulinemia, particularly of IgA. Despite this finding, serum antibody titers were generally low. The proportions of B cells were normal in all subjects. Absolute numbers of B cells, as well as of T cells, were depressed.

We considered the results of the assay of natural-killer-cell function in two ways. (1) HSV-specific natural-killer activity in lytic units per million mononuclear cells was determined directly from the lytic system. The calculation, which is based on a range of ratios of killer cells to target cells, considers all cells isolated from blood.¹² According to this standard, natural-killer activity was normal in Patients 1 and 4; it was initially very depressed, in Patient 3, but later gradually became normal. (2) Because of the severe deficiency of mononuclear cells, calculation of the lytic units per milliliter of blood, based on cell yields, was also made (Table 2). By this criterion, all subjects had severely depressed natural-killer function; Patient 2 had no measurable activity.

DISCUSSION

Ulcerative lesions caused by HSV are usually observed only in patients with severe deficits of cellular immunity associated with another underlying disease.¹⁴ That four patients who were believed not to have been previously immunocompromised had such skin lesions (with three dying after an inexorably downhill course) suggests that some factor common to all the patients was operative. The fact that all were homosexual men was striking. Reports of Kaposi's sarcoma and opportunistic infections similar to those that we observed (e.g., *P. carinii*, *Cryptococcus neoformans*, and cytomegalovirus) suggest that our findings are part of a nationwide epidemic of immunodeficiency among male homosexuals.^{15,16}

The most prominent and so-far unexplained immunologic finding in these four men was profound lymphopenia. Many of the immunologic deficits that we measured could be attributed to this state of apparent lymphocyte depletion. Skin anergy was present in all subjects. When the responses to in vitro stimulation with plant lectins and antigens could be determined, they showed moderate to marked depressions in lymphocyte proliferative ability. Difficulty in interpretation of these data arises because of the paucity of available lymphoid cells and their dilution

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Table 1. Evidence of Ulcerative Herpes Simplex and Other Infections among Four Homosexual Men.

Evidence	Infection*							
	HSV	CMV	H ₁ NAg	H ₁ Ab	Coccidia stool	Pneumocystis carinii	Adenovirus	Disseminated Mycobacter.
	no. of patients positive/no. tested							
Positive culture	4/4	0/4	†	†	2/4	†	1/4	†
Morphologic (active infection)	4/4	3/4	†	†	2/4	1/4	1/4	0/4
Serologic								
Prior exposure	3/4	2/4	0/4	2/4	†	†	0/1	1/4
Active infection (titer rise)	1/4	1/4 ‡	1/4	0/4	†	†	0/1	0/4

*HSV denotes herpes simplex virus, CMV cytomegalovirus, H₁NAg hepatitis B surface antigen, and H₁Ab antibody to H₁NAg.

†Study was either inappropriate or not performed.

‡Another patient (Patient G) had a cytomegalovirus titer below 1:8 on complement fixation when first studied; on a repeat study two weeks later the titer was 1:8.

by monocytes in the mononuclear-cell isolates. Relative monocytosis in mononuclear-cell preparations is known to lead to poor *in vitro* proliferative responses.¹⁷ Among the lymphoid cells present, there was specific depression of cells forming sheep-erythrocyte rosettes in two patients and a relative rise in cells bearing the Leu-2a phenotype in one patient. The relative rise implies an increase in the ratio of suppressor to helper cells among the lymphoid-cell populations — a finding that we (unpublished data) and others¹⁸ have observed in cases of infectious mononucleosis. Attempts to rectify the lymphoid-cell responses of one patient *in vitro* by means of thymic humoral factors¹⁹ were unsuccessful. When these findings were taken together, a severe defect in cellular

immunity, which had been suspected on clinical grounds, was confirmed. The defect can be characterized as a progressive state of lymphocyte depletion and consequent dysfunction, in which cellular immunity is principally affected.

The specific host defense against HSV is poorly understood. Although patients with depressed lymphocyte counts or T-lymphocyte-macrophage dysfunction might be expected to have severe illness secondary to HSV, the vast majority of such patients do not. Consequently, it is suspected that other factors play an important part in HSV-specific host defense. The group of patients most frequently reported to be susceptible to ulcerative HSV are those who have had immunosuppression for organ transplantation. Re-

Table 2. Immunologic Findings in Patients and Controls.

Study	Patients*				Controls mean ± S.D.
	PATIENTS				
	1	2	3	4	
Delayed-type skin response	Absent	Absent	Absent	Absent	Present
Mean lymphocyte count	657	435	316	360	1000-6000
T cells (per cent)					
Sheep rosettes	0	99, 79	28	69, 55	80±7
Leu-1	ND	89	53	65	78±5
Leu-2a	ND	20	62	29	32±9
Mitogen responses (not open †)					
Phytohemagglutinin	11,852	1,309	1,313	613	23,100
Concanavalin A	1,683	1,767	674	386	1,372
Pokeweed mitogen	5,635	1,148	3,867	766	4,136
Antigen responses <i>in vitro</i>					
Mixed leukocyte reaction	Absent	QNS	QNS	QNS	QNS
Mixed leukocyte reaction (not open †)	1,505	QNS	QNS	QNS	Positive
Natural killing of HSV-infected target cells ‡	0.2, 1.4	0	0.2-31.7	15.7	111 (52-239)
Serum immunoglobulins (mg/dl)					
IgG	864-1394	2360	1660	1370-1710	900-1900
IgA	322-375	445	435	420-1431	40-300
IgM	133-300	90	230	55-275	40-200
Isohemagglutinin					
Reciprocal					
Titers (anti-A/B)	-/8	8/-	32/8	4/0	>4
B cells (per cent IgM-positive)	0	QNS	8	8	6±2
Immune complexes	0	0.20	0.20	0.04	0.04

*ND denotes "not determined," and QNS "quantity not sufficient for determination."

†Not open = (open stimulated) - (open unstimulated control), where open = counts (per minute) of tritiated thymidine incorporated after three days' culture (five days for mixed leukocyte reaction).

‡Killing = (spontaneously toward infected target) - (spontaneously toward uninfected target), expressed as lytic units per milliliter of blood. Normal range = ±2 S.D. on long-term data.²¹

cently, cells that confer "natural" immunity and do not require prior exposure to their specific target cells have been described. Certain natural-killer cells are thought to be involved in the host defense against HSV in mice and in human beings.^{11,20} Overwhelming disseminated HSV infection in neonates and in some adults is associated with depressed natural-killer activity of this sort.¹² We measured this type of natural-killer cell in our patients because of their unusual HSV lesions. On a "per-cell" basis, the natural-killer cells in two of the four patients were abnormally hyporesponsive. Moreover, in view of the paucity of mononuclear cells present per unit of blood, the calculated herpes-directed natural-killer activity was severely depressed in all patients. Thus, a common absence of HSV-directed natural-killer activity may be involved in the development of the ulcerative skin lesions.

The cause of the immunodeficiency disorder that we observed is undoubtedly complex. Viral infection, especially in unusually heavy inoculum transmitted by enteric routes, may be an important initiating factor.

Infection by a great many viruses such as measles or rubella can result in depressed delayed-type hypersensitivity.²¹ Primary cytomegalovirus infection has been associated with a particularly prolonged cellular immunodeficiency state.^{22,23} Exposure to cytomegalovirus is known to be particularly heavy within the homosexual community; a 94 per cent prevalence has been defined by anticomplement immunofluorescence.²⁴ A series of four previously healthy homosexual men with active cytomegalovirus infections complicated by *P. carinii* pneumonia has been reported.¹⁵ In our series, disseminated cytomegalovirus was found at autopsy in Patients 1 and 3, and on biopsy and by seroconversion in Patient 2. Cytomegalovirus must be considered a candidate initiator of the immune defects observed.

Serum immunoglobulins were increased. The consistent elevation of serum IgA levels could reflect the importance of gut-associated lymphoid tissue as a primary site of immunization in this disorder. Battisto and Chase described a state of antigen-specific hyporesponsiveness occurring after oral immunization²⁵ that has recently been reported to result from the seeding of suppressor cells to non-gut-associated lymphoid tissue.²⁶ The immune deficit that we observed could likewise result, in part from the route of exposure to viral pathogens.

Since these cases are certainly rare, even among homosexuals, additional factors must be involved in susceptibility. A group may be specifically hyporesponsive to HSV, perhaps because of their genetic background — e.g., HLA-D-linked immune-response genes. Heavy exposure to HSV could lead to chronic infection, and secondary immunodeficiency could then result. At present, no group has been defined that is genetically susceptible to HSV.

Still another possibility is that among men who are homosexual, some have a latent, broad-based cellular

immunodeficiency that becomes clinically manifest only because of heavy exposure to certain pathogens in particular combinations. For example, a homosexual male nurse whom we studied recovered from pneumocystis pneumonia but eventually died at another hospital of recurrent pneumocystis and cytomegalovirus pneumonia. He had markedly depressed cellular immunity *in vitro* and increased proportions of Leu-2a-positive cells among his T lymphocytes. Extensive history taking by one of us (B.R.A.) indicated susceptibility to a variety of infectious agents over the previous 20 years, suggesting a low-grade cell-mediated immunodeficiency.

Severe malnutrition probably accentuated the immune deficits that we observed.²⁷ By the time these patients came under study, all were anorectic and cachectic and had been chronically ill for many months. Because of the specific immunosuppressive effects of zinc deficiency,²⁸ plasma zinc levels were determined; they were found to be normal in all four patients, but three were nevertheless given zinc salts empirically. In addition, efforts were made to improve overall protein-calorie intake through oral and parenteral nutritional supplements. Neither of these approaches seemed to alter the patients' clinical courses appreciably.

In view of the relative preservation of immunologic functions early in the course of the illness in Patient 4, immune deficits like those we observed appeared to be progressive with time. It seems possible that earlier recognition and prospective study of such patients will reveal an anomaly in host defense that could illuminate the pathogenesis of this disorder.

There was no obvious contact between the four men. To ascertain whether there was any epidemiologic relation among the viral strains isolated, we submitted samples of the viruses for restriction-enzyme mapping²⁹ (by Dr. Bernard Roizman, University of Chicago). The isolates, all Type 2, were found to be unrelated.

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Note added in proof: We recently studied a fifth patient, a 45-year-old homosexual man with a nine-month history of hepatitis, gradual wasting, eventual intergluteal herpes simplex ulcers, and probable herpes encephalitis. During the period of study, lymphoid function was initially normal, but it later deteriorated. Lymphopenia developed only late in the course. Natural-killer-cell activity studied while the patient had normal lymphocyte counts was very depressed.

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Dr. SIEGAL. Our laboratories, which in effect are extramural arms of the NIH, had begun to respond. And as the cases grew from two and then five, and as we heard from infectious disease specialists of other cases in New York, we turned the efforts of our laboratories from their originally intended projects to the problem of this peculiar new disease.

By now, just among our group alone, unfortunately, we have already studied more than 150 cases. Unfortunately, our studies have revealed a stereotyped pattern of progressive immunologic failure, with an unrelenting course that no one, as Dr. Conant has pointed out, has yet been able to reverse.

Dr. Michael Gottlieb at UCLA, another federally funded young clinical investigator, deserves the credit for notifying CDC about the outbreak. He and his colleagues in Los Angeles were going through much the same process there as we were experiencing in New York.

In the spring of 1981, we knew through the grapevine even before the June 1981 issue of *Morbidity and Mortality Weekly Report* what we had been clinically struggling with and puzzling over was a nationwide epidemic.

By August that year CDC had officially reported 111 cases of what we now call AIDS.

As you have heard or will hear at these sessions, CDC from the outbreak committed itself vigorously to the problem, placing at the head of its task force on AIDS one of the most brilliant and committed public health investigators I have ever had the privilege of knowing, Dr. James Curran.

I believe that the efforts of this team have been excellent and appropriate. But I understand that in order to carry out his mission in AIDS, CDC had to divert its already tight funds from other important work. Symptomatic of the funding programs was the end of free distribution of Morbidity and Mortality Weekly Report, which many of us viewed as a setback for the dissemination of information on epidemic diseases and a disservice to public health in general.

In March 1982, Dr. David Sencer, commissioner of health for the city of New York, convened the first of many monthly meetings for those involved in AIDS. Although some of us had research funds that were geared to indepth study of a few patients, they clearly were insufficient to deal with the citywide public health emergency. There was no existing mechanism to quickly obtain support for a major effort to work out the epidemiology, etiology, immunology, and therapy of AIDS.

On our behalf, Dr. Sencer requested Federal help in a letter of May 17, 1982, to Dr. Wyngaarden, Director of NIH, that I know to be available to this committee.

Three months elapsed before the first RFA on AIDS was put out under which we first received funding on May 1, 1983, almost a year after Dr. Sencer's letter, and almost 2 years after the outbreak had been officially reported by the CDC.

I am told that this RFA had a shorter turnaround time than most as a result of efforts to facilitate peer review. While I wholeheartedly agree that careful critical peer review is essential, I believe we must quickly work out how we can expedite it still further for the next public health emergency, especially if H.R. 2713 dealing with these crises should become funded.

A delay of 1 to 2 years between the perception of a major problem and its initial earmarked funding is unconscionably long.

Despite a severe lack of allocated funds, things were not standing still in AIDS research between 1982 and early 1983. Many local investigators did as we did, diverting their attention in research support from other problems to this new one. The NIH became involved early, admitting cases for study to the Clinical Center, holding meetings in Bethesda, and funding of these elsewhere.

The FDA efforts too in basic investigation and in providing guidance for the improved safety of blood products should not be forgotten.

All in all, I believe the Federal response to AIDS to have been excellent at the level of the CDC, although underfunded, but very slow and insufficient in delivering funds for specific basic research. The early gains in the disease such as its initial identification and characterization can be attributed largely to the long term public investment in academic tertiary care centers.

This in turn depended on the past commitment to basic research and to the training of young people for biomedical education which flowered because of the foresight of those in the Congress who provided the means.

Many of us thought we had pretty much seen the end of infectious diseases as a major scourge of mankind. The tremendous success of antibiotics and now even of some antiviral agents has perhaps lulled us into an inappropriate sense of security. Consequent-

ly, we have lowered our research priorities in communicable diseases including those that are sexually transmitted.

The National Institutes of Allergy and Infectious Diseases now lags behind the other institutes at NIH in its ability to fund approved research applications even in areas directly germane to AIDS. In view of the likelihood that public health emergencies will involve infectious diseases, we cannot afford to neglect that institute.

Thank you for the opportunity to share my perspective with you, Mr. Chairman and Members of Congress.

I will be happy to answer any of your questions.

Mr. WEISS. Thank you very much.

**STATEMENT OF DR. MATHILDE KRIM, ASSOCIATE MEMBER,
HEAD OF INTERFERON LABORATORY, SLOAN-KETTERING IN-
STITUTE FOR CANCER RESEARCH, NEW YORK, N.Y.**

Dr. KRIM. Mr. Chairman, my name is Mathilde Krim. I hold a Ph. D. degree and the position of associate member at the Sloan-Kettering Institute for Cancer Research in New York where I head the interferon laboratory. I have expertise in interferon research, virology, and, generally, in biology. Certain studies done in my laboratory complement those of the clinical investigators in our cancer center who explore the use of interferon preparations in the treatment of human disease, including Kaposi's sarcoma in patients with the acquired immune deficiency syndrome.

I am also the chairperson of the board of trustees of the recently-founded AIDS Medical Foundation. This Foundation was created by a group of collaborating investigators from several research institutions who are actively engaged in laboratory and clinical research on AIDS. The Foundation's purpose is to conduct and fund research on AIDS.

Its collaborative network was originally brought together by Dr. Joseph Sonnabend, of New York City.

I am reading only parts of my testimony.

Mr. WEISS. Your entire statement will be entered into the record.

Dr. KRIM. Yes, thank you.

There are two things I would like to point out with regard to the Foundation, because they were mentioned earlier here.

One is that we share with some of this morning's witnesses a great concern for the ethical problems raised by research with human subjects, particularly those afflicted with AIDS, since a large proportion of them are members of a minority which is still openly discriminated against in this country. Therefore, we have, as a Foundation, an interest in undertaking or supporting studies on the feasibility of devising protections which would not impede the provision of necessary data to legitimate research efforts but will do so only within the context of maximum protection for the identity and privacy of research subjects.

We are also concerned by the ignorance about AIDS existing in the public, and very often among caregivers themselves, which results in fear and, as a result of fears and uncertainty, there is prejudice and in certain cases even hate. This sad situation has given rise, as we heard this morning, to incidents of discrimination

against a minority group. And if identity and privacy of patients is not protected carefully, it could result also in incidents of discrimination against homosexuals.

So to make up for this great need for accurate information our Foundation will also have a program on publication of medical and scientific advances translated into simple language for the public at large and nursing personnel in particular.

Now, the substance of my testimony addresses two questions:

Why should we as a society be concerned about AIDS and what should we ask the Government to do that it is not doing yet.

The reasons for concern derive I believe from two considerations. One is humanitarian. The other one is a very pragmatic one, which breaks down into public health considerations and societal considerations.

As for humanitarian considerations, they are based on the fact that AIDS has killed, after crippling and maiming for months on end, hundreds of mostly young, previously healthy, often highly gifted, productive people. It is paralyzing with fear hundreds of thousands, if not millions, more. The anguish it is causing is immeasurable. It can hardly be placated by words of reassurance in a situation of continuing ignorance of the cause or causes of the disease, and of its precise mode of transmission.

Epidemiological data suggests transmission from person-to-person through prolonged, intimate contact, which would seem to indicate that spread of the disease may not be very rapid. But in fact it is increasing, and the rate of increase has been close to doubling every 6 months. There are also lingering doubts that perhaps there can be transmission through a single blood transfusion, for example.

Groups at risk are acutely aware of these uncertainties, and suffer great anguish from them.

An aspect of the situation that goes largely unrecognized, although it contributes to its nightmarish quality, is that of the uncertainty of diagnosis. AIDS is an insidious disease with no clear onset. No single test has as yet become available that can unequivocally diagnose AIDS before one of several life-threatening and usually uncontrollable infections makes diagnosis certain but, by then, futile.

At that point in the disease it is too late for preventative measures and, when the disease is fully established, also much too often too late for useful medical intervention. No treatment has yet proven to be life-saving.

In about 40 percent of the patients a multifocal, uncontrolled proliferation of endothelial cells occurs under the skin and internal mucous membranes, which has been called Kaposi's sarcoma. This added complication is probably not a true malignancy, but it is highly visible, progressive and irreversible if treated unsuccessfully. AIDS patients also have a high incidence of true malignancies such as lymphomas, squamous cell carcinomas, and probably other cancers.

Because the occurrence of an opportunistic infection and/or Kaposi's sarcoma or cancer, on a background of severe cell-mediated immune deficiency, constitutes the only unquestionable diagnosis of AIDS, the disease has been defined on the basis of such a combi-

nation by the Centers for Disease Control. How and when the underlying immune deficiency becomes severe enough to allow for "CDC-AIDS" to develop is still anyone's guess.

Many people from the general healthy population may present at times with transient but measurably deficient immune functions without suffering obvious ill effects. However, because of the lack of clear, early diagnostic criteria for AIDS, any immune function test that produces abnormal results in a male homosexual now spells terror.

Physicians are at a loss to provide specific advice because they cannot tell if and when a deadly infection, Kaposi's sarcoma, or cancer are likely to strike, nor can they tell concerned individuals how to prevent this from happening. Immunodeficient gay men therefore live in a limbo, left to their own devices and private despair.

There is today no effective, accepted treatment for CDC-AIDS, nor for Kaposi's sarcoma. A very high mortality rate is an undisputed fact: a 40-percent death rate 1 year after diagnosis and an 80-percent death rate after 2 years.

I suggest that humanitarian concern is in order when a disease is so cruel and so severe that it kills so many and terrorizes so many more. Mere compassion should long ago have been sufficient reason for action.

As for general public health considerations, the distinct possibility still exists that the new infectious agents might be causally involved in AIDS. Such an agent might be transmitted through blood and would undermine immune defense mechanisms important in the protection against microorganisms causing opportunistic infections, or against malignancies. Such an agent would not cause overt disease; rather, it would act slowly over a period of many months during which time the person infected by it might unknowingly be contagious. AIDS, with its dramatic late manifestations, would then only represent the end result of an insidious, much earlier infection with the hypothetical agent.

Sociocultural factors, such as degree of sexual promiscuity, would then represent only a contributing factor which merely increases likelihood of viral transmission. Alternatively, environmental factors favoring multiple infections with common microorganisms could predispose individuals to infection by a new, immunosuppressive viral agent.

If one of these scenarios proves correct, there is truly no saying where the epidemic will stop. Some 24 infants have contracted AIDS or an AIDS-like disease and 18 have already died. More than 100 women have contracted the disease, and most are dead.

Are we witnessing the slow spreading of the disease beyond the neat high risk groups identified in early epidemiological surveys? If this may be so, can we indulge in the luxury of waiting to find out if this is so, when we know that months and perhaps years may have to elapse before the clearcut CDC-AIDS develops?

Wouldn't the situation be sufficiently alarming to everyone to justify throwing the weight of the spectacular advances made in recent years in virology, molecular biology and immunology at the crucial question of whether or not a new virus, perhaps one related to the recently discovered human T-cell leukemia virus, is the real

culprit for AIDS? If such a virus were to be identified as the true cause of AIDS, vaccines could be produced and rational preventative measures could be devised.

I am concerned also about the societal consequences of AIDS. I think the preservation of hard-won civil liberties also calls for a rational, rapid and effective solution to the problems of AIDS.

Words of reassurance sound hollow to many in the face of medical ignorance of AIDS's causes, mode of spread, and effective treatment. Uncertainty breeds fear. AIDS may not only be destroying lives but also the very fabric of a humane and progressive society, on which this country prides itself.

Couples have been torn apart, thousands of young men have been abandoned by family and friends, a minority group is victimized by incidents of gross prejudice leveled indiscriminately at its members.

Our blood banks are in jeopardy. The whole blood banking system is in jeopardy in this country. Already scenarios for the quarantine of groups perceived to be "contagious" are emerging in thoughts, talk, and even writing. The atmosphere of doom and total helplessness surrounding the problem of AIDS threatens to push us back into a medieval society, complete with the equivalent of colonies of pariahs and lepers and, since homosexuality is not going to disappear from the face of this Earth, maybe we will also have colonies of "heretics" in hiding and an inquisition to find them out.

What should we ask our Government to do in this situation?

I believe that if there ever was a problem that cried for money to be thrown at it, AIDS is such a problem. Our biomedical research community is now suffering under recently imposed funding cuts which impede its healthy growth rate and, in many institutions, preclude its functioning at earlier levels of activity and excellence.

On the other hand, extraordinary scientific advances have been made in recent years in the very areas pertinent to the solution of the problem of AIDS. A much better understanding has been gained of basic mechanisms of infection, immunity, cancer development and their biological control. This is putting into our hands powerful new tools for investigations of the etiology, diagnosis and treatment of infections and cancer.

AIDS, a condition where all these pathologies are interrelated, can also be seen as an extraordinarily challenging "experiment of nature." If offered support for their studies, thousands of scientists could be enrolled virtually overnight to investigate every aspect of this intriguing condition.

As for the areas of research to be supported, I believe that scientists will want to work in the following areas: They would like to conduct thorough extensive epidemiological studies going much beyond the necessarily early superficial studies carried out so far by the CDC, which are limited to this country. The epidemiology of AIDS should be studied in Africa, where the disease has been reported and in the Caribbean region, in Latin America, and in Europe.

Epidemiological studies could precisely identify risk factors and thus make rational prevention possible.

Scientists would like to develop reliable diagnostic criteria for the disease. Only systematic prospective clinical studies involving many patients of both sexes, with different lifestyles and life histories, can result in a definition of clear predictive diagnostic criteria. Such studies are of utmost importance and urgency. They are, however, logistically and scientifically complex and therefore also costly. They are beyond the capability of any single clinic and laboratory, because they require expertise in multiple clinical and scientific disciplines. They would, however, allow rapid progress in arriving at an understanding of how AIDS develops, and they could also lead to accurate diagnosis, prognosis, and perhaps prevention.

In this regard, I believe that the Government, in addition to funding, could help in planning and in offering resource support. This would be needed in the collection and storing of clinical specimens, their distribution to a variety of laboratories representing broad biological and immunological expertise, and the storage, retrieval and analysis of a large number of laboratory epidemiological and clinical data.

I believe that the areas of virology and immunology of AIDS must be the object of a host of studies that are needed as part of an intensive laboratory search for a possible viral etiological agent for which there is a suspicion but, for the moment no proof.

Few clues exist as to which type of virus, if any, may be so involved. Until we know better, many viruses must each be suspected and investigated. Out of this research will also come the answer, for blood banks of how to identify infectious blood donations.

A systematic study of the immunological abnormalities of AIDS patients must also be carried out: how these abnormalities develop in the course of time in various high at-risk groups, how they correlate with manifestations of viral and other infections, how they correlate with a patient's genetic constitution, history, and lifestyle.

Again, these studies must involve many specialized laboratories, in order to cover the whole spectrum of specific and nonspecific immunize functions that can be studied.

The group of patients and controls studied in these biological and immunological respects, must be those followed clinically in the large prospective studies mentioned earlier. Such laboratory studies will result in information on the etiology of AIDS and its diagnosis, treatment and prevention.

And lastly, we must develop methods of treatment.

CDC-AIDS has so far been incurable. However, there are glimmers of hope. Some have come from clinical trials with interferon alpha. Over half of the interferon-treated Kaposi's sarcoma patients have not only seen their lesions regress or disappear completely, but they have remained during treatment and for several months thereafter, up to some 2 years by now, free of deadly opportunistic infections. They have even exhibited some favorable changes in their immune reactivity. Immunological improvement has not been seen following chemotherapy, although the latter has also been successful, sometimes, in making the lesions of Kaposi's sarcoma regress.

Limited clinical trials of interferon alpha in Kaposi's sarcoma have so far been sponsored only by industrial companies that produce in-

terferon from recombinant bacteria and want to develop it as a commercial product, and probably also, on a few patients, by the National Cancer Institute. Trials have been limited to a handful of patients, their numbers having been determined principally by the companies' need for information to be provided to the Food and Drug Administration.

In New York, to my knowledge, only one hospital, at the Memorial Sloan-Kettering Cancer Center, where I work, is involved in interferon trials with alpha interferon. The treatment remains unavailable to most AIDS patients.

I believe that the Food and Drug Administration should review the present evidence which comes from reputed clinical research centers in New York, in Bethesda and in California, and see whether it is not sufficient to warrant the immediate provision by the NIH of interferon alpha to interested clinicians for the treatment of patients with Kaposi's sarcoma, foregoing requirements for double blind trials in the development of this form of therapy for this particular disease.

Personally, I believe that, in the absence of any other effective and safe treatment, the present evidence of interferon's effectiveness should be considered sufficient to make this form of therapy immediately available to all those who may benefit from it. This should be done as early as possible following the appearance of Kaposi's sarcoma lesions because this is a situation clearly favoring a response.

I also believe that, at this point, not making interferon available now may literally amount to sentencing a substantial number of people to sure early death, because we know that Kaposi's sarcoma is a progressive, lethal disease and, it is clear that interferon can at least prolong life.

Furthermore, interferon is not the only promising biological. Interleukin 2, another product of human lymphoid cells, may also have immune-enhancing properties and it could potentiate interferon's effects in vivo as it does in vitro. Clinical trials of interleukin 2 alone, and in combination with interferon therapy, appear warranted immediately. The exploration of other interferons, lymphokines, and differentiation factors, alone and in combination, first in vitro and then in vivo, should be encouraged through grants from the Program of Biological Response Modifiers of the National Cancer Institute.

These are but two areas in which immediate progress in therapy might be made. There are other approaches to therapy, both for the underlying immunological disease and its infectious and malignant complications. There is the use of plasmapheresis, there are methods to remove immunoglobulin complexes, there are methods to remove suppressor cells from the blood, there are certain drugs that are not immunosuppressive that could be tried either alone or in combination with interferon.

Logistical and financial aspects to be considered in recommending Government intervention:

First of all, there is no lack of ideas in the scientific community on what to do about AIDS. I believe that the research needed can therefore be done almost exclusively through investigator-origina-

ed proposals in the form of individual research grants and/or collaborative program projects.

Central Government planning should be limited to helping with organizational and logistical problems in which the Government could be very useful in facilitating collaborations between experts in different disciplines.

Our National Institutes of Health could, if directed to do so, set up mechanisms for fair and rapid allocation of funds and so avoid long delays—such as the usual 18 months—before funding. One or more ad hoc review committees could be appointed for the very purpose of reviewing and expediting the funding of projects in AIDS research. The imagination, the talent and the ingenuity are there in the biomedical research community fully capable of addressing the many scientific and medical challenges presented by AIDS.

What is most needed from the Government is the money. And I don't mean money from the CDC or the NIH, that is, taken from Peter to pay Paul, which would cause internal disruptions, delays, and justifiable resentments.

On top of already severe cuts suffered by the CDC in 1983, it is unrealistic and almost outrageous to expect this agency to do more now, in 1984, with a budget for its AIDS program that will be exactly \$300,000 less than it was in 1983. Much the same can be said for the NIH.

What is needed in the face of a national emergency is new money such as this country has always found whenever it has set itself to do a real job.

How much money is needed? One way of calculating it is to take into account that the treatment of each CDC-AIDS patient is now well over \$100,000 per year if he is treated properly. Since much of the treatment that can be offered is experimental, much of it is already done at taxpayers' expense, through research grants, as we heard earlier from Dr. Siegal.

Even if only half the present cost of treatment is borne by taxpayers, the bill amounts already to \$100 million per year. And this covers only some 2,000 patients with CDC-AIDS with the frustrating result of seeing them die anyway.

The additional figures I think we must think of for a comprehensive program of research on AIDS must be of the same magnitude as the expenses we incur already. That is about \$100 million. If roughly doubling the present financial burden imposed by the disease may insure a resolution of the problem rather than permitting it to grow and fester as it does now, it seems clear that such an investment must be made.

Finally, for those who may still feel that not enough people have died and that AIDS has not caused sufficient tragedy and anguish, let me end by stating that an appropriate investment in AIDS research will certainly benefit all of us in the long run, and in more than one way.

Understanding AIDS will undoubtedly greatly improve our ability to understand and therefore learn to control the biological events leading to acquired immune deficiency, susceptibility to infections and cancer in general. This will benefit infinitely larger

numbers of people than only those suffering from, or at risk of, AIDS itself.

There can, therefore, only be winners in what I propose here.

Gentlemen of the committee, there is therefore no reason and no excuse not to try and your decision should be very easy.

Mr. WEISS. Thank you very much, Dr. Krim.

[The prepared statement of Dr. Krim follows:]

PREPARED TESTIMONY OF MATHILDE KRIM, PH. D., ASSOCIATE MEMBER, HEAD, INTERFERON LABORATORY, SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, AUGUST 1, 1983

My name is Mathilde Krim. I hold a Ph.D. degree and the position of Associate Member at the Sloan-Kettering Institute for Cancer Research in New York where I head its Interferon Laboratory. I have expertise in interferon research, virology and, generally, in biology. Certain studies done in my laboratory complement those of the clinical investigators in our Cancer Center who explore the use of interferon preparations in the treatment of human diseases, including Kaposi's sarcoma in patients with the acquired immune deficiency syndrome (AIDS).

I am also the Chairperson of the Board of Trustees of the recently founded AIDS Medical Foundation. This Foundation was created by a group of collaborating investigators from several research institutions who are actively engaged in laboratory and clinical research on AIDS. We are studying, in a coordinated fashion, the same large group of patients and control subjects, and we exchange information on our respective results.

This collaborative network was formed at the initiative of Dr. Joseph A. Sonnabend, himself a distinguished virologist and interferon expert who has spent much of his professional life in academia. Dr. Sonnabend presently practices medicine in downtown New York City. He was among the first physicians to observe cases of severe immunodeficiency and opportunistic infections among men living in the New York area. He became alarmed about it, since it appeared to be a new disease in this patient population, and he initiated

research into possible causes. Since no known animal model existed, research on the condition (later known as AIDS) had to be done on the patients themselves and/or on specimens of cells and body fluids obtained from them. Dr. Sonnabend enlisted the volunteer cooperation of his patients, developed an informed consent form for their use, and at his own expense and through his own efforts, collected and distributed hundreds of specimens and relevant clinical information to several laboratories. His own earlier experience in academic research made him eminently capable of contributing to the planning of the research and the interpretation of the results. A number of valuable publications by him and his collaborators resulted from these efforts.

In late 1982, those investigators collaborating with Dr. Sonnabend all felt that they were making significant findings, but all were facing great financial difficulties after several months of work without support. One of them--Dr. Michael Lange of St. Luke's Roosevelt Medical Center--obtained a grant in the amount of \$22,400, which permitted him to continue his work. This grant did not come from the Federal Government but from the New York City's Gay Men's Health Crisis group. Unfortunately, the amount soon proved inadequate for the support of his increasing AIDS work load. By the fall of '82, Dr. Lange was studying over 150 men with different stages of the disease. At great expense, he was following them prospectively through a

battery of specialized tests administered to each patient every four months.

By the spring of 1983, it was becoming clear that despite much talk of possible supplemental appropriations by Congress, no funding for AIDS research would be available for many months. Since most of us had already more than exhausted all resources available, including personal resources, we decided to form a public foundation in order to be able to continue our work through support solicited from private individuals, foundations and corporations. An announcement of the formation of the AIDS Medical Foundation was made on June 23rd, 1983. It was well received by the press. Comments of approval and encouragement were also received from many individuals. These were people from all walks of life. Some were patients or relatives of patients; others were motivated only by feelings of compassion and decency. This public response has been heartwarming. It augurs well for the Foundation's ability to accomplish its primary goal, i.e. to keep alive the work of those investigators initially involved in its creation and eventually to accept for review and funding other applications for AIDS-related projects. Without early support from the Foundation, many of these projects now face certain termination.

Foundation support will be wide open to any scientifically valid approach to the study of the new syndrome.

Selection of projects will be made--as for all Foundation-supported research--on the basis of scientific merit alone as determined by an impartial scientific peer review committee. The Foundation has an interest in studies on individuals from all high risk groups, including infants.

Although the Foundation will concentrate on biomedical studies, we are very mindful of the complex ethical problems that arise when research must be carried out on human subjects, particularly such as may be, or become, subject to public health reporting. Patient volunteers and the Foundation itself have serious and clearly legitimate concerns about possible breaches of privacy which might result in patient vulnerability to discriminatory practices.

Discrimination against homosexuals can be, and indeed still is, practiced with impunity in many States of the Union and, in particular, in New York City. Therefore, the Foundation is also interested in undertaking or supporting studies on the feasibility of devising protections which, while not impeding the provision of necessary data to legitimate research efforts, will do so only within the context of maximal protection for the identity and privacy of research subjects.

In addition, the Foundation is concerned about the consequences of irrational acts resulting from the fears bred by ignorance. Therefore, it has assigned staff to the task of translating evolving biological and medical knowledge of

the disease into language accessible to large audiences, specifically, patients, groups at risk and health personnel.

The above describes my involvement in AIDS research and with the AIDS Medical Foundation, and hence, my presence here.

I would now like to address two topics which will form the substance of my testimony.

I. WHY SHOULD WE, AS A SOCIETY, BE CONCERNED ABOUT AIDS?

Reasons for concern derive, I believe, both from humanitarian and pragmatic, health and societal, considerations.

a. Humanitarian Considerations.

AIDS has killed, after crippling and maiming for months on end, hundreds of mostly young, previously healthy, often highly gifted, productive people. It is paralyzing with fear hundreds of thousands, if not millions, more. The anguish it is causing is immeasurable. It can hardly be placated by words of reassurance in a situation of continuing ignorance of the cause or causes of the disease, and of its precise mode of transmission. Epidemiological data suggests transmission from person to person through prolonged, intimate contact. It does not preclude the possibility of low level contagion through casual contact. In view

of the likely long incubation period and a few cases which have apparently resulted from blood transfusions or alleged casual contact, no one can say for sure, at this point in the history of this epidemic, how many may be just "at risk" and how many are already doomed. Groups "at risk" are acutely aware of these uncertainties and suffer great anguish.

An aspect of the situation that goes largely unrecognized, although it contributes to its nightmarish quality, is that of the uncertainty of diagnosis. AIDS is an insidious disease with no clear onset. No single test has as yet become available that can unequivocally diagnose AIDS before one of several life-threatening and usually uncontrollable infections makes diagnosis certain but, by then, futile. At that point in the disease, it is too late for preventative measures and, when the disease is fully established, also much too often too late for useful medical intervention. No treatment has yet proven to be life-saving. In about 40 per cent of the patients, a multifocal, uncontrolled proliferation of endothelial cells occurs under the skin and internal mucous membranes, which has been called Kaposi's sarcoma. This added complication is probably not a true malignancy, but it is highly visible, progressive and irreversible if treated unsuccessfully. AIDS patients also have a high incidence of true malignancies such as lymphomas, squamous cell carcinomas and probably other cancers.

Because the occurrence of an opportunistic infection and/or Kaposi's sarcoma or cancer, on a background of severe cell-mediated immune deficiency, constitutes the only unquestionable diagnosis of AIDS, the disease has been defined on the basis of such a combination by the Centers for Disease Control (CDC). How and when the underlying immune deficiency becomes severe enough to allow for "CDC AIDS" to develop is still anyone's guess. Many people from the general "healthy" population may present at times with transient but measurably deficient immune functions without suffering obvious ill effects. However, because of the lack of clear, early diagnostic criteria for AIDS, any immune function test that produces abnormal results in a male homosexual now spells terror. Physicians are at a loss to provide specific advice because they cannot tell if and when a deadly infection, Kaposi's sarcoma, or cancer are likely to strike; nor can they tell concerned individuals how to prevent this from happening. Immunodeficient gay men therefore live in a limbo, left to their own devices and private despair.

There is, today, no effective, accepted treatment for "CDC AIDS," nor for Kaposi's sarcoma. A very high mortality rate is an undisputed fact: a 40 per cent death rate 1 year after diagnosis and an 80 per cent death rate after 2 years.

I suggest that humanitarian concern is in order when a disease is so cruel and so severe that it kills so many and

terrorizes so many more. Mere compassion should long ago have been sufficient reason for action.

b. General Public Health Considerations

If compassion is not sufficient justification for an immediate all-out national research effort, there are for all of us other, purely pragmatic and even selfish reasons for such an effort.

One such reason is simply that the distinct possibility still exists that a new infectious agent might be causally involved in AIDS. Such an agent might be transmitted through blood and would undermine immune defense mechanisms important in the protection against microorganisms causing opportunistic infections and malignancies. Such an agent would not cause overt disease; rather, it would act slowly over a period of many months during which time the person infected by it might unknowingly be contagious. AIDS, with its dramatic late manifestations, would then only represent the end result of an insidious, much earlier infection with the hypothetical agent. Socio-cultural factors, such as degree of sexual promiscuity, would then represent only a contributing factor which merely increases likelihood of viral transmission. Alternatively, environmental factors favoring multiple infections with common microorganisms could predispose individuals to infection by a new, immunosuppressive viral agent.

If one of these scenarios proves correct, there is truly no saying where the epidemic will stop. Some 24 infants have contracted AIDS or an AIDS-like disease and 18 have already died. More than 100 women have contracted the disease, and most are dead. Are we witnessing the slow spreading of the disease beyond the neat "high risk" groups identified in early epidemiological surveys? If this may be so, can we indulge in the luxury of waiting to find out if this is so, when we know that months and perhaps years may have to elapse before the clear-cut "CDC-AIDS" develops? Wouldn't the situation be sufficiently alarming to everyone to justify throwing the weight of the spectacular advances made in recent years in virology, molecular biology and immunology at the crucial question of whether or not a new virus (perhaps one related to the recently discovered human T-cell leukemia virus) is the real culprit for AIDS? If such a virus were to be identified as the true cause of AIDS, vaccines could be produced and rational preventative measures could be devised.

c. Societal Considerations

The preservation of hard-won civil liberties also calls for a rational, rapid and effective solution to the problems of AIDS.

Words of reassurance sound hollow to many in the face of medical ignorance of AIDS' cause(s), mode of spread and

effective treatment. Uncertainty breeds fear. AIDS may not only be destroying lives but also the very fabric of a humane and progressive society, on which this country prides itself. Couples have been torn apart; thousands of young men have been abandoned by family and friends; a minority group is victimized by incidents of gross prejudice levelled indiscriminately at its members. Already scenarios for the quarantine of groups perceived to be "contagious" are emerging in thoughts, talk and even writing. The atmosphere of doom and total helplessness surrounding the problem of AIDS threatens to push us back into a medieval society complete with the equivalent of colonies of pariahs and lepers.

II. WHAT SHOULD WE ASK OUR GOVERNMENT TO DO?

If there ever was a problem in this country that cried for "money to be thrown at it," AIDS is such a problem. Our biomedical research community is now suffering under recently imposed funding cuts which impede its healthy growth rate and, in many institutions, preclude its functioning at earlier levels of activity and excellence.

On the other hand, extraordinary scientific advances have been made in recent years in the very areas pertinent to the solution of the problem of AIDS. A much better understanding has been gained of basic mechanisms of infection, immunity, cancer development and their biological

control. This is putting into our hands powerful new tools for investigations of the etiology, diagnosis and treatment of infections and cancers. AIDS, a condition where all these pathologies are interrelated, can also be seen as an extraordinarily challenging "experiment of nature." If offered support for their studies, thousands of scientists could be enrolled virtually overnight to investigate every aspect of this intriguing condition.

A. Areas of Research to be Supported

I believe scientists will want to work in the following areas:

(1) Thorough, extensive epidemiological studies:

These would expand the present efforts by the Centers for Disease Control to include other countries in Africa, the Caribbean region, Latin America and Europe. I would like to see such studies done by the CDC in collaboration with academic centers selected on the basis of their epidemiological expertise. Much could be learned about the cause(s) of AIDS and, if person to person spread occurs, about the mechanisms of transmission. Epidemiological studies could precisely identify risk factors and thus make rational prevention possible.

(2) Developing reliable diagnostic criteria: Only systematic, prospective studies such as those now being carried out by Dr. Michael Lange and his colleagues will

lead to the definition of clear, predictive diagnostic criteria. Such studies are of utmost importance and urgency. They must involve large numbers of subjects, including men and women with different sexual preferences and life styles, all studied repeatedly through multiple tests, over a protracted period of time. Such studies are logistically and scientifically complex and therefore costly. They are beyond the capability of any single clinic and laboratory because they require expertise in multiple clinical and scientific disciplines. They would, however, insure rapid progress in arriving at an understanding of how AIDS develops, and they could also lead to accurate diagnosis, prognosis and perhaps prevention.

In addition to funding, government planning and resource support may be needed here for (a) the collection and storage of clinical specimens, (b) their distribution to a variety of laboratories representing broad virological and immunological expertise, and (c) the storage, retrieval and analysis of a large number of laboratory, epidemiological and clinical data.

(3) Virology and Immunology: A host of studies need to be done as part of an intensive laboratory search for a possible viral etiological agent. Few clues exist as to which type of virus, if any, may be so involved. Until we know better, many viruses must each be suspected and

appropriate efforts must be made to identify specific antibodies, viral antigens and viral genomes or genome fragments.

A systematic study of the immunological abnormalities of AIDS patients must be also carried out: how they develop in the course of time, in various "at risk" groups; how they correlate with manifestations of viral and other infections; how they correlate with the patient's genetic constitution, history and lifestyle. These studies must involve many specialized laboratories in order to cover the whole spectrum of specific and non-specific immune functions that can be studied.

The group of patients and controls studied in these respects must be those followed clinically in large prospective studies mentioned above under "b." Such laboratory studies will result in information on the etiology of AIDS and therefore on its diagnosis, treatment and prevention.

(4) Development of methods of treatment: "CDC-AIDS" has, so far, been incurable. However, glimmers of hope have come from clinical trials of interferon alpha. Over half of the interferon-treated Kaposi's sarcoma patients have not only seen their lesions regress or disappear completely, but they have remained--during treatment and for months thereafter--free of deadly opportunistic infections. They have even exhibited some favorable changes in their immune reactivity. This has not been seen following chemotherapy, although the latter can also be effective in making Kaposi's sarcoma lesions regress.

Interferon trials in Kaposi's sarcoma have so far been sponsored only by industrial companies that produce interferon from recombinant bacteria and want to develop it as a commercial product. Trials have been limited so far to a handful of patients, their numbers having been determined principally by the companies' need for information to be provided to the Food & Drug Administration. In New York, only one hospital (at the Memorial Sloan-Kettering Cancer Center) is involved in interferon alpha trials in Kaposi's sarcoma.

I believe that the Food & Drug Administration should review the present evidence (which comes from reputed clinical research centers), and see whether it is not sufficient to warrant the immediate provision, by the NIH, of interferon to interested clinicians for the treatment of patients with Kaposi's sarcoma, foregoing requirements for double-blind trials in the development of this form of therapy for this particular disease.

In the absence of any other effective and safe treatment, I personally believe that the present evidence of interferon's effectiveness should be considered sufficient to make this form of therapy immediately available to all those who may benefit from it. This should be done as early as possible following the appearance of Kaposi's sarcoma lesions, a situation clearly favoring a response. Not making interferon available now may literally amount to

sentencing a substantial number of people to sure, early death. It is clear that interferon can at least prolong life.

Furthermore, interferon is not the only promising biological. Interleukin-2, another product of human lymphoid cells, may also have therapeutic immune-enhancing properties and may potentiate interferon's effects in vivo as it does in vitro. Clinical trials of interleukin-2 alone, and in combination with interferon therapy, appear warranted immediately. The exploration of other interferons, lymphokines and differentiation factors, alone and in combination, first in vitro and then in vivo, should be encouraged through grants from the Program of Biological Response Modifiers of the National Cancer Institute. These are but two areas in which immediate progress in therapy might be made. There are other approaches to therapy, both for the underlying disease and its complications.

B. Logistical and Financial aspects.

I believe that the research needed can be done almost exclusively through investigator-originated proposals (ROIs), in the form of individual research projects and collaborative program projects. Central, Government planning should be limited to organizational and logistical problems in which the Government could be very useful in facilitating

collaborations between experts in different disciplines. The imagination, the talent, and the ingenuity are out there in the biomedical research community, fully capable of addressing the many scientific and medical challenges of AIDS.

Our National Institutes of Health could--if directed to do so--set up mechanisms for fair and rapid allocation of funds.

What is most needed from the Government is the money; not CDC or NIH money taken from Peter to pay Paul (which would cause internal disruptions, delays and justifiable resentments). On top of already severe cuts suffered by the CDC in 1983, it is unrealistic and almost outrageous to expect this agency to do more in 1984, with a budget for its AIDS program that will be \$300,000 less than it was in 1983. Much the same can be said of the NIH. What we need is the new money this country can always find whenever it sets itself to do a real job.

How much money is needed? The cost of treatment of each "CDC-AIDS" patient is now well over \$100,000 per year. Since much of the treatment offered is experimental, much of it is done at taxpayers' expense. Even if one assumes that only half the treatment expenditures are borne by taxpayers, i.e. by the Government, the bill amounts already to \$100 millions per year. This covers only some 2,000 patients

with "CDC-AIDS", with the frustrating result of seeing them die anyway.

The additional figures we must think of for a comprehensive program of research on AIDS must be of the same magnitude. The total budget of a concerted, rational attack on AIDS through basic and clinical research must also be on the order of some \$100 Million. If roughly doubling the present financial burden imposed by the disease may ensure a resolution of the problem, rather than permitting it to grow and fester, it seems clear that such an investment should be made.

Finally, for those who may still feel that not enough people have died, and that AIDS has not yet caused enough tragedy and anguish, let me end by stating that an appropriate investment in AIDS research will certainly benefit all of us in the long run, and in more than one way. Understanding AIDS will undoubtedly greatly improve our ability to understand and therefore learn to control, the biological events leading to acquired immunodeficiency, susceptibility to infections and cancer in general. This will benefit infinitely larger numbers of people than those suffering from AIDS. There can, therefore, only be winners in what is proposed here.

Gentlemen of the Committee, there is no excuse not to try and your decision should be easy.

Mr. WEISS. Again, the testimony that is being presented is extremely important. Unhappily, we do have a time problem. The House is in session and the bells may go off at any time for votes. So I would urge you to try to summarize your presentations.

Dr. Voeller.

**STATEMENT OF DR. BRUCE VOELLER, PRESIDENT, THE
MARIPOSA EDUCATION AND RESEARCH FOUNDATION**

Dr. VOELLER. First let me second the motions that my colleagues and predecessors have made thanking the committee for holding these hearings. I think they are of enormous importance, and the service being done is very great indeed, because the magnitude of the funding problem and the planning problem that exist goes far beyond what the public or governmental agencies have been aware of or certainly have publicized.

Again, others before me have quoted the administration to the effect that their first order of priority is AIDS; that from the leaders of the Public Health Service and the HHS. I think that it is important to recognize that action does not jibe with HHS proclaimed policy of "No. 1 priority."

There have now been nearly 3 years where at least some of us, significant numbers of us, have been aware of the scope and seriousness of the problem of AIDS, and during that entire time the Centers for Disease Control, the NIH, and the Food and Drug Administration, and in larger form HHS, have not convened so much as a single large-scale national meeting of scientists and physicians from the private sector as well as of government to develop a comprehensive master plan for discovering the cause of AIDS and for the developing of techniques for treating and preventing AIDS.

To be sure, there have been small-scale limited-project committees. Indeed Dr. Bove and I have served on two of those, dealing with AIDS and blood, at the invitation of those governmental agencies. But the fact remains that there has not been any major convening of people to discuss and develop an overall plan and in fact the truth is very simple, that there is no such master plan, and one is extraordinarily badly needed.

That need is because of a whole array of things:

First of all, we need to have an itemized list of all the conceivable kinds of research that could be done. You have heard by my predecessors today, a number of them, in the areas of immunology and virology and the like.

We need to have more than anecdotal lists, we need comprehensive lists. We need to have lists which are prioritized, as well, so that popular scientific areas not be the only ones on those lists, and that things which may be much less generative of publicity, of which we have seen a great deal in the press over the past year and a half or two, be supplemented by ones that may be much slower to give results, much less likely to be aimed at Nobel Prizes or in major funds for the institutions supporting the people doing the research which has the publicity.

We must not let those long-range projects lapse in favor of more popular conceptions.

We must, furthermore, have such a national master policy or plan for the purpose of peer review. The various branches of Health and Human Services, as you well know, have peer review for all manner of things considered an essential part of the fund granting process, and it absolutely needs to recognize that here, too, the Government can benefit from outside opinion, criticism, and honing of any master plan, and making sure of the things I have already mentioned as inclusions in it.

Further, we have heard here today from various people the degree to which they are conducting individual projects. There is unwitting duplication; there is redundancy, because people do not know what the Government is planning or what others are up to. So we must have a master plan which can in fact let all of us know what the Government plans either to do, or through its resources to support others doing outside the Government.

Finally, we need to be able to coordinate the roles the Government at the Federal level and State and city levels play.

As you probably know, New York State and the city of San Francisco have already allocated sizable funds for AIDS research and the State of California has funds pending. They need to be integrated into the planning. We cannot afford the loss of time and precious resources that will come from unwitting duplication, redundancy, and repetitiveness.

It has to be said, I think very clearly, that there has been an overall lack of Federal leadership in this area, and that the research that has been done has been fragmented and ill-coordinated. Lacking a master plan, it should be obvious as well that no realistic budget can be devised.

For the administration and the Congress to be considering small amounts of money, from my point of view, and from what you have heard from others who have testified here, creates an enormous problem. If you don't have a master plan, how can you produce a meaningful, valid budget? So it becomes obvious from that factor alone that a master plan is called for, needed, and wanted.

And I will tell you that the size and amounts of the moneys that are being talked about are a drop in the bucket compared to what is really needed. If we look at only one or two examples, it will become evident.

Take one, a smaller one actually. Interleukin 2 is reported to cost about \$125,000 per patient to test at the NIH. Four people are being tested, a tiny number in terms of any kind of medical or scientific research for testing something that then would have to be used on masses of people. If we were to look at something on the order of 50 people at \$125,000, we are talking already nearly half of the budget initially asked for by the administration in this country for all AIDS research—\$14 million.

Second, if we look at a far more costly example, one of the clear things that was mentioned earlier today as well was the need for an experimental animal model. In order to determine a cause—this is classic Koch's Postulates, which if you had any biological training you learned in high school or in college medicine—you must first isolate what you think is the causal agent, then find a host to reintroduce it into to see if the host contracts the disease. We don't have an animal to test it in.

It is fine to believe this or that virus may cause AIDS. It is fine to carry out an array of immunological and virological studies. But at some point we have to go back and study whether or not the agent we believe is the causal agent is in fact the real one, before we go to the enormous cost and time-consuming process of developing vaccines.

I could not agree more with Dr. Conant, with what he had to say about working on prevention. We first need to know if we have identified the right beast before we do that.

Well, most of the standard laboratory animals have been looked at. Things such as rabbits, rats, guinea pigs, et cetera, appear not to be susceptible to AIDS tissues or fluids from patients with AIDS. Consequently, we must move to the rather more time consuming, costly and difficult area of using primates. No one has a clue at this point whether any primate will be susceptible to AIDS. But what we do need to do immediately, because of the much greater medical affinity and physiological affinity of primates to human beings, is begin to look to see if any primate species is susceptible to human AIDS. Marmosets don't seem to be.

I have calculated—and I won't go through all the figures here, inasmuch as they are in my written presentation to you—that if one looks at only six species of primates, and takes the relatively small number of 25 individual animals per species—and since we believe that AIDS has an average incubation of close to 2 years in human beings, and have no reason to suspect it would be particularly different among primates—if you multiply all those factors out, plus one extremely critical one from the Centers for Disease Control, a cost of approximately \$100 a day per animal to raise primate animals for this kind of research, then you end up with a figure of almost \$200 million merely to discover an animal which then can be used for tests. Such an animal could be used to determine whether or not any of our short-term scientific tests have been effective in identifying a causal agent. We are then also more able to go forward to do the kind of logical step-by-step slow research which could lead to the isolation of a product or a virus or whatever may turn out to cause AIDS.

Just to flesh that theoretical skeleton out a bit, if we think that blood may be the causal agent out of an array of things which might cause, or at least carry AIDS, we would want to test whole blood in our animal. This is after we have an experimental animal to introduce it into.

Then we would want to fractionate blood to see whether or not the active AIDS factor was associated with plasma, with red cells, with white cells, with some subset of any of those, whether it was a protein, whether it was in fact susceptible to cleaning up, if you will, whether it was liable to heat treatment, to various enzymes, to pH changes or treatment with urea, all of which would have relevance in terms of treatment of persons with AIDS, or who must have AIDS-free blood products, as well as in developing a vaccine.

So the point is that merely to discover an animal which is susceptible amongst the primates, to conduct our research on, could readily and easily cost \$200 million or more, might even end up costing a great deal more because of the limited number of ways

we can set about doing such trials. Only then do we begin the kind of research that I have described.

I want to point out a couple of things that I think are important in connection with all of this.

One of them is that I am delighted that as many people have spoken as have here today about the costs that are associated with doing this work.

I would like to point out, however, that in the circle of people that I have approached and talked to about this, including people from the various branches of the Federal agencies dealing with AIDS, and with people at universities around the country, they are frankly afraid to come and testify at hearings like this because of fear. In the case of the governmental workers, repeatedly they have told me that they cannot say the things that I am saying, much as they concur in them, because they are under an effective gag order by the administration in terms of any public statement or private statement that differs from the administration's policy that budgets in these areas are not to be increased.

The same holds for many researchers. They, too, are dependent upon Federal grants from the NIH or other institutions in the Government, and are extremely reluctant and fearful of the consequences and reprisals that will happen if they publicly state the things I am telling you. I am not alone in my point of view that I am presenting here. And I wish those people could and would come forth. But I can see why they do not.

All of this, these realities of the need for a master plan and the costs which I think can hardly be expected to be less than half a billion dollars over the next couple of years, not the few millions that we have been talking about, but upward of half a billion dollars, can only be evaluated by taking steps to get a proper assessment outside the government itself.

Because of its commitment to defense and not to social service projects, I think the administration disqualifies itself instantly. We have had repeated testimony today that confirms my view. Why is there not even a master plan? Because if there were, everyone could see the gross funding deficiency.

What can be done?

The National Academy of Science was created, I believe by President Lincoln a century ago, roughly, to do just this kind of work, which is to advise the Government on matters of science. The Institute for Medicine at the Academy, or some private group, such as the American Public Health Association, should I think be asked to do a crash review of all of these issues, and to make recommendations of a comprehensive, depoliticized plan of action, and assign a properly prepared budget recommendation to accompany the plan.

It is my belief that unless these steps are taken, hundreds of thousands of Americans and people around the world will be killed needlessly and inexcusably by AIDS. It has been reported by others before me that the cost of medical treatment is about \$100,000 per person. Since AIDS has been around nearly 3 years now, if we look forward another 3 years, we can expect something of the order of at least 50,000 people to have AIDS, at \$100,000 apiece. Coldhearted as looking at mere dollars and treatment and hospitalization

may be, we are talking \$5 billion in the hospital and medical care for these people.

It seems to me that a half billion dollars for research—just 10 percent of those hospital costs is a very economical amount of money for us to be looking at in the Congress to deal with this AIDS crisis by comparison.

Finally, as a scientist who has observed what has happened and who has seen how his colleagues are suffering from a lack of funds and the kind of master battle plan that is needed, I begin to wonder with a certain cynicism if perhaps the only route by which we are realistically going to get the needed Federal leadership is when the Armed Forces begin to turn up cases of AIDS.

And that disaster is happening, though it is not a matter of public information yet. Indeed, it is rather shocking to me that the public and probably all of you in Congress don't know, but there are now at least a dozen cases of AIDS in the U.S. Armed Forces. Perhaps there, where budgets seem to be without limit, we may ultimately find the moneys to do the things we should already be doing. We cannot wait.

Thank you.

Mr. WEISS. Thank you very much.

[The prepared statement of Dr. Voeller follows:]

AIDS RESEARCH AND FUNDING

by Bruce Voeller, PhD

*President, The Mariposa Education
and Research Foundation

In testimony before Congress in the past month, Assistant Secretary for Health, Edward Brandt, stated that AIDS is "our number one priority," a public policy H.H.S. Secretary Heckler echoed to the press. H.H.S. action does not jibe with its proclaimed policy, however.

Despite three years of intense interest in the disease, H.H.S. has not convened a single national meeting of research scientists and physicians from the private sector and government to collaborate in developing a comprehensive master plan for discovering the cause of AIDS and of developing techniques for preventing and treating AIDS.

Nor has H.H.S., or its component agencies, even yet named standing or ad hoc panels of outside authorities to advise and counsel the Department on AIDS, a procedure they consider essential in their Department's review of applications for scientific research grants given out by the Department. In fact, hastily convened ad hoc meetings have been called only on such limited issues as AIDS and blood, and AIDS in monkeys (simian AIDS). In addition, the scientific community interested in AIDS has received extremely little information from H.H.S. to assist in research or education. As an invited panel member and scientist at two of the interagency meetings sponsored by the CDC, NIH and FDA (AIDS and Blood), I have receive no follow-up reports, no research documents... in fact no information whatsoever following the meetings. Indeed, I have had to purchase a subscription of the CDC's Morbidity and Mortality Weekly Report (MMWR) for myself. Nor have I received a single issue of the AIDS update bulleting announced publicly by Secretary Heckler. Even highly publicised (through press conferences) announcement of "breakthroughs" on T-cell viruses found in AIDS patients (at NIH) and on trials with Interleucin 2 (NIH and FDA) were known to me and fellow scientists through personal contacts and national media, rather than scholarly communication from the agencies releasing the publicity.

*for identification purpose only

The need for the federal government to develop a comprehensive master plan and to convene a major council of advisors to review and comment upon the plan is imperative. The master plan is needed in order:

- 1) to assure that all conceivable research concepts and directions are envisioned and enumerated now, not merely a list hastily compiled, or ones composed mainly of fashionable research areas currently popular in select scientific circles,
- 2) to assure prioritization of the diverse research projects, in order to see that our best leads are pursued now and with vigor, and also to assure that long-term projects which may take several-years to complete are not neglected. We dare not risk playing out fashionable leads, seductive because of their attendant publicity and celebrity for the researchers carrying them out. as well as their supporting institutions, only to discover two or five years from now that the leads were dead ends...only than to realize we should have begun the methodical, long-term research which was actually needed. We can always terminate long term projects if serendipitous short term work finds the answers we seek; we can never regain the the lost time and lost lives if we are forced to begin the traditional, plodding projects at the end of a period of unsuccessful attempts to find quick results,
- 3) to assure that each of the many projects which should be listed be periodically and systematically scrutinized anew, as fresh information and hypotheses emerge which might shift our perception of the relative significance...either upward or downward,
- 4) to assure close examination of the government's AIDS master strategy using the same creative and critical peer review which is a standard procedure at first-rank scientific journals and research funding institutions, including all branches of the H.H.S. We cannot afford to have good hypotheses tested through protocols with foreseeable limitations or flaws which might have been avoided or circumvented,
- 5) to coordinate privately funded research with that undertaken by the federal government, or financed by it; we must avoid wasteful, unwitting duplication of efforts and the consequent wasting of resources of money and time,

- 6) to coordinate studies at other governmental levels, including recent commitments made by the City of San Francisco, the state of New York, and pending in the state of California,
- 7) to develop a budget for AIDS research authentically tailored to meet the financial requirements generated by a comprehensive master plan, rather than invented to fall within the Administration's policy of frozen social service funding.

In the absence of the federal leadership so badly needed in the form of such a master plan and its correlated budges, we have seen more than two years of fragmented and ill coordinated research conducted on AIDS. The consequence is that a cure or preventive procedure for AIDS evades us and the cause of AIDS remains completely unknown to us.

Lacking a master plan accompanied by a realistic cost analysis, the Administration continues to resist budgetary increases for AIDS. It has repeatedly demurred to Congressional suggestions of additional funding for medical research on AIDS. Fortunately, Congress has taken steps to add about \$12,000,000 to the AIDS budget. The fact is, however, funds vastly greater than any included in proposals so far heard from the government are manifestly needed if one even considers a few of the many projects which would be essential in a master plan.

For example, in order even to begin the long process of systematically identifying the transmissible agent believed to cause AIDS, we first must find an experimental animal which is susceptible to AIDS. We need to be able to introduce a suspected causal fluid or tissue from someone with AIDS into the experimental animal to see if it does indeed cause AIDS in the animal...a part of the celebrated "Koch's Postulates" taught every beginning student of biology or medicine. Only in this way can we be sure we have identified the correct causal agent, even if we have used sophisticated new techniques to bypass much traditional procedure for discovering a causal agent. We must do this even if we have, for instance, the strongest suspicion that a particular virus may be the cause of AIDS.

Once a suitable experimental animal is located, it will be possible to test suspected agents. A lucky breakthrough might occur this way. More

likely to be the case, and more laboriously, if no such quick breakthrough occurs, test animals can be used to see if fluids and tissues from those with AIDS induce the disease in the animals. In this fashion we can see whether blood, semen, Kaposi tumour tissue, etc., carry AIDS, and then begin to analyze what part of semen, for example, carries the causal agent. Or if blood is found to be a major carrier of the infectious agent, we can see if it is in (or associated with) the plasma, or the white cells, or the red cells. Is it a small molecule which will diffuse through membranes? is it a protein? a virus-size particle? is it heat labile? susceptible to treatment with urea or to pH changes, or to enzymatic inactivation? Each question can be answered by testing the purified or treated blood product in an experimental population of animals.

Testing of standard laboratory animals such as hamsters, mice, rabbits, for their AIDS susceptibility, has failed so far. Therefore we must test as many different primate species as possible, because of their far greater medical and physiological similarity to human beings. There is no way, however, to predict which species of primate will be susceptible, or even if any will be. Furthermore, we must test each for as long as two years inasmuch as in humans, AIDS incubates close to that duration on the average before it manifests itself. If the period in primates proves as long as in humans, experimental primate research will be both very slow and very costly. We must start now.

According to several different sources at CXC and at American primate centers, rhesus monkeys and chimps, for example cost about \$100 per day to house and to care for in research such as we will need for AIDS studies. To intravenously expose twenty-five animals in each of six species of primates, with blood from AIDS patients, and to house them for two years, comes to

\$10,950,000 [25 X 6 X 2 X 365 X \$100]

To test just five other body fluids and tissues besides blood, e.g., saliva, semen, tumour tissue and fecal material and urine, would be six times more:

\$65,700,000 [\$10,950,000 X 6]

Since we are unclear what route of introduction of the test materials into the animal would work, merely testing three routes...intravenous, intramuscular and intraperitoneal injection...would cause the cost to soar another threefold to

\$197,000,000

This staggering figure is merely a limited array of tests designed only to discover a susceptible species of animal...so the real research can begin. [Note that AIDS contamination of animal housing facilities in these studies may well render them unsuitable for future use.]

The fact is that the cost of this single project is nearly twenty times the entire budget the Administration has until recently been proposing for all AIDS research.

The cost of experimental testing of interleucin 2, to consider another example, to determine if it is a useful treatment drug for AIDS, is reportedly \$125,000 per patient. The NIH is, I understand, testing only four patients. A full scale test might be of the order of fifty patients, if their is sufficient purified, isolated interleucin 2 to do the studies. At the stated price, the cost of such a study will be about \$6,000,000, inasmuch as we cannot justify waiting many additional months in the hopes that 'synthetic' recombiant process interleucin 2 will be available presently at a cheaper cost per patient.

Callous as raw economics can seem, solving the AIDS mystery is plainly cost-effective compared with the price of hospital care alone, which now approaches \$100,000 per case. The number of known AIDS cases nearly doubles every six months. AIDS has been around at least three years; projecting forward a similar periods of three years, to 1986, we can expect at least 50,000 AIDS cases. By the end of that period, the national AIDS treatment bill will be over \$5,000,000,000 -- five billion dollars.

In talking with numerous research scientists, both within the government and in the private sector, I find they agree with my analysis presented here... the desperate need for a federal master plan and for the level of financial resources I have given a small indication of here. Sadly, most of my colleagues are unwilling to come forward to state their support and concurrence publicly. Those in government quite reasonably fear quick termination of their government careers if they state their considered scientific beliefs in the face of explicit government gag orders. University researchers equally clearly tell me that they fear governmental reprisal if they appear before these hearings or speak their minds. These women and men are dependent upon government research grants in order out their scientific research...the sort of work that has won America so many Nobel Prises and made us prominent in science and technology.

All these realities lead me to the conclusion that a more impartial authority than the current Administration is needed to create a master plan for AIDS research and to attach realistic costs to the plan. We may in fact need an AIDS counterpart, crash-program similar to the Manhattan Project of the 1940's.

The National Academy of Science was created by President Lincoln a century ago to do just this kind of work -- advise the government on matters of science. The National Academy, the Institute of Medicine or the American Public Health Association should be asked to review the issues and recommend a comprehensive, de-politicized plan of action and assign a properly prepared budget recommendation for it.

It is my belief that unless such steps are taken hundreds of thousands of Americans and people around the world will be killed needlessly and inexcusably by AIDS.

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Mr. WEISS. Dr. Bove.

STATEMENT OF DR. JOSEPH R. BOVE, PROFESSOR OF LABORATORY MEDICINE, YALE UNIVERSITY SCHOOL OF MEDICINE, AND DIRECTOR, BLOOD BANK, YALE-NEW HAVEN HOSPITAL

Dr. BOVE. Thank you.

Mr. Chairman and members of the committee, I am Joseph R. Bove, M.D., professor of laboratory medicine at Yale University School of Medicine and director of the blood bank at the Yale-New Haven Hospital.

I have devoted all of my professional life to blood-banking and transfusion practice, and, among other things, chair both the Food and Drug Administration's Advisory Committee on Blood and Blood Products and the American Association of Blood Banks Committee on Transfusion-Transmitted Diseases.

As you might imagine, much of my recent medical effort has been devoted to AIDS and its effect on our blood banks and transfusion recipients. I will be brief with my statement so that your questions can focus on whatever may be of specific concern to you.

First, let me address one area that seems to be of major interest to nearly everyone: Has AIDS contaminated our blood supply? As of July 11, 1,831 cases of AIDS had been reported to the CDC United States only. Of these, 71 percent were in gay males, 17 percent in IV drug users, 5.4 percent in Haitian entrants, 0.8 percent in hemophiliacs, and 5.8 percent, or 107 cases, in individuals with no apparent risk factors.

To the best of my knowledge, this latter group includes fewer than 20 individuals who have received blood transfusions and have come down with AIDS. In one case, and one case only, has the epidemiologic investigation identified a donor with AIDS. In several other cases—still under investigation—there are suspect donors, but, as far as I know, in only this one case is a transfusion recipient with AIDS linked to a donor with AIDS. Thus, the current total of transfusion-related AIDS cases is fewer than 20, with only 1 in which an AIDS donor is linked to an AIDS recipient.

The current AIDS epidemic began in late 1979 or early 1980. In 1980, the latest year for which there are data, 10,880,079 units of blood were collected from volunteer donors and transfused into 3,271,792 recipients.

I have no reason to believe that the numbers for 1981, 1982, or 1983 differ significantly, so we can assume with confidence that over 10 million persons have received over 30 million units of volunteer blood since the AIDS epidemic began. In this vast experience the number of transfusion-related cases is under 20. If—and there is no evidence yet that this is so—but if all 20 cases under investigation by CDC finally turn out to be transfusion-related, the incidence will be less than 1 in a million. We do not know that AIDS can be spread by transfusion, but that possibility cannot be discounted.

But if AIDS can be spread by transfusion, what we know now suggests that the risk is minimal. Much less than the risk of many other well-known and accepted risks associated with transfusion,

with medical practice and with life, itself. Some of these are detailed in the appended table.

Over the past 20 years our blood-collecting agencies--the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers--have worked together to develop the very fine system of voluntary blood banks that serves the American public. Over 98 percent of all blood transfusions now come from volunteer blood donors. The system is working and working well.

Even if--and it still is a big if--a small number of AIDS cases turn out to be transfusion related, I do not believe that this can be interpreted to mean that our blood supply is contaminated. Probably not, and if not, what has caused the problem facing our blood banks?

First and foremost is the element of hysteria that surrounds the disease and anything even remotely related to it. In my view, this hysteria is fueled partly by an overreacting press and partly by a paucity of public information about the exact nature and number of suspected transfusion-related cases. In a setting where the amount of information is limited, rumor and anxiety run rampant. This anxiety has produced a whole host of unfortunate consequences. In some areas--certainly not in all, and probably only in a few--significant blood shortages are being seen. We cannot be sure these are AIDS related, but there is a suspicion that they are. Potential recipients and their families are beginning to fear transfusion and, in some instances, are resisting appropriate medical treatment because of these fears.

There has been pressure on blood banks to allow patients to select their own donors rather than relying on the community resources. Such requests have the potential to undermine a fine volunteer system to the point where it might no longer be able to supply the blood needs of most patients who require transfusion. The collecting agencies have recognized this and taken a strong position against such directed donations.

Our blood banks are mindful of the heavy responsibility they shoulder for a safe blood supply. To this end, they have quickly and willingly implemented the FDA's suggestion to provide all potential blood donors detailed information about groups at high risk of AIDS and ask individuals in any of these groups to refrain voluntarily from donation. If there had been even a small risk of transfusion-transmitted AIDS in the past, these measures, in place since late March, should lower it even further.

I am in a difficult and delicate position. We are dealing with a highly fatal disease of unknown cause which is spread in ways we do not understand. Much about the disease suggests that it is an infectious illness caused by an unidentified agent.

There is no test for AIDS and no way to know who, if anyone, is a carrier. In this forest of unknowns, a few people who have had transfusions have also come down with AIDS. This may be coincidence, but it seems possible that in an occasional case the two events are related. We really do not know.

Our needs now are to be calm and realistic in appraising the medical situation; to take whatever new steps are needed when, and only when, they can be justified on medical, scientific, and epi-

demiologic grounds; to continue to support and nurture the volunteer blood bank system and to reassure—as best we can—those who need transfusion.

We look to CDC for ongoing up-to-date information on which we can base future decisions about the Nation's blood supply; to NIH for research leadership and support; to FDA for whatever regulatory authority may be needed; and to the Congress, ladies and gentlemen, for financial and emotional support, financial in the sense that the ultimate solution to the AIDS problem will require research and medical-care dollars, and emotion—if that is the right word—so that the public can look to the Hill and see clearcut, unambiguous support for America's volunteer blood bank system.

I thank you for this opportunity to appear before your committee and am pleased to answer any questions you may have.

[The table entitled "Societal and Medical Risks," follows:]

SOCIETAL AND MEDICAL RISKSTransfusion Related Risks

Transfusion transmitted AIDS	1:1,000,000 (perhaps)
Transfusion transmitted hepatitis	5-7% of all recipients
Transfusion transmitted malaria	1:1,000,000
Death from the wrong unit of blood	1:500,000

Medically Related Death Rates¹

Appendectomy	1:5,000
Tonsillectomy	1:10,000
Cholecystectomy	1:625
Hernia Repair	1:5,000
Dilatation and Curettage	1:580

General Risks (Death/Person/Year)²

Automobile racing	1:10,000
Professional boxing	1:14,300
Motorcycling	1:50
Struck by automobile	1:16,600
Earthquake (California)	1:588,000
Floods	1:455,000

1. Hospital Mortality. PAS Hospitals, United States 1974-75.
2. Dinman BD. JAMA 1980;244:1226-1228.

Mr. WEISS. Thank you very much, Dr. Bove. I want to thank all of you on this panel. It was extremely important and informative testimony.

We are now going to break for about a half an hour.

The cafeteria is still open and will remain open until 2:30; so it will allow for some replenishment. We will then resume our activities at 2:45 p.m.

Hopefully, you can all return for questions at that time, and we will complete the afternoon's activities with the last remaining panel.

Thank you.

The committee stands in recess until 2:45 p.m.

[Whereupon, at 2:10 p.m., the subcommittee recessed, to reconvene at 2:45 p.m. the same day.]

AFTERNOON SESSION

Mr. WEISS. The subcommittee will come to order, and if all of our witnesses on this panel will resume their place at the witness table, we will proceed.

First, let me apologize for keeping you longer by breaking, but I was afraid if we did not, and the questions ran over, there would be no occasion for lunch, because the cafeteria closes at 2:30.

I do appreciate your cooperation and your returning.

Dr. Bove, let me address a question to you, if I may.

What steps, in the light of your testimony, do you feel need to be taken to allay public concern about the Nation's blood supply?

Dr. BOVE. Information, sir; information. I think we need an ongoing and open line of information from the CDC, which is currently the locus from which the case reporting stems to the public. I think those of us who are in the blood-collecting industry, who have responsibility for the Nation's blood-collecting systems, need to know exactly how many suspected cases there are, where they are, and at what stage the investigation is.

Do we have suspect donors? I think that information ought to be available not only to us in the blood-collecting group, but to the public. This is really public health information, and I think the people of this country need to know as quickly as possible what our CDC knows about the risks.

Mr. WEISS. Why do you believe that information has not been forthcoming?

Dr. BOVE. I can't answer that, Congressman. I think you have to ask others, but I know that there is a feeling on my part, and I suspect on the part of others, that the kind of openness about the information we think we need has not been available from CDC.

Mr. WEISS. One of you, though I don't know who, testified that the Morbidity and Mortality Weekly Report was changed from a free distribution to a paid-for distribution, and I gather from the testimony that this was done to comply with budget restraints.

It is your judgment that the same problems may be present in getting all kinds of information from CDC?

Dr. BOVE. I really am not competent to answer that question. You better ask the CDC people.

Mr. WEISS. Well—

Dr. BOVE. The Morbidity and Mortality Weekly Report is still out, still published every week, and there is an opportunity for CDC to write and publish in that information about suspected cases, just as they talk about measles, mumps, and chicken pox. They could certainly tell us about the suspected transfusion cases.

Mr. WEISS. When Mr. Brownstein testified earlier, the impression I got from his testimony was that he felt that organizationally, the National Hemophilia Foundation was, in fact, being reached out to by the CDC.

I guess what you are saying is that whatever information they give NHF may be in the very narrow area of their concern, but as far as broader information is concerned, to allow you to do your work, that information is not available?

Dr. BOVE. I feel that is correct, sir.

I learned this morning the CDC is supplying the National Hemophilia Society on an ongoing basis about a number of cases of hemophilia and details about them that are suspected and related to transfusion of blood products, but the three major blood-collecting organizations have not received that information.

Now that I have learned that it is available, I will see if I can get it; but why did I have to learn it here this morning in this way?

Mr. WEISS. All of you have referred in one way or another to what seems to be a lack of a comprehensive approach to dealing with this problem.

Would any of you care to offer some suggestions as to what you think ought to be done; how can we get a better-coordinated approach to deal with this problem?

Dr. Conant?

Dr. CONANT. Yes, sir, and I think there are a number of different ways. It would seem a problem of this magnitude involving as many different aspects of our society as it does, and it will continue to involve more aspects of society.

We learned last week that there is now an indication that health care workers have acquired the immune deficiency syndrome from dealing with patients.

Questions will be raised about the safety of doing cardiopulmonary resuscitation on people who may be suffering from AIDS, and so there are going to be a variety of different issues arising in the immediate future that need to be addressed.

We should have contingency plans how we will educate the public and deal with those problems as each arises in turn.

I would think that a blue-ribbon overseer committee, answerable to the executive branch of Government, perhaps HHS, which could look at the various issues that will arise because of this epidemic, and assay what is available in the community to respond and come up with plans so the Government could respond quickly, could be appropriate.

We have watched the spectre of a 2½-year wait to get funding for research. Some of the issues that could arise regarding this problem, we cannot wait 2½ years, and I would see this overseer committee looking at not only informational areas—the public need areas—but also the research areas as well.

We heard the other day that a young man in the military had been summarily discharged without medical benefits because he

had developed AIDS. It was suggested that he acquired the disease through his own misconduct. I don't need to remind you gentlemen that we have Veterans Administration hospitals full of individuals who are there because they smoked for many, many years. They acquired chronic lung disease, and alcoholism was mentioned earlier.

If a young man is in a motorcycle accident while on active duty and drinking, he is cared for by the military. This man is being deprived medical benefits because he was summarily discharged with the argument being he got this through his own misconduct.

In all probability his attorney will be able to get that overturned in 2 or 3 years. He needs medical benefits now. He will be dead in 2 or 3 years. There are a whole variety of issues exactly like this, where some overseer committee responding to this emergency could be extremely useful.

Dr. VOELLER. I think it is essential there either be standing or ad hoc advisory committees from outside the Government to CDC, FDA, and NIH on AIDS in general, just as there were to some extent with Federal panels which met two different times concerning AIDS and blood, a year ago now and back on January 4. Two of us here served on those panels.

There is a need to have panels of outside people who can help focus and hone plans and bring in new thoughts and ideas to research programming. I repeat that I think that the most fundamental thing of all goes beyond that; it is the need to have a politically independent voice, from people who are competent scientists, for an overall master plan that probably can only be developed by some such agency as the National Academy of Science or the American Public Health Associations, as I mentioned earlier.

Only through that, then, can we turn to a properly conceived budget, not plans drawn by political necessities or points of view of the administration on the relative importance of the defense budget versus health and human services budgets.

Mr. WEISS. Dr. Siegal?

Dr. SIEGAL. I would like to comment on a need for redundancy and investigation in this and other diseases. We should not forget the importance of serendipitous observations in what should be obvious to anybody who knows anything about the real process of science.

I don't think that a close finger on how research is done by a steering committee and who does it, and in what type framework, is necessarily an approach to be handed down.

Mr. WEISS. You are not saying that we ought not to make sure that the effort is sufficiently well organized, so that we know that each area of research is, in fact, being undertaken, or are you?

Dr. SIEGAL. No, no. I think that it is important to have a general plan of attack. It is clear that we ought to know that the areas of importance are being covered and questions that need to be addressed are being addressed, but to narrowly take that to mean that only one individual laboratory should pursue a particular perspective, I think, would be a mistake.

Dr. VOELLER. I agree.

Dr. KRIM. I would enlarge, approve strongly what Dr. Siegal just said. In research, a certain amount of duplication is good and nec-

essary, because no two people approach the same problem exactly the same way, and confirmation of results is always necessary.

One has to come to the same results two and three times before they become completely reliable, and, it is better if confirmation is obtained done by different people.

In my statement, I emphasized that Government should be involved in the overall planning, but not go into the specifics of the research. The latter should be left to the investigators themselves; the Government should make sure that all basic areas are covered by a sufficient number of laboratories, and that certain facilities and resources are made available to them. There is a need for a central repository for clinical specimens, for example, because many investigators don't have access to patients. Investigators should be able to write to somebody and say, I need this type of blood sample, or cell, or virus probe, and the Government should help make these available. But investigators must be able to work independently and freely, and not be asked to verify a hypothesis formulated by others.

Mr. WEISS. All of you are saying basically the same thing. Thank you very much.

Mr. WALKER. Dr. Bove, I would like to get a couple of things for the public record here.

Is it safe to have a blood transfusion in this country today?

Dr. BOVE. In terms of AIDS?

Mr. WALKER. Yes.

Dr. BOVE. As far as I know, I think it is. That is my professional opinion right now.

Mr. WALKER. Is it safe to give blood?

Dr. BOVE. Absolutely; unquestionably.

Mr. WALKER. Well, I think it is important that we establish those two things with an expert for the record, and I thank you for your statement on that.

Dr. Conant, you made three basic points earlier, and I thought that your testimony was very good. There was one thing that puzzled me, based upon my own reading on this, as to how it relates, and that is—not from the standpoint of what you said, but its application to AIDS—and that is that you said that you don't think that we in any way can expect in the context of dealing with this disease, that we can expect anyone to cease being human in terms of expressing their own sexuality, and that is absolutely a fact. I don't disagree with that.

However, it does seem to me that the expression of sexuality in our society is most often in monogamous types of relationships. Is it not true that we are dealing with something other than monogamous relationships in most cases and dealing not just in terms of dozens of different sexual liaisons, but in the case of many of the people who originally contracted this disease, we are dealing with hundreds of different sexual liaisons, which is hardly an expression of sexuality which we would normally think was healthy in any part of our population?

I wish you would deal with that question.

Dr. CONANT. It gives me an opportunity to stress a point that we have all been making this morning, and that is that the research

in this particular case, the epidemiological research, has not been adequate.

An epidemiological study is only so good as the design of the study, the questions you are asking as a scientist, and the time, appointed time, at which you do the study.

As you heard from some of the patients this morning, the CDC study, unfortunately, was not well designed. I don't know whose fault that was. It may be that we were dealing with a new history, but it was not well defined and not yet even been published, even though it was done in the fall of 1981, almost 2 years ago.

That study showed that the people coming down with AIDS at that time were highly promiscuous men, and yet I can tell you, as a physician who sees about three new AIDS patients a week now, that is not what we are seeing today. We are seeing men who are physicians, nurses, attorneys, who are in not totally monogamous relationships, but essentially such, and we are seeing large numbers of them; in my practice, probably 50 percent of the patients.

I had a patient last week, a young man 28 years old, and he came in and said, "I think this is Kaposi's sarcoma," and I looked up and said, "I think you are right. We will take a biopsy and see."

He started crying, and he said, I jog 25 miles a week, go to the gym every week; I only had sex with three people in my entire life. How could this happen to me?"

Now, the point I would like to make here is that if we had done an epidemiological study the morning after Pearl Harbor, we would assume that Japan won the war. We need to do ongoing epidemiological studies as this disease evolves, look at who is at risk, why are certain people getting it?

We pointed out in San Francisco we have the largest Asian community outside of Asia, and yet there have been only four cases in Chinese, Japanese, or Filipinos. Their sexual behavior is no different.

So we need funds to do these ongoing epidemiological studies.

Mr. WALKER. I don't disagree with that. My question came as a response, though, to your point that—I gathered from your points that the lifestyle issue should not be considered as a part of this, and it seems to me that, based upon the evidence we now have before us, we cannot totally ignore some of the lifestyle issues.

Dr. CONANT. We have to consider every issue that presents itself. Early on, the men we were seeing were very promiscuous men, but we are not seeing that today.

Mr. WALKER. You made a reference to the health workers that have been discovered recently. Do you have any evidence that those are people who were in contact with AIDS victims?

My understanding of that was that the health workers who have come down with AIDS were not people who had had contact with AIDS victims.

Do you have different information on that?

Dr. CONANT. I can give you the information published in the MMWR last week, and I can tell you what we know from our health-care workers at the University of California.

They cited four individuals who had come down with AIDS. At least one of the four cases, the man as far as the CDC can tell, had no other risk factors. He was not gay, not a hemophiliac, not a Hai-

tian, nor a drug user. He worked without gloves frequently in areas where surgical procedures were done, and he did report a needle stick some 18 months before he became ill. It is not known that that needle was contaminated with blood from someone who had AIDS.

He developed pneumocystis and died of that disease. It is only inferential; the suggestion, of course, is that he was inoculated in some way.

The reason that we think that that is significant is that, as you heard this morning, the AIDS epidemic has many parallels to hepatitis B. If it is a viral agent, it would appear that it is being transmitted in such a way hepatitis D is. Other groups that are at risk for acquiring hepatitis B are health-care providers and physicians, who do procedures without using gloves.

We would not be at all surprised to see an occasional health-care worker who did acquire AIDS by exposure to these patients.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. WEISS. Mr. McCandless?

Mr. MCCANDLESS. I would like to ask the panel, as a whole, this question:

It is my understanding that embarking upon an experimental program for finding an ultimate solution is a building-block process. As you begin to develop the necessary basic criteria, more and more people can become involved in trying to further different paths that have surfaced. Whether it becomes a dead end, or the ultimate solution each path is further broadened until finally you have a breakthrough.

Is this essentially how it works, or do we have the wrong impression?

Dr. SIEGAL. It very often works that way, but many of the most important breakthroughs that have occurred in biomedical research have been sheer accidents, and the discovery of penicillin is perhaps the best example, but there are lots of others. The discovery of the hepatitis B was the result of an accidental observation by someone who was prepared to go part of the way and be helped out by others.

Dr. VOELLER. It is important to say that, too, in the context we are talking about, we all hope something serendipitous will happen, that some lucky break will occur. But we can't bank on that or be caught 3 years from now with 50,000 or more people dead from AIDS, not having taken the logical steps I spoke of earlier.

I think it is important not to limit ourselves with the hopes that some lucky breakthrough will come up, because we may end up with dead ends, even though sometimes the lucky break pays off.

Dr. SIEGAL. They don't happen unless there are enough people looking.

Mr. MCCANDLESS. My concern is this "Government" tends to find answers through money, in the sense, that if we throw enough money at it, we will ultimately find a solution.

My Science and Technology Committee believes if we spend enough money on a certain type of design for a wing, we will come up with a solution to the problem. People tell us we can only spend so much and do so much research at a time.

In this particular case, it would appear to me that the number of available resources ultimately simulate research but are somewhat limited until such time as other projects or activities have worked their way out and these technicians and scientists become available.

Is that correct?

Dr. KRIM. I think in this case—I tried to say this in my statement—in this case we have an enormous amount of expertise out there, in several areas—biology, genetics, immunology, epidemiology—talent available and willing. Some researchers are working already on a shoestring; others would like to work on AIDS but have no means to do so now.

The case of the group which formed the AIDS Medical Foundation is a good example. We wanted to continue our work, and we were sinking for lack of financial support for it.

I really think that in the case of AIDS research, the major obstacle is lack of money, and only then lack of a certain amount of organizational talent that the Government can provide; but money could be spent very quickly, and most usefully.

Also, AIDS is a problem that has a lot of different facets. It is not one narrow problem where one can go only one step at a time. There is a range of things one can start doing immediately in different areas, and many avenues of research can usefully be carried out in parallel.

Dr. CONANT. I share with you your concern that the hysteria around this—we will make this go away by throwing enough money at it, and we will quickly get the answer, and the whole problem will go away—all of us understand that that is not the case. If you don't put enough money there to do the necessary research, we will never get the answers that we need to stop this problem.

At our institution, for example, which has done a great deal of research on this problem, our leading cancer virologists had specimens from patients with AIDS and was beginning to do work on animal models to try to see if he could isolate the virus. It was appropriate; the university became concerned that the centrifuge he was using would become contaminated; and so, from November 1982 until we got funding in May 1983, that tissue sat there fallow with nothing being done because we did not have one \$30,000 centrifuge.

The State of California last month voted \$3 million to supplement the research that we are prepared right now to do, but we cannot find funding at the national level; so, while I agree with you that you could throw too much money at it, and it could be wasteful, a certain amount of money—and I am afraid that is going to be a large amount of money—is going to be necessary if we are going to find an answer.

Mr. McCANDLESS. One other point here, if I may, Mr. Chairman.

Our public health figures in the various categories show in fiscal year 1983 we will have spent \$14,532,000 in this field.

If I understand correctly, there has been no central coordination or an information bank set up from which information can be disseminated. If it were, all parties involved could benefit from it in their research.

I think the terminology is, you have not had any kind of scientific meeting on this at the national level. Is this correct?

Dr. VOELLER. Two things—yes, you did—first, there is no master plan.

There are bits of research being done in different laboratories, both in the private sector and in the governmental sector at the NIH, et cetera, but there is no master plan that has been developed and publicly put forward by the Government which people from all the different sectors then could relate to in planning and strategizing what they wish to do.

When I say a master plan, I don't mean it will be dictated or overseen by the Government to make sure everybody is doing exactly what is supposed to be done, but rather a listing of the things which we ought to be attending to and different quarters ought to be conducting those at this point. We need a general battle plan to wage a successful war.

An example of what's missing: a notion to which we have only given lip-service—is raising the funds and conducting the experiments needed to get a primate animal model to use for further research.

The answer to the second part of your question is, as an example of it, Dr. Bove and I both served on the two blood and AIDS panels held by the Government, as invited guests of the three governmental agencies, and neither of us has received any followup reports whatever. We have not even received the update bulletin that Secretary Heckler announced would be put out on AIDS, and indeed, I had to subscribe on my own to the MMWR published by the CDC, as was mentioned.

We have gotten no information whatsoever, even as members of a Federal panel working with the agencies.

Other people are in equally bad or worse positions because we at least have contacts through our meetings, so we can put in a telephone call and say, what should I know? What has happened? But the rest of the people in the field are dependent upon published resources and repeatedly seeing press conferences held by members of Government, or elsewhere, to publicize research.

Mr. McCANDLESS. You talked about the primate animals, and this says a syndrome resembling AIDS in humans has been observed in groups of rhesus monkeys at two of the seven NIH divisions of research-resources-funded regional primate research centers. One of these is located in Massachusetts, and the other is in California. You go on to talk about the comparison of the symptoms, and indicate that it occurs in some cages, but not in others. It would appear to me that this would be the animal or subject you are looking for if they come up with the same conclusion or possible disease without us even getting involved with it.

Dr. VOELLER. So far as simian AIDS is concerned, there is no reason to believe it is the same or identical to that found in human beings. There are experiments being conducted by the NIH in collaboration with people in Massachusetts and the University of California at Davis on that. There is I repeat, no, foundation for believing that it is the same disease. It is, however, a very important and striking parallel model which may serve to edify in what we do with human beings.

Dr. SIEGAL. I would like to comment on what I believe to be in terms of the Federal response. There, in fact, have been several meetings held; held at NIH in September of 1981. We had a meeting at Mount Sinai in July of 1982 that attracted 600 people, and it was funded by NIH.

The people who have been funded already under the first RFA met already in May, and plan to meet roughly quarterly, to coordinate our own efforts; and within the city of New York, David Sencer has been holding meetings monthly at which all the investigators who were working on AIDS were initially a bit standoffish. There has now been a lot of coordination between various groups willing to provide information to other people on an ongoing basis, and we are seeing a good deal of cooperation and interaction between people at the level of grass-roots investigators.

Dr. VOELLER. We do note that out of all of that discussion, there is no master plan circulating for comment, review, or collaboration.

Mr. WEISS. Thank you very much, Mr. McCandless. I have one or two questions as a followup.

The testimony we have just heard from this panel as well as from Ms. Apuzzo was outstanding in delineating the areas of unmet needs that we ought to be focusing on in order to have a comprehensive way of dealing with this situation.

Dr. Conant, your statistics, your projections are really awesome—I guess is the word that comes out of my mind. Again, you said, I think, that by the end of next year, there would be 12,000 cases, if nothing intervenes, and you said there would be over three million by when?

Dr. CONANT. By the time the next President goes out of office, 5 years from now, and that is assuming that we continue to double every 6 months.

Now, there is a worst-case scenario, of course. The best-case scenario is we come up with a vaccine and stop this horror.

There are cities: if you plot the incidents in New York and then the incidents in San Francisco, two curves are identical except they are about a year apart. Looking at the appearance of the disease in New Orleans, Washington, and Denver, they all have the same parallel curves a year or so down the line, because the incubation period is about 18 months, so we expect not only to continue to see the disease rise in high incidence areas, but we expect to see the base widen across the country.

The numbers I gave are based on the figures, doubling it every 5 or 6 months for the next year.

As the base enlarges, then the rate of doubling will increase, and one could come up with a figure that it soon will not be doubling every 6 months, but every 5 months, and then every 4 months, and then every 3 months, and the figure might reach as high as 20 million cases 5 or 6 years from now.

Mr. WEISS. Do the rest of you generally agree with those projections? Any of you disagree with the projection?

Dr. Siegal?

Dr. SIEGAL. I think that is clearly the worst-case scenario, and it is also perhaps fair to argue that infectious diseases tend to use up a substratum and eventually saturate a population.

I don't know whether we can really expect that kind of geometric progression going on. People are changing to a certain degree the way they behave, and those ways favor the spread of an agent, and I think we might expect the changes in behavior will continue to increase as this disease increases, but it is quite clear that it has to increase to a certain extent because there are a lot of cases in the pipeline already about which we can clearly do nothing.

Mr. WEISS. Right, and, finally, Dr. Voeller, and I think certainly others of you, talked about numbers of dollars that would be involved to stop the epidemic.

Dr. Krim did not mention a specific dollar, but brought out the alternative to not spending dollars.

Are you all in general agreement that, for example, the figures that Dr. Voeller used of \$197 million, roughly, to find the appropriate animal on which to do the research is an accurate projection and beyond that, I think somebody else had said that we are really talking about a total package somewhere in the vicinity of half a billion dollars, \$500 million.

Do those numbers seem to be realistic numbers to you as to what the unmet needs are at this moment?

Dr. Krim?

Dr. KRIM. I mentioned in my statement that we should certainly think for something in the order of \$100 million, and in addition to the \$100 million we spend already for these patients who are now in experimental treatment. That was my estimate of a reasonable amount; that would make a difference.

Mr. WEISS. I want to place this difficult matter in context. We are going to have the CDC and other HHS officials here tomorrow.

The subcommittee has found it almost impossible to get past budget numbers until very recently. We still have not been able to get future budget projections, because the administration takes the position that they are prohibited or forbidden by an Executive order from sharing them with us, a total misreading, as far as I am concerned, of their obligations and our responsibilities.

In any event, suffice it to say that for this year, the outside number is about \$25 million, including \$12 million that we more or less thrust upon CDC, NIH, HHS. We are a long, long way from the kind of dollars that you are talking about.

You want to make a comment, Dr. Krim?

Dr. KRIM. Yes, Mr. Chairman. These figures of \$25 million spent in 1983 puzzle me. I don't see any evidence for them among my colleagues.

I know of a few hundred thousand dollars that have been spent, actually given to three major institutions that I know. But even if this was done nationwide, it would amount to \$25 million, or \$30 million, or \$40 million.

Mr. WEISS. We will try to tie that down tomorrow, when we have Department officials before us.

Dr. KRIM. You should really ask how they arrived at these figures, because the NIH has a way of calculating amounts spent on one health problem that is often very puzzling.

For example, AIDS involves immunology. The NIH could say that all immunology research is AIDS research.

Mr. WEISS. Dr. Conant?

Dr. CONANT. I wanted to second that. In my testimony I referred to double bookkeeping, where any type of cancer which may vaguely be associated with Kaposi's sarcoma appears to be figured into the NIH budget, and it would be very good for you to question: what are these moneys being used for? Was this research that was already underway before the AIDS epidemic even began?

Mr. WEISS. Thank you.

Mr. Levin?

Mr. LEVIN. Mr. Chairman, just let me say—and I am sorry I missed the question-and-answer session—but, as I understand it, you have been covering the points that I wanted to raise, or I hoped would be raised, trying to project or discuss projections into the future, and how conjectural they were, and the potential costs to try to combat the problem.

I will, with interest, try to obtain from your staff, Mr. Chairman, as well as the people who are working more directly with me, the responses, because, as I sat through this morning's testimony, it struck me how important is our oversight responsibility.

We are not here as advocates, and we are not here to try to approve a preordained position. We are here to determine the scope of the problem and the adequacy of the response to the problem by various institutions, including, and because of our oversight responsibilities, especially governmental institutions, and I hope very much that we can proceed in that spirit, and not to do something otherwise, and I think that the testimony that I missed, from what I can determine, was especially important in trying to help describe the potential dimensions and the varying points of view about this, and it should be helpful as we proceed with the rest of this hearing and then as we proceed to take testimony from CDC and NIH.

Mr. WEISS. All right. Thank you very much.

I assume that this panel, too, would find it amenable to respond to questions which may be submitted later.

Thank you all very, very much. We appreciate your contribution and your patience.

The last panel consists of representatives from volunteer service organizations: Mel Rosen, Harold Daire, and Christopher Collins.

Let me mention a few things about the organizations that are represented. The Gay Men's Health Crisis represented by Mr. Rosen and the Dallas AIDS Project represented by Mr. Daire were established specifically to provide support for communities victimized by the epidemic.

These organizations and others like them across the country have mobilized an exemplary effort to battle not only the medical problem, but also to cope with the social, psychological and economic problems associated with AIDS.

Also with us today are representatives from the Lambda Legal Defense and Education Fund, which dedicates itself to protecting civil rights of gay men and lesbians, including the issues of confidentiality. We welcome all of you.

Mr. Mel Rosen, member of the board of directors, and former executive director, Gay Men's Health Crisis, Mr. Harold Daire, founder and director, Oaklawn Counseling Center, Dallas AIDS

Project, and Mr. Christopher Collins, cooperating attorney, Lambda Legal Defense and Education Fund.

If you will stand, I will administer the affirmation.

Do you affirm to tell the truth, the whole truth and nothing but the truth?

Mr. ROSEN. I do.

Mr. DAIRE. I do.

Mr. COLLINS. I do.

Mr. WEISS. Let the record indicate that each of the witnesses have indicated affirmatively.

I appreciate the fact that you have been here for the bulk of the day, but because the House is in session, we may be called away for a vote at any time.

We have your prepared statements, and they will be entered, without objection, into the record in their entirety.

If you summarize your prepared statement and respond to questions, as time allows, it may be the most effective way of proceeding. I think we will start with you, Mr. Rosen, and then proceed to Mr. Daire and Mr. Collins.

STATEMENT OF MEL ROSEN, GAY MEN'S HEALTH CRISIS, NEW YORK CITY

Mr. ROSEN. Thank you, Mr. Chairman.

I will actually skip through my prepared statement and go down to the second page and talk to you about the specific services we have had to create within our organization because the community and basically the existing social service agencies do not meet the emergent needs of people with AIDS.

When a person is told he or she has AIDS it is not like hearing that they have cancer, for example. When you have cancer you are told what the diagnosis, prognosis and treatments are. When you are told that you have AIDS you are hearing that you have a time bomb inside of you, that any day you will get an opportunistic infection and one of these infections would kill you, usually within 3 years.

The person goes into a crisis. In many cases the person with AIDS does not have a nuclear family for support. We therefore created a crisis intervention unit of trained lay counselors who get to the person with AIDS within 12 hours of their initial phone call to us. This counselor actively works with the person with AIDS and helps them cope during this initial period. We started with 15 counselors last October; today we have 175.

Hopefully the person realizes after a while that they may not die tomorrow, next month or next year. At this point we introduce them to one of our support groups. People learned to cope from each other's experiences. In October we started one group. Today we have 12 groups not only for people with AIDS but groups for husbands, wives, lovers, friends, mothers, fathers, and significant others. Although our name starts with the word "gay," our services are offered to and used by all affected people and those around them.

We found that there were many people sent home from hospitals who were too sick to take care of themselves. We therefore created

a buddy system or home attendant service made up of people who cook, clean, and generally care for the person at home with AIDS who is too sick to take care of themselves. In one case a person with AIDS was being thrown out of their house so the buddies found him a new apartment and moved him in one weekend. We started with 7 buddies; we now have 75.

The disease does not discriminate for or against people who are rich or poor. We found that people making \$40,000 a year like my client were losing everything they had. Even people who were well-insured were wiped out after numerous stays in the hospitals. Each opportunistic infection could mean a month or more in the hospitals.

We set up a financial aid committee that assisted people with AIDS to apply for public assistance benefits they were entitled to. We also assisted numerous legislators to put pressure on the Social Security Administration to create a definition for AIDS so people could get disability insurance. Even when the definition was added, it was inadequate. Only people with the CDC definition of AIDS are eligible today; for example, herpes oysters is not included.

This forces people with prodromal symptoms to continue to work when it is possible that working could hasten a case of full-blown AIDS. Our financial aid committee is stretched to its limits at this point.

Dr. Irving Selikoff at Beth Israel Hospital asked me to read into the record the case of one person who is not considered to be a CDC-defined person with AIDS. I won't do that now because of time, but I will give this to you to add into the record.

Mr. WEISS. Without objection.

[The information follows:]

Irving J. Selikoff, M.D.

Int. S. Univ. Med. Center

4. Results.a. Initial medical findings.

Immunological status of the study group exhibited far greater complexity than had been anticipated on the basis of previous reports.

Many of the 100 men had general symptoms that have been reported as associated with AIDS manifestation. Fever lasting more than one week was acknowledged by 17%, night sweats by 14%, unexplained weight loss greater than ten pounds by 11% and unusual headaches by 17%. On physical examination 48% had palpable lymph nodes felt by the examining physician to be clinically abnormal. Inguinal nodes were palpable in 47% and 34% had palpable nodes at two or more noninguinal sites. Anogenital lesions were noted in 37% by the dermatologist.

Infections were frequent with venereal infections being most common. Gastrointestinal symptoms were common, with 31% having diarrhea lasting more than one week, and respiratory symptoms were also prominent, with episodes of dyspnea in 27%.

Each examinee was sent a summary report of findings (Appendix 2); at his request, details of findings were also sent to his physician.

Case 1 demonstrates the range of symptoms which may be present without CDC criteria for AIDS being satisfied.

Case 1

The patient reported having had many sexually transmitted diseases. Hepatitis B occurred in 1979 with relapses in 1979, 1981 and 1982. His health in general had been poor with a 20 pound weight loss, night sweats, chills, lymphadenopathy, malaise, fatigue, increased nasal stuffiness, moderately severe episodes of shortness of breath, arthralgias, absence of semen on ejaculation, progressive muscular weakness and loss of memory. On physical examination, he had generalized palpable nodes, abdominal tenderness, hyperactive tendon reflexes, muscular weakness, and molluscum contagiosum on his neck. All routine laboratory tests were normal. His H/S ratio was 0.8. Other immunological tests were normal except that B-cell function was decreased (48; normal $^{30-65}$). The IgG level was 1,777 mg/dl (normal $^{1-1,500}$). His C-reactive protein level was 0.1 (normal $^{0-0.9}$). He had no response to recall antigens for PPD, mumps, dermatophytin. There was a 19 mm response to candida. Subsequent to our examination, he developed hepatosplenomegaly and received treatment for arthralgias with plasmapheresis to remove circulating immune complexes. He remains under the care of his physician (July 6, 1983).

Mr. ROSEN. Our hotline which I mentioned earlier started receiving about 20 calls a week last summer. It now handles over 1,000 calls a week. Callers range from those in search of a medical doctor familiar with AIDS to people calling in a complete panic over what they perceive as a symptom. Thirty volunteers and one full-time staff member operate this line.

While misinformation or sensationalistic reporting has created the perception that the general public can contract AIDS through casual contact, the reality is that people with AIDS can contract opportunistic infections through casual contact with the general population. People with AIDS sometimes become shut-ins. We have tried to combat this by creating recreational groups that get people out of their homes and into social and recreational situations.

People with AIDS have an average age of 35. In addition they often are in nontraditional conjugal relationship. These two factors create a multitude of legal problems in terms of wills and power of attorney. Hospitals in many cases do not recognize what should be considered a common law relationship between two people. We have attempted to deal with these legal problems by coordinating a network of legal services which advise the person with AIDS of their legal rights and responsibilities.

We have networked with the American Red Cross to establish a transportation service providing the means for people with AIDS to get back and forth from hospital treatments. In addition, the Red Cross trains our buddies in modern home attendant care practice.

The nonresponse by the public health agencies at all levels of Government forced us to create and furnish educational and informational services. Two newsletters which were really booklets containing everything we know to date have been distributed across the country to anyone who asks for them at no charge. This includes not only people who request them but hospitals, clinics, mental health facilities, and public health facilities.

In addition, we created a health recommendation brochure which has been distributed to half a million people. This brochure contains information ranging from the symptoms of this new disease to a recommendation by a number of physicians for people to limit their number of multiple sexual contacts.

We have an AIDS information van which travels to different neighborhoods and distributes educational materials. Trained counselors are available to speak with people who feel the need to talk with someone.

We have traveled across the United States to give technical assistance to any group who wish to start an AIDS self-help organization.

We have rented auditoriums and presented seminars to the community presenting doctors, social workers, psychologists, psychiatrists, legal experts, and insurance experts. At our last open forum seminar 2,500 people showed up. No one can understand what problems develop when young people in the community are thrust into the mind set of elderly people who are adjusted to death as a fact of life.

We present seminars in hospitals to doctors, nurses, and social workers. These seminars focus in on the psychosocial effects of AIDS. The Health and Hospital Corp. has contracted with us to

present these seminars to every one of the hospitals within their system. We are currently providing seminars to at least one voluntary hospital each week. So many health groups have asked for seminars that we had to procure an auditorium and present a seminar to all of them at once.

In the area of research, we have granted \$60,000 to research projects which would have had to stop for lack of funding, or which could not have gotten started because funding is so slow.

In the past 3 months a new problem has developed: Housing. People with AIDS are being discharged from hospitals penniless and homeless. The most that can be done through the city at this time is placement in an SRO building. These buildings are dirty, dangerous, and certainly not a place where a very sick person should live. The distorted image that the press has given this disease has caused many people with AIDS to be thrown out of their homes. Although we would rather not get into the housing business, we are being pushed to buy a house in order to shelter these sick people. I don't think this is our job.

Over the past year we have gone from an organization of 40 volunteers to 1,000 volunteers. We now have a full-time core staff of 7, everyone else volunteering their time. As a not-for-profit agency, we, of course, want to provide medical insurance to our staff. However, every major carrier we have contacted has turned us down. If this is a sign of the future, then we must act swiftly so that people in high-risk groups are not discriminated against when applying for insurance.

The Federal Government has not done its share. You must appropriate massive sums of money for research into this disease. You must appropriate money to the States so they can distribute moneys to local self-help organizations or set up their own programs. If you are not motivated to help disenfranchised groups, let me tell you something as a professional social worker.

Although it is not much talked about, sexuality is not static. People have different sexual preferences throughout their lives. This is part of the human condition. Talk by people who would turn a medical problem into a political one is disgraceful and belongs in the dark ages. For those who would consider legislating morality, this has been tried before without success. The human condition is continuously in flux.

Since most researchers and health officials have determined that this disease is sexually transmitted, it is probably the long incubation period that has kept the disease for the most part confined to certain groups. This will change shortly. There is a steaming locomotive roaring down the tracks at the general population. The people of this country depends on your God-given wisdom to ascertain the eventuality of certain events and to protect them.

I call upon you to not only appropriate the necessary funds but to create an office inside the Department of Health and Human Services that does two things: one, to establish a national effort that coordinates services to affected individuals and a national educational effort to the public at large and, two, gives resources and technical assistance to States and self-help organizations in locations where the disease is spreading or likely to spread.

[The prepared statement of Mr. Rosen follows:]

PREPARED STATEMENT OF MEL ROSEN, GAY MEN'S HEALTH CRISIS, NEW YORK CITY

In January 1982 about 80 people who had lost friends and loved ones to a new and mysterious disease gathered at author Larry Kramer's apartment in New York City. There they learned from Dr. Alvin Friedman-Kien of New York University Medical Center that what appeared to be a new disease was spreading among a number of divergent populations. Dr. Friedman-Kien warned that if the numbers continued to rise in the following months as they had in the previous months we would shortly be in the middle of a new epidemic. One member of the group which was predominantly gay commented that this could turn out to be a terrible health crisis for gay men, hence the name Gay Men's Health Crisis. The group decided that they would raise funds for research into this new disease and organized a fundraiser that April which netted \$50,000. At this point they applied for tax exempt not-for-profit status. The money raised went to research and the establishment of an AIDS hotline.

Two months later I read about this new organization giving away its money to research and was so impressed that I sent them a letter offering help, explaining that I was Vice President of a large social service agency. Within 24 hours, (the mail service worked that day) I was having lunch with the President of the Board who asked me to put an organization together. While I did not say I would do so, I promised to look into the matter. Over the next two weeks I spoke with doctors, researchers and patients. I did an unscientific needs assessment survey which made me come

to the shocking conclusion that the automatic safeguards that I thought the government had in place to warn and protect people from epidemics did not exist in this case. In a conversation with the CDC at that time I remember asking for month-by-month statistics on cases and mortality. I remember telling the CDC that either they were crazy or I was crazy but their numbers reflected an epidemic. I remember visiting Dr. Roger Enlow at Beth Israel Hospital who introduced me to a dying patient. Imagine my horror when that patient turned out to be an acquaintance of mine. The patient did not die during that bout with that opportunistic infection but became my client (I am a social worker) whom I followed through a progression of terrible and painful infections until his death three weeks ago. This was a man who made \$40,000 per year but died destitute. By carrying him as a client I was able to help build an agency which would respond to the special needs of people with AIDS. Most of these services would have been automatic for any terminally ill patient. In the cases of the AIDS patients those services were not forthcoming. Fear of the diseases, fear of death, fear of disenfranchised minorities all added to the lack of services by private and government agencies. What we did to compensate is the following.

(When a person is told he or she has AIDS it is not like hearing that they have cancer, for example. When you have cancer you are told what the diagnosis, prognosis and treatments are. When

you are told that you have AIDS you are hearing that you have a time bomb inside of you. That any day you will get an opportunistic infection and one of these infections would kill you, usually within three years. The person goes into a crisis. In many cases the person with AIDS does not have a nuclear family for support. We therefore created a Crisis Intervention Unit of trained lay counselors who get to the person with AIDS within 12 hours of their initial phone call to us. This counselor actively works with the person with AIDS and helps them cope during this initial period. We started with fifteen counselors last October; today we have 175.

Hopefully the person realizes after a while that they may not die tomorrow, next month or next year. At this point we introduce them to one of our support groups. People learned to cope from each other's experiences. In October we started one group. Today we have 12 groups not only for people with AIDS but groups for husbands, wives, lovers, friends, mothers, fathers and significant others. Although our name starts with the word "gay," our services are offered to and used by all affected people and those around them.

We found that there were many people sent home from hospitals who were too sick to take care of themselves. We therefore created a Buddy System or Home Attendant Service made up of people who cook, clean and generally care for the person at home with AIDS who is too sick to take care of themselves. In one case a person with

AIDS was being thrown out of their house so the buddies found him a new apartment and moved him in one weekend. We started with 7 buddies; we now have 75.

The disease does not discriminate for or against people who are rich or poor. We found that people making forty thousand dollars a year like my client were losing everything they had. Even people who were well-insured were wiped out after numerous stays in the hospitals. Each opportunistic infection could mean a month or more in the hospitals. We set up a financial aid committee that assisted people with AIDS to apply for public assistance benefits they were entitled to. We also assisted numerous legislators to put pressure on the Social Security Administration to create a definition for AIDS so people could get Disability Insurance. Even when the definition was added it was inadequate. Only people with the CDC definition of AIDS are eligible today. This forces people with prodromal symptoms to continue to work when it is possible that working could hasten a case of full blown AIDS. Our Financial Aid Committee is stretched to its limits at this point.

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containing everything we know to date have been distributed across the country to anyone who asks for them at no charge. This includes not only people who request them but hospitals, clinics, mental health facilities and public health facilities. In addition, we created a health recommendation brochure which has been distributed to half a million people. This brochure contains information ranging from the symptoms of this new disease to a recommendation by a number of physicians for people to limit their number of multiple sexual contacts.

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In the past three months a new problem has developed: housing. People with AIDS are being discharged from hospitals penniless and homeless. The most that can be done through the city at this time is placement in a SRO building. These buildings are dirty, dangerous and certainly not a place where a very sick person should live. The distorted image that the press has given this disease has caused many people with AIDS to be thrown out of their homes. Although we would rather not get into the housing business we are being pushed to buy a house in order to shelter these sick people. I don't think this is our job.

Over the past year we have gone from an organization of 40 volunteers to 1,000 volunteers. We now have a full time core staff of 7, everyone else volunteering their time. As a not-for-profit agency we of course want to provide medical insurance to our

staff. However, every major carrier we have contacted has turned us down. If this is a sign of the future then we must act swiftly so that people in high risk groups are not discriminated against when applying for insurance.

I sit before you a very changed man from a year ago when I called the CDC. I have discovered that medicine, research and the so-called safeguards we have in place to warn us about pending disasters are political and do not work when disenfranchised minorities are involved. When toxic shock and Legionaire's disease first came on the scene there was an immediate response by government and press. Why did hundreds of people have to die before anyone moved in this case? Single people pay a very high percentage of their salaries to the federal tax structure. Since most of the affected individuals affected by AIDS are single they expect something back from the government they trust. It is the American way for us to respect and care for the individual person who is in trouble in our country. I have become disillusioned about this in the past year in relation to our government. However, I take heart in the response of the community itself. People from all walks of life have come forward. The President of our board is a Fortune 500 corporate executive who was a Green Beret in Vietnam. Our Crisis Intervention Coordinator was a marine in Vietnam. We have policemen, firemen, doctors, nurses, social workers, priests, rabbis; people from all walks of life volunteer with us.

The federal government has not done its share. You must appro-

priate massive sums of money for research into this disease. You must appropriate money to the States so they can distribute monies to local self-help organizations or set up their own programs. If you are not motivated to help disenfranchised groups let me tell you something as a professional social worker. Although it is not much talked about, sexuality is not static. People have different sexual preferences throughout their lives. This is part of the human condition. Talk by people who would turn a medical problem into a political one is disgraceful and belongs in the dark ages. For those who would consider legislating morality, this has been tried before without success. The human condition is continuously in flux. Since most researchers and health officials have determined that this disease is sexually transmitted, it is probably the long incubation period that has kept the disease for the most part confined to certain groups. This will change shortly. There is a steaming locomotive roaring down the tracks at the general population. The people of this country depends on your God-given wisdom to ascertain the eventuality of certain events and to protect them.

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Thank you for the opportunity to speak with you.

Mr. WEISS. Mr. Daire.

**STATEMENT OF HAROLD P. DAIRE, FOUNDER AND DIRECTOR,
OAKLAWN COUNSELING CENTER, DALLAS AIDS PROJECT,
DALLAS, TEX.**

Mr. DAIRE. I am deeply honored my testimony has been requested.

The following presentation represents my attempts at reporting conditions, feelings, needs and recommendations of Texans as objectively as I am able.

We have been forced to spread educational, clearing house, and patient support services to AIDS patients and their loved ones throughout the State. We also sponsor a 24-hour hotline. However, the medical problems of AIDS are really what I have come to speak about.

Solving the AIDS problem requires response and coordination of resources at all levels of our society. We are dealing with a medical unknown which has vast psychological and sociological implications. We must shut the moral door and deal with a medical issue now, nonjudgmentally.

In Texas many efforts are being undertaken in attempts to combat the AIDS problem. Attempts at defining the problem are uncoordinated and by no means systematic. A Federal task force is necessary to help local health officials define their roles. Local health care delivery systems are straining internal resources in dealing with the AIDS registry in Dallas. There is no registry in Houston. Attempts at estimating cases in San Antonio were futile with numbers ranging from 10 to 34, depending upon whom I contacted.

The time to contain the growth of this epidemic is now, not 2 years from now. It is imperative that communitywide networks be established providing surveillance, health care, and followup. In dealing with AIDS, a format by which existing agencies could provide some form of health services is in place. It has been suggested that we apply strategies already practiced for the containment of sexually-transmitted disease. This format must address need without antagonizing confidentiality and without judging lifestyle. To effectively implement the program, the resources of existing structures such as the Counseling Center must be increased.

The definition of AIDS must be reexamined. The current Centers for Disease Control definition addresses only those people with AIDS who have developed malignancies or opportunistic infections.

Physicians at M.D. Anderson Hospital in Houston, Tex., have expanded the CDC definition to include the term "AIDS-related complex." This has enabled the physicians to intervene as early as possible in order to affect cure or remission. It enables health officials to conduct follow-up on exposed individuals early, allowing staff to contact those individuals who are at risk, providing them with information necessary to contain the spread of AIDS. AIDS-related complex does not necessarily develop into AIDS. Some recover from the symptoms spontaneously.

To support a statement made by Dr. Hirsh recently, in combating AIDS, research is of primary importance. However, reason

must be used in assigning projects which may be harmful. A case in point: According to Dr. Peter Mansell of M. D. Anderson, Houston, chemotherapy is not the first treatment of choice for Kaposi's sarcoma in most patients. Dr. Evan Hirsh of M. D. Anderson, Houston, stated, "Chemotherapy is often lethal to KS/AIDS patients * * *." Both recommended the use of interferon drugs.

It has been described as a critical issue of major importance that the FDA approve the use of interferon without randomized clinical trials. Patients will be killed using the trials. Based on studies in San Francisco, New York, Los Angeles, and Houston, interferon studies are the same. Interferon is relatively nontoxic. It is important to advocate the patient's right to select among treatment modalities and to know what is being dripped into their veins.

Along the lines of patient support, the overriding issue in Texas stems from the destructive effect of AIDS on a person's entire social network. People with AIDS often lose jobs, residence, money, friends, and family.

In Texas, as in other major areas of the United States, communities have organized groups to meet patient's psychosocial needs and provide education. Unlike New York City, San Francisco, and Los Angeles, organizations in Dallas and Houston are entirely dependent upon private contributions to fund support services. The KS AIDS Foundation and Committee for Public Health Awareness of Houston, the Oak Lawn Counseling Center AIDS Project, the Dallas Gay Alliance and the Dallas AIDS Action Project have been hampered in their efforts to petition for State and municipal funds because time and energy must be devoted to combat groups such as Dallas Doctors Against AIDS and Alert Citizens of Texas. Any efforts to express needs for State AIDS funding have been neutralized by the negativism of these groups.

On the municipal level, community organizations have petitioned their cities for support. How the cities have responded so far amounts to little more than lip service. The city of Dallas passed a resolution supporting the need for the release of Federal funds. The city of Houston appropriated \$78,000 to fund a State-mandated AIDS registry. In Houston, the funds have not become available nor the registry established.

On a national level, funds are being released at a trickle, not nearly in amounts needed to stem the tide of an epidemic termed "the number one health priority of the Public Health Service." None of the funds are earmarked for education or patient support.

Federal funds are needed by community agencies in order to enable them to realistically provide support to people with AIDS and their respective communities. Major cities with AIDS problems such as Houston and Dallas are in need of residences, halfway house, social services, food transportation, and nursing services. Community volunteer groups are becoming financially strained. Funds must be made available to support these efforts.

Evidence of grassroots concern is supported by the fact that nationally on local levels, independently nearly 40 AIDS support organizations have been formed over the past year. These groups have coalesced to form a national AIDS support federation, the federation of AIDS-related organizations. Why isn't there a coordinated response from governmental health agencies?

After completing the investigation and assimilating the feelings of many individuals, I have become convinced that the lack of response from every health agency in this country is intentional.

Denial of the problem is evidenced by the fact that there is no workable definition of AIDS. Denial of the problem's magnitude is evidenced by the fact that there are no effective registries operating in the State. Lack of concern is evidenced by the fact that there is no support of organizations which provide support and followup, nor have programs been implemented which could stem the growth and spread of the epidemic. The disease, although renamed AIDS, still invokes the classical response toward the homosexual community. "We don't care. Furthermore, drop dead." The irony of this lack of response by the Federal Government is potentially telling all U.S. citizens to drop dead.

I thank you for this opportunity for presentation.

Mr. WEISS. Thank you very much.

[The prepared statement of Mr. Daire follows:]

PREPARED STATEMENT OF HAROLD P. DAIRE, DALLAS, TEX.

Mr. Chairman and Members of the Committee:

My name is Harold Paul Daire. I am a resident of Dallas, Texas. I am a licensed mental health counselor in Texas, I am Founder and Executive Director of the Oak Lawn Counseling Center in Dallas, Founder and Coordinator of the Oak Lawn Counseling Center AIDS Program in Dallas, co-founder and patient support chairman of the Dallas AIDS Action Project. I am a member of the Dallas Gay Alliance, an organization which maintains an AIDS Task Force for the Dallas Community. I have been actively involved in local public health issues since 1980.

Early in 1980, I watched while a friend wasted away and finally died of a rare cancer and pneumonia. The case was baffling to medical practitioners. Since then I have experienced the loss of six others. I have been affected. I am saddened, I am afraid, I am more sensitive, I am concerned, I am involved, I am angry.

AIDS is a disease which is relatively new to us, bringing with it new sets of problems. Medical scientists are puzzled. Health workers are misinformed. The general public is panic stricken, reacting with fear, paranoia and anger towards high risk group. Those defined at high risk for AIDS are rallied in concern, pushing themselves beyond points of exhaustion to provide assistance and support to one another. People with AIDS are living each day coping with moralistic stigmas attached to a medical phenomenon, hoping each new day will uncover clues to solve the mystery, yet knowing that without solutions, each new day brings them one day closer to almost certain death.

Solving the AIDS problem requires response and coordination of resources at all levels of our society. We are dealing with a medical unknown which has vast psychological and sociological implications. We must shut the moral door and deal with a medical issue now, non-judgmentally.

In Texas, many efforts are being undertaken in attempts to combat the AIDS problem. Attempts at defining the problem are uncoordinated and by no means systematic. A federal task force is necessary to help local health officials define their roles. Local health care delivery systems are straining internal resources in dealing with the AIDS registry in Dallas. There is no registry in Houston. Attempts at estimating cases in San Antonio were futile with numbers ranging from ten to thirty four depending upon whom I contacted.

The time to contain the growth of this epidemic is now. Not two years from now. It is imperative that community-wide networks be established providing surveillance, health care and follow-up. In dealing with AIDS, a format by which existing agencies could provide some form of health services is in place. It has been suggested that we apply strategies already practiced for the containment of Sexually Transmitted Diseases (S.T.D.s). This format addresses needs without antagonizing confidentiality and without judging lifestyle. To effectively implement the program, the resources of existing structures must be increased.

The definition of AIDS must be reexamined. The current Center for Disease Control definition addresses only those people with AIDS who have developed malignancies or opportunistic infections. Physicians at M. D. Anderson Hospital in Houston, Texas have expanded the CDC definition to include the term AIDS Related Complex. This has enabled the physicians to intervene as early as possible in order to affect cure or remission. It enables health officials to conduct follow-up on exposed individuals early, allowing staff to contact those individuals who are at risk, providing them with information necessary to contain the spread of AIDS. AIDS Related Complex does not necessarily develop into AIDS. Some recover from the symptoms spontaneously.

In combatting AIDS, research is of primary importance. However, reason must be used in assigning projects which may be harmful. A case in point: According to Dr. Peter Mansell of M. D. Anderson, Houston, chemotherapy is not the first treatment of choice for Kaposi's Sarcoma in most patients. Dr. Evan Hirsh of M. D. Anderson, Houston, stated, "chemotherapy is often lethal to K.S./AIDS patients. . .". Both recommended the use of Interferon drugs. It has been described as a critical issue of major importance that the F.D.A. approve the use of Interferon without randomized clinical trials. Patients will be killed using the trials. Based on studies in San Francisco, New York, Los Angeles and Houston, interferon studies are the same. Interferon is relatively non-toxic. It is important to advocate the patient's right to select among treatment modalities and to know what is being dripped into their veins.

Along the lines of patient support, the overriding issue in Texas stems from the destructive effect of AIDS on a person's entire social network. People with AIDS often lose jobs, residences, money, friends and family.

In Texas, as in other major areas of the U.S., communities have organized groups to meet patient's psychosocial needs and provide education. Unlike New York City, San Francisco and Los Angeles, organizations in Dallas and Houston are entirely dependent upon private contributions to fund support services. The K.S./AIDS Foundation and Committee for Public Health Awareness of Houston, the Oak Lawn Counseling Center AIDS Project, The Dallas Gay Alliance and the Dallas AIDS Action Project have been hampered in their efforts to petition for state and municipal funds because time and energy must be devoted to combat antagonistic groups such as Dallas Doctors Against AIDS and Alert Citizens of Texas. Any efforts to express needs for state AIDS funding have been neutralized by the negativism of these groups.

On the municipal level, community organizations have petitioned their cities for support. How the cities have responded so far amounts to little more than lip service. The City of Dallas passed a resolution supporting the need for the release of Federal funds. The City of Houston appropriated \$78,000 to fund a state mandated AIDS registry. In Houston, the funds have not become available nor the registry established.

On a national level, funds are being released at a trickle, not nearly in amounts needed to stem the tide of an epidemic termed "the number one health priority of the Public Health Service." None of the funds are earmarked for education or patient support.

Federal funds are needed by community agencies in order to enable them to realistically provide support to people with AIDS and their respective communities. Major cities with AIDS problems such as Houston and Dallas are in need of residences, halfway houses, social services, food, transportation and nursing services. Community volunteer groups are becoming financially strained. Funds must be made available to support these efforts.

Dallas and Houston media and press have presented balanced, non-judgmental coverage. This has assisted our groups in maintaining a minimal level of paranoia in the community which is being created by Dallas Doctors Against AIDS and Alert Citizens of Texas.

Evidence of grass roots concern is supported by the fact that across the nation at local levels, nearly 40 independent AIDS support organizations have been formed over the past year. These groups have coalesced to form a national AIDS support federation . . . the Federation of AIDS Related Organizations. Why isn't there a coordinated response from governmental health agencies?

After completing the investigation and assimilating the feelings of many individuals, I have become convinced that the lack of response from every health agency in this country is intentional.

Denial of the problem is evidenced by the fact that there is no workable definition of AIDS. Denial of the problem's magnitude is evidenced by the fact that there are no effective registries operating in the State. Lack of concern is evidenced by the fact that there is no support of organizations which provide support and follow-up, nor have programs been implemented which could stem the growth and spread of the epidemic. The disease, although renamed AIDS, still invokes the classical response towards the homosexual community. . . "We don't care. . . furthermore. . . drop dead." The irony of this lack of response by the Federal Government is potentially telling all U.S. citizens to. . . "Drop dead."

OAK LAWN COUNSELING CENTER
A.I.D.S. Action Project - Dallas

214-528-2181

The AIDS Action Project - Dallas consists of three components (1) Community Education; (2) Clearinghouse; (3) Patient Support Services. Each component is briefly outlined below with an indication of some tasks required to carry out the activities.

I. Community Education

A. Target group(s) - The Dallas and North Texas gay community, local health professionals, and the media.

B. Objectives

1. To inform target groups about: a) the nature and extent of the AIDS problem, especially in the Dallas area; b) the steps recommended/available to prevent, detect, and treat AIDS-related conditions; and the types of services available in the Dallas area.

2. To motivate target groups to: a) take potentially appropriate preventive actions; b) seek screening, diagnostic, treatment and support services as necessary; c) support the AIDS Action Project through fund giving, volunteering or other assistance

C. Description - Major elements of the community education program include:

1. Distribution of educational materials
2. Produce quarterly AIDS Information Forums
3. Provide video tapes of the AIDS Forums and other AIDS information for viewing at the OLCC.
4. Promote articles, news reports, and public service announcements which emphasize accurate, up-to-date, "non-judgemental" and balanced information about AIDS and AIDS services.

II. Clearinghouse

A. Target group(s) - the Dallas metroplex and northern Texas gay community; local health care professionals and facilities.

B. Objectives

1. To collect and monitor information about AIDS medical cases.
2. To answer community inquiries concerning the AIDS problem, available services, and types of assistance community members can provide to the AIDS Action Project.
3. To refer individuals to screening, diagnostic, treatment, and support services as appropriate.

C. Description - Major clearinghouse activities include:

1. Establishment of an ongoing system at OLCC for reporting and monitoring of AIDS cases
2. Implementation of an AIDS Information Line to answer community inquiries, refer individuals to needed services, collect possible case information, and respond to special requests from the medical community.

III. Patient Support Services

A. Target group(s) - those diagnosed as having acquired immune deficiencies and/or AIDS related conditions; family, friends and loved ones of AIDS patients.

B. Objective:

1. To provide a coordinated program of counseling and social support services for target group members.

C. Description - services will be provided through the OLCC (but not necessarily be limited to).

1. Individual and group counseling of AIDS patients, family members, friends, and loved ones to assist them to "work through" the stages of illness and cope with the medical and social - psychological implications of AIDS
2. Establishment of a "buddy system" for AIDS patients. Under this system, volunteers would be trained to assess patient needs during home or hospital visits and provide support services.

DALLAS A.I.D.S. ACTION PROJECT

(DAAP)

To Our Friends In The Community,

The Dallas AIDS Action Project (DAAP) would like to invite you to join us on Sunday, June 19, at 8:00 PM at the Gran Crystal Palace in Dallas for a benefit performance by Samantha Samuels.

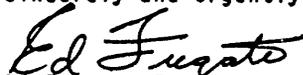
Proceeds from this event will be used to fund the activities of the DAAP in the Dallas area. These activities include:

- 1) Research to find a cure for AIDS
- 2) Education to increase public awareness about AIDS
- 3) Epidemiology to trace the epidemic aspects of AIDS
- 4) Patient support to assist those in need of treatment

I know that you feel as we do that AIDS is a frightening, malicious, life-threatening disease. Since the government is responding very slowly in providing sufficient funding for these projects, the private sector (you and I and the entire community) must act, and we must act immediately!

Your contribution is tax deductible and will be greatly appreciated. Please contribute. Please help end the nightmare of AIDS. Please join us in taking action now against AIDS.

Sincerely and Urgently,



Ed Fugate, Fund Raising Director
Dallas AIDS Action Project

TICKET PRICE: \$10.00 per person

Make Checks Payable to: DAAP (Dallas AIDS Action Project)

Pick up tickets at: (1) Crossroads Market on Cedar Springs, or
(2) Oak Lawn Mail Services, 3527 Oak Lawn

Call for more information: 521-8919 or 522-6900

DAAP COMMITTEE MEMBERS: Dr. Jim Wheeler, Mark Harris, Terry Tebedo, Al Leviton, Ed Fugate, Ed Frick, Paul Fielding, Mike Burnett, Jerry Campbell, Howie Daire, and many other concerned friends in the community

Involvement of the Dallas Gay Alliance in AIDS in Dallas

Since one of the primary purposes of the Dallas Gay Alliance is education, we strive to educate the gay community about AIDS, and how it affects them. We have published three brochures, one on what is known about AIDS, one on blood donations, and the third is on safe sex practices.

We have printed approximately 15,000 of the first AIDS brochure, and know that several other cities in Texas, including Houston asked if they could copy it. Funding for printing was from the Club Baths and AIDS Action Project.

The Blood Bank brochure was used only by a couple of blood plasma centers, because shortly after meeting with all the blood banks in Dallas, the ABBA came out with their own guidelines, and they have all decided to use them in some form. The meeting however, with all the blood banks was a useful exchange of information, and an opportunity for us to show the concern that the gay community has for this problem, and that we wanted to cooperate in any way possible.

Our latest brochure on safe sex practices will have an initial printing of 10,000 copies, and will be funded by either/or the Dallas County Health Department or Dallas Aids Action Project.

We also undertook a petition drive, that has gotten over 6,000 signature of people from throughout North Texas that are concerned about AIDS, and requesting that congress appropriate funding for research. Copies of these petitions were personally delivered to Martin Frost and Steve Bartlett. John Bryant was contacted, and said since he would support funding that we did not need to send copies of the signatures to him.

The Dallas Gay Alliance met with Craig Holcomb, City Councilperson, and he presented a resolution, that passed unanimously, and called for the federal government to fund new research dollars to AIDS. This was the first southern city to pass such a resolution.

Observations:

The biggest problem in Dallas now is the fear in the gay community of what AIDS is, and how they may catch it. Many of us have instantly self diagnosed any illness as AIDS, and this fear keeps many from being well.

Dallas needs money for research projects that can be accomplished here at Southwestern Medical School. The funding for such projects should be made more expediently that has been reported in the past.

We also need money for support services, for AIDS patients, and those that are affected by the loss of a patient.

Tom Hatfield

INTRODUCTION BY
REPRESENTATIVE BILL CEVERHA

On August 17, 1982, Federal Judge Jerry Buchmeyer, declared the Texas Sodomy Law, Section 21.06 of the Texas Penal Code, to be unconstitutional. A notice of appeal was filed by Attorney General Mark White, on November 1, 1982. On March 11, 1983, the last day on which a new bill could be introduced in the House of Representatives, Attorney General Jim Mattox, dropped the State's appeal of the Baker v. Wade decision. In dropping the appeal, Mr. Mattox suggested that the legislature should reintroduce a sodomy law if it thought it was in the public's interest.

The Baker v. Wade case was tried in June of 1981. No evidence of the public health threat caused by homosexual conduct was introduced at the trial court. The Attorney General has made no effort to ask the District Court to reopen the evidence to introduce the overwhelming medical evidence concerning the public health threat caused by homosexual conduct.

The diseases being transmitted by homosexuals and being caught by homosexuals during their sexual practices threaten to destroy the public health of the State of Texas. One of the most recent and deadly diseases is Acquired Immunological Deficiency Syndrome ("AIDS"). Two recent articles in "Time" magazine, March 28, 1983, and "Newsweek" magazine, April 18, 1983, confirm the deadly consequences of AIDS. Both articles also confirm that AIDS first occurred in the homosexual community either through their sexual practices, blood donations or through close contact with the heterosexual community.

The citizens of the State of Texas must be protected from the spread of AIDS and other sexually-transmitted diseases which occur as a result of homosexual conduct. House Bill 2138 has been introduced for the purpose of preventing and deterring homosexual conduct which causes the transmission of disease.

CSH B. No. 2138

A BILL TO BE ENTITLED AN ACT

relating to defining deviate sexual intercourse, sexual intercourse, intimate sexual contact, sexual contact, homosexual conduct, public lewdness, medical purposes, and defining the penalties for homosexual conduct, public lewdness, including the offering, agreeing with or solicitation of such conduct; providing penalties for homosexual conduct or the offering, agreeing with or solicitation of homosexual conduct, or intimate homosexual contact, amending the Penal Code, Sections 21.01, 21.04, 21.06, 21.07, 21.10, 21.11, and adding thereto a new section 21.14, and declaring an emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS

SECTION 1. Section 21.01, Penal Code, is amended to read as follows:

21.01. Definitions in this chapter

(1) "Deviate sexual intercourse" means (A) any contact between any part of the genitals of one person and the mouth or anus of another person, or (B) the penetration by one person of the genitals or the anus of another person with an object, except for medical purposes, (C) any contact between the mouth of one person and the anus of another person, or (D) the penetration by one person of the genitals or the anus of another person with any portion of the body (including, by way of example, but not limitation, a finger, hand or foot), except that any penetration of the female sex organ by the male sex organ shall not be included, and except for medical purposes.

(2) "Intimate sexual contact" means the touching by one person of the anus, breast, or any part of the genitals of another person with the intent or purpose of arousing or gratifying the sexual desire of any person.

(3) "Sexual contact" means the touching by one person of any part of the body of another person with the intent or purpose of arousing or gratifying the sexual desire of any person.

(4) "Sexual intercourse" means any penetration of the female sex organ by the male sex organ.

(5) "Medical purposes" means any medically necessary treatment by or at the direction of a physician or other health care practitioner licensed to practice medicine in this State.

SECTION 2. Section 21.04, Penal Code, is amended to read as follows:

21.04. Sexual Abuse (a) A person commits an offense if, without the other person's consent and with intent to arouse or gratify the sexual desire of any person, the actor

(1) engages in deviate sexual intercourse with the other person, not his spouse, whether the other person is of the same or opposite sex, (2) compels the other person to engage in sexual intercourse, deviate sexual intercourse or intimate sexual contact with a third person, whether the other person is of the same sex as or opposite sex from the third person, (3) engages in intimate sexual contact with the other person, not his spouse, whether the other person is of the same or opposite sex, or (4) engages in sexual contact with the other person, not his spouse, whether the other person is of the same or opposite sex.

(b) The conduct referred to in subsection (a) is without the other person's consent under one or more of, but not limited to, the following circumstances:

(1) the actor compels the other person to submit or participate by force that overcomes such earnest resistance as might be reasonably expected under the circumstances, (2) the actor compels the other person to submit or participate by any threat, communicated by actions, words, or deeds, that would prevent resistance by a person of ordinary resolution, under the same or similar circumstances, because of a reasonable fear of harm, (3) the other person has not consented and the actor knows the other person is unconscious or physically unable to resist, (4) the actor knows that as a result of mental disease or defect the other person is at the time of the act incapable either of appraising the nature of the act or of resisting it, (5) the other person has not consented and the actor knows the other person is unaware that the act is occurring, (6) the actor knows that the other person submits or participates because of the erroneous belief that he is the other person's spouse, or (7) the actor has intentionally impaired the other person's power to appraise or control the other person's conduct by administering any substance without the other person's knowledge.

SECTION 3. Section 21.06, Penal Code, is amended to read as follows:

(a) Deviate Sexual Intercourse

(1) A person commits an offense if he engages in deviate sexual intercourse with another individual of the same sex.

(2) An offense under this subsection is a Class A misdemeanor unless the actor has previously been convicted under this subsection in which event it is a felony of the third degree.

(b) Intimate Sexual Contact

(1) A person commits an offense if he engages in intimate sexual contact with another individual of the same sex.

(2) An offense under this subsection is a Class B misdemeanor unless the actor has previously been convicted under this subsection, in which event it is a Class A misdemeanor.

SECTION 4. Section 21.07, Penal Code, is amended to read as follows:

21.07. Public Lewdness

(a) A person commits an offense if he knowingly or recklessly engages in any of the following acts in a public place or, if not in a public place, he is reckless about whether another person is present who will, or may, be offended or alarmed by his act:

(1) an act of sexual intercourse, (2) an act of deviate sexual intercourse, (3) an act of intimate sexual contact, (4) an act involving contact between the person's mouth or genitals and the anus or genitals of an animal or fowl.

[Emphasis added.]

(b) A person commits an offense if he knowingly or recklessly engages in sexual contact with a person of the same sex in a public place or, if not in a public place, he is reckless about whether another person is present who will, or may, be offended or alarmed by his act.

SECTION 5. Section 21.11, Penal Code, is amended to read as follows:

21.11. Indecency with a Child.

(a) A person commits an offense if, with a child younger than 17 years and not his spouse, whether the child is of the same or opposite sex, he

(1) engages in sexual contact or intimate sexual contact with the child, or (2) exposes his anus or any part of his genitals, knowing the child is present, with intent to arouse or gratify the sexual desire of any person.

(b) It is a defense to prosecution under this section that the child was at the time of the alleged offense 14 years or older and had, prior to the time of the alleged offense, engaged promiscuously in

(1) sexual intercourse, (2) deviate sexual intercourse, (3) intimate sexual contact, (4) sexual contact, or (5) indecent exposure as defined in subsection (a)(2) of this section.

(c) It is an affirmative defense to prosecution under this section that the actor was not more than two years older than the victim and of the opposite sex.

SECTION 6. Chapter 21, Penal Code, as amended, is amended by adding thereto Section 21.14 to read as follows:

21.14. Homosexual Conduct - Offering, Agreeing, or Soliciting

(a) Deviate Sexual Intercourse

(1) A person commits an offense if he offers, agrees with, or solicits another individual of the same sex to engage in deviate sexual intercourse for the purpose of arousing or gratifying the sexual desire of any person.

(2) An offense under this subsection is a Class B misdemeanor unless the actor has previously been convicted under this subsection, in which event it is a Class A misdemeanor.

(b) Intimate Sexual Contact

(1) A person commits an offense if he offers, agrees with, or solicits another individual of the same sex to engage in intimate sexual contact for the purpose of arousing or gratifying the sexual desire of any person.

(2) An offense under this subsection is a Class C misdemeanor unless the actor has previously been convicted under this subsection, in which event it is a Class B misdemeanor.

SECTION 7. The importance of this legislation and the crowded condition in both houses create an emergency and an imperative public necessity that the constitutional rule requiring bills to be read on three several days in each house be suspended, and this rule is hereby suspended, and this Act take effect and be in force from and after its passage, and it is so enacted.

It is declared that deviate sexual intercourse, intimate sexual contact, and sexual contact as defined in Section 21.01 of the Texas Penal Code, as amended hereby, between persons of the same sex, is against the public policy of this State, inasmuch as such acts are the means for the transmission of diseases which threaten the health of the public at large, inasmuch as such acts threaten the public safety through their frequent association with violent conduct, inasmuch as such acts lead to and result in further acts against the policy of the State, and inasmuch as such acts constitute, contribute to and promote immorality and indecency.

It is further declared the public policy of this State to discourage and to refrain from encouraging or promoting (to the full extent of this State's constitutional power to do so) the promotion of the practice of sad sexual practices (deviate sexual intercourse, intimate sexual contact, and sexual conduct) between persons of the same sex and to discourage and to refrain from encouraging or promoting (to the full extent of this State's constitutional power to do so) the placing of persons who promote or engage in sad sexual practices between persons of the same sex in positions of public trust (including, but not limited to, positions as public school teachers, food handlers or processors, health care practitioners, public safety officers or any other position of public leadership or responsibility).

The agencies, political subdivisions, officers, employees, schools, colleges, universities and other instrumentalities of this State or of its political subdivisions are hereby directed to comply with the public policy of this State as set forth in Section 7 of this Act. The Attorney General, all district attorneys, City attorneys and law enforcement officers of this State are hereby authorized and directed to defend the constitutionality of this Act, to enforce this act and the public policy expressed herein, and to defend this State and the agencies, political subdivisions, officers, employees, colleges, universities, and other instrumentalities of this State or its political subdivisions in their actions in support of the public policies of this State as expressed in this Act. This Act shall be liberally construed to carry out these objectives and purposes.

ACTION ALERT!

This is happening to you...

THE BILL ON THE OTHER SIDE OF THIS SHEET HAS BEEN INTRODUCED
IN THE TEXAS HOUSE OF REPRESENTATIVES BY BILL CEVERHA OF RICHARDSON.
IT IS NOW BEING CONSIDERED BY THE CRIMINAL JURISPRUDENCE COMMITTEE.

WHAT YOU CAN DO

YOU CAN HELP US DEFEAT THIS ATTEMPT TO INVADE THE PRIVACY OF ALL
TEXANS BY WRITING LETTERS TO THE FOLLOWING CRIMINAL JURISPRUDENCE
COMMITTEE MEMBERS:

Wayne Peveto -- chair
Tom Waldrop
Terral Smith
Dick Burnett
Al Granoff
Joe Hernandez
Sam Hudson
James Hury
Debra Danburg

An example letter would be (do not copy exactly since
legislators do not respond well to form letters. Use personal
stationery, not an organization's letterhead):

April __, 1983

The Honorable _____
Texas House of Representatives
P.O. Box 2910
Austin, Texas 78769

Re: House Bill 2138

Dear Representative _____:

I understand that you will be considering the above
bill since you are a member of the House Criminal Jurisprudence
Committee. I urge you to oppose this bill because it represents
a major invasion of the privacy of all Texans.

Consensual sexual behavior between adults in private is
of no concern to the State of Texas.

(At this point, although it is not necessary, you may want to
add your personal reasons for objecting to the bill. Keep it short
and to the point)

Thank you for your consideration.

Sincerely yours,



Don't delay; Write now



PO Box 3045
Houston, Texas 77253
(713) 529-0504

Committee for Public Health Awareness

The purpose of this organization is to increase public awareness of health issues. Achievement of this goal will come through education of people as individuals and as groups in business, professional organizations, private institutions, and government agencies. Local, state, and national governments will also be lobbied on specific health issues to provide adequate research funding and necessary health services for all citizens.

The following projects will also be used to further public health awareness:

- Educational forums.
- Electronic media programs.
- Petition drives and letter campaigns.
- Briefing of political leaders.
- Lobbying for health related legislation.
- Document deviation from standard policy by agencies.
- Networking with other health related organizations.

Our funding is from donations and projects are implemented as funding becomes available. If you are interested in participating or have resources or helpful contacts, please fill out a membership card. Public health is everyone's responsibility.

Mr. WEISS. Mr. Collins.

STATEMENT OF CHRISTOPHER J. COLLINS, COOPERATING ATTORNEY, LAMBDA LEGAL DEFENSE AND EDUCATION FUND

Mr. COLLINS. Mr. Chairman and representatives of the subcommittee, I am Christopher J. Collins, a cooperating attorney with Lambda Legal Defense and Education Fund. Lambda is a national nonprofit, tax-exempt organization whose primary goal is to promote and protect the civil rights of lesbians and gay men through litigation.

I am a member of the Committee on Confidentiality of the New York City AIDS network, and am director of the St. Mark's Clinic, a community health center serving the lesbian and gay community of New York City.

The broad issue to be addressed by this subcommittee is how the Federal Government responds to the overall needs of disenfranchised groups. Specifically, in this particular instance the issue to be addressed is the relationship of the Government to three disenfranchised groups in this country: gay men, Haitians and IV drug users, who are most directly affected by a disease known as acquired immune deficiency syndrome.

The specific issue I wish to address concerns the treatment that is to be afforded confidential information that is submitted by these three groups to governmental agencies, both State and Federal, either as part of the Government's ongoing surveillance program of AIDS cases, or as a part of research conducted by the Government or private institutions and researchers.

How has the Government responded to the needs of gay men, Haitians, and drug users during this health emergency?

What is it doing to combat the disease?

And what information is the Government collecting from these groups and what does it intend to do with that information once it is collected?

This last question, the question of confidentiality, is the subject of this presentation.

For at least the past year, the Centers for Disease Control, through local health departments, has been collecting a vast array of information concerning patients diagnosed with AIDS, under the pretext of doing epidemiological surveillance. This surveillance report requests information relating to specific conditions and opportunistic infections, other infections, signs and symptoms prodromal to AIDS, diseases or conditions preceding or coexisting with diagnosis of AIDS, medical immunosuppressive therapy and laboratory and hospital data.

In addition, the surveillance report requests the following information:

- (1) Name.
- (2) Date of birth.
- (3) Residence.
- (4) Occupation.
- (5) Marital status.
- (6) Living arrangements.
- (7) Immigration status.

(8) Parents' origin of birth.

(9) The use of needles for injection of nonprescription drugs.

(10) Sexual orientation.

(11) Pregnancy.

(12) During the previous 5 years preceding diagnosis of AIDS.

(a) Sexual history of the patient, including specific sexual practices.

(b) Did the patient receive the hepatitis B vaccine, hepatitis B immune globulin, other immune globulins, factor VIII concentrate, cryoprecipitate, factor IX concentrate, blood transfusion.

(c) Was the patient in jail or serving a jail term.

The concern of the gay community is what happens to this information once it is collected, what is done with this information, who has access to it and what can be done to insure that access to that information is adequately restricted and protected from disclosure to unauthorized personnel.

The obvious reason for this concern is that the Government, specifically the CDC, is utilizing a surveillance report which requests information that in many States is still considered illegal and would compromise and/or jeopardize the needs of a person with AIDS.

For instance, in Tennessee, homosexuality is still considered a crime which carries with it a penalty of imprisonment for a period of time not to exceed 1 year. In other States, the use of nonprescriptive intravenous drugs is illegal.

Many Haitians are in this country illegally, which simply complicates the reporting problem further. The paranoia among the general population amidst cries for quarantine and imprisonment by fringe factions in this country have further added to the need for special protection of this information to insure that it will not be used in the future to satisfy some purely arbitrary need of one or more third parties.

Until recently, the information that has been collected on persons diagnosed with AIDS, together with the information identifying those persons, has been turned over by most local health departments to the CDC. The CDC, in turn, on at least three separate occasions, has released a list of names identifying those individuals diagnosed as having AIDS to the New York Blood Center, a private institution regulated by the Office of Biologics of the Department of Health and Human Services, to certain individuals involved in the so-called Los Angeles cluster study and, most recently, the CDC has released its national list of people with AIDS by mistake to the New York City Department of Health.

In addition, until recently, the CDC regularly released the names of people with AIDS in each State to that State's health department, as well as a specific city-wide list to the New York City Health Department. The CDC must take responsibility for its actions in releasing those lists to unauthorized personnel.

We believe that the release of the information to the New York Blood Center by the CDC was and is a violation of Federal law. The apparent justification for this last ongoing breach of confidentiality was that a comparison of national AIDS lists with a list of those who participated in the New York Blood Center's program for the development of the hepatitis B vaccine would be useful in deter-

mining any possible correlation between hepatitis B and AIDS. Whether or not this is so, this example raises a number of important questions. If the CDC is willing to turn over confidential information to a nongovernmental agency, can we safely assume that they will not make this same information available to governmental agencies?

Moreover, once that information has been released to a private institution, there is no longer any control over that information and its subsequent distribution. We view these breaches of confidentiality with the utmost gravity and suggest that these are the precise reasons why the present surveillance system cannot continue in its present form, and why there is a special need for legislation to protect records and information collected by the Government on these groups. Our concern is that further use of the current surveillance report may lead to additional leaks.

The current system of reporting has likely resulted in significant underreporting of cases by physicians and institutions who simply do not trust the procedures that are presently in place to maintain patient confidentiality. Physicians, wary of their obligation to maintain physician/patient confidentiality, are loath to report cases of AIDS when they know that confidentiality cannot be maintained.

Patients, some of whom may be very ill, refuse to seek medical assistance for fear that they might be deported, considered gay, fired from their jobs, or irrationally tagged with the stigma of having a disease. It is conceivable that false information is being collected on patients too fearful that they will lose their jobs or, worse yet, to be quarantined or isolated by the Government.

These are very serious issues that are confronting the CDC and the medical profession which will not go away. They must be addressed, and adequate assurances must be provided to instill confidence and trust that patient records will be secure from disclosure to third parties for whatever reason absent that patient's consent.

What we would propose at present—we have suggested that a statute be enacted, legislation be enacted to protect that information that is obtained from these patients, not be disclosed to third parties for arbitrary reasons.

It has been acknowledged today that identifying information is arguably needed for followup study, for further research, for comparisons. And no one is objecting to that possibility. In that event the need to protect the identifying information though is essential. We propose that new legislation be enacted in the form we have attached with my statement, which is designed to protect the confidentiality of information collected by the Federal Government acting on its own or through local governmental agencies or institutions.

Such a statute is based in part upon prior legislation that has been adopted by Congress to protect the confidentiality of patient records of participants in federally funded drug and alcohol abuse programs.

Under the proposed legislation, records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of surveillance research of AIDS conducted, regulated, or directly or indirectly cited by any depart-

ment or agency of the United States shall be confidential, and would only be disclosed under certain limited exceptions spelled out in the statute.

The legislation would provide that the information could only be disclosed in one of three ways, pursuant to the patient's consent; where written consent is not forthcoming the information could be disclosed only to researchers and only so long as the identifying information will be protected by those researchers. And where written consent—the third possibility would be where written consent has not been obtained, the information could be disclosed only if authorized pursuant to court order or upon a showing of good cause and pursuant to prior notice to the subject or participant.

The proposed legislation would provide further that in no event may the information be used to initiate or substantiate any criminal charges against the patient or to conduct any investigation of a patient.

The need for legislation of this type is apparent given the long history of abuse that we have seen. The need is heightened by the nature of the disease and the groups principally affected by this disease, and we would urge its passage. It is respectfully submitted that confidentiality of records regarding AIDS patients and AIDS research is a very serious problem which must be addressed promptly.

The bottom line is simple. We support and encourage research. However, the Government must demonstrate that it is capable of conducting that research in such a manner that it will protect and not jeopardize the health of the human subject or the research participant. Its failure to do so will continue to result in inaccurate reporting, falsified information, and a general mistrust of our Government by all of its citizens.

I thank you for your attention and consideration.

Mr. WEISS. Thank you very much, Mr. Collins.

[The prepared statement of Mr. Collins follows:]



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**Statement of Christopher J. Collins, Esq.
Cooperating Attorney,
Lambda Legal Defense and Education Fund**

**Presented to the Intergovernmental Relations
and Human Resources Subcommittee of the
Committee on Government Operations
United States House of Representatives
August, 1, 1983**

Mr. Chairman and Representatives of the Subcommittee, I am Christopher J. Collins, a cooperating attorney with Lambda Legal Defense and Education Fund. Lambda is a national non-profit, tax-exempt organization whose primary goal is to promote and protect the civil rights of lesbians and gay men through litigation. I am a member of the Committee on Confidentiality of the New York City AIDS Network and am Director of the St. Mark's Clinic, a community health center serving the lesbian and gay community of New York City.

I. The Problem

The broad issue to be addressed by this sub-committee is how the federal government responds to the overall needs of disenfranchised groups. Specifically, in this particular instance the issue to be addressed is the relationship of the government to three disenfranchised groups in this country--gay men, Haitians and IV drug users who are most directly affected by a disease known as acquired immune deficiency syndrome ("AIDS").

The specific issue I wish to address concerns the treatment that is to be afforded confidential information that is submitted by these three groups to governmental agencies--both state and federal--either as part of the government's on-going surveillance program of AIDS cases, or as a part of research conducted by the government or private institutions and researchers.

How has the government responded to the needs of gay men, Haitians and drug users during this health emergency? What is it doing to combat the disease? And, what information is the government collecting from these groups and what does it intend to do with that information once it is collected? This last question--the issue of confidentiality--is the subject of this presentation.

II. The History of the Problem

For at least the past year, the Center for Disease Control ("CDC"), through local health departments, has been collecting a vast array of information concerning patients diagnosed with AIDS, under the pretext of doing epidemiological surveillance. (Attached is a Case Report Form used by the CDC.) This "surveillance report" requests information relating to specific conditions and opportun-

istic infections, other infections, signs and symptoms prodromal to AIDS, diseases or conditions preceding or coexisting with diagnosis of AIDS, medical immunosuppressive therapy and laboratory and hospital data. In addition, the "surveillance report" requests the following information:

1. name;
2. date of birth;
3. residence;
4. occupation;
5. marital status;
6. living arrangements;
7. immigration status;
8. parents' origin of birth;
9. the use of needles for injection of non-prescription drugs;
10. sexual orientation;
11. pregnancy;
12. during the previous five years preceding diagnosis of AIDS:
 - a. sexual history of the patient, including specific sexual practices;
 - b. did the patient receive the hepatitis B vaccine, hepatitis B immune globulin, other immune globulins, Factor VIII concentrate, cryoprecipitate, Factor IX concentrate, blood transfusion;
 - c. was the patient in jail or serving a jail term.

The concern of the gay community is what happens to this information once it is collected, what is done with this information, who has access to it and what can be done to insure that access to that information is adequately restricted and protected from disclosure to unauthorized personnel.* The obvious reason

*Serious thought must be given to whether or not this information is even essential or relevant to an understanding of AIDS. It is submitted that this "information" has little, if any, practical relevance in research relating to AIDS. Questions such as what is the sexual orientation of this patient raise issues that are subjective in nature and provide no hard basis for scientific study. What is the difference between homosexuality and bisexuality?

for this concern is that the government, specifically the CDC, is utilizing a surveillance report which requests information that in many states is still considered illegal and would compromise and/or jeopardize the needs of a person with AIDS. For instance, in Tennessee, homosexuality is still considered a crime which carries with it a penalty of imprisonment for a period of time not to exceed ~~fifteen~~^{one} year. In other states, the use of nonprescriptive intravenous drugs is illegal. Many Haitians are in this country illegally, which simply complicates the reporting problem further. The paranoia among the general population amidst cries for quarantine and imprisonment by fringe factions in this country have further added to the need for special protection of this information to insure that it will not be used in the future to satisfy some purely arbitrary need of one or more third parties. (See The New Republic, August 1, 1983, "The Politics of a Plague," p. 18.)

Until recently, the information that has been collected on persons diagnosed with AIDS together with the information identifying those persons has been turned over by most local health departments to the CDC. The CDC, in turn, on at least three separate occasions, has released a list of names identifying those individuals diagnosed as having AIDS--to the New York Blood Center (a private institution regulated by the Office of Biologics of the Department of Health and Human Services), to certain individuals involved in the so-called Los Angeles cluster study and, most recently, the CDC has released its national list of people with AIDS by mistake to the New York City Department of Health. In

addition, until recently, the CDC regularly released the names of people with AIDS in each state to that state's health department, as well as a specific city-wide list to the New York City Health Department. The CDC must take responsibility for its actions in releasing these lists to unauthorized personnel.

We believe that the release of the information to the New York Blood Center by the CDC was and is a violation of federal law, 5 U.S.C.A. §552a(b). The apparent justification for this astounding breach of confidentiality was that a comparison of the national AIDS list with a list of those who participated in the New York Blood Center's program for the development of the hepatitis B vaccine would be useful in determining any possible correlation between hepatitis B and AIDS. Whether or not this is so, this example raises a number of important questions. If the CDC is willing to turn over confidential information to a non-governmental agency, can we safely assume that they will not make this same information available to governmental agencies? Moreover, once that information has been released to a private institution there is no longer any control over that information and its subsequent distribution. We view these breaches of confidentiality with the utmost gravity and suggest that these are the precise reasons why the present "surveillance" system cannot continue in its present form, and why there is a special need for legislation to protect records and information collected by the government on these groups. Our concern is that further use of the current surveillance report may lead to additional "leaks."

III. Why Is Confidentiality an Issue?

The current system of reporting has likely resulted in significant underreporting of cases by physicians and institutions who simply do not trust the procedures that are presently in place to maintain patient confidentiality. Physicians, wary of their obligation to maintain physician/patient confidentiality, are loath to report cases of AIDS when they know that confidentiality cannot be maintained.

Patients, some of whom may be very ill, refuse to seek medical assistance for fear that they might be deported, considered gay, fired from their jobs, or irrationally tagged with the stigma of having a disease. It is conceivable that false information is being collected on patients too fearful that they will lose their jobs, or worse yet, be quarantined or isolated by the government. These are very serious issues that are confronting the CDC and the medical profession which will not go away. They must be addressed, and adequate assurances must be provided to instill confidence and trust that patient records will be secure from disclosure to third parties for whatever reason absent that patient's consent.

IV. Surveillance vs. Research

The present report used by the CDC is of questionable value. That is a question for this sub-committee and the medical profession and I only raise this issue to heighten the overall significance of the problem.

Moreover, the need for this type of information by the CDC for its surveillance function is also questionable. On its face, the "surveillance report" is actually a research tool. In order

to undertake its arguably mandated duty of surveillance, the CDC has no need for accumulating the kind of data sought in the "surveillance report." Rather, it merely needs to know the number and type of cases that are being reported.

If, however, the CDC is engaged in epidemiological research, then the information may possibly become more relevant. In either case, the need to protect the information that is solicited and obtained is apparent and must be resolved.

V. Proposals

1. Surveillance

Where the information collected by the CDC emanates purely from the CDC's surveillance function, then we would propose that no identifying information be collected. It is that simple. There is no need for data identifying AIDS patients when the information is provided for strictly surveillance purposes. Accordingly, instead of collecting the information that is presently being accumulated, we would propose that the following information be collected:

1. first, middle and last initials of the person diagnosed with having AIDS;
2. birth date;
3. place of birth;
4. sex;
5. race;
6. diagnosis;
7. onset of symptoms;
8. date of report;
9. reporter and telephone number of reporter;
10. mother's maiden last name.

We believe that identifying information can be properly safeguarded at the site where the diagnosis of AIDS is made (e.g., hospital or physician's office). This adequately safeguards the

patient's right to privacy and alleviates physician's concerns regarding physician/patient confidentiality. At present, the health department in Washington, D.C. is requiring physicians to report only initials, date of birth, city of residence and reporting physician in cases where there has been a diagnosis of AIDS. The precedent is there for this type of reporting and it should be implemented by the CDC nationwide.

2. Research

Where the information sought emanates from a research function, then identifying information is arguably needed for follow-up studies, further research, etc. In that event, the need to protect that identifying information is essential. We propose that new legislation be enacted in the form attached hereto which is designed to protect the confidentiality of the information collected by the federal government acting on its own or through local governmental agencies and institutions.

Such a statute is based in part on prior legislation that has been adopted by Congress to protect the confidentiality of patient records of participants in federally funded drug and alcohol abuse programs. (See 21 U.S.C. §1174.) Under the proposed legislation records of the identity, diagnosis, prognosis or treatment of any patient which are maintained in connection with the performance of surveillance or research of AIDS conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall be confidential and would only be disclosed under limited circumstances. (See subsection (a) of the proposed legislation which is attached.) The legislation would

provide that the information could only be disclosed in one of three ways: (1) pursuant to the patient's written consent, (2) where written consent is not forthcoming, the information could be disclosed only to researchers and only so long as the identifying information has been removed, and (3) where written consent has not been obtained, the information may be disclosed only if authorized pursuant to a court order upon a showing of good cause. (See subsection (b) of the proposed legislation.)

The proposed legislation would further provide that in no event may the information be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. (See subsection (c) of the proposed legislation.) Severe penalties would be authorized for any violations of the legislation. Finally, the legislation would require that the Secretary of Health and Human Services consult with the heads of other agencies affected by AIDS to promulgate regulations designed to carry out the purposes of this legislation. The Secretary would be required to prescribe regulations establishing procedures to insure that all surveillance and research be carried out only with the full and informed consent of the patient or subject. (See subsection (f) of the proposed legislation.)

The need for legislation of this type is apparent given the long history of abuse by the federal government in this area. The need is heightened by the nature of the disease and groups principally affected by the disease. We urge its passage.

CONCLUSION

It is respectfully submitted that confidentiality of records regarding AIDS patients and AIDS research is a very serious problem which must be addressed promptly. The bottom line is simple: we support and encourage research. However, the government must demonstrate that it is capable of conducting that research in such a manner that will protect and not jeopardize the health of the human subject or research participant. Its failure to do so will continue to result in inaccurate reporting, falsified information and a general mistrust of our government by all of its citizens.

Thank you for your attention and consideration.

PROPOSED STATUTE ON
CONFIDENTIALITY OF PATIENT RECORDS

Disclosure authorization

(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any surveillance or research of AIDS (Acquired Immune Deficiency Syndrome) conducted, regulated, or directly or indirectly assisted by an department or agency of the United States shall be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(b) (1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (f) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation upon 30 days prior written notice to the patient at his or her last known address, but in any event, such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(B) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. The patient or research subject should be afforded a reasonable opportunity to participate in, or object to, the application. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient/research subject, to the physician-patient relationship, and to the treatment services. Upon granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

Prohibition against use of record in making criminal charges or investigation of patient

(c) No record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

Continuing prohibition against disclosure irrespective of status as patient

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

Penalty for first and subsequent offenses

(e) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$5,000 in the case of a first offense, and not more than \$10,000 in the case of each subsequent offense.

Regulations; interagency consultations; definitions, safeguards,
and procedures, including procedures and criteria
for issuance and scope of orders

(f) The Secretary of Health and Human Services, after consultation with the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b) (2) (C) of this section, as in the judgement of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. The Secretary shall prescribe regulations establishing procedures to insure that all surveillance and research be carried out only with the full and informed consent of the patient or subject or, in appropriate cases a designated representative thereof.

STATE OF NEW YORK

8197

1983-1984 Regular Sessions

IN ASSEMBLY

June 26, 1983

Introduced by COMMITTEE ON RULES -- (at request of M. of A. Ta. Bianchi, Siegel, Bragman, Catapano, D'Amato, Daniels, Dugan, E. Flanagan, Goldstein, Gottfried, Grannis, Harenberg, Hevesi, Hil Jacobs, Jenkins, Koppell, Lasher, Marchiselli, M. H. Miller, Murtagh, Nadler, Newburger, Orazio, Passannante, Pillittere, Robles, Sanders, Schimminger, Serrano, Tonko, Vann, Wertz, Wilson, Yevoli) -- read once and referred to the Committee on Health

AN ACT to amend a chapter of the laws of nineteen hundred eighty-three, amending the public health law relating to acquired immune deficiency syndrome (AIDS), as proposed in legislative bill no. S. 5930, in relation to further amending the public health law by creating the acquired immune deficiency syndrome institute and making appropriations therefor

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Sections two through eleven and section thirteen of a chap-
2 ter of the laws of nineteen hundred eighty-three, amending the public
3 health law, relating to acquired immune deficiency syndrome (AIDS), as
4 proposed in legislative bill no. S. 5930, are REPEALED, and a new sec-
5 tion two is added to read as follows:

6 § 2. The public health law is amended by adding a new article twenty-
7 seven-E to read as follows:

ARTICLE 27-E

THE ACQUIRED IMMUNE DEFICIENCY SYNDROME INSTITUTE

10 Section 2775. The acquired immune deficiency syndrome institute.

11 2776. Powers and duties.

12 2777. Research council.

13 2778. Advisory council.

14 2779. Reports by the commissioner.

15 § 2775. The acquired immune deficiency syndrome institute. 1. There is
16 hereby established within the department of health the acquired immune
7 deficiency syndrome institute. The institute shall have the central

EXPLANATION--Matter in *italics* (underscoring) is new; matter in brackets [] is old law to be omitted.

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1 responsibility for administering the provisions of this article and
 2 otherwise coordinating the state's policies with respect to acquired im-
 3 mune deficiency syndrome.

4 2. The commissioner shall appoint a director of the institute and may
 5 assign such personnel within the amounts appropriated as is necessary to
 6 carry out the provisions of this article.

7 § 2776. Powers and duties. 1. The institute shall have the following
 8 powers and duties:

9 (a) to develop and promote scientific investigations into the cause,
 10 prevention, methods of treatment, and cure of the acquired diseases of
 11 immunosuppression;

12 (b) to develop and promote programs of professional education and
 13 training and improvements in instrumentation as necessary adjuncts to
 14 such scientific investigations;

15 (c) to develop and maintain a clearing house within the department for
 16 information collected on acquired immune deficiency syndrome, including
 17 a catalogue of the existing medical literature and the results of exist-
 18 ing epidemiological studies;

19 (d) to develop and promote an outreach campaign directed toward
 20 targeted high risk populations to provide coordinated information
 21 regarding the treatment and counseling programs and sources of financial
 22 assistance available; and

23 (e) to promote the availability of supportive services for affected
 24 persons.

25 2. Personal data in any investigations, reports and information relat-
 26 ing thereto shall be kept confidential and be afforded all of the
 27 protections provided by the provisions of paragraph (j) of subdivision
 28 one of section two hundred six of the public health law. The institute
 29 may, however, from time to time publish analyses of such scientific in-
 30 vestigations in such a manner as to assure that the identities of the
 31 individuals concerned cannot be ascertained.

32 § 2777. Research council. 1. There shall be established within the in-
 33 stitute a research council composed of seven members to be appointed by
 34 the commissioner. The members shall be representative of recognized cen-
 35 ters engaged in the scientific investigation of acquired immunosuppres-
 36 sive diseases.

37 2. The research council shall be responsible for making recommenda-
 38 tions to the institute for the purpose of carrying out the provisions of
 39 paragraphs (a) and (b) of subdivision one of section twenty-seven hun-
 40 dred seventy-six of this article.

41 3. The council shall meet at least four times a year. Special meetings
 42 may be called by the chairman, and shall be called by him at the request
 43 of the commissioner.

44 4. The members of the council shall receive no compensation for their
 45 services, but shall be allowed their actual and necessary expenses in-
 46 curring in the performance of their duties hereunder.

47 § 2778. Advisory council. 1. There shall be established within the in-
 48 stitute an advisory council composed of thirteen members who shall be
 49 appointed in the following manner: two shall be appointed by the tem-
 50 porary president of the senate and one by the minority leader of the
 51 senate; two shall be appointed by the speaker of the assembly and one by
 52 the minority leader of the assembly; seven shall be appointed by the
 53 governor. The governor shall designate the chairman of the advisory
 54 council. The members of the council shall be representative of the pu-
 55 blic, educational and medical institutions, local health departments and

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1 nonprofit organizations, including organizations providing services to
 2 high risk populations.

3 2. The advisory council shall be responsible for advising the commis-
 4 sioner with respect to the implementation of this article and shall make
 5 recommendations to the institute for the purpose of carrying out the
 6 provisions of paragraphs (c), (d) and (e) of subdivision one of section
 7 twenty-seven hundred seventy-six hereof.

8 3. The council shall meet at least four times a year. Special meetings
 9 may be called by the chairman, and shall be called by him at the request
 10 of the commissioner.

11 4. The members of the council shall receive no compensation for their
 12 services, but shall be allowed their actual and necessary expenses in-
 13 curved in the performance of their duties hereunder.

14 § 2779. Reports by the commissioner. The commissioner shall make a
 15 first preliminary report to the governor and the legislature of its
 16 findings, conclusions, and recommendations not later than December
 17 first, nineteen hundred eighty-three, a second preliminary report of its
 18 findings, conclusions and recommendations not later than March first,
 19 nineteen hundred eighty-four and a final report of its findings, conclu-
 20 sions and recommendations not later than March first, nineteen hundred
 21 eighty-five, and shall submit with its reports such legislative propo-
 22 sals as it deems necessary to implement its recommendations.

23 § 2. Such chapter of the laws of nineteen hundred eighty-three is
 24 amended by adding a new section three to read as follows:

25 § 3. The sum of four million five hundred thousand dollars
 26 (\$4,500,000), or so much thereof as may be necessary, is hereby appro-
 27 priated to the department of health from any moneys in the state treas-
 28 ury in the general fund to the credit of the state purposes account not
 29 otherwise appropriated for the purpose of entering into contracts for
 30 research and for necessary costs of administration in relation to par-
 31 agraphs (a) and (b) of subdivision one of section twenty-seven hundred
 32 seventy-six and sections twenty-seven hundred seventy-seven and twenty-
 33 seven hundred seventy-eight of the public health law, is added by sec-
 34 tion two of this act. No moneys shall be available for expenditure for
 35 this appropriation until a certificate of approval has been issued by
 36 the director of the budget and a copy of such certificate or any amend-
 37 ment thereto has been filed with the state comptroller, the chairman of
 38 the senate finance committee and the chairman of the assembly ways and
 39 means committee.

40 § 3. Section fourteen of such chapter of the laws of nineteen hundred
 41 eighty-three is amended to read as follows:

42 § [14] 4. The sum of [three] six hundred [fifty] thousand dollars
 43 [((\$350,000)] (\$600,000), or so much thereof as may be necessary, is
 44 hereby appropriated to the department of health out of any moneys in the
 45 state treasury in the general fund to the credit of the state purposes
 46 account and not otherwise appropriated, for contracts with nonprofit
 47 community organizations for programs designed to alert and educate the
 48 populations at risk and the general public about the nature of the ac-
 49 quired immune deficiency syndrome (AIDS) crisis; providing patient sup-
 50 port services [including] which may include, but need not be limited to,
 51 the operation of a hot line, [maintenance of] crisis intervention
 52 [units] services, home attendant [teams] services, legal [aid units] as-
 53 sistance and ameliorative and supportive therapies.

54 § 4. Section twelve of such chapter of the laws of nineteen hundred
 55 eighty-three is amended to read as follows:

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1 § [12] 5. The sum of one hundred fifty thousand dollars (\$150,000), or
2 so much thereof as may be necessary, is hereby appropriated to the
3 department of health from any moneys in the state treasury in the gen-
4 eral fund to the credit of the state purposes account not otherwise ap-
5 propriated to establish, promote and maintain a public information pro-
6 gram regarding the acquired immune deficiency syndrome (AIDS) for the
7 purpose of providing [educational,] outreach, health and counseling ser-
8 vices for the general public, health professionals and targeted high
9 risk populations. No moneys shall be available for expenditure from this
10 appropriation until a certificate of approval has been issued by the
11 director of the budget and a copy of such certificate or any amendment
12 thereto has been filed with the state comptroller, the chairman of the
13 senate finance committee and the chairman of the assembly ways and means
14 committee.

15 § 5. Section fifteen of such chapter of the laws of nineteen hundred
16 eighty-three is renumbered section six.

17 § 6. This act shall take effect on the same date as such chapter of
18 the laws of nineteen hundred eighty-three takes effect.

Library References

Chemical Dependents \Rightarrow 11.C.F.R. Drugs and Narcotics $\{$ 221.

Code of Federal Regulations

Nondiscrimination requirements, see 45 CFR 84.1 et seq.

§ 1175. Confidentiality of patient records*Disclosure authorization*

(a) Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(b)(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the

court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

Prohibition against use of record in making criminal charges or investigation of patient

(c) Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

Continuing prohibition against disclosure irrespective of status as patient

(d) The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

Armed Forces and Veterans' Administration; interchange of records

(e) The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

Penalty for first and subsequent offenses

(f) Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

(g) Except as provided in subsection (h) of this section, the Secretary of Health and Human Services, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

This report is authorized by law (Public Health Service Act of 1946, Title 42, USC 2635) and is intended for use by the Centers for Disease Control and Prevention. It is necessary for the understanding and control of this disease.

DATE OF REPORT

Month Day Year

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

FORM APPROVED
OHS NO. 9820-0008

CDC CASE REPORT NUMBER

STATUS OF THIS REPORT

New case Update report

STATE/LOCAL CASE REPORT NUMBER

Report number box

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
CASE REPORT

I. BASIC PATIENT INFORMATION

PATIENT'S NAME

First Middle Maiden/Other

DATE OF BIRTH

Month Day Year

AGE AT DIAGNOSIS AIDS

Years

SEX

Male Female

RACE/ETHNIC ORIGIN

White Asian/Pacific Islander
 Black American Indian/Alaskan Native
Is patient of Hispanic (Latin American) origin? Yes No

RESIDENCE AT ONSET OF ILLNESS SUGGESTIVE OF AIDS

City County State/(Country) Zip Code

CURRENT CONDITION/PROGNOSIS

Outpatient/ambulatory
 Hospitalized, not critical
 Hospitalized, critical
 Dead

IF DEAD, DATE OF DEATH

Month Day Year

AUTOPSY PERFORMED?

Yes No

CDC USE

City
County
State

II. SPECIFIC CONDITIONS AND OPPORTUNISTIC INFECTIONS MOST FREQUENTLY ASSOCIATED WITH AIDS

Check all that apply, indicate anatomic site if appropriate, and give date of diagnosis or specimen collection and the most specific or reliable method of diagnosis used (write in code number from list at bottom of page).

	DATE OF SPECIMEN OR DIAGNOSIS	METHOD OF DIAGNOSIS	
	Month Year		
<input type="checkbox"/> Kaposi's Sarcoma (check all anatomical sites that apply) <input type="checkbox"/> Lymph Nodes <input type="checkbox"/> Mouth/Pharynx <input type="checkbox"/> Skin <input type="checkbox"/> Anus/Rectum <input type="checkbox"/> Internal Organs* <input type="checkbox"/> Other*	Month Year		Sites
*Specify site _____			
<input type="checkbox"/> Pneumocystis carinii pneumonia	Month Year		
<input type="checkbox"/> Toxoplasmosis, encephalitis or brain abscess	Month Year		
<input type="checkbox"/> Atypical (non-tuberculous) Mycobacterial infection (symptomatic disseminated, e.g. bone marrow or multiple organ involvement) <input type="checkbox"/> M. avium-intracellulare <input type="checkbox"/> Other species*	Month Year		Species
*Specify species _____			
<input type="checkbox"/> Candida esophagitis (Candida infections at others sites may be reported on Page 2)	Month Year		
<input type="checkbox"/> Cryptosporidiosis with chronic diarrhea (persisting > 1 month)	Month Year		
<input type="checkbox"/> Cytomegalovirus infection* (symptomatic disseminated, especially with documented pathology of lungs, intestine; exclude mononucleosis syndrome)	Month Year		Sites
*Specify site(s) _____			
<input type="checkbox"/> Cryptococcal infection: <input type="checkbox"/> Meningitis <input type="checkbox"/> Other	Month Year		Sites
<input type="checkbox"/> Herpes simplex infection, chronic ulceration (persisting > 1 month) Specify site(s) _____	Month Year		
<input type="checkbox"/> Progressive multifocal leukoencephalopathy (Papovavirus infection, brain)	Month Year		

METHODS OF DIAGNOSIS: (Not all methods are appropriate or acceptable for all diseases)

- 1 = Microscopy: cytology, histology
- 2 = Culture/microbiologic techniques
- 3 = Endoscopy: bronchoscopy, sigmoidoscopy, etc.
- 4 = Serology: Antibody titer, any technique
- 5 = Antigen detection, any technique
- 6 = Physical examination
- 7 = X-ray, fluoroscopy, etc.
- 8 = Ultrasound, CAT scan, etc.
- 9 = Unknown

OTHER OPPORTUNISTIC INFECTIONS AND CANCERS, some of which are listed below, may be associated with AIDS. In the following spaces, list these or other diseases the patient has had, the site of occurrence, the date of diagnosis or specimen collection, and the most specific or reliable method of diagnosis used (use code number from list below).

- o Tuberculosis, especially severe or disseminated (e.g., involving liver, marrow)
- o Nocardia infection (Nocardiosis)
- o Coccidioides infection (Coccidioidomycosis)
- o Lymphoma or reticulum cell sarcoma involving the brain only
- o Burkitt's lymphoma
- o Diffuse, pleomorphic, undifferentiated, non-Hodgkin's lymphoma

PATHOGEN/DISEASE	ANATOMIC SITE	DATE OF SPECIMEN OR DIAGNOSIS		METHOD OF DIAGNOSIS	CDC USE	
		Month	Year		Pathogen/Disease	Anatomic Site
_____	_____	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
_____	_____	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
_____	_____	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

METHODS OF DIAGNOSIS: (Not all methods are appropriate or acceptable for all diseases)

1 = Microscopy: cytology, histology 4 = Serology: Antibody titer 7 = X-ray, fluorescence, etc.
 2 = Culture/microbiologic techniques 5 = Antigen detection, any technique 8 = Ultrasound, CAT scan, etc.
 3 = Endoscopy: bronchoscopy, sigmoidoscopy, etc. 6 = Physical examination 9 = Unknown

III. INFECTIONS/CONDITIONS OCCURRING WITH BUT NOT SPECIFIC FOR AIDS OR AIDS PRODROME
 Check all that have occurred: None Unknown

- Amebiasis, persistent
- Herpes simplex, chronic or persistent vesicular infection
 - Mouth/Pharynx Genital Anal/Rectal Other
- Herpes zoster
 - Localized Disseminated
- Candida infection
 - Oral/Pharyngeal (thrush)
- Idiopathic/Autoimmune thrombocytopenic purpura
- Autoimmune hemolytic anemia
- Nephrotic syndrome
- Other (Specify) _____

<input type="text"/>	<input type="text"/>
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IV. SIGNS/SYMPTOMS PRODROMAL TO AIDS

Check all signs/symptoms persistent at least one month before onset of a specific infection/disease suggestive of AIDS. None Unknown

- Fever
- Night sweats
- Malaise/Fatigue
- Chronic lymphadenopathy, > 3 non-contiguous sites
- Arthralgias/Myalgias
- Weight loss, unexpected, > 15 pounds or > 10% normal body weight
- Chronic diarrhea
 - No pathogen/cause identified
 - Specific pathogen/cause identified (Specify) _____
- Persistent bone marrow dysfunction
 - Leukopenia (<4300/mm³) Lymphopenia (<1500/mm³)
 - Thrombocytopenia (<100,000/mm³)
- Other (Specify) _____

Approximate Date Onset
 First Sign/Symptom

<input type="text"/>	<input type="text"/>
Month	Year

<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>
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V. DISEASES OR CONDITIONS PRECEDING OR COEXISTING WITH DIAGNOSIS OF AIDS

Check all that have occurred: None Unknown

- Leukemia
 - Acute lymphocytic Chronic lymphocytic Non-lymphocytic
- Hodgkin's disease
- Non-Hodgkin's lymphoma
- Multiple myeloma
- Diabetes mellitus, insulin-dependent
- Renal failure, chronic
- Hepatitis, chronic
- Congenital immune deficiency syndrome (specify) _____
- Bleeding disorder/Clotting factor deficiency
 - Factor VIII deficiency (classical Hemophilia)
 - Factor IX deficiency
 - Other requiring factor replacement therapy (specify) _____
- Other (specify) _____

<input type="text"/>	<input type="text"/>
----------------------	----------------------

<input type="text"/>	<input type="text"/>
----------------------	----------------------

<input type="text"/>	<input type="text"/>
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VI. MEDICAL IMMUNOSUPPRESSIVE THERAPY

None Unknown

During 3 months preceding diagnosis of AIDS, did patient receive (check all that apply):

Systemic corticosteroids Cytotoxic chemotherapy/other immunosuppressive therapy

If yes, did symptoms of specific infectious disease precede immunosuppressive therapy? Yes No

VII. SOCIAL AND RISK FACTORS (Check all that apply)

Usual occupation(s) of patient during last 5 years _____

Marital Status: Never married Married Widowed Separated Divorced Unknown

Living arrangement of patient during year preceding diagnosis of AIDS:
 Alone With spouse With children With male companion(s) With female companion(s)

Was patient born in U.S. (50 states)? Yes No If no, date of arrival in U.S.

If patient or either parent were born outside U.S., what was country/territory of birth/origin?
 Canada Cuba Dominican Republic Haiti Mexico Puerto Rico

Cambodia/Vietnam/Laos Other (specify country/territory) _____

Has the patient ever used needles for self-injection of non-prescription drugs? Yes No Unknown

What is the sexual orientation of this patient?

Heterosexual Homosexual Bisexual None Unknown

Was the patient pregnant while ill with AIDS? Yes No Unknown

Has the patient delivered a live-born infant during the last 5 years? Yes No Unknown

During the five years preceding diagnosis of possible AIDS, did this patient:

	Yes	No	Unknown		Yes	No	Unknown
<input type="checkbox"/> Have sexual relations with a male partner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Been in jail or served a prison term?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Have sexual relations with a female partner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Receive Factor VIII concentrate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Have sexual relations with a person who now has AIDS?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Receive cryoprecipitate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Have close, non-sexual contact with a person who now has AIDS?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Receive Factor IX concentrate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Receive hepatitis B vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Receive blood or packed red cell transfusion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Receive hepatitis B immune globulin (HBIG)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Receive other blood components, e.g., platelets, plasma, etc?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Receive other immune globulins?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Donate blood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Undergo hemodialysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Donate plasma?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If patient has donated blood or plasma, what is the name and address of the last or most frequently used donation center?

Approximate date of last donation

Name of blood/plasma center _____ City _____ State _____ Month Day Year

VIII. LABORATORY DATA: Results before use of immunosuppressive therapy (cytotoxic drugs, steroids) preferred.

WHITE BLOOD CELL COUNT

PERCENTAGE LYMPHOCYTES

%

PLATELET COUNT (lowest value)

Date of Laboratory Tests

Month Day Year

T-LYMPHOCYTE SUBSET COUNTS: Check if T-cell studies not performed

Check if patient received steroids/other immunosuppressive therapy during month before T-cell studies

Percentage of Lymphocytes

T-HELPER (OKT-4, Leu-3) %

Percentage of Lymphocytes

T-SUPPRESSOR (OKT-8, Leu-2) %

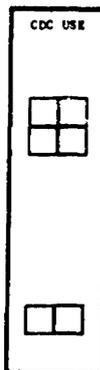
Date of T-Lymphocyte Tests

Month Day Year

T-HELPER/T-SUPPRESSOR (T_H/T_S) RATIO

Interpretation of T_H/T_S ratio for THIS patient is: Normal High Low

Range of normal values for T_H/T_S ratio at this laboratory: High normal Low normal



NEW YORK STATE AIDS TASK FORCE
INITIAL REPORT TO THE GOVERNOR

JUNE 21, 1983

Submitted by:

David Axelrod, M.D.
Commissioner of Health
AIDS Task Force Chairman

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AIDS: State Concerns and Responsibilities

The phenomenon of AIDS now looms as a major public health issue for government and science -- because of the puzzle that it represents for researchers, the peril with which it threatens certain people, and the anxiety it generates in the populace.

There are many questions which still lack answers. We know that AIDS primarily attacks intravenous drug users and homosexual males. But we don't know why. We don't even know if the syndrome represents a single disease entity.

This report emphasizes the urgent need for answers to address the concerns of designated "high risk" groups, service workers who care for AIDS victims or potential victims, and society at large before fear overcomes reason.

While AIDS may not compare to heart disease or auto accidents as a killer, it does represent a major and immediate challenge. The recommendations for action included in this report fall into four major categories of government responsibility:

1. Civil Rights. There is a pressing need to act firmly and directly to protect the civil rights of persons who are caught up in the AIDS fear that is spreading more quickly than the disease itself. Whole groups in our society are in danger of being needlessly ostracized and isolated. Haitians are being fired from their jobs for no reason other than their national origin, doctors are reluctant to treat patients, funeral directors are calling for a moratorium on full services for AIDS victims, and some voices in the popular press are suggesting that "God's revenge" is being visited upon certain members of our society. All state agencies, departments, boards, commissions and officers must avoid any prejudicial activity toward AIDS victims, their families, or the widely labeled "risk" groups. Furthermore, every available tool should be used to prevent such discrimination by others, primarily in the service industries.

2. Education. Ignorance, fear and misinformation are threatening to overtake science and reason. This is partly due to an apparent opportunism on the part of some scientists, and the natural impact of heightened publicity. There is no credible scientific evidence, for instance, that what we commonly call AIDS is actually a communicable disease. Yet it is frequently being defined as an infectious or communicable disease, resulting in escalating fears about AIDS spreading through casual contact, on dinner plates, in prisons, on bed sheets, on public transportation, and through blood transfusions.

To allay public fears, to stop the increasing isolation of persons identified as members of risk groups, and to disseminate accurate information on this issue, we must expand and accelerate our current education efforts. Just as we have worked with the Corrections Department to address the concerns of employees and inmates, we must provide relevant factual information to other occupational groups, such as doctors, hospital workers,

sanitation men, laundry workers, drug counselors and others. People need to understand that the only known routes of transmission are through homosexual activity and IV drug use, and that the risks outside those activities are not significant. We believe blood transfusions do not present a risk, but the public at large needs to learn and understand that fact, and many others.

3. Treatment. The tragic victims of this disease are mainly young, largely male, and commonly suffer from months or even years of anxiety as they wait for an opportunistic infection to attack their defenseless bodies. Because of fear and prejudicial treatment, they may also suffer from isolation, loneliness, loss of job and income, as well as the disease itself. It is more difficult to protect such persons from the infections that threaten them when society's normal network of support services desert them. We also have a significant number of AIDS victims in our state institutions, and they need special consideration.

Therefore, the state must make a major effort to provide appropriate treatment facilities for all institutionalized AIDS victims, to care for them in a comforting setting that protects them as much as possible from infection. And we must also use what authority and persuasive powers we have to assure that non-institutionalized AIDS patients are provided the care they need -- the care we would expect to be made available to any victim of a debilitating disease in our society. Furthermore, the state should continue to support, and expand, counseling programs for victims and potential victims and their families.

4. Research. With so much of what is now known about AIDS based on incomplete research reports, thumbnail sketches and inadequate data, there is a large gap in the scientific as well as popular understanding. Epidemiological questions about localized clusters of the disease, about drug use habits, about certain sexual practices, about the significance of the "risk groups" and the infections which strike them, all need investigation. As New York State is the unhappy host to roughly half the known cases, we have an ideal opportunity and a responsibility to pursue this research.

A whole range of clinical issues also needs to be investigated. Research on the immune system, which is already going on in connection with other diseases, must be expanded to focus on AIDS directly. The two main types of infections striking AIDS Patients may have some relationship to different strains of AIDS, different ratios of immune system actors in our bodies. The questions are numberless.

The risk to the general population appears now to be virtually nil, for the percentage of cases outside the basic risk groups is remaining constant at approximately 5%, even as the caseload mounts. But that is small comfort to those unfortunate people who live with the knowledge that they are susceptible. We have a grave responsibility, as the home of half the known victims. But we also have the opportunity, as you said on June 17, "...to set an example for the nation..." in attacking AIDS. Without hysteria, but with reason; without anger, but with compassion; without fear, but with honesty -- we can serve well all the people of New York.

Current Information About AIDS

During the past two years, a significantly increasing incidence of non-inherited immune suppression has appeared in the United States and to some extent in other countries. While the label Acquired Immune Deficiency Syndrome (AIDS) has been given to these cases, there is no definitive evidence that we are witnessing a single disease entity, with a common causative agent or etiology. Much of the current epidemiological and medical data, in fact, does not support the single disease concept.

Medical data

AIDS has been defined by the federal Centers for Disease Control (CDC) as the occurrence of specific, rare opportunistic infections or cancer in persons with no known cause for diminished resistance to these diseases. Such diseases include Kaposi's Sarcoma (a previously rare cancer); Pneumocystis carinii pneumonia (previously seen only in the very elderly or among patients undergoing chemotherapy or immunosuppressive therapy associated with organ transplants); or such serious opportunistic infections as central nervous system toxoplasmosis, gastrointestinal candidiasis, cryptococcal meningitis, a diarrheal illness caused by cryptosporidium and nontuberculosis mycobacteriosis. Unexplained combinations of prolonged fever, weight loss and swollen lymph glands may represent early forms or a mild variant of the syndrome.

Laboratory tests of AIDS victims indicate a significant reduction in the numbers of T helper lymphocytes (white blood corpuscles in the lymph glands) which are primarily responsible for cellular immunity. Lymphocytes of AIDS patients also show grossly depressed proliferation response to mitogens and antigens (foreign matter) in the blood stream.

It is noteworthy that the opportunistic diseases which affect AIDS patients are somewhat specific to the various "risk" groups. Homosexual and bisexual males tend to develop Kaposi's Sarcoma as the initial disease manifestation; IV drug user victims, Haitians and hemophiliacs most frequently develop Pneumocystis carinii pneumonia as the most virulent and fatal opportunistic infection. A few patients (approximately 10%) have developed both conditions.

The cause of AIDS is still unknown, although research is in progress at CDC and a number of medical centers across the U.S. Although all evidence indicates that the syndrome is not communicable through casual contact, it does appear in persons who have intimate sexual contact or who have experienced repeated intravenous injections. This phenomenon has led some researchers to speculate that the causative agent for AIDS may be a virus similar to hepatitis B. Whether an infectious agent is actually involved has not been established.

Since the disease tends to affect specific groups and has not spread beyond these groups, some physical or environmental factor or factors common to the host (or victim) may be contributory or causatory to development of the syndrome. One hypothesis is that the immune system of AIDS victims may already be damaged or compromised in some way, thereby increasing certain individuals' susceptibility to the condition. We know, for example, that certain infections, including hepatitis B, are more common among IV drug users and active homosexuals than among the general population. A number of AIDS victims also had a previous history of sexually transmitted disease (including herpes, gonorrhea, etc.) and laboratory tests have confirmed antibodies in the blood for hepatitis B and cytomegalovirus (CMV) among many of these victims.

Epidemiologic data

The national case summary issued by the Centers for Disease Control reports that nearly 95% of AIDS victims have been male, with more than 90% between the ages of 20 and 49. Based presumably on case histories provided by the victims, CDC has allocated approximately 71% of AIDS cases to the homosexual or bisexual "risk" category, and 17% to the intravenous (IV) drug use "risk" group. Approximately 5% of national AIDS cases have been reported among Haitian immigrants. A few persons with hemophilia, who are receiving pooled factor VIII concentrate therapy, have been diagnosed as having AIDS. A small number of cases nationally which currently do not appear to fall within these four risk categories are under investigation by CDC and local health agencies.

AIDS cases presently are clustered in certain geographic areas, with 80% of cases concentrated in six metropolitan areas, primarily in New York and California. Approximately 50% of all AIDS cases have been reported from New York State. Nearly 90% of IV drug associated cases have been identified in the northeastern U.S., primarily New York and New Jersey.

National incidence

Through May 18, 1983, 1,450 AIDS cases were confirmed nationally by CDC. Of these 558 had died, for a case fatality rate of 39%.

Of the 1,450 confirmed cases, 26% presented with Kaposi's Sarcoma (KS), 51% with *Pneumocystis carinii* pneumonia (PCP), 8% with both KS and PCP, and 15% with other opportunistic infections (OI) without KS or PCP.

Cases occurred in whites (57%), blacks (28%), and Hispanics (14%). Major risk groups include homosexuals or bisexuals (71%), IV drug users (17%) and Haitians (5%). Eighteen AIDS cases have been reported in hemophiliacs: 14 in the United States, 4 from overseas. CDC is also investigating 18 possible transfusion related cases.

New York State Incidence

Through May 18, 1983, 700 or 48% of the total United States CDC reported AIDS cases were in New York State residents: 660 or 45% from New York City and 40 or 3% from Upstate New York.

The epidemiologic features of New York State AIDS cases are determined from a statewide case registry in the Health Department which is updated on a monthly basis. Features of New York State AIDS cases are similar to United States cases in terms of:

	<u>NYS</u>	<u>USA</u>
% Male	93%	94%
% Black	29%	28%
% homosexual/bisexual	73%	71%
% aged 20-49	92%	91%

but differ in:

% White	50%	57%
% Hispanic	21%	14%
% with IV drug use	33%	17%

Of the 40 upstate New York AIDS cases reported by CDC as of May 18, 1983, 21 occurred among inmates in State prisons. As of June 7, 1983, the State Health Department has reports of 36 confirmed AIDS cases among State prison inmates with 7 other possible cases under review. All evidence indicates that these inmates contracted AIDS prior to imprisonment. The syndrome is now thought to have an incubation period of up to two years and virtually all inmates with confirmed AIDS had a prior history of IV drug use in the New York City area prior to incarceration. New Jersey inmates with AIDS also have a history of drug use in New York City. New Jersey is the only other state reporting AIDS prison cases.

If the prison inmate cases are removed from the upstate case total, as appears more appropriate, it is evident that AIDS is not a major disease entity in New York outside of New York City.

Risk to the General Population

At the present time there is no evidence that AIDS represents a risk to the general population. As indicated by the national case data, only 5% of reported cases currently appear to fall outside of the identified "risk" categories. That percentage has held steady even as overall case reports climb.

	<u>no. cases</u>	<u>% of total</u>
homosexual, bisexual	1031	71.0
IV drug use	248	17.0
Haitian	75	6.0
hemophiliac	12	0.8
* no apparent risk group	83	5.2

* These cases are still under study by CDC and state and local health personnel in an effort to discern potential risk factors. Some cases, initially reported "outside of the risk groups" have proven, upon further investigation, to fall within one of the risk categories.

It is noteworthy that not a single case of AIDS has been reported among health personnel, laboratory personnel or funeral directors. While some infection control precautions are now generally taken with AIDS patients' blood samples and body fluids, there was an approximate two year period before the syndrome was identified when AIDS patients' and laboratory specimens were handled in a routine manner.

Secondary cases, involving potential non-sexual transmission to household members or close companions of AIDS victims, have not been reported.

Based on all epidemiologic data to date, there is no evidence that AIDS is transmitted through casual contact, including:

- sneezing, coughing or spitting
- handshakes or other non-sexual physical contact
- toilet seats, bathtubs or showers
- utensils, dishes or linens used by an infected person
- food prepared or served by an infected person
- articles handled or worn by an infected person
- being around an infected person, even on a daily basis over a long period of time.

Blood Transfusion Risk

Following intensive evaluation of all data by a special AIDS task force appointed in 1983, the New York State Council on Human Blood and Transfusion Services concluded that the risk of developing AIDS from blood transfusions is remote and that adequate precautions to safeguard the blood supply to the maximum extent possible are being taken.

The following resolution was passed unanimously by the Council on June 8, 1983:

"Analysis of all the data collected to date has demonstrated no significant risk for recipients of blood or blood products for contracting the acquired immune deficiency syndrome (AIDS). Until further data now being accumulated can be evaluated, the added precaution being taken as a standard public health measure, is the voluntary exclusion of donors who are at high risk for exposure to AIDS. Evaluation of the laboratory tests currently available has failed to demonstrate that any one test or combination thereof has proven to be more effective than those measures already in place."

More than 12 million units of blood and blood components are administered to about 3 million people each year. There also are approximately 15,000 hemophiliacs in the U.S., each of whom has received frequent transfusions of pooled factor VIII, a blood clotting component which requires several thousand donors for each transfusion.

There have been 14 cases of AIDS reported among hemophiliacs in the U.S. and fewer than 10 additional cases which are currently under investigation for a possible link to blood transfusions. In only one case (a California infant with a platelet deficiency) was CDC able to identify an AIDS victim as a donor. The remainder of the blood acquired from this donor was administered to other recipients who did not develop AIDS. In addition, it is impossible to rule out congenital immune deficiency or immune system defects in the case of an infant.

Risk Groups

The reason for AIDS incidence among specific groups is not known. Outlined below is the known information potentially relevant to AIDS case identification among the various "risk" groups.

Drug Users: Virtually all AIDS victims who report intravenous drug use are from the northeastern U.S., primarily New York City. There is very little incidence of AIDS among IV drug users on the West Coast. It is presumed at this time, that AIDS case finding among IV drug users is related to sharing or re-using dirty needles, since Hepatitis B can be transmitted from person-to-person through this route. It is of note, that the Office of Drug Abuse reports that there are known "shooting galleries" in the New York City area where drug injection paraphernalia may be rented and that such equipment is not discarded or disinfected after each use.

One research group has published a study indicating that children born to IV drug user AIDS victims may have contracted the syndrome. The researchers acknowledge that the diagnosis of AIDS in these children is not confirmed, and that congenital immune defects and deficiencies are sometimes present in young children. All children involved in this study developed symptoms of immune deficiency within the first two years of life, generally within the first year. This may indicate that the condition was congenital or that AIDS may be acquired simultaneously by the mother and child across the placenta during gestation or through blood comingling at the time of birth.

Homosexual & bi-sexual men: Nearly 75 percent of AIDS cases occur in young men (ages 20-40) who acknowledge homosexual or bi-sexual activity. These cases are clustered in big cities (New York, San Francisco, Miami, Los Angeles) where large gay communities exist and sexual contact among strangers is readily available. A large percentage of the homosexual and bi-sexual AIDS victims report multiple sexual contact in "gay bath houses" or other "gay pick up" type facilities or clubs.

One CDC researcher in California was able to link 40 homosexual AIDS patients as having had sexual exposure to at least one other case. Of the 27 cases for which detailed information was available, 81.5% of the men were reported to have engaged in a sexual practice involving rectal trauma during the year before they fell ill. The practice, called "fisting" involves the insertion of a portion of the hand, or even the entire fist into the anus of another person. The males in this study also appeared to be very sexually active. The 27 men had a median of 120 sexual partners (50 percent of whom were strangers) during the year before the onset of symptoms. One individual reported up to 250 sexual partners in each of the three years prior to symptom onset.

The possibility of AIDS transmission through rectal trauma (fisting or anal intercourse) is under study as a potential risk factor associated with reported cases among homosexual males.

To date, there have been no reported cases of AIDS among known female homosexuals. The frequency and type of sexual activity engaged in by homosexual female partners differs from male homosexual behavior.

Haitians: Cases of AIDS have been identified among Haitian immigrants to the U.S. and also within the resident population in Haiti. The U.S. Public Health Service has epidemiologic investigators in Haiti attempting to determine whether AIDS cases there appear to represent the same syndrome, with similar "risk" factors to U.S. cases.

Tuberculosis and other infectious diseases are more widespread and less well-controlled in Haiti than in the U.S. The hypothesis has been made that the immune system of some Haitians may be compromised or "overloaded" by previous exposure to infectious agents.

Hemophiliacs: The fact that some hemophiliacs have developed AIDS has led to the concern that AIDS is transmitted through blood products. It is important to note that there are approximately 15,000 hemophiliacs in the U.S., yet only 14 cases of AIDS have been identified among this reported "high risk group." Hemophiliacs receive frequent transfusions of Factor VIII, a blood component derived from several thousand donors for each transfusion.

Blood clotting, like inflammation and wound healing, is part of the body's immune system response. Hemophiliacs, therefore, may be characterized as a group whose immune system is compromised by an inherited defect.

Preventive Measures

Based upon all available data on AIDS, the following preventive measures appear prudent until the exact cause of the condition is identified.

1. Illicit drug use should be avoided, particularly intravenous drug use;
2. Sexually active homosexuals should be advised to limit the number of sexual partners and to avoid sexual contact with individuals whose past health history is not known.

DEPARTMENT OF HEALTH

Submitted by: Dr. David Axelrod, Commissioner

Agency Concerns:

1. Public misconceptions: The Centers for Disease Control has adopted a premise that AIDS is caused by an infectious agent. The public has interpreted this to mean that AIDS is a highly communicable disease. Anxiety levels have risen among health care workers, prison guards and inmates, funeral directors, laundry workers, members of "high risk" groups and the general public - primarily in New York City. Daily press reports of specific AIDS cases and highly speculative research findings published almost daily in scientific journals has built a body of belief in misinformation and inaccurate data disseminated by opportunistic researchers, uninformed medical professionals and government spokespersons.

2. Inadequate case reporting & followup: AIDS is not yet a nationally mandated reportable condition. Voluntary reporting by physicians and hospitals has been occurring, however, there are no established protocols for required case data or followup, resulting in a lack of completeness, consistency and comparability in case information. Information on AIDS incidence and case data provided back to all states monthly by the Centers for Disease Control has been sketchy, often inaccurate and significantly delayed. Inconsistent coding of cases to place of treatment or death, rather than to place of residence at the time of onset of the syndrome has complicated local epidemiologic followup and research activities.

3. Civil rights concerns: The designation "high risk" has been assigned to specific sub-groups within the population, without accurate denominator counts of individuals within these groups as compared to reported numbers of AIDS cases. This labeling, combined with growing public panic about AIDS, can generate or reinforce prejudicial attitudes and lead to infringement of the human and civil rights of AIDS victims. With half of the AIDS cases nationwide, New York State should take a leadership role in pursuing epidemiologic descriptions of actual risk to sub-set populations and basic science research activities aimed at determining the characteristics of such populations which place them at risk for immune disorders.

Department Actions

1. Public Information & Education: The Health Department has granted a total of \$197,000 to the Gay Men's Health Crisis, Inc. in New York City for use in carrying out educational activities within the gay community. The organization has established a toll-free AIDS hotline and also provides personal counseling for victims and family members.

A total of 50,000 brochures, prepared by the Health Department, have been distributed within the State prison system in an effort to clarify misinformation which has prompted anxiety among guards and inmates. Brochures currently are being printed for dissemination to the general public through local health departments, health care facilities and other State agency outlets.

2. Addressing health personnel concerns: In March, 1983 the Department disseminated information on AIDS and general recommendations for patient care protocols to all hospitals in New York State. While we do not consider isolation of AIDS patients necessary, we have recommended that to allay employee concerns hospitals may wish to follow infection control protocols currently in place for patients with hepatitis B. Similar information has been provided in response to inquiries from laboratory personnel handling AIDS specimens and to funeral directors who expressed concerns about embalming the bodies of AIDS victims.

3. Case followup: The Department has worked cooperatively with CDC, local, county and New York City health department staff on AIDS surveillance activities to obtain voluntary case information on New York AIDS patients. A separate surveillance system for prison cases has been established in conjunction with the Department of Corrections.

4. Confidential Mandatory Reporting: At the request of the Department, the Public Health Council has taken emergency action to make reporting of AIDS cases by hospitals and physicians mandatory in New York State (effective June 20, 1983) to ensure the confidentiality of such data under the Public Health Law. The department will develop case reporting forms and detailed questionnaires to obtain accurate, consistent case data for use in case followup and research activities. The case reports will be used to establish a confidential statewide registry of New York cases.

5. Retrospective Prison Case Studies: The departments of Health and Corrections have worked cooperatively in evaluating AIDS cases among prison inmates. These epidemiological studies, published in three scientific articles, have demonstrated that virtually all AIDS cases among inmates in State prisons involve individuals with a prior history of IV drug abuse in the New York City area. There is no evidence that AIDS was contracted during incarceration or passed from one prisoner to another.

6. Laboratory Services: The Department's Center for Laboratories and Research (CL&R) provides general laboratory analysis for State and local government agencies and special laboratory services not otherwise available for hospitals and diagnosing physicians. Ongoing analyses related to AIDS diagnosis and treatment include:

Serology for: hepatitis virus
 cytomegalic virus
 Barr-Epstein virus
 Toxoplasmosis parasite
 Various fungi and yeasts
 Syphilis (treponema pallidum antibody)

Virus isolation of: Cytomegalic virus
 other common viruses

Identification and characterization: atypical mycobacteria.
 Pathologic diagnosis: Pneumocystis infection.

Recommendations:

1. Public information: The Governor's AIDS task force should mount a coordinated, multi-faceted informational campaign in an effort to convey accurate information to the general public, to dispel rumors and allay unwarranted public fears and to address the specific concerns of service workers who by nature of their occupations may come into proximity with AIDS victims. Planned activities include:

a. Establishment of an AIDS hotline within the Health Department to answer public inquiries.

b. Initiation of periodic seminars for representatives of the news media, during which questions may be addressed to State agency personnel knowledgeable in various AIDS issues. It is hoped that this technique may prompt the press to look toward the State for accurate background information and balanced perspective on "breaking" AIDS stories.

c. Distribution of informational materials on AIDS through all appropriate State agency outlets and mechanisms.

d. Identification of all State personnel and other professional and service occupations (physicians, health care workers, funeral directors, EMTs, institutional employees, drug counselors, life guards, etc.) which may have concerns about AIDS. Development and dissemination of accurate information to address the general and specific concerns of these groups.

2. Research Activities:

a. Prospective Prison Inmate Study: The department's Bureau of Communicable Disease Control (CDC) and Center for Laboratories and Research (CLR) are preparing tandem grant applications to be submitted to the National Institute of Health to evaluate New York State Correctional Facility inmates who are previous IV drug-abusers and hence "at high risk for AIDS."

The first stage of this research project involves a prospective cohort evaluation in which all entering inmates will fill out an extensive risk factor questionnaire on drug history and will receive a thorough physical exam and laboratory evaluation. The second phase proposes more extensive and sophisticated laboratory evaluation of blood and body fluids of those identified in the initial workup as potentially "high risk" for AIDS.

b. Lupus/AIDS research: The recent finding of abnormalities or "inclusions" in the cells of patients with lupus erythematosus, some forms of cancer, and immunodeficiency diseases including AIDS will be investigated by the Department's Center for Laboratories and Research. A grant proposal to expand on-going NIH-supported research activities will incorporate a simultaneous study of inclusions in AIDS patients.

c. Hemophilia: The department's recognized expertise in hemophilia research and hematology will be beneficial in further investigation of potential risk factors associated with reported AIDS cases among hemophiliacs. Our hematology laboratory is currently collaborating with the

Northeastern New York branch of the American Red Cross in an attempt to develop practical methods to improve the yield of factor VIII concentrates made by cryoprecipitation of single unit or small pool donations. This would provide an alternative for those mildly hemophilic patients who do not require large pool factor VIII concentrate. Research also is in progress to improve the safety and minimize the risk of potential contamination through factor VIII therapy. Information materials addressing the fears and concerns of hemophiliacs are currently under development.

d. Detection of Opportunistic Infections: AIDS victims most often die of the opportunistic infections or Kaposi's Sarcoma. These opportunistic infections are caused by an exotic group of microorganisms including bacteria, viruses, fungi and yeast. The Department's Center for Laboratories and Research currently functions as a statewide reference laboratory for identification of most of these organisms and, as such, provides assistance to State laboratories and health care facilities in the diagnosis of these agents. As an extension of these reference services, the Center will work toward:

-- Development of a serological test for *Pneumocystis carinii* (PCP) which could provide early warnings of the impending illness and, if so, allow therapeutic intervention. At present the diagnosis of PCP is made by microscopic examination of bronchial washings from suspected patients.

-- Development of a simplified test for toxoplasmosis which, along with PCP, is one of the more frequently detected opportunistic infections in AIDS victims.

-- Enhancement of the laboratory's current capability for isolating and subgrouping of cytomegalovirus (CMV) virus to determine if a particular subgroup of CMV is specific to AIDS patients.

DEPARTMENT OF CORRECTIONAL SERVICES

Submitted by: Dr. Raymond Broaddus, Assistant Commissioner for Health Services

Background Data

The first confirmed case of AIDS in the State prison system occurred in November, 1981. Since that time, 35 prison AIDS cases have been reported, with 18 deaths among inmates. Virtually all prison inmates with confirmed AIDS had a previous history of intravenous drug use in the New York City area. All evidence indicates that they contracted AIDS prior to incarceration; since the condition appears to have a one to two year incubation period.

Agency Concerns

1. Care for inmate AIDS patients: The correctional health service is basically designed to provide ambulatory care, with provisions for transfer of inmates requiring acute care to secure wards in outside hospitals. While this methodology has worked reasonably well in the past, it is being severely tested by the AIDS situation. Transferring a suspected AIDS case to an outside hospital for diagnosis and treatment is fairly routine. The problem develops when the outside facility discharges the inmate back to the institution. The inmate-patient whose opportunistic infection may have been arrested or stabilized is then placed in the receiving institution's infirmary which is geared to provide intermediate care and, when indicated, isolation. The above arrangement has become problematic given the limited isolation capability available within prison infirmaries.

2. Protection of inmate AIDS patients: While it is widely accepted that the primary mission of the Department of Corrections is to confine individuals committed by the courts so that society at large will be protected from them, there is also an obligation to protect inmates from other inmates who might be inclined to harm them. Given the existing public perception of AIDS as a "communicable disease" and the alarmingly high rate of anxiety among corrections' staff, (both uniform and non-uniform) and the inmate population, we have to consider AIDS patients as being victim prone.

Recommendations

To provide the most comprehensive care to inmate-patients who have contracted AIDS, a hospital setting, preferably in the New York City area, is prerequisite. The benefits to be derived from this go beyond the medical and psychological wellbeing of the inmate-patients. Since all prison AIDS patients are from the greater New York City area, their care in the City would simplify visits from family members.

Removing the AIDS inmate-patients from the prison system would greatly alleviate the fear and paranoia among staff and more importantly would greatly diminish the potential for a hostile and volatile reaction on the part of certain inmate factions.

The Department is prepared to negotiate reasonable financial arrangements with a contracting hospital subject to the approval of Division of Budget, and is committed to working out the security considerations for the proposed endeavor so that the interest of public safety will be appropriately served. It would be preferable to contract with New York City for the provision of security services for the secure hospital ward. In the event, however, that this proves to be impractical the Department is prepared to assume this responsibility.

COMMISSION OF CORRECTION

submitted by J. Kevin McNiff, Chairman

Background

In addition to the 35 reported cases of AIDS among State prison inmates, several cases have been diagnosed among prisoners awaiting sentencing at the Riker's Island facility. Fears and concerns are being expressed by correctional staff at all levels of the criminal justice system, including State and City facilities, county jails and local lockups.

Recommendations

1. Education: Development and continuation of educational programs on AIDS for inmates and employees is essential at all levels of the criminal justice system.
2. Evaluation and Diagnosis: Protocols are needed for use in the prison system regarding currently accepted procedures for evaluation and diagnostic workup of AIDS patients. The plan should be developed on a systemwide basis to ensure continuity and accuracy in evaluation, treatment and statistical analysis.
3. Patient Care: Definite plans should be developed for uniformity and continuity of care at the primary, secondary and tertiary levels, including the possible concentration/consolidation of services.
4. Safeguards: Plans should be developed for implementing safeguards to reduce risks for unaffected inmates and employees within the limits of current knowledge regarding AIDS.
5. Program Services: It is important to ensure that AIDS inmate-patients undergoing treatment are afforded reasonable access to program services as their conditions permit, particularly if consolidation of services is anticipated.

INSURANCE DEPARTMENT

submitted by James P. Corcoran, Superintendent of Insurance

Background

The Insurance Department has the responsibility of informing the public about insurance matters. As part of this responsibility the Department has directed its efforts to educate insurance consumers as to the scope and level of coverage available to them under health insurance contracts.

Issues

A comprehensive health insurance policy delivered or issued for delivery in New York State will provide coverage for AIDS to the same extent that coverage is provided for other illnesses. Coverage for a specific disease or syndrome such as AIDS may not be excluded from the contract. If the health insurance contract covering an individual who has contracted AIDS provides benefits for preventive care and diagnostic and screening services, such coverage will be provided when the services are rendered as a result of AIDS. It should be noted, however, that many insurance policies do not provide coverage for preventive, diagnostic and screening services. Other policies, such as hospital indemnity insurance, are not comprehensive and would not provide benefits for physicians' services rendered to a victim of AIDS.

DIVISION OF SUBSTANCE ABUSE SERVICES

submitted by Julio A. Martinez, Director

Background

Intravenous (IV) users of illicit drugs account for the second largest group of AIDS victims; in New York City IV users account for 33 percent of identified AIDS cases. Current Center for Disease Control reporting methods count AIDS patients who are both homosexuals and IV drug users only as homosexuals. This significantly undercounts the proportion of IV drug users, who may account for as many as 25 percent of AIDS victims nationally.

There are 35,000 former IV drug users currently in methadone maintenance and drug-free treatment programs in New York State. An additional 250,000 persons have used drugs intravenously within the past three years; about 75,000 of this group are current IV drug users. While heroin is the major abused drug, the recent sharp increase in cocaine use (which is continuing to climb) has contributed to a further growth of IV users.

The problem is most acute in New York City, where the majority of IV drug users reside and where there is a proliferation of "shooting galleries." Injection paraphernalia are rented at the galleries, where observations indicate that needles are almost never sterilized and are typically used by at least 25 persons before being discarded. There are a minimum of 1,000 such "galleries" in New York City.

Recommendations

1. Education: Education efforts should be instituted to alleviate undue concern among clients and program staff, to ensure reporting of suspected cases and delivery of prompt medical attention, and to reduce activities currently implicated in AIDS, such as IV drug use. All the publicity that AIDS has received in the media has caused concern, similar to that of the prison guards, among program and laboratory staff personnel. The education efforts should be targeted for treatment program staff, for current and former IV drug users, and for the spouses and families of these individuals.
2. Monitoring: Monitoring should be undertaken to assess the incidence of AIDS among former and present IV drug users, to ensure identification of all AIDS cases, to define those groups at risk, and to note any changes in risk groups. These efforts should include monitoring of former IV users now in methadone or drug-free treatment for AIDS symptoms and for knowledge of persons who have AIDS symptoms, and monitoring and epidemiological surveillance of active street IV drug users.
3. Research: Research is necessary to explore and define the etiology of AIDS, to study possible methods of transmission, and to ascertain possible effective treatment and preventive measures. Research efforts should include reexamination of pathology reports and tissue samples of suspected but unconfirmed IV user AIDS deaths; case control studies among IV drug users, "shooting gallery" IV drug users, and current IV AIDS cases, and natural history studies of active IV AIDS cases.

OFFICE OF MENTAL HEALTH

submitted by William Morris, Acting Commissioner

Background

As of May 31, 1983, among the forensic facilities and New York City psychiatric centers, one confirmed AIDS case was reported. This patient is being treated in a community hospital. There has also been a suspicion of AIDS in the death of two staff persons over the last year.

The Office of Mental Health (OMH) serves some 23,000 inpatients in 27 adult and forensic psychiatric centers throughout the State. An additional 110,000 patients are served through the outpatient system. Medical literature and the general, yet limited, knowledge available regarding AIDS indicates that two subsets of the OMH inpatient population may be at significant risk of contracting the disorder: the 1,325 forensic patients admitted each year to two OMH free-standing forensic facilities and four regional forensic units; and some 11,000 patients admitted annually to our five New York City psychiatric centers.

If homosexuality and intravenous drug abuse are contributing factors in the development of AIDS, the OMH forensic population, which sometimes mirrors the correctional population and patients admitted to New York City psychiatric centers, where there is a history of high incidence of drug abuse on admission, are patient groups that may require special intervention. These assumptions can be more seriously considered when we recognize that:

- 90% of all patients admitted to Central New York Psychiatric Center (CNYPC), an acute care forensic facility, come directly from State correctional facilities where they are serving sentences. Upon discharge from CNYPC, patients usually return to the correctional system.

- 98% of all patients admitted to Mid-Hudson Psychiatric Center (MHPC) come directly from county jails. This population includes patients found incompetent to stand trial, and those not responsible by reason of mental disease or defect. Upon discharge, depending on their legal status, these patients may be transferred to jails, prisons, or adult psychiatric centers.

- The incidence of intravenous drug abuse among patients admitted to New York City Psychiatric Centers may be as high as 20%.

Concerns

1. Care for AIDS patients: OMH facilities will encounter difficulties in dealing with AIDS patients due to a limited ability to provide in-house treatment, and current difficulties OMH facilities encounter in acquiring services from community hospitals. The demand by some hospitals that OMH facilities send 24-hour staff supervision with patients admitted for care imposes a heavy burden on already diminished inpatient staff resources.

2. Information: There is a need for OMH facilities to receive current information and guidance on prevention and treatment of AIDS patients.

Recommendations

1. An interagency information/education process should be considered to reduce the fear and stigma attached to this syndrome.

2. OMH would like additional clinical support and direction from the Department of Health in planning for the medical treatment needs of OMH patients, including laboratory diagnoses.

3. The possibility of developing an interagency uniform screening process, to be used at admission and discharge, should be considered. This system would assist in early detection and more accurate diagnosis of the syndrome. Blood transfusion history should be considered in the process.

4. Statewide interagency guidelines should be developed defining adequate diagnosis and preventive measures for AIDS. A uniform reporting procedure, which generates consistent data, should be considered when developing such guidelines.

5. Research being conducted at the State level or through CDC should also be targeted to potential high risk groups in the OMH inpatient population.

6. OMH requests the assistance of the Department of Health in identifying community hospitals in each region for the prudent transfer, treatment and isolation of suspected or confirmed AIDS cases.

Mr. WEISS. Mr. Rosen, in the course of your testimony you referred to the fact that only patients with the CDC-defined AIDS have any chance at all of receiving assistance from the Government. Has there been any discussion with CDC or SSA that you know of about altering the definition of AIDS for the purpose of disability benefits?

Mr. ROSEN. Not that we know of. There has been no discussion with the CDC from ourselves and from any of our attorneys. But we are beginning to get more and more complaints from more and more people, people who have diseases like herpes oster, people who have programmable symptoms of AIDS and who really should not be working but are not able to get disability insurance.

The CDC definition is a very limited definition of a certain number of diseases.

Mr. WEISS. We have had testimony about the medical cost per patient, and how it overburdens not just the individuals, making them in many instances destitute, but also the institutions and the localities in which they receive the health care.

The numbers we have received range from \$60,000 to \$100,000. Do you know how those figures were arrived at and whether they are accurate?

Mr. ROSEN. Those are not my figures, except I can tell you those figures are accurate. I am a social worker, Mr. Chairman, I have clients, I have about four clients now who have AIDS. One of my clients passed away 3 weeks ago. He was a man who made \$40,000 a year at the time of his death—after being in the hospital four times over the course of 2 years, his hospital bills were approximately \$100,000. I don't know what the numbers were testified about before would come to. But I can tell you they are certainly accurate based on reality.

Mr. WEISS. Did that involve, if you know, any costs for the experimental drugs such as interferon that were referred to earlier by Mr. Ferrara?

Mr. ROSEN. No, they were not, not in my cases.

Mr. WEISS. And finally, in the course of your testimony, I think on page 9, you refer, but only obliquely, to what you see as the potential for the disease, the epidemic, crossing the relatively narrow at-risk communities where they are now prevalent.

Could you expand on that? I am not sure that I really understood what you were saying.

Mr. ROSEN. Well, most of the researchers—not everyone would agree with this—but many researchers would say that whatever this is, it seems to be transmitted sexually. And people in their lifetime at different points in their lives have different types of sexuality. People are not static in their sexuality. People are not all heterosexual, they are not all homosexual. Some people are bisexual. And throughout their lives they cross over. It is sort of a line that goes back and forth. Not everybody goes back and forth, but some people do, more people than you might want to hear about.

If those people, and people are bisexual, and people are having sexual contacts with men and with women, it stands to reason that somewhere down the line, if we have an incubation period of from 1 to 3 years here, the epidemic is going to spread out of it to the at-risk populations.

Mr. WEISS. Thank you very much.

Mr. Walker.

Mr. WALKER. I have no questions.

Mr. WEISS. Mr. McCandless?

Mr. MCCANDLESS. I have no questions.

Mr. WEISS. I guess I have one area that I want to ask about.

You referred to the Doctors Against AIDS, was it?

Mr. DAIRE. Yes, Dallas Doctors Against AIDS.

Mr. WEISS. Tell me about that. What is it about?

Mr. DAIRE. First of all, none of these doctors are Dallas doctors. They all live in suburban areas of the Dallas region. Two are medical directors, one is a dentist, and the others are doctors of philosophy. None of them have approached the subject of AIDS from a combating AIDS standpoint. In fact, attached to my testimony is an introduction of a bill by Representative Bill Severa which was very strongly supported by the Dallas Doctors Against AIDS, and it is very easy to see that it is not really Dallas Doctors Against AIDS, it is Dallas doctors against homosexuality and our lifestyle, nothing to do with AIDS, except the fact that they use AIDS as a weapon against us.

Mr. WEISS. The attachment that you have will be entered into the record, without objection.

Incidentally, I had forgotten to request earlier that the attachment Dr. Siegal had in his testimony also be entered into the record.

Finally, Mr. Collins, how real is the concern that individuals have, in your estimation, about having their rights of privacy and confidentiality violated by the Government?

We have heard references not only from you, but from other witnesses. Is that an abstract civil liberties concern, or is this a real concern of real people about what will happen to them individually?

Mr. COLLINS. I believe it is a real concern, as has been demonstrated several times today in other testimony.

Moreover, we have heard the call for a central information bank for research purposes. And I would fully support that. But should such an information bank be set up, there does need to be some sort of control over that kind of information. We have seen a blossoming of lists. In my limited amount of work that I have done, I have heard of lists in the blood centers, I have heard of lists in the CDC, I have heard of lists in the health departments, in State health departments, I have heard of the CDC sending a list to the State health departments, I have heard of mistakes by the CDC. And that is the real issue.

The issue is human error as well. There is room for human error. The more you generate more lists, the much more room for human error. There needs to be some built-in protection, especially in light of the information that is being collected.

Mr. WEISS. I want to thank all of you, indeed all of our witnesses today. Your testimony was just outstanding. We appreciate your giving us the benefit of your knowledge and expertise in this area.

I know that we will make good use of the testimony in the course of the ongoing proceedings of this subcommittee.

With your testimony, the hearings today are concluded, if there are no further questions by members of the panel.

Tomorrow we will reconvene at 9:30 and we will hear from the administration and its representatives as well as from public health officers from various parts of the country. The time for the hearing tomorrow morning is 9:30. It will be in this room.

The subcommittee now stands in recess until tomorrow morning.

[Whereupon, at 4:10 p.m., the subcommittee adjourned, to reconvene at 9:30 a.m., Wednesday, August 2, 1983.]

FEDERAL RESPONSE TO AIDS

TUESDAY, AUGUST 2, 1983

HOUSE OF REPRESENTATIVES,
INTERGOVERNMENTAL RELATIONS
AND HUMAN RESOURCES SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:41 a.m., in room 2154, Rayburn House Office Building, Hon. Ted Weiss (chairman of the subcommittee) presiding.

Present: Representatives Ted Weiss, John Conyers, Jr., Sander M. Levin, Buddy MacKay, Robert S. Walker, Alfred A. (Al) McCandless, and Larry E. Craig.

Also present: Representative Barbara Boxer.

Staff present: James R. Gottlieb, staff director; Susan Steinmetz, professional staff member; James F. Michie, chief investigator; Gwendolyn S. Black, secretary, and Hugh Coffman, minority professional staff, Committee on Government Operations.

Mr. WEISS. The subcommittee will come to order.

The purpose of this 2-day hearing is to explore a number of questions relating to the outbreak of AIDS:

Are adequate resources available for research, treatment, and prevention?

How comprehensive are the research and surveillance activities?

Has the Government's response been timely?

What is the extent of coordination of the efforts to fight the epidemic?

What is the scope of public education and how effective is it?

How accessible is health care for persons with AIDS?

Is the confidentiality of those who suffer from AIDS being protected?

After listening to the witnesses who testified before the subcommittee yesterday, I have grave concerns about the Federal Government's response to the AIDS emergency.

Three men who have AIDS courageously came forward and told their individual stories. The most disturbing aspect of their testimony was what they viewed as an agonizingly slow response by Federal health agencies. One person suffering from AIDS said, "I came here today in the hope that my epitaph would not read 'Died of red tape'."

A physician echoed that sentiment when he described the Federal effort as "bordering on the negligent."

In the testimony of the 16 people we heard from yesterday—representatives of the affected communities, the medical and research

communities, and volunteer service organizations—most frequently vocalized was the desperate need for additional funding. Money is required for greatly expanded epidemiology research and surveillance activities, for dissemination of accurate information about AIDS to both the medical community and the public, and for an array of support services such as outreach, early screening, therapy, legal assistance, home and hospice care, medical referrals, and crisis intervention.

The witnesses also spoke about specific weaknesses in the Federal response to this public health emergency, weaknesses that deserve the close scrutiny of this subcommittee: a lack of adequate financial resources for research into the cause, cure, and prevention of the disease; a lack of a comprehensive plan to coordinate research efforts across the country, and a lack of sensitivity toward the victims' need for confidentiality.

To meet even the limited AIDS research budget it has allocated to date, it became clear yesterday that the Federal Government may be funneling funds away from crucial research activities in other health areas. The impression that the administration is trading one public health program for another to satisfy politically imposed budget constraints is inescapable.

There was also evidence to suggest that the present epidemic of fear could have been avoided if an aggressive education and research campaign had been undertaken by Centers for Disease Control.

The many concerns raised by these witnesses, when combined with the refusal of the Department of Health and Human Services to provide this subcommittee with full access to its staff and records during the course of our oversight work, lead me to question very seriously whether the administration is indeed committed to mobilizing maximum Federal resources as swiftly as is humanly possible to conquer this dread disease.

I look forward to the testimony of the officials representing HHS who will explain the Federal position in the second half of today's hearing.

Because of the refusal of HHS, beginning with Secretary Heckler, to cooperate with this subcommittee in discharging our constitutional responsibilities, we are lacking the full documentation that would normally be available to us prior to questioning administration officials. Consequently, I intend to schedule future hearings once we have obtained the appropriate documents.

We will begin with the testimony of three public health professionals. But before I call on them, let me take note of the fact that we do have a quorum present; that we again have Mrs. Boxer, who is a member of the full committee, with us. Without objection, she will continue to participate with the subcommittee in the course of today's hearings.

And at this time let me call on our ranking minority member, Mr. Walker, for whatever opening remarks he may choose to make.

Mr. WALKER. Thank you, Mr. Chairman.

I think that you have outlined with some specificity the concerns that were raised by the groups that appeared before us yesterday, and the individuals that appeared before us. Hopefully today's hearings will begin to put some of those concerns into perspective,

by giving us an opportunity to hear from the professionals in the Government who have been dealing with the problem and will give this subcommittee and the Nation a little better idea of what the response has been to the AIDS problem, and what our future course of action will be with regard to same.

Thank you, Mr. Chairman.

Mr. WEISS. Thank you, Mr. Walker.

Is there any other member of the subcommittee who wishes to make an opening comment?

Mrs. Boxer?

Mrs. BOXER. Thank you, Mr. Chairman. Again I have an opportunity to thank you for allowing me to sit in with the subcommittee and tell you that I share the concern that you expressed yesterday, I share with you the concern that you expressed regarding this whole matter—concern about the inadequate level of funding for AIDS research, concerned about the slow pace of Federal action, concerned about the lack of an overall program emanating from the Federal Government, and I am very concerned about the stigma given to the Haitian community. I think Haitians have been stigmatized with what appears to be sloppy questioning and research. I am hopeful we can get to the bottom of that today.

I am also looking forward to the testimony so that I can leave this room today feeling a little better about the state of this whole program.

Thank you again for this opportunity.

Mr. WEISS. Thank you very much, Mrs. Boxer.

We have two panels this morning. Our schedule is to continue through the morning and the early afternoon. We will have to adjourn when the House begins to consider legislation which this subcommittee is directly involved in, specifically the revenue sharing program. I anticipate that to be somewhere between 1 and 2 p.m., therefore, we will not be breaking for lunch. We may take a brief break just to allow all of us a chance to move about for a little bit.

We will begin the testimony with three public health professionals: Dr. David Sencer, commissioner of health, New York City, and Dr. Mervyn Silverman, director of health, San Francisco, will explain how the local health departments in the two U.S. cities most hard hit by the epidemic are coping. We will also hear from Stanley Matek, immediate past president of the American Public Health Association, who will offer a broad public health perspective.

We will seek to learn the panel's views regarding the sufficiency of resources available to public health workers at the local level.

As you gentlemen may know, this subcommittee is an investigative and oversight committee and, therefore, swears in its witnesses. So if you would at this point rise, I will offer the oath of affirmation.

Do you affirm or swear that you will tell the truth, the whole truth, and nothing but the truth?

Let the record indicate that each witness nodded in the affirmative.

Thank you very much.

Let me welcome all three of you on behalf of the subcommittee. Dr. Sencer, if you will begin, we will continue from there.

**STATEMENT OF DAVID J. SENCER, M.D., M.P.H., COMMISSIONER
OF HEALTH, NEW YORK CITY, N.Y.**

Dr. SENCER. Thank you, Mr. Chairman, members of the committee.

I am Dr. David Sencer, commissioner of health in the city of New York. It is an honor to appear before you today to discuss the problems that the city is facing because of the continuing occurrence of AIDS. It is a problem to the city; it is a problem to the people with AIDS, to the general public and the city government.

First, to talk of the problems that the people with AIDS have. As of July 13, 1983, 877 individuals in New York City had been diagnosed to have AIDS. At least 351 have died. Seventy percent were homosexual or bisexual males, and 22 percent were IV drug abusers.

These data illustrate the extent of the problem. But what do these figures mean to the persons with AIDS? It means a long debilitating illness, usually culminating in death. It means loss of income. It means medical bills that can't be paid because insurance coverage runs out, because coverage is disallowed for many of the procedures that are necessary for the diagnosis and often experimental treatment or because they have no coverage.

It means discriminatory actions by employers, landlords, and the general public. It means a constant threat to the privacy of the individual with the disease—the risk of public knowledge of an individual's sexual orientation or illegal habit or residence status.

I would like to add a word on behalf of the plight of the drug addict. They have no spokespersons. Yet, they represent at least 20 percent of the diagnosed cases in New York City. It is a tragedy that the programs for drug abuse that could obviate the need for dirty needles are at this point in time being cut back when a new and deadly health problem is moving through this population.

What are the problems for the general public? Fear of the unknown. How is this expressed? By suggestions of quarantine, by discriminatory actions, by irrational behavior.

What are the problems for the city? Coping with close to 1,000 persons in need of a completely different type of assistance, and a different approach to problems. At any one time, about 200 patients are in the hospitals of New York City requiring complicated intensive care, expensive beyond comprehension. For each one of the persons in the hospital, there are two patients not in need of hospitalization, but in need of income maintenance, housing, home nursing care, a job. Because of the diagnosis, barriers are erected that would not be there for a patient with a disease such as Hodgkin's Disease.

What approaches have been taken by New York City to cope with these problems? First has been the need for an educated professional population, for without this base it is difficult to develop patient and public understanding. A monthly seminar is held for all health care professionals working with the patients, to facilitate early and informal interchange of information. To develop this information, an intensive surveillance function is provided by the health department in conjunction with and support of the Centers for Disease Control.

The information from this surveillance is reported monthly, a copy of which is attached to this testimony. We are about to enter into a collaborative study to verify the reporting of cases in the surveillance.

Second, there is a need for informed and understanding care givers. To this extent, Mayor Koch has established an interagency task force which meets biweekly, with representatives from all the city agencies involved with health, welfare, housing, and other social services. This group is augmented by representatives of the gay community and the Haitian community, as well as persons with AIDS and other concerned groups. The role of this group is to identify problems and seek ways in which they can be solved.

Unfortunately, they cannot all be solved. For example, there is no way in which such a group can prevent loss of jobs because a patient has AIDS. But it can be established that this is a problem and ways sought to educate employers that AIDS patients are not a risk to others in the normal course of employment. This is being done, for example, by working with the New York City Business Group for Health, which reaches most of the major employers and the personnel departments of most corporations.

Also, there is a need to keep the health care providers supplied with current accurate information so that patient care is not compromised by ignorance. This is a subject of another monthly meeting of hospital administrators, labor unions, and physician groups.

Third, there is a need to provide accurate and timely information to the public to prevent or modify concerns. This is done through pamphlets, hotlines, speaker's bureaus, press conferences. The mayor's last statement is attached.

I could continue to describe the multitude of activities undertaken in the city, but I prefer to focus on two issues: confidentiality and costs.

There is great concern among the various risk groups that their privacy not be invaded, and that there be guarantees that when their names are given, there will be adequate protection of the names from groups who have no need to know. It is also in the interest of the individual patient and his health care giver to have available in a protected manner the names, so that patients can be contacted when necessary, if new tools of diagnosis and treatment become available.

It is also in the interest of scientists engaged in finding cause, prevention and cure to be able to match records accurately. It is for these reasons that the city health department is not furnishing names to other agencies, but has developed a system to assure the safeguarding of names within the department and providing matching services to others in the legitimate medical research community.

Finally, a few words about costs. The cost of suffering and social ostracism cannot be measured. The costs of medical care for the syndrome are next to impossible to estimate. But let us make a few assumptions, erring on the conservative side.

We estimate about 200 patients to be in hospitals in New York City on any given day. If we assume a cost of care to be \$1,000 per day, this leads to an annual cost of \$73 million. If this is not catastrophic illness, I don't know what is.

I would hope that a lasting legacy to those who have suffered from AIDS might be a reconsideration of reimbursement policies with a goal of broader coverage for those illnesses that no individual or no single community can afford.

I will be pleased to answer any questions.

Mr. WEISS. Thank you very much. All the attachments mentioned in the course of your statement will, without objection, be entered into the record.

[The attachments follow:]

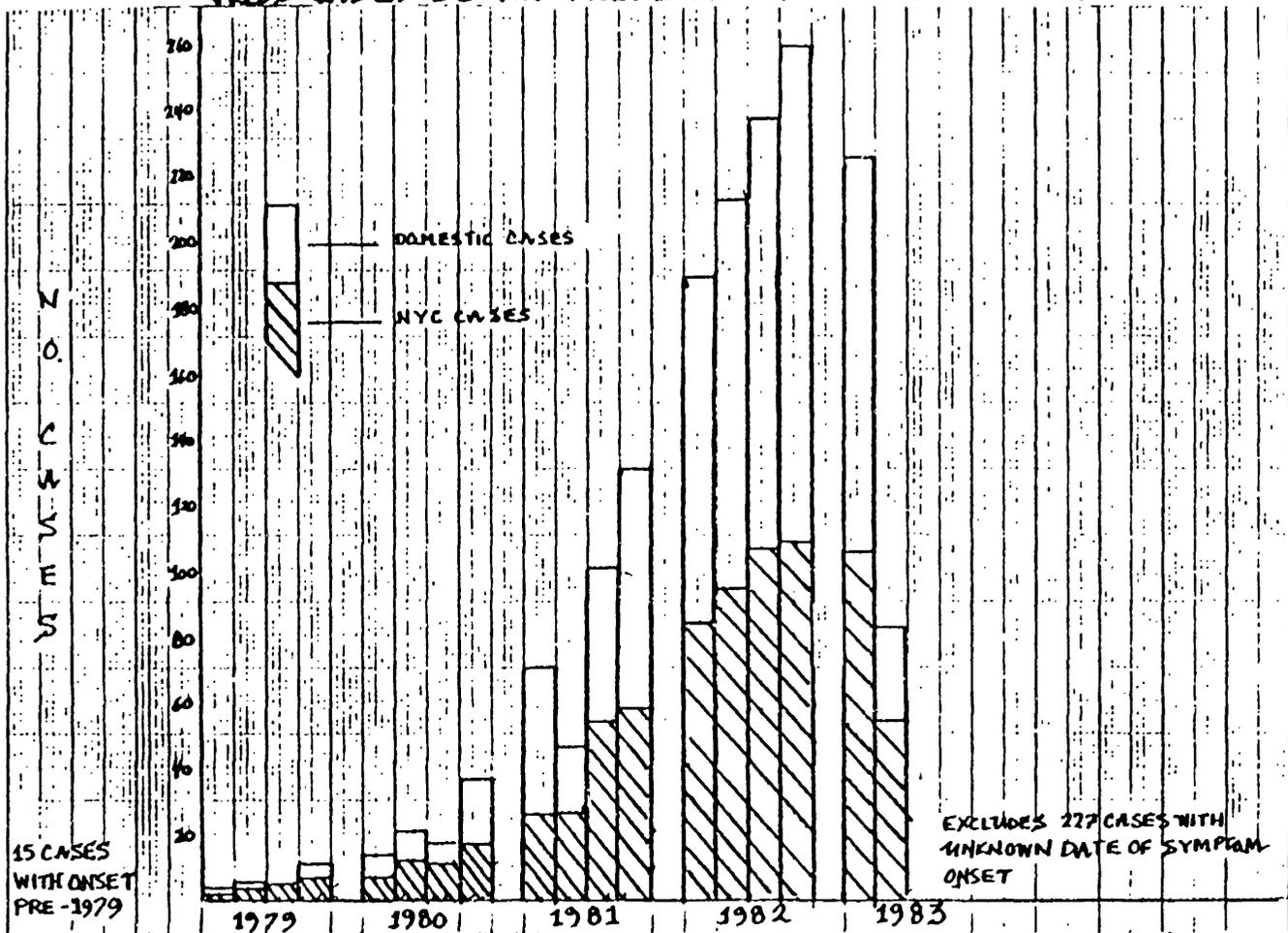
AIDS - SURVEILLANCE UPDATE*

JULY 27, 1983

SURVEILLANCE OFFICE: (212) 566-3630

*THESE DATA ARE OF A PRELIMINARY NATURE FROM AN ONGOING INVESTIGATION

AIDS CASES BY QUARTER YEAR OF SYMPTOM ONSET



NEW YORK CITY SURVEILLANCE - REPORTED CASES: June 16 - July 13, 1983

<u>MALES</u>	<u>NEW CASES</u>	<u>TOTAL CASES</u>	<u>%TOTAL MALE CASES</u>
Kaposi's sarcoma (KS)	38	299	(37)
<u>Pneumocystis carinii</u> pneumonia (PCP) without KS	34	374	(46)
Other opportunistic infections (OOI) without PCP or KS	8	133	(17)
TOTAL MALES:	80	806	
<u>FEMALES</u>	<u>NEW CASES</u>	<u>TOTAL CASES</u>	<u>% TOTAL FEMALE CASES</u>
KS	0	4	(6)
PCP	3	44	(62)
OOI	5	23	(32)
TOTAL FEMALES	8	71	
TOTAL CASES	88	877	
CDC National Surveillance:	July 16, 1983		
Total Domestic Cases:	1902		
Total Foreign Cases :	121		

TRENDS: AIDS CASES BY MONTH, NEW YORK CITY

<u>Month</u>	<u>Number Diagnosed</u>		<u>Number Reported</u>
	<u>As of 7.13</u>	<u>As of 6.15</u>	
<u>1982</u>			
July	33	(31)	36
August	41	(39)	42
September	45	(45)	38
October	51	(51)	30
November	44	(43)	47
December	39	(37)	39
average no./mo.	42		37
<u>1983</u>			
January	62	(61)	55
February	43	(42)	68
March	51	(47)	65
April	52	(40)	49
May	46	(28)	58
June	48	(9)	81
July	5		20
average no./mo. (Jan. - June)	50		63

OTHER OPPORTUNISTIC INFECTIONS IN CASES WITHOUT KS OR PCP
NEW YORK CITY

	<u>No.</u>	<u>(%)</u>
Candida (esophageal)	41	26
Cryptococcus (CNS)	28	18
Toxoplasmosis (CNS)	27	16
Cytomegalovirus	17	11
Herpes simplex (lesion 1 mo.)	15	10
Atypical mycobacterium	11	6
Cryptosporidium	9	6
Mycobacterium tuberculosis*	5	3
Lymphoma (CNS)	1	1
Progressive multifocal encephalopathy	4	3

* These individuals subsequently had a second, more serious opportunistic infection diagnosed.

AIDS CASE MORTALITY BY HALF YEAR OF DIAGNOSIS, NEW YORK CITY

	<u>No.</u> <u>Diagnosed</u>	<u>No.</u> <u>Dead</u>	<u>(%)</u>	<u>Cumulative</u> <u>No. Dead</u>	<u>(%)</u>
1st half 1978	0	0	(0)	0	(0)
2nd half 1978	2	0	(0)	0	(0)
1st half 1979	1	1	(100)	1	(33)
2nd half 1979	5	4	(80)	5	(63)
1st half 1980	9	6	(67)	11	(65)
2nd half 1980	15	14	(93)	25	(78)
1st half 1981	41	30	(73)	55	(75)
2nd half 1981	93	67	(72)	122	(75)
1st half 1982	146	60	(41)	182	(58)
2nd half 1982	253	95	(38)	277	(49)
1st half 1983	301	74	(25)	351	(41)

7-16-83

AIDS CASES BY MUTUALLY EXCLUSIVE RISK GROUP, BY
HALF YEAR OF SYMPTOM ONSET, NEW YORK CITY

<u>Year</u>	<u>Number of cases</u>			
	<u>Homosexual/bisexual</u>	<u>IV User</u>	<u>Haitian</u>	<u>Other</u>
1st half of 1978	8	0	0	0
2nd half of 1978	0	0	0	0
1st half of 1979	4	1	1	1
2nd half of 1979	8	2	0	1
1st half of 1980	15	1	0	0
2nd half of 1980	32	4	1	1
1st half of 1981	51	10	2	0
2nd half of 1981	86	17	2	3
1st half of 1982	119	45	6	13
2nd half of 1982	143	64	9	7
1st half of 1983	92	37	10	17

AIDS CASES BY MUTUALLY EXCLUSIVE RISK GROUP, NEW YORK CITY

<u>Risk Group</u>	<u>Number</u>	<u>% Total Cases</u>
Homosexual/bisexual males	611	(70)
IV drug user (no history of homosexuality)	190	(22)
Hemophiliac	0	(0)
Other or unknown	76	(8)
Total cases:	877	

AIDS CASES WITHOUT APPARENT RISK GROUP NEW YORK CITY

Haitian (no history of homosexuality or IV drug use)	31
Unknown - died prior to interview	14
Possible background Kaposi's sarcoma	2
Possible transfusion associated	3
Sexual partner of an "at risk" group	12
Others:	
Interviewed - no risk factors established	9
Open cases - under investigation	5
Total	76

AIDS CASES BY RESIDENCE, NEW YORK CITY

	<u>Number</u>	<u>(%)</u>
Manhattan	421	(48)
Brooklyn	117	(13)
Bronx	91	(10)
Queens	68	(8)
Richmond	5	(1)
NYC-boro unknown	107	(12)
New York State	15	(2)
New Jersey	24	(2)
Other	25	(3)
Unknown	4	(1)

AIDS CASES, AVERAGE AGE BY MUTUALLY EXCLUSIVE RISK GROUP
NEW YORK CITY

<u>Risk Group</u>	1980	<u>Year of Primary Diagnosis</u>		1983
		1981	1982	
Homosexual/bisexual	n=19 38	n=108 37.7	n=275 37.3	n=199 38.3
IV user	n=6 36.8	n=17 34.8	n=94 32.3	n=70 34.5
Haitian	n=1 31	n=4 33	n=12 29.8	13 32.2
Other		n=5 39.4	n=16 36.7	n=24 35.2

THE CITY OF NEW YORK

OFFICE OF THE MAYOR

EDWARD I. KOCH

Tel: 566-5090

143-93

For Release:
Monday, June 6, 1983

STATEMENT BY MAYOR EDWARD I. KOCH

I HAVE JUST CONCLUDED A MEETING WITH A NUMBER OF MY COMMISSIONERS WHOSE DEPARTMENTS DEAL WITH THE GENERAL PUBLIC AND OCCASIONALLY WITH PATIENTS SUFFERING FROM ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS). AT THIS MEETING, DR. WILLIAM FOEGE, DIRECTOR OF THE UNITED STATES PUBLIC HEALTH SERVICE'S CENTER FOR DISEASE CONTROL IN ATLANTA, GEORGIA, AND DR. DAVID SENCER, COMMISSIONER OF THE CITY'S DEPARTMENT OF HEALTH, REVIEWED FOR THEM AND FOR ME THE CURRENT SITUATION ON AIDS.

THERE ARE A NUMBER OF RUMORS ASSOCIATED WITH AIDS. DR. FOEGE AND DR. SENCER ARE HERE TO HELP DISPEL SOME OF THE RUMORS, AND TO KEEP US ALL UP TO DATE ON THE FACTS.

HERE ARE SOME OF THOSE FACTS:

-- 722 CASES OF AIDS HAVE BEEN REPORTED IN NEW YORK CITY SINCE THE BEGINNING OF THE OUTBREAK IN 1978.

-- ALMOST ALL OF THE NEW YORK CITY CASES THAT CAN BE TRACED HAVE BEEN RELATED TO THE PREVIOUSLY DESCRIBED RISK GROUPS -- MAINLY SEXUALLY ACTIVE HOMOSEXUAL MALES OR INTRAVENOUS DRUG ABUSERS. THESE ACCOUNT FOR 94 PERCENT OF THE REPORTED CASES.

-- ABOUT 3.5 PERCENT OF THE CASES HAVE OCCURRED IN RECENT ARRIVALS FROM HAITI.

-- ABOUT 2 PERCENT DIED BEFORE THEY COULD BE INTERVIEWED.

-- THREE CASES MAY BE RELATED TO BLOOD PRODUCTS, AND ONLY 4 AT THIS TIME CANNOT BE ASSIGNED TO ONE OF THE RISK GROUPS.

A SMALL GROUP OF VERY YOUNG CHILDREN HAVE SOME OF THE CONDITIONS THAT ARE ASSOCIATED WITH AIDS, BUT THE PEDIATRICIANS OF THE COMMUNITY ARE NOT SURE THAT THIS IS THE SAME DISEASE.

THERE ARE ANY NUMBER OF RUMORS ABOUT THE SPREAD OF AIDS. THESE INCLUDE ALLEGATIONS THAT THE DISEASE IS SPREAD THROUGH FOOD, THROUGH THE AIR, OR MERELY BY TOUCHING AN AIDS VICTIM.

THESE RUMORS ARE NOT TRUE.

AS FAR AS WE CAN TELL, AIDS IS SPREAD THROUGH SEXUAL CONTACT, THROUGH BLOOD PRODUCTS, OR THROUGH CONTAMINATED HYPODERMIC NEEDLES.

RUMORS ABOUT AIDS HAVE PROMPTED IN MANY PEOPLE AN UNREASONING AND UNREASONABLE FEAR OF CONTRACTING THIS DISEASE. THIS FEAR IS UNFOUNDED.

LET ME DETAIL FOR YOU SOME OF THE THINGS THIS CITY IS DOING, BOTH FOR AIDS PATIENTS AND THEIR FAMILIES, AND TO COUNTERACT THESE RUMORS.

-- WE HAVE ESTABLISHED AN OFFICE OF GAY AND LESBIAN HEALTH CONCERNS, AND HAVE CONTRACTED WITH THE GAY MEN'S HEALTH CRISIS FOR SOCIAL SERVICES AND TRAINING IN HOSPITALS;

-- WE ARE CONVENING ALL LOCAL AIDS RESEARCHERS ON A MONTHLY BASIS, HAVE ESTABLISHED A REPORTING SYSTEM WITH CITY HOSPITALS TO KEEP TRACK OF THE SPREAD OF THE DISEASE, AND ARE WORKING WITH THE NEW YORK BLOOD CENTER AND THE CENTERS FOR DISEASE CONTROL TO HELP FIND THE CAUSE OF AIDS;

-- WE ARE DIAGNOSING OR TREATING MORE THAN ONE-THIRD OF THE NEW YORK AIDS CASES IN HEALTH AND HOSPITALS CORPORATION FACILITIES, AND ARE INVESTIGATING WHETHER OR NOT A HEALTH FACILITY DESIGNED FOR AIDS PATIENTS AND THEIR FAMILIES CAN BE ESTABLISHED IN A CITY-OWNED BUILDING IN GREENWICH VILLAGE;

-- WE ARE ENCOURAGING CONGRESS TO APPROPRIATE MORE FUNDS FOR AIDS RESEARCH;

-- THE HUMAN RESOURCES ADMINISTRATION IS PREPARING TO ISSUE A REQUEST FOR PROPOSALS FOR ORGANIZATIONS THAT WISH, UNDER CONTRACT WITH THE CITY, TO PROVIDE HOME CARE FOR AIDS PATIENTS;

-- A COMMITTEE DRAWN FROM CITY AGENCIES THAT DEAL WITH AIDS CASES NOW MEETS TWICE A MONTH, AND OFFICIALS FROM THE DEPARTMENT OF HEALTH ARE MEETING WITH UNION REPRESENTATIVES TO HELP ALLAY THE FEARS OF CITY WORKERS WHO DEAL WITH AIDS PATIENTS;

-- WE WILL BE SUPPLEMENTING OUR TELEPHONE HOTLINES TO INCLUDE INFORMATION ON AIDS FOR THE GENERAL PUBLIC.

WE ARE HERE TODAY TO HELP ALLAY PUBLIC FEARS ABOUT THIS DISEASE. BUT I DO NOT WANT TO MAINTAIN THAT THERE WILL NOT BE MORE AIDS CASES IN THIS CITY.

WE CAN, UNFORTUNATELY, EXPECT MORE OCCURRENCES IN A CITY OF THIS SIZE. A CASE MAY WELL DEVELOP IN A SCHOOLTEACHER, A SOCIAL WORKER OR A HEALTH CARE WORKER. SOME OF THESE INDIVIDUALS MAY HAVE A RISK FACTOR THAT THEY DO NOT WANT

MADE PUBLIC. BUT AS LONG AS WE KEEP IN MIND HOW AIDS IS SPREAD, WE CAN BE SURE THAT THEIR OCCUPATION HAS NOT PUT THEM OR OTHER PEOPLE AT RISK.

I, AND THE MEMBERS OF THIS ADMINISTRATION, ARE PLEDGED TO KEEP YOU INFORMED ABOUT THIS SITUATION. SCIENTISTS MAY MAKE IMPRECISE STATEMENTS, HEADLINE WRITERS MAY DRAW ON THESE IMPRECIATIONS.

BUT IF I, OR MEMBERS OF THIS ADMINISTRATION, THOUGHT THAT THE RISKS WERE DIFFERENT FROM THOSE I HAVE JUST DESCRIBED, I WOULD SAY SO. AND IF THE SITUATION CHANGES, WE WILL TELL YOU SO.

Mr. WEISS. Dr. Silverman.

STATEMENT OF MERVYN F. SILVERMAN, M.D., M.P.H., DIRECTOR OF HEALTH, SAN FRANCISCO, CALIF.

Dr. SILVERMAN. I am pleased to have the opportunity to speak before the subcommittee both as the director of health of San Francisco, and as the vice president of the U.S. Conference of Local Health Officers, on what is considered to be the number one public health problem facing this country today.

Although the total numbers of those afflicted do not approach other health problems such as heart disease, cancer and stroke, the mortality rate of AIDS certainly places it at the top of the list. I am sure that you are aware that the care of these patients has become a local public responsibility. San Francisco now has the second highest number of AIDS cases in the country—239 as of July 18, with 74 deaths. For a city and county of 700,000 population, this makes us No. 1 on a per capita basis.

To deal with this problem, it is obvious that San Francisco did not earn its title "The City That Knows How" without good reason. Several years ago, before AIDS had become a household word, the mayor and the department of health were already at work trying to create a continuum of services to meet the needs not only of the victims of this horrible disease, but their partners, friends, families and the public at large.

The involvement of the department has followed four distinct program themes: epidemiology, clinical diagnosis and treatment, education and training, and coordination of activities. None of these program activities could have been possible without the local provision of funds to support them.

Beginning with epidemiology, the department in July of 1981 established a reporting system and case registry for AIDS cases diagnosed in San Francisco and the surrounding bay area counties. This was done in collaboration with CDC and the California State Department of Health Services. We then established liaison with

local health and medical agencies involved with AIDS epidemiology, treatment, and research. This included such things as conferring with local treatment facilities about therapy and research efforts.

A third activity involved investigating and interviewing AIDS cases. We worked with the University of California in San Francisco and our San Francisco General Hospital in their cross-sectional studies, investigating blood transfusion-associated cases and the DCD hepatitis cohort study of AIDS cases. Six months ago, I requested that all cases of AIDS seen by private physicians be reported to my health department. It is now a reportable illness in California.

The second major program theme is clinical diagnosis and treatment. In October 1982, a multidisciplinary AIDS clinic was begun at San Francisco General Hospital. This clinic provides AIDS screening, diagnosis, treatment and followup as well as education and counseling and, because of the increased patient load, it is now operating on an expanded schedule. Two of the city's district health centers and the city's clinic for sexually transmitted diseases also provide AIDS screening to patients in order to relieve some of the burden on our hospital.

About a week ago, a medical special care in-patient unit opened at San Francisco General Hospital. This is an 11-bed unit, primarily for AIDS patients. I want to stress it is for the protection of the AIDS patients—not for the purpose of isolating them. We feel they have more to risk from us than we have from them. And we also want to try and provide a complete care, not only the medical aspects but the psychiatric aspects, the social aspects, and provide a total treatment program so that all their needs are met.

An important aspect of AIDS therapy is the psychosocial component. Certain city-funded nonprofit community agencies, as well as our community mental health centers, and staff at San Francisco General Hospital provide professional and lay counseling to patients, their loved ones and to the worried, well—those individuals at risk of contracting AIDS who are extremely anxious about it.

The third program area is education and training, which are integral parts of all of our AIDS activities. The focal points for these activities have been the department's Lesbian/Gay Coordinating Committee, staff from the University of California and San Francisco General Hospital, and two city-funded nonprofit agencies. Since May of 1982, this committee has sponsored over 30 training sessions for a variety of groups, including health workers, police personnel, social service employees, the general public and members of the gay community.

Individuals within and outside the department have participated in these sessions and have appeared on local radio and television. Information has also been developed and distributed about AIDS to the professional and lay community. In May, we sponsored a citywide symposium on AIDS. Over 500 people attended a Sunday morning meeting to learn more about this public health problem. This month, a major symposium is planned for health care workers.

The last program area deals with coordination of activities. In July 1982, a community coordinating committee was established

with the purpose of bringing together people representing all aspects of the epidemic. This included clinicians, researchers, health educators, patients, gay activists, and many others. Information is shared, gaps identified in the system, and recommendations are made to the city and the department. This group has developed a community aids resource directory and has made recommendations for new services.

In order to keep abreast of current treatment and research, I have appointed a medical advisory committee, composed of clinicians and researchers, who meet with me on a regular basis to discuss and recommend policy guidelines relative to AIDS. This committee has been instrumental in reviewing the infection control guidelines prepared by the university and my office.

After many weeks of work, through consultation with CDC and representatives of the academic, research and general medical community, we have put together what we have purposely called guidelines, because each medical facility may have specific situations which warrant greater or lesser emphasis on the various aspects contained within this document.

In June, I met with representatives of the many different businesses serving the gay male population in San Francisco. As a result of that meeting, we have complete support for the posting of signs and distribution of flyers which indicate the measures that can be taken to reduce the spread of the disease.

With the exception of a portion of our epidemiologic activities, the city has financed all of the AIDS services I have described. Additionally, the city has funded nonprofit community agencies to address specific components of the AIDS problem. For example, the AIDS and Kaposi's Sarcoma Foundation was funded to establish an educational clearinghouse and to produce materials focusing on the at-risk population. The Shanti project, which is an agency serving the emotional needs of terminally ill patients, their loved ones, and friends, was funded to provide counseling and to set up residences for displaced AIDS patients.

Last month, the mayor and the board of supervisors approved spending an additional \$2 million from within our budget, which doubles the money presently being spent annually by the Department of Health for AIDS services. The rapidly increasing incidence of AIDS, along with the secondary problems of anxiety, misinformation, displacement of patients and difficulties in treatment, was the motivation behind this authorization—this money now totaling \$4 million, which will increase the services in the areas that I have mentioned.

I have also hired an AIDS coordinator to try and coordinate all of the activities that are taking place, so that we have a better handle on the problem, both the social, psychological, and medical issues.

Obviously, San Francisco and other impacted communities cannot continue to meet these needs without Federal support. Federal funds are needed to supplement these costs as well as the research component. Education, counseling, screening, outpatient and inpatient and hospice services as well as residential facilities are costly at a time when local governments are least able to meet increased demands. One form of relief would be the immediate avail-

ability of medicare coverage for AIDS patients rather than the 24-month waiting period. Also, SSI should be granted as presumptive eligibility on diagnosis rather than the 60- to 90-day wait that presently exists.

AIDS patients who apply for SSI regularly must wait several weeks or months for certification. This is because rules require the submission of medical records to a separate agency in another city. This is not the case in 11 specific categories of inpatients where the Social Security district office may make a determination of presumptive disability on the spot. A diagnosis of AIDS should be added to this list to facilitate the immediate granting of SSI. The relevant social security regulations are located in title XX of the code, Federal regulation 416.931 to 416.934.

An alternative approach that may be quicker would be to get social security to interpret rather than change social security regulation 416.933 to include AIDS diagnosis. 416.933 states that, and I quote:

We may make a finding of presumptive disability or presumptive blindness if the evidence available at the time of the presumptive disability or presumptive blindness decision reflects a high degree of probability that you are disabled or blind.

It is interesting to note that no disease has ever been eradicated through treatment—only through prevention. That is why it is imperative to have sufficient funding to establish the cause, provide the necessary treatment, and, most importantly, put into effect the preventive measures which will eliminate AIDS from its dubious distinction as the No. 1 public health problem facing America today.

Thomas Adams summed it up very well over 300 years ago when he said: "Prevention is so much better than healing because it saves the labor of being sick."

Thank you.

Mr. WEISS. Thank you very much, Dr. Silverman.

Mr. Matek.

**STATEMENT OF STANLEY J. MATEK, IMMEDIATE PAST
PRESIDENT, AMERICAN PUBLIC HEALTH ASSOCIATION**

Mr. MATEK. Thank you, Mr. Chairman, members of the committee.

You have our written statement, so I will try to just highlight the key points instead of reading it.

Mr. WEISS. Without objection, your entire statement will be entered into the record.

Mr. MATEK. Thank you, Mr. Chairman.

In the light of your opening comments about your interest in hearing from the administration, I would like to emphasize one point we take very seriously: Dr. Brandt is a professional seriously committed to these issues. But we must recognize that he takes his orders from above. We don't think that the Centers for Disease Control or the National Institutes of Health or Dr. Brandt ought to be the focus of criticism when, in fact, the decisions on what will or will not be done in the allocation of moneys and in service and research programs are being made by the Office of Management and Budget and by the White House. We wish to emphasize that in

looking to ultimate responsibility and to decisionmaking power, we must all look there.

APHA recognizes that although CDC and NIH are doing as much as they can, they are not doing enough. They are not doing enough because they don't have the resources, because they are understaffed. We look to Congress to remedy that situation.

We would like to see leadership from the White House. It has not yet been forthcoming.

The priority now, as we see it, in this Nation relative to AIDS is for the prompt development of a comprehensive research surveillance and monitoring program. If we don't have that—and if we don't have it quickly—any money, any time or any talent put into the AIDS effort is going to be in large part wasted, because without a comprehensive plan, we are merely shooting in the dark with scientific scatter guns.

We, therefore, ask—and we ask urgently—that within the next 45 days Assistant Secretary Brandt convene a meeting of national experts in epidemiology, immunology, medical research, and other appropriate disciplines for the purpose of developing an AIDS research master plan, from which will follow a realistic budget and a priority list.

We then ask that that research plan be used to guide AIDS grant awards in the National Institutes of Health, and that the administration refrain from counting among its AIDS activities those previously funded projects which are only tangentially related to AIDS and which are not part of that master plan. We need, first of all, to have a realistic fix on what is or is not being done in a focused and organized way. We don't have that yet.

Then we think that Dr. Brandt needs to appoint a standing expert advisory panel which includes people from outside NIH and the Department, as well as from inside. That is not just a sunshine provision; it is intended to give the programing, the planning, and the analysis an enriched dimension.

We also respectfully ask that Dr. Brandt assign for prompt implementation the interprofessional AIDS update report which has been talked about now for several months, but which we have not yet seen.

And, finally, we would like to make some brief points relative to programing. First, we recognize that CDC cannot do everything by itself. The job is getting too big and the problems are too spread out. Adequate surveillance and monitoring cannot be done only from the center. We would therefore like to see the efforts relative to AIDS surveillance, monitoring, and applied research decentralized, at least to the point that those cities where the major AIDS case clusters occur become capable of doing surveillance and monitoring themselves. And we recognize that it is going to take some Federal money. We would like Dr. Brandt to order such a decentralization and to plan for its implementation as soon as possible.

Second, we believe it is necessary for AIDS to be declared a reportable disease nationwide. However, we recognize the problems that occur relative to the distorting of incidence data when reporting programs are instituted; therefore, we ask that a definitive plan for protecting the confidentiality of the caseload and the privacy of the patients be created.

We understand that that plan is now being developed in conjunction with Dr. Sencer in New York City, and CDC. We would like to add one item to that proposal, namely that Zip codes be used in the identifying information, because without Zip codes it will not be as easy to do proper applied research or good treatment planning.

Third, we would like to urge that funding be provided for treatment and prevention—as we understand, Mr. Chairman, it is in legislation you are introducing. But we would like to note that because our hospital system is now such a high-cost system, money for treatment and prevention usually gets used exclusively for treatment. Our hospital system tends to consume whatever is available because we have a high technology orientation to treatment.

If we are serious about having money for prevention, we are going to have to segregate it. And we call that to your attention so it can be done—if not in legislation, then in regulation.

As Dr. Silverman pointed out, prevention is what really works. Prevention is what protects the population. But unless we budget specifically, we tend to lose that money.

We would plead also with the White House, with OMB, with Secretary Heckler, and everyone involved in dealing with AIDS to acknowledge the epidemiological urgency of this problem. We know there are problems. We know NIH moves slowly. We recognize that CDC does not have a practice of decentralized approach to problems. We recognize that Congress itself likes to fund things categorically. And we know that these are all system problems. But the AIDS issue should not be the issue on which we seek to leverage reform of our systems—not now; not with this problem.

Finally, we urge that instead of belaboring past failures, we all look to the next steps toward solution. It doesn't so much matter what our mistakes were yesterday as what our solutions are today, and what our actions will be tomorrow.

We are grateful to Congress because that is whence the leadership for change has come relative to AIDS. We urgently hope that you will continue that initiative.

The American Public Health Association volunteers to do anything you or the administration or CDC or NIH might think that we can do to be of help.

We thank you for this opportunity to talk with you.

[The prepared statement of Mr. Matek follows:]

Testimony Of STANLEY J. MATEK,
Immediate Past President,
AMERICAN PUBLIC HEALTH ASSOCIATION
before the
Intergovernmental Relations and Human Resources Subcommittee
of the
Committee on Governmental Operations

Mr. Chairman, Honorable Members, Ladies and Gentlemen:

I am here this morning on behalf of the American Public Health Association, the world's largest association of public health professionals. We are particularly grateful to have this opportunity to comment on current efforts to deal with Acquired Immune Deficiency Syndrome, because the morphology of this illness qualifies it beyond any question as the most serious public health disease issue in decades. On the basis of incubation period alone, AIDS is an epidemiological nightmare, the horrors of which are only beginning to unfold. The extent of exposure, the scope of susceptibility, and the real rate of incidence are all unknown. The agent is only hypothesized, and the mode of transmission is but vaguely suspected. There is no known form of treatment, the disease career is protracted, and the associated expenses are phenomenal. The situation demands the immediate use of the full armamentarium of public health techniques. Unfortunately, our response thus far fails to measure up to that demand.

It cannot accurately be said that the Public Health Service or the National Institutes of Health have been derelict. They have done what they could with the resources available to them, going even so far at CDC as to siphon funds quietly away from other necessary programs. But it must be acknowledged that AIDS-related efforts in all quarters of our system thus far have been ad hoc, largely expedient, and gravely incomplete.

These inadequacies stem neither from a lack of ability nor a lack of good will within our public systems, but clearly and almost completely from a lack of resources. It has been disappointing to hear recent charges of unresponsiveness on the part of CDC and NIH relative to their AIDS-related activities. But such appearances can be understood easily enough by reference to the fact that these agencies are underfunded, understaffed and overworked. It is clear,

moreover, that the Administration's marching order to these program directors is unequivocal: "Don't ask for any money; make us look as good as you can with what you've got."

It is obvious that additional funds must be made available; AIDS cannot be addressed on the basis of existing budgets. The 50,000 members of APHA are unanimously grateful to you, Mr. Chairman, to Congressman Waxman and to the others in Congress, on your staffs and elsewhere who have contributed thus far to the procurement of additional monies for AIDS research and treatment. We ask fervently for persistence in these efforts.

But we must caution that even if additional funds are made available, that will not in itself enable us to cope competently with the AIDS problem. Thus far our quests both for cause and cure represent little more than mere shooting in the dark with scientific scatter guns. The application of the public health model of practice to this situation is long past due.

The APHA Executive Board at its July meeting reviewed the AIDS situation and concluded that the nation's single most urgent current need is the prompt development of a comprehensive AIDS research, surveillance and monitoring plan. Without such a plan we will unwittingly waste much of whatever time, talent and money are applied to the AIDS problem.

We, therefore, ask that within the next forty-five days Assistant Secretary Brandt convene a meeting of national experts in epidemiology, immunology, medical research and other appropriate disciplines for the purpose of developing an AIDS research master plan, a realistic budget, and a priority list.

We ask that this research plan be used to guide AIDS grant awards by NIH, and that the Administration refrain from including in its AIDS activity reports any projects funded for other purposes, which are only tangentially related to AIDS, and which are not part of the master plan.

Then, because priorities will need to be changed as new information becomes available, we ask that Dr. Brandt designate a standing expert advisory panel, which includes members from outside NIH and the Department.

We respectfully urge also that Dr. Brandt assign for prompt implementation the interprofessional "AIDS update" report which has been talked about now for several months.

And finally, because any master plan must address and in certain senses must rest upon various policies, procedures and interagency agreements, we would like to make the following brief points:

First, the achievement of adequate surveillance and monitoring will necessarily require that these activities be decentralized by the Center for Disease Control, at least to the extent of expanding local health department

capacities in those jurisdictions where the major AIDS case clusters occur. At present these would include at a minimum the cities of New York, San Francisco, Los Angeles, Miami, Philadelphia, Boston and Newark. We ask that Dr. Brandt direct such decentralization, and convene a meeting of these local health officers and CDC task force leaders to develop implementation policies.

Second, we believe it is essential that AIDS be declared a reportable condition nationwide. But we recognize that a particular problem with confidentiality is involved, and we note the well-known distorting influence which this factor can have on incidence statistics. The recent downturn in the number of new cases identified in New York, for example, might well be an artifact of that state's new reporting requirement combined with well-founded concerns about our system's ability to assure adequate privacy. We understand that New York City Health Commissioner Senser and the National Gay Task Force have devised a workable plan for dealing with the privacy issue, and we commend them. We would, however, like to add one important item to their proposal: We urge that any reporting system include the zip code of residence, because that information will have significant utility in applied research, and especially in efforts at prevention and service planning.

Third, we wish to note that although it may presently be necessary to combine under one legislative provision new funds for AIDS treatment and prevention, we have long and conclusive experience which demonstrates that treatment urgencies in our high cost hospital system will consume whatever funds become available. If, therefore, we intend to have funds for prevention, it will be necessary to assign them specifically by percentage or dollar amount, either in legislation or regulation. To neglect this point will be to lose once again any viable efforts at meaningful prevention.

Fourth, we plead with the White House, OMB, Secretary Heckler, the National Institutes of Health, and all others involved in the question of AIDS funding decisions to recognize the epidemiological urgency of this situation, and to resist any temptation to draw inappropriately rigid policy lines, or to use the AIDS crisis as leverage for the reform of flaws in our current systems. The imperfections in process at NIH, the tendency towards solo performance at CDC, and the limitations of the categorial funding approach long favored by Congress are all well known problems. They are worthy of attention and remedy. But not now, not using the AIDS crisis as the lever. Efforts at system reform must not be made on the backs of AIDS victims and the hundred of thousands of our citizens now at risk.

Finally, Mr. Chairman, we at APHA hope that your Committee, Mr. Waxman's Committee, and the Congress of the United States will continue to press forward on this issue, giving leadership where the White House thus far has not. We urge the Department and Dr. Brandt to take the necessary next steps. And we sincerely offer APHA's assistance and participation wherever the Department, the Congress or the Administration might desire it.

On behalf of all the membership of APHA, I thank you for this opportunity.

Mr. WEISS. Thank you very much.

Before we start our questioning, may I indicate again that we will be operating under a 5-minute rule. I have only one question.

I thought that the testimony was very clear and precise. I am impressed by the efforts which your local organizations and the American Public Health Association have undertaken, as well as by the responsibilities which have been assumed by other localities.

I am also impressed by the cooperation and coordination that apparently exists between the departments of health in your cities, and especially the gay community, which is the community most affected in this situation.

We have had discussions over the course of not only these past 2 days but since we have taken note of the problem in Congress as to the budgetary problems involved. Dr. Sencer, you have indicated in your testimony that if you assume that only 200 patients are hospitalized per day in New York City at a \$1,000 per day cost, that you are talking about a bill of around \$73 million a year.

Could each of you try to give us what you consider to be your overall best guess or judgment as to what kind of moneys are needed for research, treatment, and the various corollary educational and other services that you each have spoken about? What kind of money are we talking about annually or over the course of the next 3 years?

Dr. Sencer?

Dr. SENCER. Speaking only for the city of New York, it is our estimate that in the health department alone we are expending on—(this does not get into the matter of diagnosis or treatment)—purely the public health aspect, surveillance, public education—we are spending about \$1 million at the present time. And \$125,000 of that is in the form of a cooperative agreement from CDC for the type of decentralized surveillance that Mr. Matek was talking about. The rest is out of direct city funds—we had a \$250,000 new appropriation—we are using other existing funds.

Other departments such as the welfare department, are spending an untold amount. And the Hospital Corporation is part of that \$73 million.

I would estimate that in New York City, the cost of treatment of AIDS plus the prevention work, the surveillance work, the community support is going to come close to \$100 million. And most of that is going into the treatment aspect of it.

Mr. WEISS. Do you have any estimate or any basis for making any estimate as to what you think ought to be spent at the national level, both for research as well as the other activities you spoke about?

Dr. SENCER. I would not want to speak to the amount of money that should be spent for treatment. Let me just speak to the research. I think research is driven by the individuals who are capable of doing the research. Rather than approach it from a finite dollar, I think that in a situation like this there needs to be a certain open-endedness of the appropriation system and the NIH research grant administration, so that as fundable good research becomes available, it can be funded in a situation such as this.

I just hate to say \$15 million, \$20 million, because it depends really upon the ideas and upon the capability of the investigators

in the field rather than Congress or the administration setting a dollar figure to shoot at. This is when you end up with other things being charged against that particular budget.

Mr. WEISS. Thank you.

Dr. Silverman?

Dr. SILVERMAN. Yes.

As I mentioned, we are spending over \$4 million a year in San Francisco. And just a rough estimate for most of the prevention activities, the counseling activities, the educational activities, all of these kinds of things, in looking at it, I would suggest—and this would also help for the outpatient activities and some of the inpatient activities—about \$25,000 per case. Obviously, that averages out when someone is in the hospital that it is a lot more.

I think for treatment, rather than getting into a specific number, if we can change the medicare policies so that the cities are not burdened with this, and if we can change the SSI policies, so that would take some of the burden off, that would reduce the local expenditure.

With regard to research, it is a hard one, but I also know that when a great deal of money is put into research and it is carefully distributed, results do appear. And a lot of the research that we are talking about that I want to see besides the basic research is epidemiologic research, and that costs a lot of money because there is a lot of investigation, a lot of interview. And I think the figure of about \$50 million for 1984 is a pretty good ball park number.

Now, it is hard to get much more specific than that. But I think that is a number that we feel would hopefully be adequate.

Mr. WEISS. Mr. Matek.

Mr. MATEK. Mr. Chairman, I would comment that Dr. Silverman's figure of \$50 million represents not a final, total budget but a next step. It might be an annual allocation to get things rolling.

Bluntly speaking, there is no responsible answer to your question now. There could be within about 90 days if Dr. Brandt would convene the panel we recommended very promptly. I would propose that Dr. Brandt be given 100 days to give you a responsible answer to your question on condition that the answer not be censored by OMB first.

Mr. WEISS. Thank you very much.

Mr. Walker.

Mr. WALKER. Thank you, Mr. Chairman.

Dr. Sencer, I have been reviewing some of the attachments that you sent along with your statement with regard to the number of cases and so on. It interests me that in 1983 we have seen a significant drop in the number of cases, where you show the onset of symptoms, particularly in the second quarter of 1983.

Is there any explanation you can give us?

Dr. SENCER. Yes, there is an explanation. This is the date of onset of symptoms, and many of the cases are not reported until they have been ill for a period of time because sometimes the onset of symptoms is not pathognomonic of AIDS.

If you look at the next page, the bottom of the page, "Trends," you will see we are having an average of 50 cases reported a month in New York City. It is up a little over last year, when we were

having 42 cases a month. This year, we are seeing 50 cases a month. So I don't think this is an artifact of the reporting process.

Mr. WALKER. That helps clarify. Thank you.

The other thing that I noticed is that you have recently stated that the Haitians should be removed from the list of major AIDS risk groups. Certainly, in some of the testimony we had yesterday, it would seem to suggest that, too. But in your statistical list, the AIDS cases without apparent risk group that you gave us does indicate that the highest number there are Haitians without a history of homosexuality or intravenous drug use.

Dr. SENCER. Let me try and explain this.

Mr. WALKER. Fine.

Dr. SENCER. We feel that there is a good scientific explanation for the transmission of disease in the homosexual male population, in the IV drug abusing population, and in the hemophiliacs. In the Haitian population, we still do not know what the mode of transmission is. And so, therefore, we are saying that this is a group that is under investigation, that we do not know—we lack information rather than anything else on this population.

We have had some of our Haitian individuals in New York City who have been diagnosed as being drug abusers, and at that point they are removed and placed in the category of an IV drug abuse patient. A few of them have also been diagnosed as being homosexual males, and they are then included in that population.

It could be that this will end up with a residual in which we will not be able to determine what the risk factor is. But our attempt has been to describe the principal risk factors by the modes of transmission that we know of at the present time.

Mr. WALKER. Would you recommend that the Federal Government take the Haitians off as a risk group?

Dr. SENCER. I think that it depends upon how the Federal Government desires to describe the risk group. I think that one of the nice things about scientific investigations is that you can have honest differences of opinion. It is my feeling that until we find out the method of transmission of the disease within the group, I don't think that they should be included as a risk group.

You will notice that we have sexual partners of at-risk groups in that situation, too. Most of these are sexual partners of IV drug abusers. And we cannot be sure beyond doubt that it may not be from some sharing of needles that have not been reported. So this is a group in which we are trying to determine what the mode of transmission is.

Mr. WALKER. Thank you.

Dr. Silverman, you put a great deal of emphasis on the prevention, which I think is very encouraging. Could you be more specific about what you would recommend to an individual who wants to avoid AIDS?

Dr. SILVERMAN. The prevention for individuals—you mean what actions people can take?

Mr. WALKER. What actions people can take that would reduce the risk.

Dr. SILVERMAN. I believe the obvious one with the IV drug abusers is hopefully not to keep shooting up drugs. But, if you do, use clean needles, sterile needles. That probably is not going to

take place. But I feel that as long as those needles have to be gotten surreptitiously, they are going to be contaminated, and that is always going to be a problem.

With regard to sexual practices, I consider most important is not sharing bodily fluids; and specifically we are talking right now specifically—though all fluids are suspect—about semen. And the use of a condom, though not a guarantee, can certainly reduce the exchange of bodily fluids.

I believe that knowing your partners is an important factor in the transmission or in the control of the transmission of any sexually transmitted disease, and I don't think this one is any different than other sexually transmitted diseases. And knowing your partner is helpful, not only to individual, but it also helps us in public health when we are trying to track down the spread of disease, to know the contacts.

Mr. WALKER. Mr. Matek, you were critical of several Government processes, and specifically with regard to the administration. But you also included in your statement some criticism of the categorical funding process that Congress uses.

Could you be more specific about that?

Mr. MATEK. Well, my perspective on that comes from years in administration, trying to find ways to be flexible, to meet local problems, and working with Federal regulations and programs which have rather strict boundaries. There is a popular school of thought in health administration that would propose the breakdown of these categorical programs, and allow people at State and regional levels to coordinate programs based on local needs. This is difficult to do when you have categorical funds.

One of the proposals made for AIDS is that there be a separate AIDS funding program similar to the end-stage renal disease program. And, of course, when you propose a program like that, people in my field tend to say, "Oh, no, not another one!"

What I am suggesting is that, yes, it may indeed be necessary to have yet another one, at least this time. And I would hate to see us try to use this problem as the occasion for system-wide reform, because system reform just takes too long. This is an epidemiologic emergency. We don't have any time to waste.

Mr. WALKER. I understand that. But it sounds as though what you are saying is that the administration moving toward block grant proposals in some of these fields, including the health field, does in fact have some merit with regard to application in local areas and making certain that money can be used in a responsive way when these emergencies arise in local areas.

Mr. MATEK. The block grant concept could be useful relative to AIDS in a limited sense. And that would be in providing money for local treatment, money to local health departments for education, and prevention activities, and possibly certain kinds of applied research. However, to get at the issues epidemiologically and scientifically now, we need to be working primarily through CDC and through the National Institutes of Health in a focused way.

So I see Federal level involvement as the priority of the moment, which is not to say that block grants wouldn't be useful down the line.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. WEISS. Mr. Conyers.

Mr. CONYERS. Thank you, Mr. Chairman.

I am going to have to ask to be excused. There is a whip check in the Speaker's office on the Martin Luther King bill today.

Mr. WEISS. We are glad you could spend any time at all with us today.

Mr. CONYERS. I want to commend the witnesses I have heard. There could hardly be a more thoughtful presentation made by them. And I think the chairman's description of the problem is one that does not beg any difference of view.

Here we are in an American political system, intelligently discussing an acute emergency. We have come up with—I counted seven reasonable ways to move on the problem. And the issue that is raised, of course, is what in God's name are we going to really do and what is going to happen after today's session.

I suppose like all emergencies, this requires special action. I won't argue with that. The 200,000 people starving in Detroit require special action; 11 million people out of work require special action. We have got lots of requests for special action. This is one. And standing on its own merit it should be treated that way.

But to think that we are going to whip through intelligently, through this screwed up system, just because of this emergency, is to intelligently beg the question, because we are going to have to make changes in who pays and who decides what actually happens and who pays for not deciding what actually happens.

This is a political question, like every one of the others that we are presented with. And so I am not quite so sure if this issue should not be made the basis for the reform of the systems. It must be. It must be treated specially, as well.

What in God's name can people in Government say to you when we spend \$900 billion a year of the people's money, a quarter of it going on weapons of insanity that further destabilize the planet, when we meet here in this room and discuss a very critical health problem? And I think that it has to be a call to action for not just those victims and their friends and those who intelligently understand this as a medical-social problem, but somehow we have the responsibility to teach the rest of the American people that this critical problem has to be part of the systemic reform. It has to be part of the understanding that goes into making this a more livable Nation and, in the end, a more livable world.

So I am prepared to bring this issue down to brass tacks. I am going to be very sympathetic to all the Federal witnesses. I am hoping that our former colleague, Mrs. Heckler, will on the advice of her many friends on this subcommittee choose to intervene in a way that is in keeping with her spirit as a Congresswoman—we worked together for many years—that we really break through immediately on an emergency basis and systemically as well. And then those of us, if we succeed, join with the other challenging social problems that are here; and if we don't succeed, I think we have to do what is mandatory in our society.

It has to become part of the political decisionmaking as to who represents you locally and nationally. Because unless that part is added on to it, unless this dimension is honestly discussed here, we are really being superficial. We are acting like somehow, some-

where, somebody else is going to miraculously solve the problem. We, in this room, are the people whose intelligence and energies are going to determine what actually happens.

I invite the witnesses to make any response they choose.

Mr. MATEK. Mr. Congressman, I understand what you are saying and I agree with you. Again, we will just put out the fact that APHA is ready to do whatever it is we are asked to do.

Dr. SILVERMAN. That is also certainly true of the local health officers. I am speaking for the U.S. Conference of Local Health Officers. I think there is one other thing, if I might mention, that I think is most important. It hasn't been addressed today. That is what some people have termed the second epidemic, and that is the anxiety which has grown up around this disease.

I spend probably as much or more time trying to deal with that as I do with the prevention of the spread of the disease in the affected communities. I think it goes to something that Stan said. It is most important that there be a coordinated effort from CDC and the local health officials and APHA, in the dissemination of information, because, as information comes out, sometime if it is not carefully put out or if it is put out before it probably should be, we fuel the flames of this anxiety, and the social impacts of that are incalculable.

Dr. SENCER. Mr. Conyers, I am touched at your concern over this as a major social problem.

Dr. Silverman talks about the epidemic of anxiety. I think this is being fueled by an epidemic of homophobia. It is giving people who disapprove of a certain lifestyle an opportunity to come forth and be against that by picking on the disease rather than venting their spleen, their bile, upon something that they disagree with.

I think that it is reminiscent of the problems of the 1960's and the civil rights movement. I think that if anything good comes out of our struggles against the disease, it may be a better understanding of the rights of individuals to their own lifestyles. It is very troublesome to see the sorts of things that are proposed in public forums and in the newspapers. It is going to take leadership at all levels to try and combat this.

Mr. WEISS. Thank you very much.

Thank you, Mr. Conyers.

Mr. MATEK. Mr. Chairman, it just occurred to me as my colleague spoke that it might be helpful for the members of the committee to invite comment from the National Institute of Mental Health on what it is they plan to do relative to the issue of stress and anxiety as connected to this problem.

Mr. WEISS. Thank you.

Mr. McCandless?

Mr. MCCANDLESS. Thank you, Mr. Chairman.

I certainly agree that society should be concerned. But I would also point out that those of you who consider this some kind of a back-breaking, all-out emergency, that there is another disease that has been on the face of the Earth for quite some time that I am very concerned about, and that is cancer.

I would like to be more specific, though.

Dr. Sencer, you mentioned in your opening remarks, and then followed up in one of your addendums, on page 3, the statistical

analysis of AIDS cases by mutual exclusive risk groups in New York City. This then was broken down into three categories.

You have your homosexual-bisexual males, which encompasses 70 percent of the cases. Second, there are the IV drug users, with no history of homosexuality, which represents 22 percent of your total group. Third are hemophiliacs, which you have none at this time. And finally, there are the others or unknown category which number 76, and are 8 percent of the total.

Can you expand on this, as to who might be in this last group?

Dr. SENCER. Yes. It is in the table just below that, where, of that 76, 31 are individuals who are of Haitian origin, who do not have a history of homosexuality or drug abuse. There are 14 that died before they were interviewed, so we have no adequate information.

Mr. McCANDLESS. Was this determined by an autopsy?

Mr. SENCER. These are people who were diagnosed as having AIDS, but there was not an interview conducted to determine whether there were IV drug abuse patterns or homosexuality. Most of these were in the early days of the disease when the risk factors were not associated.

Kaposi's Sarcoma is a disease that occurred at a level of about two to three cases a year in New York City, prior to the current outbreak we are seeing. It has a different age distribution. It is mainly in older males of Mediterranean origin. And we think that because of the way the definitions are set up, these two cases are probably background cases rather than involved with the epidemic.

At the present time there are three people whose only risk factor may have been the blood transfusions. And we are investigating those at the present time.

As I mentioned, we have 12 individuals who are sexual partners of individuals in the at risk. One of those was a woman whose sexual partner was a bisexual male who developed AIDS. The others, all except two on which we have no adequate history, are sexual partners of IV drug abusers. And here you are always left with a little bit of wonder whether there may also be some sharing of the needle in the home.

And then there are 14 that we have under investigation at the present time which we have not yet come to a conclusion on.

Mr. McCANDLESS. Would you say there is a medical parallel between the increase in AIDS and that of venereal disease?

Dr. SENCER. No, sir. As a matter of fact, one of the things that gives us some hope that there is a change in patterns that Dr. Silverman was mentioning, the occurrence of infectious syphilis and gonorrhea in the one large area of New York City that serves principally the homosexual male population, incidence of these two venereal diseases is down. And we believe that this may be an indication that there is some lifestyle change.

There are similarities in that we know that with venereal disease the person who has multiple sexual partners, particularly unknown sexual partners, anonymous sexual partners, is more likely to develop venereal disease than those who have a single partner or fewer partners. And this has been part of the advice that originates within the gay groups themselves.

The Association of Physicians for Human Rights has recommended that gay males limit the number of sexual contacts, particularly

with anonymous individuals. So I think this is bringing about some change at least in New York City of the lifestyle.

Mr. McCANDLESS. Dr. Matek, you have emphasized the emergency that faces us. I think you used the word "catastrophic" at one point. Maybe I am misinformed but your emphasis seems rather strong. Could you define to what extent you consider this an emergency?

Mr. MATEK. Congressman, the urgency I feel is based on the epidemiological character of this problem and on our lack of knowledge about the basic mode of functioning for this disease, its morphology. The death rate from AIDS is the highest of any disease with which we are currently dealing. That is the basis on which I consider it urgent.

Second, we know not what it is, where it comes from, how it gets where it goes, and where it is going from there. When you recall that this is a disease with an incubation period of 1 to 2 years, the next question is: how long during that incubation period is the disease transmissible? And how many people are exposed during those 12 to 24 months by each carrier?

The possibilities are phenomenal. The implications are devastating, given the high cost of treatment and the high death rate. So we in APHA are concerned that we are dealing with the small tip of a very large iceberg.

Mr. WEISS. The gentleman's time has expired.

Mr. McCANDLESS. Thank you, Mr. Chairman.

Mr. WEISS. Mrs. Boxer?

Mrs. BOXER. Thank you, Mr. Chairman.

I want to thank the panel for being so direct and responsive to questions.

Dr. Sencer and Dr. Silverman, you are really in the trenches. You are really there. And from your reports, I think you are just doing an exceptional job. But I get the feeling that you are there really by yourselves in terms of the cities handling the problem.

What I would like you to tell me, if you can try to put this into a percentage, we know how much you are spending from local funds on the disease, what percentage of the effort that is being expended in your cities can you attribute to the Federal Government, because one of our purposes here is to assess how helpful we are being in this whole fighting of this disease. And I wonder, Dr. Silverman, if you can give me a guesstimate of the percentage of the effort in San Francisco that you can say is directly attributable to the Federal Government?

Dr. SILVERMAN. We have now in San Francisco at this time at least one representative from CDC helping us in our epidemiologic investigations. If you eliminate that, you eliminate pretty much the Federal input into the funding for this—for our problems. It is probably 98-plus percent local funds.

Mrs. BOXER. What was the first year that this whole issue of AIDS was called to your attention as being a serious problem?

Dr. SILVERMAN. We started getting involved in 1981, and really in large part almost a department-wide effort, in 1982.

Mrs. BOXER. So from 1981 to 1983 you can state that the attack on AIDS has been launched by the city and county of San Francisco, up to 98 percent of the effort?

Dr. SILVERMAN. I think that would be a fair estimate.

Mrs. BOXER. Dr. Sencer?

Dr. SENCER. Doing a quick calculation, we have a contract with CDC for \$125,000. We have two epidemiologists assigned to the city health department who are working full time on AIDS; their salary, probably another \$100,000. We have a public health adviser. So I think probably roughly \$250,000 of direct support comes from the Federal Government. That is out of our estimated health department.

I am not talking about hospitals or diagnostic service. About 25 percent may come from Federal assistance.

Again, part of that \$100,000—part of the costs of one of the epidemiologists is not directly from CDC. It is the one opportunity we have had to use the block grant.

Mrs. BOXER. Okay, you don't have to go into specifics. We can say about 75 percent of the effort—

Dr. SENCER. Local money.

Mrs. BOXER. Has been from the city of New York in this case?

Dr. SENCER. That is right.

Mrs. BOXER. I just want to state, Mr. Chairman, I think this is shocking information, absolutely shocking. And it is very important information for us to know. And I would like to ask Mr. Matek something. And I particularly want to thank you, because I think you gave us some very concrete ideas as to what to ask our Federal people here.

I have heard, and this is not something I have seen, but I have heard that the White House is going to come in with a recommendation that \$18 million be allocated for next year. I can tell from the answers of the panel that that would not be anywhere near adequate.

I want to ask you, Mr. Matek, in your experience has there ever been any other public health emergency that you know of in this country where the health people in the Federal Government have had to be pushed so hard by outside groups, by Members of Congress? It is my feeling, having served in local government, we the elected officials are always being pushed by the health professionals, but in this case, as you pointed out, it is Members of Congress that seem to be pushing on the health professionals.

Do you know of any other example where this has been the case?

Mr. MATEK. Eighty-five years ago it was the American Public Health Association that pushed the President to send Walter Reid to Cuba. Since that time there has not been such a dramatic inconsistency between public health goals and administration goals as now exists. We understand the pressures on the economy. We understand the priorities of the Administration. But we need to point out the inconsistencies which exist in this case.

I do not know of other similar examples. But in all candor, I must confess I don't know of similar circumstances either

Mr. WEISS. The gentlelady's time—Dr. Silverman.

Dr. SILVERMAN. Just a quick one.

The subject came up, why the emergency? I think when we talk about 1,800, maybe 2,000 individuals, that looks small. But right now it is universally fatal. And it is the snuffing out of young people's lives, not that one can place a value at any age level. But here

are people in their most productive time of life, who should be providing services back to the communities and working actively in the community. And these are just the people who are dying. I think with that mortality rate, it is a real emergency. Maybe the problem is that the Federal Government in the past has been looking at the number rather than the problem itself.

Mr. WEISS. Thank you, Mrs. Boxer.

Mr. Craig?

Mr. CRAIG. Thank you very much, Mr. Chairman, and to all of you panelists. I appreciate your testimony, and the depth of it.

A couple of questions.

Dr. Sencer, we heard yesterday some figures that, by their surface and by their composition, are startling and important in the consideration of this issue—that the reported or diagnosed cases are doubling approximately every 6 months. That figure was used by several professionals yesterday.

Apparently they are using national averages, based on the information that is available and that is now currently being collected.

In looking at your addendum on page 1—speaking of trends of AIDS cases by month in New York City—you don't seem to demonstrate, based on the 1982 monthly average of 42 versus the 1983 monthly average of 50, to be experiencing that kind of doubling effect.

I guess the best thing then to ask you is, what are you seeing in your city as to the increase factor, or the ratio, of increase?

Dr. SENCER. As you point out, for the last 2 months we have been talking about the fact that it does not appear to be increasing as rapidly in New York City. Still 50 new cases a month is certainly a matter of continued concern.

Mr. CRAIG. Absolutely.

Dr. SENCER. It may be that our reporting is not as good as we would hope to be, and this is why we are undertaking an intensive review in conjunction with the hospitals of New York, of the diagnoses, to see whether we are missing cases.

It could be the fact that some of the advice that Dr. Silverman was talking about is being heeded, that there is a change in lifestyle that puts people at less risk. It could be that the disease is not as infectious as we had once feared that it would be.

Pure speculation would be that perhaps there are enough sub-clinical cases, people who do not actually become ill, who develop an immunity to the disease.

I know that it is continuing to increase in other parts of the country. It may be that the disease has not been there and is being seen more now. But we in New York at the present time are in a bit of a plateau. I could go home tomorrow and find it is up again. I certainly hope not. We do not see the doubling at the present time.

Mr. CRAIG. Dr. Sencer, you say you are going to review your information-collecting capability within the next couple of weeks?

Dr. SENCER. Yes; what we are doing is reviewing diagnoses in hospitals to see whether there are laboratory diagnoses that have not been reported.

Mr. CRAIG. Could you make available to this committee that information, if you find the trends you indicated here have substantially changed or need correction?

Dr. SENCER. It will be well-known, sir; yes, sir.

Mr. CRAIG. Also, Dr. Sencer, I was, frankly, a little surprised, but pleased, to hear of the frankness of Dr. Silverman as it relates to what he feels these communities ought to be doing as a preventive approach to this problem while we struggle with getting on with trying to find some cure and/or method of prevention through inoculation or whatever.

I am not trying to place any higher level of importance on what I am about to ask. I see the aforementioned subjects as two separate, but jointly very important things, in the total problem.

I assume that you and Dr. Silverman, and if you are not I wish you would indicate, doctor, in the San Francisco Department of Public Health are communicating very loudly and clearly to the communities involved what your recommendations as to how they live their lifestyles ought to be conducted in a preventive way.

Are the city of New York and the health departments of New York, approaching this in a similar fashion?

Dr. SENCER. I think that our approach in New York has been—I wouldn't say loud, but we have tried to work with the various population groups at risk to get them to bring out the recommendations on behavior rather than this being something that comes down from city hall or from the health department.

As San Francisco has done, we have met with the owners of bathhouses to convince them to develop their own types of standards for education within this particular milieu. As I mentioned, we meet biweekly with the affected communities, as San Francisco does. We have a full-time office of gay and lesbian health concerns that helps in this communication to the population group affected.

Mr. WEISS. Thank you, Mr. Craig.

Mr. CRAIG. Could I have one last followup on this question?

Mr. WEISS. Very, very brief, please. We have had Dr. Brandt waiting for an hour.

Mr. CRAIG. As you come to us and encourage increased levels of Federal support into the millions of dollars, which I am certainly sympathetic to based on the scope, the magnitude and the unknownness of this problem, don't you believe there is some level of responsibility at the public health level—not to be quiet about practices or alternative lifestyles as it relates to this problem, but that maybe you ought to be really quite loud about it—as to what you now see as methods of prevention or practices of prevention?

Dr. SENCER. I think that there are ways in which this could be accomplished without taking to the soapbox.

I certainly believe that the information is going to be better accepted and come from a stronger support if it comes from the affected communities themselves.

This is not to say that we do not publicly make these statements in New York. I have made them, the mayor has made them. It is a matter of public record. But I believe that our approach has been one of working with the affected groups to try and develop the capabilities within—particularly within the gay community to educate the people that they can communicate with. There are gay newspapers that are a much better communicator to that population than our New York newspapers, the general circulation. I

think that it is through working with this approach that we can accomplish our goals.

I think that public exhortation has not stopped the spread of venereal disease. It has been by making adequate treatment available to individuals with venereal disease, it has been by finding cases and bringing them to treatment. So I think when we are dealing with a personal behavior of this nature, mere exhortation without good epidemiologic assistance to bring them in for adequate diagnosis and treatment has not proven itself to be of much use in venereal disease.

Mr. WEISS. Thank you, Mr. Craig.

Dr. SENCER. Mr. Chairman—I am very pleased that this hearing is taking place, because here we are talking about the problems of communicating about sexual behavior, about sexual patterns. I can remember when it was within my lifetime that the Surgeon General was cut off the radio for talking about syphilis. So I think we have come a little ways in 50 years.

Mr. WEISS. The Congress is very bold these days.

Mr. Levin?

Mr. LEVIN. Mr. Matek, in your written testimony you say it has been disappointing to hear recent charges of unresponsiveness on the part of CDC and NIH related to their AIDS-related activities. But such appearances can be understood easily enough by reference to the fact that these agencies are underfunded, understaffed, and overworked. It is clear, moreover, that the administration's marching orders to these program directors is unequivocal—in quotes—"Don't ask for any money, make us look as good as you can with what you have got."

Would you elaborate on both of those serious charges?

Mr. MATEK. Those are my conclusions based on observing behavior over the past 2 years. Those are my conclusions based on repeated discussions with various officials, asking them why certain things could not be undertaken in epidemiological research or in intervention.

I have received a uniform answer: "There is no money. We have gone to the administration to ask for money and been told no. There is no new money for social programs."

We have witnessed the recommendations of OMB over two budget periods now, consistent with that principle, that policy commitment. And we are now observing the budgetary consequences within our operating programs.

I am left with no other conclusion, Congressman, and I wish that someone would prove me wrong. I certainly invite the White House to come forward and show me that I am wrong.

Mr. LEVIN. Thank you.

Mr. WEISS. Thank you very much, Mr. Levin.

Gentlemen, I want to again express my appreciation for the work that you are doing in your own communities and across the country, and for giving us the benefit of your knowledge and of your experience.

Thank you.

Our next panel is the panel from the Department of Health and Human Services: Dr. Edward Brandt, Assistant Secretary for

Health, and Dr. William Foege, Director, Centers for Disease Control, are our chief witnesses.

I understand that they are accompanied by a number of their associates and colleagues who will be in the front row behind them or accompanying them at the witness table, as you so please, Dr. Brandt and Dr. Foege.

Just identify the people who are with you if you will, so that the reporter and those of us up here will be able to know who is speaking at any particular time.

Dr. Fauci, Deputy Clinical Director, National Institute of Allergy and Infectious Diseases; Dr. Henney, Deputy Director, National Cancer Institute; Dr. Quinnan, Director, Division of Virology, Office of Biologics, Food and Drug Administration; Dr. Chernoff, Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute.

I understand that Mr. Thomas Donnelly, Assistant Secretary for Legislation, is also in the audience. Since we will be getting into some issues with which he has been involved, I think it would be helpful for him to join the other panelists at the witness table.

Before we start, let me just indicate how pleased I am that we have this opportunity to discuss with Department officials some of the concerns that have been expressed in the last day and a half as well as to explore some of the issues which the subcommittee has been examining over the course of these past 8 or 10 weeks.

Let me first start by swearing you in or offering the affirmation.

Would you all stand?

Do you swear or affirm to tell the truth, the whole truth, and nothing but the truth?

Let the record indicate that each of the witnesses has so indicated.

Dr. Brandt, as you know, we have your prepared statement. It is very long and very detailed, and we welcome it. It will be entered, without objection, into the record in its entirety.

Because of time constraints, the subcommittee would appreciate if you would try to summarize rather than read the entire statement. That way we would be able to spend the bulk of our time with questions which I know I and the other members of this panel have.

Let me indicate at this point that we have had some concern which we will be getting into in greater depth as the hearing goes on regarding the obligations and responsibilities of this subcommittee toward not just you individually, but the Health and Human Services Department and its various subagencies and representatives.

As you may know, this committee, the Government Operations Committee, of which we are a subcommittee, was created specifically to provide oversight for the various programs not only in the health field, but in all fields of Government, to see how programs which Congress enacted are being implemented, how they are working, which programs are effective, which are not, how the responsibilities are being discharged by those people in the executive branch who have been delegated to deal with those programs.

I understand that most executive branch staff, not only in this administration but in every administration that I have been famil-

iar with at all levels, Federal, State, and local, view the ideal oversight as being a situation where they come in and tell us what a wonderful job they are doing, and we let it go at that.

We view the responsibility somewhat differently. Our responsibility is in fact to go out and check to see what kind of job you are doing. That means and has meant since the beginning of this Republic the right of Congress and its committees and subcommittees to reach into the agency, to have access to the personnel of those agencies, to have access to the files of those agencies. The right of Congress to that access has been repeatedly affirmed by the Supreme Court and other courts that have dealt with it. This matter is really not at issue, not in doubt.

I must tell you that it has been a difficult experience over the course of these last 10 weeks to experience what in essence has been stonewalling from Secretary Heckler on down in our efforts to discharge our responsibilities. As I say, we will be going into specifics and details as we go along.

At this time, Dr. Brandt, I would welcome your testimony.

STATEMENT OF DR. EDWARD BRANDT, ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. WILLIAM FOEGE, DIRECTOR, CENTERS FOR DISEASE CONTROL; DR. JANE HENNEY, DEPUTY DIRECTOR, NATIONAL CANCER INSTITUTE; DR. ANTHONY FAUCI, DEPUTY CLINICAL DIRECTOR OF INTRAMURAL RESEARCH, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; DR. AMOZ CHERNOFF, DIRECTOR, DIVISION OF BLOOD DISEASES AND RESOURCES, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE; DR. GERALD QUINNAN, DIRECTOR, DIVISION OF VIROLOGY, OFFICE OF BIOLOGICS, FOOD AND DRUG ADMINISTRATION; AND THOMAS DONNELLY, ASSISTANT SECRETARY FOR LEGISLATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. BRANDT. Thank you very much. We appreciate the opportunity we have to discuss with you the acquired immune deficiency syndrome [AIDS].

You have already recognized my colleagues, Mr. Chairman. You are correct that we do have long and complex testimony. And I will attempt to summarize it, yet try to make what I consider to be some of the more important points.

AIDS has been officially recognized by Secretary Heckler as the Department's highest priority emergency health problem. During the past 2 years, AIDS has caused suffering and death in far too many people.

AIDS is a recently recognized health problem which is characterized by a severe and persistent breakdown in part of the immune system.

For epidemiologic purposes, CDC defines an AIDS case basically as an individual: First with a reliably diagnosed disease that is at least moderately indicative of underlying cellular immune deficiency, and second with no known underlying cause for that deficiency or any other cause of reduced resistance reported to be associated with that disease. Persons with AIDS are susceptible to some types

of cancer, such as Kaposi's sarcoma and other B cell lymphomas, and a variety of life-threatening infections, the most common of which is *Pneumocystis carinii* pneumonia. There has been no case reported in which the immune system of an AIDS patient has returned to normal.

From June 1981 until July 26, 1983, the Centers for Disease Control has received reports of 2,044 persons with AIDS—122 of these cases were reported from 20 foreign countries. In the United States, 1,922 cases have been reported from 39 States, the District of Columbia, and Puerto Rico. A complete breakdown by State is included in the testimony.

The average age of AIDS victims is 35 years; 93 percent are men. Death has been reported in at least 743 or 39 percent of the 1,922 cases. Of the 598 people diagnosed more than 1 year ago, almost two-thirds have died.

To date, reported cases fall into five categories: homosexual or bisexual men with multiple sexual partners, intravenous drug abusers, persons of Haitian origin, persons with hemophilia, and others. Eighty-eight percent of the reported cases from the United States fall into the first two risk groups. Because sociocultural differences may lead to problems in obtaining sensitive information from Haitians residing in the United States, the apparent lack of overlap between the Haitian and other groups must be interpreted cautiously.

The 6 percent of patients who have not been placed in any of these groups are the subject of intensive investigation. Included in this group are 19 people who are sexual partners of risk group members, 17 patients who received blood transfusions within 3 years of becoming ill, 10 patients who have Kaposi's sarcoma but normal immunological studies, and 15 individuals on whom complete medical histories have been obtained but who cannot be further classified in relation to known high risk groups. The remaining cases have been reported in individuals on whom complete medical histories could not be obtained.

The Federal response to AIDS began in June 1981 with the investigation and subsequent publication in CDC's Morbidity and Mortality Weekly Report (MMWR) of the first five cases reported from Los Angeles. Medical epidemiologists were immediately dispatched from CDC to investigate additional cases in New York City and California.

The admission of the first AIDS patient to the Clinical Center at the National Institutes of Health occurred on June 16, 1981, approximately 11 days after the first cases were reported in the United States. Subsequently, the FDA and the Alcohol, Drug Abuse, and Mental Health Administration became actively involved in the AIDS investigation. Because of the extensive multi-agency involvement, I appointed a Public Health Service Executive Committee on AIDS to formalize coordination of the response of these agencies to the AIDS problem.

Because there are gaps in our understanding and because of the complex nature of AIDS and AIDS investigations, the public is appropriately concerned about AIDS and the Public Health Service's response to this problem. Therefore, it may be useful to review some of the specific questions that have been raised by the public.

We believe AIDS is transmitted sexually; less frequently through transfusion of blood or blood products; or by the misuse of needles. There is no evidence that the disease is spread through air, food, water, or other casual contact. On the contrary, AIDS is a difficult disease to contract.

The risk of acquiring AIDS through a blood transfusion is extremely small. We do not yet know the cause of AIDS, but the evidence is strong that we are dealing with an infectious agent with a long incubation period. The most plausible agents are viruses.

Treatment is available for Kaposi's sarcoma and for some of the infections which affect AIDS victims. Though a cure is not presently available, we are convinced that steps can be taken to prevent the acquisition of AIDS. And in March 1983, we published our recommendations in the MMWR.

All collected information used to identify an individual patient is generally protected under the provisions of the Privacy Act. CDC has a longstanding position of protecting patient confidentiality, a position which has been upheld many times in the courts. However, because of recent concerns expressed in the press and by some State and local health officials, a system is being developed by CDC whereby information on new AIDS cases will be reported to CDC with all identifying information deleted by health departments and the case identified by a code number.

As to expenditures, the Public Health Service spent \$5.5 million directly on AIDS in fiscal year 1982 and will spend \$14.5 million in fiscal year 1983. In addition, the recently signed supplemental appropriations bill provides an additional \$12 million for obligation in fiscal 1983 and fiscal 1984.

To address these and other public health concerns, the Public Health Service has established a national AIDS hotline and has made a factsheet and biweekly information package available to the public and to the professions.

With your permission, Mr. Chairman, I would like to submit for the record copies of the material used on the hotline as well as the factsheet and the most recent biweekly information package.

On May 24, 1983, I issued a press release to clarify the hazard of AIDS and the status of Public Health Service efforts in combatting the AIDS problem. Let me now present the Public Health Service operational plan which we have followed in attempting to solve the AIDS problem.

First, I'll talk about CDC. The activities of the CDC fall into four major areas: surveillance, epidemiologic studies, laboratory investigations, and dissemination of information.

Using epidemiological studies, CDC has sought to determine risk factors and modes of transmission for AIDS. Laboratory work has been in the areas of immunology and infectious diseases. CDC has disseminated timely information to medical and public health personnel and the general public about the AIDS problem. Between June 1981 and July 1983, 21 articles related to AIDS have appeared in the Morbidity and Mortality Weekly Report.

Turning now to the NIH, it is supporting a wide range of AIDS research by its own scientists and by university and private investigators. Collaborative as well as independent research efforts have been undertaken both intramurally and extramurally by the Na-

tional Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), departments of the NIH Clinical Center, and other components of the NIH.

Thus far, 69 AIDS patients have been treated at the NIH Clinical Center, of whom 15 have died.

Extramural activities have included the issuance of two requests for applications (RFA's) jointly sponsored or funded by the NCI and the NIAID. The purpose of this recent RFA, entitled "Infectious Etiology of Acquired Immune Deficiency Syndrome and Kaposi's Sarcoma," is to encourage studies on the search for the isolation and the characterization of the biological agents which may be the primary causative factor in AIDS and Kaposi's sarcoma.

There are more than 30 individual research projects within the intramural laboratories of NIAID which directly relate to AIDS. The NIAID intramural program has recently awarded a contract to the New York Blood Center to obtain specimens of blood, semen, feces, and saliva from several groups of individuals considered at high risk of acquiring AIDS. These specimens will be obtained regularly and stored. If AIDS develops in any of the studied participants, these specimens will provide valuable material for many of the projects concerned with determining the etiologic agent, developing detection methods, and studying modes of disease transmission.

Four applications have been funded in response to the NCI request for application on AIDS research that was issued in August 1982. Other funds support research project grants not submitted in response to the RFA, including the effects of cytomegalovirus on cell-mediated immunity, plus AIDS projects at ongoing NIAID Sexually Transmitted Disease Centers and Centers for Interdisciplinary Research on Immunologic Diseases.

NCI intramural activities can be divided into research concerned with AIDS and peripheral research examining the immune system from a broader perspective. NCI has called upon a variety of resources in an effort to respond quickly. Mechanisms of response and support include grants, cooperative agreements, and contract awards, the development of specialized RFA's, special workshops, the establishment of an extramural working group, and presentations to and discussions with the NCI advisory bodies.

In September of 1981, roughly 4 months after this disease was first defined, the NCI sponsored a workshop on AIDS involving NCI-supported scientists, along with NCI staff. The workshop was developed for the NCI's Division of Cancer Treatment Board of Scientific Advisers. Three meetings have taken place recently. One of these brought together all of the cooperative agreement grantees. Two meetings involved the combination of NCI AIDS intramural task force staff and outside Federal and university scientists active in the area of retrovirus and AIDS.

The NCI continues to encourage investigator-initiated grant applications and expedites the review of any applications related to AIDS that are received. NCI has formed an extramural working group which consists of all NCI funded grantees and includes NCI and other NIH staff with participation from CDC. This group

meets regularly to discuss ongoing research and share preliminary findings.

NHLBI is primarily involved in two aspects of the AIDS problem. One, in regard to its responsibility for hemorrhagic disorders, such as the hemophilias, NHLBI is concerned with the care and treatment of these patients with blood and blood products; and two, in regard to blood and blood products, the Institute has a major concern for the safety of these products. NHLBI sponsored a conference on the association of blood and blood product use with AIDS on March 15, 1983. It was attended by 35 scientists, clinicians and administrators to develop research recommendations for the Institute.

With the cosponsorship of the NCI and the NIAID, NHLBI will hold a research workshop on the epidemiology of AIDS in September 1983. A meeting of the inter-agency technical committee on heart, blood vessel, lung, and blood diseases and resources which focused on the current state of knowledge regarding AIDS was held on May 4, 1983.

FDA's efforts have been focused in two areas: The safety of blood and blood products with regard to infectious agents transmissible through these products; and research directed toward elucidating the etiology of AIDS. FDA has issued guidelines to blood collection centers on the prevention of AIDS through the screening of donors at increased risk.

FDA is also working with blood product manufacturers in an evaluation of methods which might be applied to clotting factor concentrates to increase the safety of their use. Research has been performed at FDA regarding the etiology, pathogenesis, and treatment of AIDS. Studies pertaining to the etiology of AIDS have been directed toward studying the significance of herpes viruses in these patients.

A series of workshops have been held involving the Blood and Blood Products Advisory Committee, the Office of Biologics staff, outside expert consultants, manufacturers and representatives of the American National Red Cross, the Council of Community Blood Centers, the American Association of Blood Banks, the American Blood Resources Association and the National Hemophilia Foundation.

Through these collaborative efforts, progress in developing new procedures for increasing the safety of clotting factor concentrates have been accelerated. One such product is currently available, and others are at a late stage of development.

The National Institute for Drug Abuse is undertaking several investigations to study AIDS and drug abusers. A technical review to examine issues surrounding risk factors related to drug abuse was convened on July 25 of this year. NIDA is developing programs for staff education at drug treatment centers and assisting with the distribution of other Public Health Service materials.

The National Institute of Mental Health held a research planning workshop yesterday to address the mental health aspects of AIDS. Research will be encouraged in several areas. A workshop to address the emotional concerns and support needs of AIDS patients and health care providers will be held on August 3.

It is important to recognize that a number of nongovernmental organizations have worked with the Public Health Service in planning studies of AIDS or in making recommendations for AIDS prevention, and we have listed some of those on page 25 of my testimony.

Mr. Chairman, members of the subcommittee, let me assure you that we are making every effort to cooperate and assist you in meeting the subcommittee's responsibilities in a manner which does not violate the confidence placed in us by patients, physicians, and State and local health officials.

I appreciate the opportunity to present our story on the AIDS efforts to the members of this subcommittee. The continuing commitment of all of our energies is required. I hereby pledge to eliminate the suffering and death caused by this problem.

My colleagues and I shall be glad to respond to any questions which you or other members of the subcommittee may have.

[The prepared statement of Dr. Brandt follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

Statement By

Edward N. Brandt, M.D., Ph.D.
Assistant Secretary for Health
Department of Health and Human Services

on

Acquired Immune Deficiency Syndrome (AIDS)

before the

Intergovernmental Relations and Human Resources Subcommittee
Committee on Government Operations
House of Representatives
Congress of the United States

August 2, 1983

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to discuss with you the acquired immune deficiency syndrome (AIDS).

I am accompanied by: Dr. William H. Foege, Director, Centers for Disease Control; Dr. Amos I. Chernoff, Director, Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute; Dr. Anthony S. Fauci, Deputy Clinical Director of Intramural Research, National Institute of Allergy and Infectious Diseases; Dr. Jane Henney, Deputy Director, National Cancer Institute; and Dr. Gerald Quinnan, Director, Division of Virology, Office of Biologics, Food and Drug Administration.

AIDS has been officially recognized by Secretary Heckler as the Department's highest priority emergency health problem. During the past two years, AIDS has caused suffering and death in far too many people.

AIDS is a recently recognized health problem which is characterized by a severe and persistent breakdown in part of the immune system. For epidemiologic purposes, CDC defines an AIDS case basically as an individual (1) with a reliably diagnosed disease that is at least moderately indicative of underlying cellular immune deficiency, and (2) with no known underlying cause for that deficiency or any other cause of reduced resistance reported to be associated with that disease. Persons with AIDS are susceptible to some types of cancer, such as Kaposi's sarcoma and other B cell lymphomas, and a variety of life-threatening infections, the most common of which is Pneumocystis carinii pneumonia. There has been no case reported in which the immune system of an AIDS patient has returned to normal; fatality rates of AIDS cases have been very high.

From June 1981 until July 26, 1983, the Centers for Disease Control (CDC) has received reports of 2,044 persons who have AIDS. One hundred-twenty-two of these cases were reported from 20 foreign countries. In the United States,

1,922 cases have been reported from 39 states, the District of Columbia, and Puerto Rico (Figure 1). More than 60 percent of these cases were reported from New York City, San Francisco, and Los Angeles. Of the cases from the United States, 47 percent were reported in the last 6 months. The average number of cases reported per day has gradually increased during the past year from approximately 2 per day to 7 per day presently (Figure 2). The average age of AIDS victims is 35 years; 93 percent are men. Death has been reported in at least 743 (39%) of the 1,922 cases. Of the 598 patients diagnosed more than 1 year ago, almost two-thirds have died.

To date, reported cases fall into five categories: homosexual or bisexual men, intravenous drug abusers, persons of Haitian origin, persons with hemophilia, and others. Eighty-eight percent of the reported cases from the United States are homosexual or bisexual men or abusers of intravenous (IV) drugs (Figure 3). Of the patients who are homosexual or bisexual men, 12 percent have a history of IV drug abuse. Of patients who are IV drug abusers, 33 percent are also homosexual men. A much smaller number of cases has occurred in persons of Haitian origin who now live in this country (most of whom entered the U.S. within the last five years) and in persons with hemophilia. Because sociocultural differences may lead to problems in obtaining sensitive information from Haitians residing in the United States, the apparent lack of overlap between the Haitian and other groups must be interpreted cautiously.

The 6 percent of patients who have not been placed in any of these groups are the subject of intensive investigations. Included in this group are 19 cases who are sexual partners of risk-group members, 17 patients who received blood transfusions within 3 years of becoming ill, 10 patients who have

Kaposi's Sarcoma but normal immunologic studies, and 15 individuals on whom complete medical histories have been obtained but who cannot be further classified in relation to known high risk groups. The remaining cases have been reported in individuals on whom complete medical histories could not be obtained.

The federal response to AIDS began in June 1981 with the investigation and subsequent publication in CDC's Morbidity and Mortality Weekly Report (MMWR) of the first five reported cases from Los Angeles. Medical epidemiologists were immediately dispatched from CDC to investigate additional cases in New York City and California. These investigations led to a second MMWR report in July 1981 clarifying the national scope of the problem. The admission of the first AIDS patient to the Clinical Center at the National Institutes of Health (NIH) occurred on June 16, 1981. Subsequently, the Food and Drug Administration (FDA) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) became actively involved in the AIDS investigation. Because of the extensive multi-agency involvement, I appointed a Public Health Service Executive Committee on AIDS to formalize coordination of the response of these agencies to the AIDS problem.

Public Concerns

Before I outline the activities of these agencies, I shall discuss briefly several concerns which have been raised by the public.

Because there are gaps in our understanding of AIDS and because of the complex nature of AIDS investigations, the public is appropriately concerned about AIDS and the Public Health Service's response to this problem. Therefore, it may be useful to review some of the specific questions that have been raised by the public.

1. How is AIDS transmitted?

Based on the best available information, we believe AIDS is transmitted sexually, particularly among homosexual partners; less frequently, through transfusion of blood or blood products; or by the misuse of needles. We have no evidence that the disease is spread through air, food, water, or "casual" contact. To the contrary, AIDS is a difficult disease to contract.

2. What is the risk of acquiring AIDS through a blood transfusion?

At present, the risk of acquiring AIDS through blood transfusion appears to be extremely small. Although as many as 10 million Americans received transfusions during the 3 years of the AIDS epidemic, CDC is investigating approximately two dozen AIDS cases in which transfusions may be a risk factor. We believe that the PHS recommendations issued in March 1983, which suggested that members of groups at increased risk not donate blood, will decrease the current risk.

3. What is the cause of AIDS?

Although we do not yet know the cause of AIDS, the evidence is strong that we are dealing with an infectious agent with a long incubation period. Public Health Service laboratory scientists are using the most sophisticated methods available in the search for this putative agent. The most plausible agents are viruses. The absence of illness in animals already inoculated with specimens may be a reflection of the long incubation period or may indicate that the "AIDS agent" affects only humans. Unfortunately, it is not possible to predict when the cause of AIDS will be found.

4. Is there a cure for AIDS?

Treatment is available for Kaposi's sarcoma and for some of the infections which affect AIDS victims. However, the persistent immune defect means that many AIDS patients who survive one of the complications of the disease are likely to succumb to another of its manifestations. We are hopeful that new treatment methods designed to improve immune function will result in improved survival or even cure. Though a cure is not presently available, we are convinced that steps can be taken to prevent the acquisition of AIDS, and in March 1983 we published the recommendations in the MMR.

5. How does the government guard the confidentiality of the sensitive information it collects on AIDS patients?

All collected information used to identify an individual patient is generally protected under the provisions of the Privacy Act. CDC has a long standing position of protecting patient confidentiality; a position which has been upheld many times in the courts. However, because of recent concerns expressed in the press and by some State and local health officials, a system is being developed by CDC whereby information on new AIDS cases will be reported to CDC with all identifying information deleted by health departments and the case identified by a code number. Patient names already recorded at the CDC will be deleted and replaced by a code number. During early August all States will be informed of this reporting system. Calls on our new hotline are treated confidentially. No individually identifiable record of the call is made.

6. How much is the Public Health Service spending on AIDS research?

The Public Health Service spent \$5.5 million on AIDS in fiscal year 1982, and will spend \$14.5 million in fiscal year 1983. In addition, the recently signed supplemental appropriations bill provides an additional \$12 million for obligation in fiscal year 1983 and fiscal year 1984 for AIDS activities. We are reassessing continually the resources necessary to respond to this problem in fiscal year 1984 as new information becomes available. Because AIDS is the top emergency health priority of the Department, funds have been and will continue to be redirected, as needed, within PHS agency budgets to respond to this problem.

To address these and other public concerns, the Public Health Service has established a national AIDS-hotline, and has made a fact sheet and bi-weekly information package available to the public. We are distributing over 12,000 individual copies of the material monthly. In addition, interested groups are reprinting and distributing the material. In a presentation July 27, 1983, Secretary Heckler announced the expansion of the nationwide AIDS hotline from three to eight lines. Information will be available on a 24-hour basis. Currently 8,000-10,000 calls are received per day. On May 24, 1983, I issued a press release to clarify the hazard of AIDS and the status of Public Health Service efforts in combating the AIDS problem. We have issued press releases on all PHS AIDS activities as they occur. As evidence of her concern and compassion, Secretary Heckler has visited with AIDS patients at the NIH Clinical Center and has written to all Department employees asking them to

continue to donate blood. This was done to demonstrate the importance of maintaining an adequate blood supply and to dispel rumors that there is a risk of getting AIDS when donating blood. We are also working with Union groups to produce educational materials aimed at specific groups - health care workers, paramedics, correctional personnel, morticians and others.

I shall now present the PHS operational plan which we have followed in attempting to solve the AIDS problem.

Centers for Disease Control (CDC)

The activities of the CDC fall into four major areas: surveillance, epidemiologic studies, laboratory investigations, and dissemination of information.

The goal of surveillance is to describe accurately the scope of the AIDS epidemic by time, place, and person, and requires the use of a standard case definition and report form. The CDC surveillance system is largely based on the voluntary submission of case reports from State and local health departments and individual physicians. Additional cases are obtained through reviews of requests for pentamidine, a drug used to treat Pneumocystis pneumonia and only available through the CDC. The case reports from these sources are the basis of all national AIDS statistics. Within the past 6 months, surveillance has been strengthened by a CDC funded cooperative agreement in New York City and by the assignment of federal public health advisors to assist health departments in New York City, Miami, Los Angeles, and San Francisco. The CDC is working closely with the Conference of State and Territorial Epidemiologists to improve the surveillance of AIDS nationwide. As of July 15, 1983, 16 States have mandated reporting of AIDS cases, and an additional 22 have officially proposed such a requirement. In

addition, a special surveillance project to determine the incidence of AIDS in hemophilia patients was completed in collaboration with the National Hemophilia Foundation.

Using epidemiologic studies, the CDC has sought to determine risk factors and modes of transmission for AIDS. A national case-control study of AIDS in homosexual men was conducted in the fall of 1981. This study established that homosexual men with large numbers of sexual partners are at increased risk for AIDS. Further evidence of sexual transmission was found in 1982 from the investigation of a cluster of homosexual male AIDS patients who were linked by sexual contact. Other investigations in 1982 found evidence for AIDS in individuals with hemophilia who had received clotting factor concentrates and, possibly, additional persons who had received other blood products. Investigations now being implemented include a study of risk factors for AIDS in Haitians living in Miami and New York City, a study of a cohort of almost 7,000 homosexual men in San Francisco, and a study of the risk of AIDS in health care workers. AIDS patients not belonging to known risk groups continue to be investigated as they are reported.

Laboratory work at the CDC has been in the areas of immunology and infectious diseases. Through collaboration with scientists inside and outside the Public Health Service, CDC investigators have helped characterize the specific immune defect caused by AIDS and have studied the immune status of apparently healthy homosexual men and patients with hemophilia. In our search for the causative agent of AIDS, we have used advanced techniques of virology and molecular biology. CDC scientists are collaborating with investigators at

the National Cancer Institute and the Harvard School of Public Health to examine the possible role of a retrovirus, identical or similar to the human T-cell leukemia virus, in causing AIDS. Animal studies into the cause of AIDS are in progress.

The CDC has disseminated timely information to medical and public health personnel and the general public about the AIDS problem. Between June 1981 and July 1983, 21 AIDS-related articles have appeared in the CDC Morbidity and Mortality Weekly Report (MMWR). Included were articles on general prevention recommendations (March 1983) and safety precautions for health care workers (November 1982). These MMWR articles on AIDS have regularly been described by the print and electronic media to the general public. CDC investigators have also published articles in scientific journals, spoken at medical and scientific meetings and public forums, and been available to the media.

CDC is in frequent daily contact with local and State health officials, representatives of concerned groups and health professionals.

National Institutes of Health (NIH)

The NIH is supporting a wide range of AIDS research by its own scientists and by university and private investigators. Collaborative as well as independent research efforts have been undertaken both intramurally and extramurally by the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), departments of the NIH Clinical Center, and other components of the NIH.

NIH intramural scientists have been involved collaboratively in treating patients at the Clinical Center since 1981. Thus far, 69 AIDS patients have been treated at the hospital, of whom 15 have died. Currently 54 patients are under treatment, 12 of these are inpatients. The other 42 cases are being treated as outpatients, or as inpatients whose stay may be only 1 to 2 days in length.

Extramural activities have included the issuance of two Requests for Applications (RFAs) jointly sponsored or funded by the NCI and the NIAID. The most recent of these RFAs was issued in May 1983, with an application deadline of August 1 and awards to be made early in fiscal year 1984.

The purpose of this recent RFA, entitled "Infectious Etiology of Acquired Immune Deficiency Syndrome (AIDS) and Kaposi's Sarcoma," is to encourage studies on the search for the isolation and the characterization of the biological agent(s) which may be the primary causative factor(s) in AIDS and Kaposi's sarcoma.

Examples of the types of studies that might be appropriate include:

- Direct in vivo and in vitro efforts at isolation, identification, and characterization of the causative biological agent;
- Analysis of human tissue with appropriate tests indicative of the presence, state of integration, and location of viral or pro-viral DNA, or some other infectious forms;
- Recognition and identification of marker antigens of pathognomonic significance;
- Cytogenetic analysis for chromosomal changes that relate to disease induction; and
- In vitro search for direct morphological transformation and/or cytopathology of appropriate target cells.

National Institute of Allergy and Infectious Diseases (NIAID)Intramural Research

There are more than 30 individual research projects within the intramural laboratories of NIAID which directly relate to AIDS. These involve studies on the nature of the immune deficiency, development of methods for early detection of disease, isolation of possible etiologic agents, and attempts to transmit the disease to nonhuman primates and therapeutic trials.

Research on therapeutic procedures includes trials of immune interferon and interleukin 2 for their effectiveness in treating AIDS. In addition, studies are underway for the use of bone marrow transplants for the reconstitution of the cellular immune system of AIDS patients. Several studies are aimed at understanding the nature of the immune dysfunction, including investigations on the activation and immunoregulation of B lymphocyte function and characterization of the nature of the defect in purified populations of T4 lymphocytes. The latter project also involves attempts to clone helper T-cells and isolate the agent involved in AIDS. Studies are also in progress of the alterations in the reticuloendothelial system. The process and nature of immune complexes in AIDS patients are under investigation. Plasma from AIDS patients is being studied for its effect on various cell functions.

Projects related to the development of early detection methods include the serologic evaluation of blood from patients for the detection of Beta-2 microglobulins and studies to determine if B cell activation is a marker of disease.

Many intramural projects involve attempts to identify a possible etiologic agent for AIDS. Studies are underway using various DNA

hybridization, isolation and serologic techniques to identify microbial agents. Emphasis is being placed on various agents including retroviruses, adenoviruses, cytomegalovirus, Epstein-Barr virus, various parvoviruses, rickettsia and chlamydia. In addition, a search is being made for the presence of slow viruses in brains of AIDS patients who develop dementia. Attempts are being made to transmit AIDS to nonhuman primates; in addition, the immunologic changes seen in primates following injection of AIDS infectious tissues and blood are being studied.

The NIAID Intramural Program has recently awarded a contract to the New York Blood Center to obtain specimens of blood, semen, feces, and saliva from several groups of individuals considered at high risk of acquiring AIDS. These specimens will be obtained regularly and stored. If AIDS develops in any of the study participants, these specimens will provide valuable material for many of the projects concerned with determining the etiologic agent, developing detection methods, and studying modes of disease transmission. These specimens will be particularly valuable as they will have been collected at the time the AIDS infection was first transmitted, a time which may precede diagnosis by months or even years.

Extramural Programs

Four applications have been funded in response to the National Cancer Institute (NCI) Request for Application (RFA) on AIDS research that was issued in August 1982. The NIAID Advisory Council was polled by telephone several weeks prior to the May 1983 meeting in order to expedite the funding of these applications. The applications include studies on the following:

- potential drug treatments for Pneumocystis carinii pneumonia in an animal model;

- the prevalence and transmission of cryptosporidiosis, a recently identified parasitic disease that can cause severe and potentially fatal diarrhea in the immunosuppressed patients;
- the development of opportunistic infections in infants born to mothers who were sexual partners of AIDS patients; possible routes of transmission of AIDS among contacts of adult heterosexual patients; and
- evaluation of chemotherapeutic and naturally occurring substances for the treatment and prevention of AIDS, as well as the study of immunologic defects in AIDS patients and the possible relationship of cytomegalovirus to the cause of AIDS.

Other funds support research project grants not submitted in response to the RFA, including the effects of cytomegalovirus on cell-mediated immunity, plus AIDS projects at ongoing NIAID Sexually Transmitted Disease Centers and Centers for Interdisciplinary Research on Immunologic Diseases which include: a study to define the interrelationship between the "AIDS prodrome wasting syndrome" and fully developed AIDS in case control and cohort studies; a study of life style and other factors influencing occurrence of AIDS in homosexually active young males, including association of sexual practices with altered helper/suppressor T-cell ratios; and a study analyzing T-lymphocytes of AIDS patients by molecular hybridization with specific DNA probes in order to detect and quantitate the number of genome copies of cytomegalovirus and herpes simplex virus type II DNA in these lymphocytes.

On May 9, 1983, NIAID issued a Request for Proposal (RFP) ("Study of the Natural History of Acquired Immune Deficiency Syndrome (AIDS) in Homosexual Men") which will support a prospective study with the following specific objectives:

- To prospectively observe and study the natural history of the disease in enough persons in high risk groups who are not known to be infected at the outset to yield a number of cases of AIDS sufficient for meaningful estimates of risk;
- To build a repository as a national resource for specimens and data from men to traverse the entire course from well to ill; it would permit testing of hypotheses about etiologic factors; and
- To complement similar smaller, but less well standardized, follow-up studies performed in different places and times.

Twenty-five proposals in response to the RFP were received by July 8, 1983. All were reviewed, and at least four of these proposals are expected to be funded by the end of October 1983.

National Cancer Institute (NCI)

Intramural Research

NCI intramural activities related to AIDS can be divided into research which is concerned with AIDS and peripheral research which examines the immune system from a broader perspective. Both human studies and animal models are needed in this endeavor. Intramural research which is directly related to human AIDS is divided into clinical and laboratory efforts.

Clinical Efforts

- AIDS patients who have developed Kaposi's sarcoma are being treated through a variety of approaches in the NCI's Clinical Oncology Program.
- Treatment protocols of Kaposi's sarcoma are composed of chemotherapy regimens which involve combinations of cytotoxic drugs.
- Kaposi's sarcoma skin lesions - a prominent feature of the disease - are being treated through radiotherapy procedures which involve Phase

I and II trials of total skin electron beam therapy.

- Experimental treatment of Kaposi's sarcoma is being attempted with human lymphoblastoid interferon - a substance that may reduce tumors while not further depressing the patient's immune system.
- In an effort to restore the patient's diminished immune system, the NCI is attempting to use purified human T-cell growth factor (interleukin 2) with AIDS patients.

Laboratory Efforts

- A major focus of the NCI's efforts is to determine the possible causative role of human T-cell leukemia virus (HTLV) in AIDS. Active projects involve cellular biology, immunology, and molecular cloning of the many viral isolates obtained thus far.
- Mechanisms of the immune dysfunction found in AIDS are being studied at the genetic, viral, and pharmacologic levels; HTLV appears to be the only known infectious agent which is detected at a high degree of frequency in AIDS patients, and a lesser degree in lymphadenopathy syndrome, and at a very low frequency in matched control homosexual populations.

Other

- NCI epidemiologists are conducting epidemiological studies of immunological profiles of healthy homosexual men and profiles of hemophiliacs with symptoms, as well as individuals with AIDS or members of population groups at risk of developing AIDS. NCI staff have studied individuals at risk in New York, Washington, D.C., and in Denmark. An analysis of the epidemiology of HTLV incidence in Japan and the Caribbean is being correlated with the distribution of HTLV in lymphadenopathy and AIDS patients.

Intramural AIDS Task Force

Because of the unique expertise in HTLV within the NCI, the Institute established an in-house task force composed of a basic science, clinical, and extramural staff. The intramural task force is responsible for coordinating research efforts within the NCI and for maintaining close collaboration with other interested national and international scientists. Specific collaboration on the molecular biology of HTLV involving nucleic acid and protein sequencing and synthesis is going on. Recently the task force has expanded its efforts to include the Frederick Cancer Research Facility (FCRF), research and support contracts. These units have the unique ability and expertise in virus and lymphokine production as well as a ready scale-up capacity.

Extramural Programs

The NCI has called upon a variety of resources in an effort to respond quickly to AIDS. Mechanisms of response and support include grant, cooperative agreement and contract awards, the development of specialized Requests for Applications (RFAs), special workshops, the establishment of an extramural working group, and presentations to and discussions with the NCI's advisory bodies. i.e., Boards of Scientific Advisors and the National Cancer Advisory Board (NCAB).

Workshops and Presentations

- In September of 1981, shortly after the CDC first learned about AIDS, the NCI sponsored a workshop on AIDS. NCI-supported scientists along with NCI staff came together to discuss preliminary research leads and discuss a coordinated course of research activities.

- A workshop also was developed for the NCI's Division of Cancer Treatment's Board of Scientific Advisors.
- The NCI alerted the NCAB to the growing problem of AIDS early on and has discussed its research directions at every subsequent board meeting. Investigators from the CDC have discussed their findings with the Board. The NCAB is closely following research related to AIDS and has agreed to an accelerated review process for AIDS applications.
- Three meetings have taken place recently. One of these brought together all the cooperative agreement grantees. Two meetings involved a combination of NCI AIDS intramural task force staff and outside federal and university scientists active in the area of retrovirus and AIDS.

Extramural Awards

- In an effort to respond quickly to this new public health problem, the NCI awarded supplemental funding in September 1982 to encourage AIDS research.
- An RFA entitled "Studies of Acquired Immunodeficiency Syndrome" was developed, and cooperative agreement awards have been and continue to be made as a result of this announcement. Studies being funded include:
 - Epidemiologic studies designed to identify possible etiologic factors in affected patients or in individuals with prodromal conditions;
 - Basic research projects on etiology and pathophysiology. These include studies in such areas as immunology, microbiology, virology, toxicology, etc., and include studies of AIDS, Kaposi's sarcoma, and allied conditions; and
 - Innovative clinical treatment and prevention research protocols which are linked to hypotheses of etiology.

- To date, nine cooperative agreements have been funded, and the NCI will continue to fund approved applications from the RFA. The review process that led up to these and subsequent awards was substantially shortened at all stages, with the NCAB participating in a mail ballot rather than wait for a regular board meeting.
- The NCI continues to encourage investigator-initiated grant applications and expedites the review of any applications related to AIDS that are received.
- Contracts also have been employed to help in the AIDS research effort. In general, contracts are used to support laboratory and epidemiologic studies.

Extramural Working Group

The NCI has formed an extramural working group which consists of all NCI-funded grantees and includes NCI and other NIH staff with participation from the CDC. This group meets regularly to discuss ongoing research and share preliminary findings. This mechanism allows for a fast exchange of information among investigators and obviates the need to wait for published results. The NCI felt this type of information exchange would be essential for a continued quick response to this public health emergency. Members of the working group are included in the NCI's intramural task force enhance coordination of research efforts.

National Heart, Lung, and Blood Institute (NHLBI)

NHLBI is primarily involved in two aspects of the AIDS problem: (1) in regard to its responsibility for hemorrhagic disorders, such as the hemophilias, NHLBI is concerned with the care and treatment of these patients with blood and blood products; and (2) in regard to blood and blood products, the Institute has a major concern for the safety of these products. It is

under the latter rubric, blood safety, that efforts to identify carriers of AIDS by means of various screening tests are being carried out.

Intramural Research

- NHLBI has established an intra-agency agreement with the CDC to investigate possible changes in the immune system in patients with hemophilia, sickle cell anemia, and Cooley's anemia, all of whom receive numerous infusions of blood and blood products. Approximately 200 patients from New York are being studied.
- NHLBI also has an intra-agency agreement with the Clinical Center, NIH, which will attempt to transmit AIDS to chimpanzees using plasma obtained from patients with AIDS. If AIDS is caused by a transmissible agent, using material from active cases and injecting it into nonhuman primates offers a good chance for identifying the agent.
- NHLBI sponsored a conference on the association of blood and blood-product use with AIDS, March 15, 1983. The conference was attended by 35 scientists, clinicians, and administrators to develop research recommendations for the Institute.
- An intramural research project involves study of the immune system of sickle cell anemia and Cooley's anemia patients who receive numerous infusions of blood. Specific components on the surface of certain white cells are being investigated as possible markers for changes in the immune system of patients with AIDS.
- With the co-sponsorship of the NCI and the NIAID, the NHLBI will hold a NIH Research Workshop on the Epidemiology of AIDS in September 1983. This meeting will focus on the relationship of various factors that determine the frequency and distribution of AIDS in the community.

- A meeting of the Inter-Agency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases and Resources focused on the current state of knowledge regarding AIDS was held on May 4, 1983.

Extramural Programs

- On July 15, 1983, the NHLBI published an RFA to encourage investigators to develop tests that can be used to rapidly, simply, and specifically identify carriers of AIDS. Presently there is no laboratory test to identify individuals who carry the disorder.
- The NHLBI will soon issue an RFP to solicit contract proposals for a large scale prospective study on the association of blood and blood products to AIDS. The RFP will be issued by the middle of August. The work conducted under the contract will: (1) examine alterations in immune function among patients who receive many blood transfusions to determine whether these alterations bear any relationship to the development of AIDS; (2) compare post-transfusion changes among populations receiving many blood transfusions (patients with sickle cell anemia, Thalassemia, and those undergoing treatment for trauma) with the incidence of the alterations among control groups; and (3) establish a blood serum and blood cell repository that can be used in future research efforts in AIDS.
- NHLBI is supporting a research project grant to study, prospectively, changes in the immune system in patients with hemophilia. This project will provide useful information concerning the natural history of immune disturbances observed in hemophiliacs.
- Researchers in two program project grants are studying the possible link between blood product use and AIDS. These studies focus on genetic and immunologic factors that may contribute to the development of AIDS.

National Institute of Neurological and Communicative Disorders and Stroke(NINCDS)

The NINCDS is involved in a number of intramural projects, including investigations on the interaction between viruses and the host immune system to examine mechanisms of protection as well as disease production in the case of acute or chronic infections of the cerebral nervous system. The NINCDS is also involved in a collaborative effort with the California Primate Center to study Simian Acquired Immune Deficiency Syndrome (SAIDS), a disease in Macaque monkeys similar to humans. This disease has been transmitted in the laboratory, but the etiological agent has not been identified. In addition, Institute staff are seeing patients admitted by the NCI and the NIAID at the NIH to study the deterioration of neurological functions in patients with AIDS.

Food and Drug Administration (FDA)

FDA's efforts have been focused in two areas: 1) the safety of blood and blood products with regard to infectious agents transmissible through these products; and 2) research directed toward elucidating the etiology of AIDS. With respect to the first of these efforts, the work of the FDA has centered on issues of blood collection, processing, and use while coordinating with various blood service organizations. FDA has issued guidelines to blood collection centers on the prevention of AIDS through the screening of donors at increased risk. FDA is also working with blood product manufacturers in an evaluation of methods which might be applied to clotting factor concentrates to increase the safety of their use. In collaboration with scientists at the CDC, 200 separate lots of clotting factor concentrates prepared by the four major U.S. manufacturers were assayed for virus contamination. The results of these studies were negative.

Research has also been performed in the FDA regarding the etiology, pathogenesis and treatment of AIDS. Studies pertaining to the etiology of AIDS have been directed towards studying the significance of herpes viruses in these patients. Through these studies it has been found that two herpes viruses, cytomegalovirus and Epstein-Barr virus, are extremely common in AIDS patients and are frequently associated with Kaposi's sarcoma. These results are the basis for current efforts to determine whether the associations are in any way indicative of an etiological role for one or both of these viruses.

Studies of the pathogenesis of AIDS have been designed to determine what the abnormality of the immune system is that causes patients to be susceptible to opportunistic infections. These studies have demonstrated that AIDS patients are susceptible to opportunistic infections, at least in part if not totally, as a result of an arrest in maturation of immune cells. This defect can be corrected in vitro by treating cells from AIDS patients with a lymphokine, interleukin 2. The cause of this maturation arrest is under investigation.

Studies of treatment of AIDS patients have involved close collaboration in clinical studies being performed at the NIH. The FDA has done substantial testing to evaluate the effects of experimental treatments on the immune systems of the patients.

The future directions of these research programs will be to continue to pursue the leads that have been developed in each of these studies. These studies will be extended to individuals in high risk groups. In addition, as clues are developed from basic research on the etiology and immunology, laboratory tests which detect abnormalities which are specific for AIDS will be pursued as possible screening tests. Plans are under development now to begin experimental application of one such test.

FDA has made a special effort to maintain a broad dialogue with the scientific and manufacturing community and with the various organizations of the blood service complex. To this end a series of workshops have been held involving the Blood and Blood Products Advisory Committee, the Office of Biologics staff, outside expert consultants, the manufacturers, and representatives of the American National Red Cross, the Council of Community Blood Centers, the American Association of Blood Banks, the American Blood Resources Association, and the National Hemophilia Foundation.

At its July 19 meeting, FDA's Blood Products Advisory Committee discussed the safety of plasma derivatives. This is of concern because hemophilic patients require treatment with a product, antihemophilic factor (AHF), derived from plasma which is pooled from thousands of donors. However, I would emphasize that the risk of transmitting AIDS to an individual hemophilic from a special lot of AHF is very small, if it exists at all. The Committee recommended that no regulatory requirements regarding the recall or destruction of lots of AHF, which may contain plasma from an AIDS donor, be developed but that any cases that are identified be examined individually. In reaching such a conclusion, a number of variables must be considered such as: the degree of specificity of the diagnosis, the time of onset of symptoms in relation to the time of donation, the potential effect upon the immediate supply of AHF and the long-term production of this essential plasma derivative. Let me emphasize that the health of the individual hemophilic patient will be a continuing concern for the PHS.

Additionally, through these collaborative efforts, progress in developing new procedures for increasing the safety of clotting factor concentrates have been accelerated. One such product is currently available and others are at a late stage of development. This ongoing cooperative effort will continue to

monitor the nation's blood supply in attempts to insure maximum safety and at the same time maintain adequate supplies of blood and blood products.

Alcohol, Drug, and Mental Health Administration (ADAMHA)

Seventeen percent of all AIDS cases are intravenous (IV) drug abusers. ADAMHA's National Institute for Drug Abuse (NIDA) is undertaking several investigations to study AIDS in drug abusers. A technical review to examine issues surrounding risk factors related to drug abuse was convened on July 25, 1983. Epidemiological investigations will include case-control studies of IV drug abusers, studies of children of IV drug abusers, and studies of potential synergy between homosexual lifestyle and drug abuse in predisposing to AIDS. Laboratory investigators will study the effect of abused drugs on the immune system. In addition, NIDA is developing programs for staff education at drug treatment centers and assisting with distribution of PHS materials.

The National Institute of Mental Health (NIMH) held a research planning workshop on August 1, 1983 to address the mental health aspects of AIDS. Research will be encouraged in several areas: (1) the effects of stress on the immune system; (2) the psychological effects of AIDS on high risk groups; (3) how to meet the psychological and emotional needs of AIDS patients; (4) anxiety in health care workers; and (5) the role of community and family in providing emotional support. A workshop to address the emotional concerns and support needs of AIDS patients, relatives, and health care providers will be held on August 3, 1983.

Non-governmental Organizations

It is important to recognize that a number of non-governmental organizations have worked with Public Health Service agencies in planning studies of AIDS or in making recommendations for AIDS prevention. These organizations include, among others:

1. Public and private medical centers providing care for AIDS patients and/or conducting scientific studies of AIDS.
2. City, county, and State Health Departments;
3. The Conference of State and Territorial Epidemiologists;
4. The Association of State and Territorial Health Officers;
5. The American Association of Physicians for Human Rights;
6. The National Gay Task Force;
7. The Association of Haitian Physicians Abroad;
8. The National Hemophilia Foundation;
9. The American Red Cross;
10. The American Association of Blood Banks;
11. The Council of Community Blood Centers;
12. The American Blood Commission
13. The National Funeral Directors Association;
14. American Federation of State, County, and Municipal Employees;
15. The American Public Health Association.

Mr. Chairman, Let me assure you that we are making every effort to cooperate and assist you in meeting the subcommittee's responsibilities in a manner which does not violate the confidence placed in us by patients, physicians, and State and local health officials.

I appreciate the opportunity to present the PHS story on our AIDS efforts to the members of this subcommittee. A continuing commitment of all our energies is required and pledged to eliminate the suffering and death caused by this problem.

My colleagues and I shall be glad to respond to any questions which you or other members of the subcommittee may have.

Thank you.

Figure 1

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) CASES REPORTED TO CDC, BY STATES—UNITED STATES, JULY 26, 1983

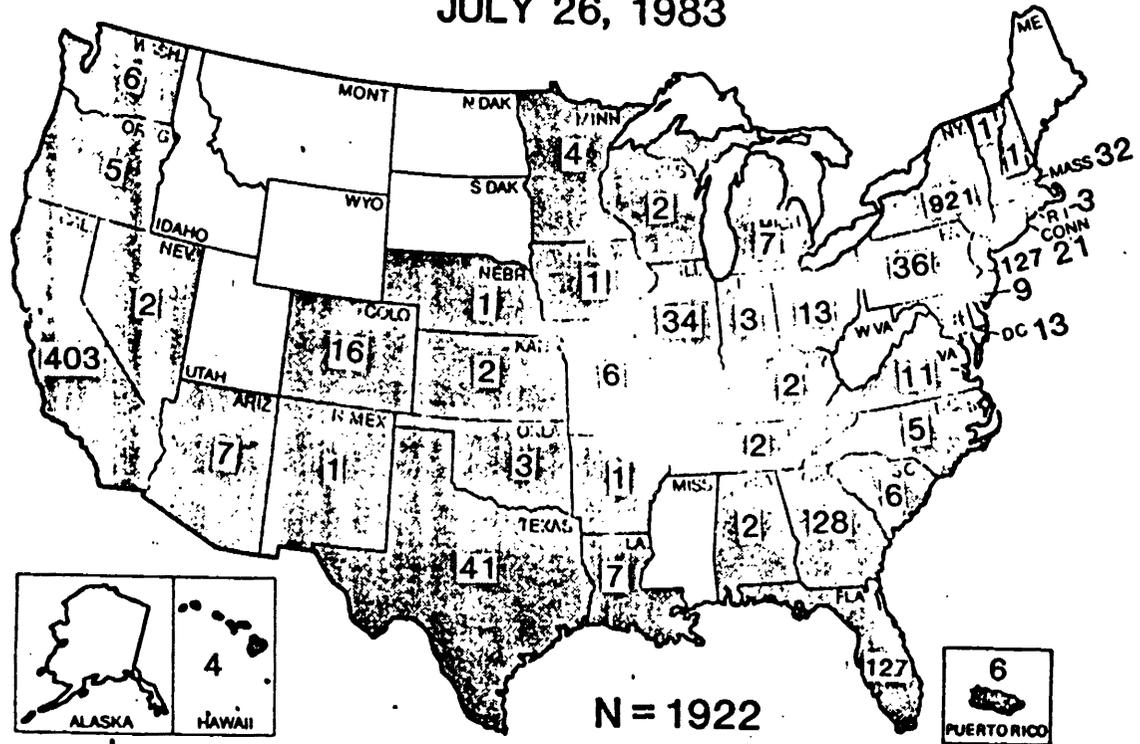
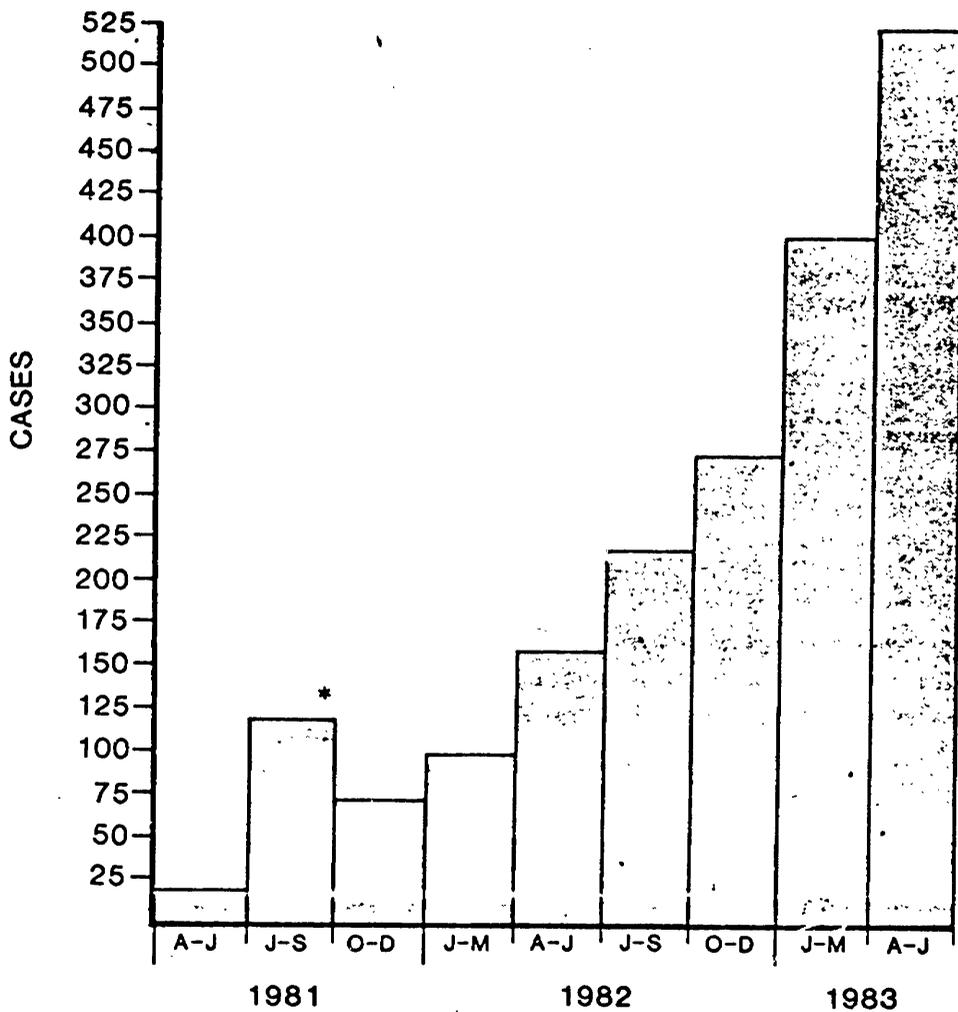


Figure 2

**CASES OF ACQUIRED
IMMUNODEFICIENCY SYNDROME (AIDS)
BY QUARTER OF REPORT
SECOND QUARTER 1981 - SECOND QUARTER 1983
UNITED STATES**



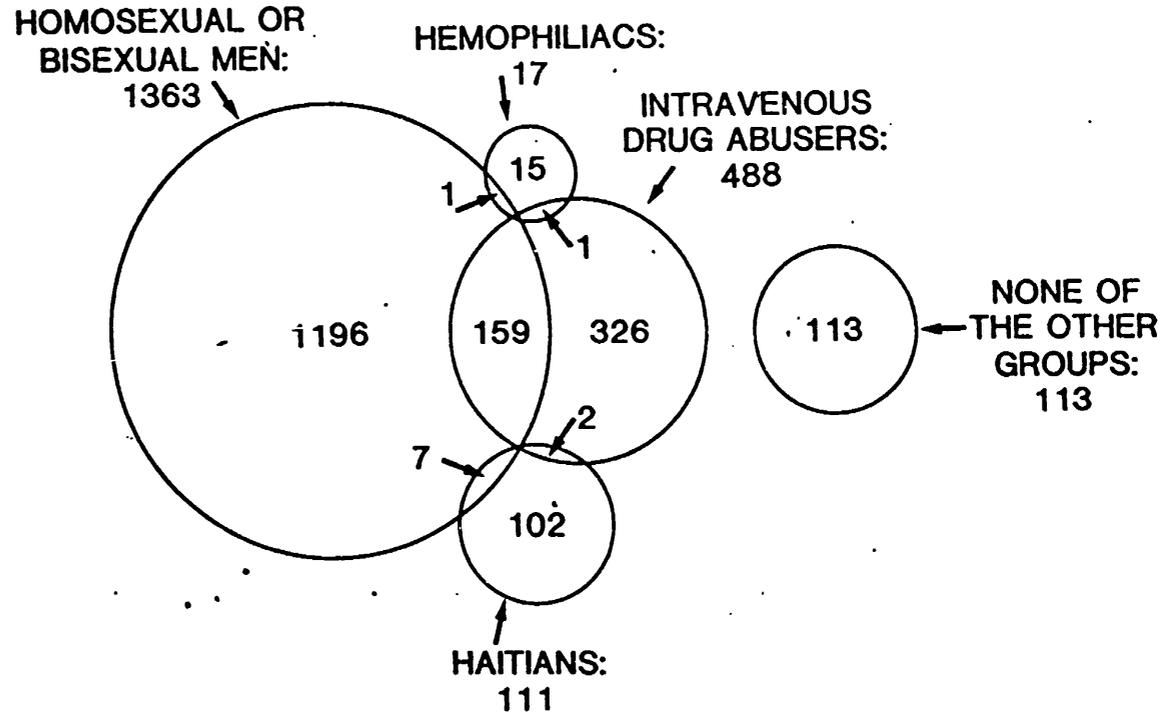
* Includes backlog of cases identified at beginning of CDC surveillance

FIGURE 3

OVERLAP OF GROUPS AT INCREASED RISK FOR AIDS

UNITED STATES, JULY 26, 1983

N=1922



Mr. WEISS. Thank you very much, Dr. Brandt.

Let me state at the outset, before any questions are asked, that I have been impressed with the high regard with which you and your colleagues are held by people in the profession and the communities in which you have dealt, even through this particular crisis and epidemic. So I want you to understand that none of our questions are directed at you personally by way of questioning or attacking your professional capacity or professional integrity. This goes for all of you.

At the outset, let me address the issue that I had raised before you began to testify, because we have a limited time for a hearing today. We will have other hearings later on. But I do want to try to resolve the open question of access. I understand that we have had some developments within the last day or so.

Let me address you, Dr. Foegen, in this regard. I know of your concern for the confidentiality of patients' names and information about them. We share that. And indeed we have tried to make clear from the very beginning that we not only are not interested in seeing those names ourselves, but we question whether in fact CDC ought to have those names. I gather that you are now moving in that direction from the testimony that was just given; that is, you are not requesting the names to be sent on to CDC.

We have, within the last week, forwarded to you a proposal whereby it would be absolutely clear, no matter what the rights of the subcommittee are—as a matter of constitutional and legal right, we have the right to see files in their entirety, including names—that none of our staff and none of the members of the subcommittee would get to see any of the names of AIDS patients. There was an eight-step procedure that we submitted to you.

I wonder if you would tell us what your reaction is to that proposal and how we will proceed as we go on to the question of confidentiality?

Dr. FOEGE. Thank you, Mr. Chairman.

I think the proposal made last week is a great step forward. I think it is unfortunate that we have had this difference of opinion. With your permission, I think it might be useful if we would include for the record the correspondence that we have had between you and myself and other members of the Department on this.

Mr. WEISS. Without objection, that correspondence will in fact be included in the record.

[The information follows:]

WIDE R.V. CHAIRMAN
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NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
HUMAN RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

BAYBURN HOUSE OFFICE BUILDING, ROOM B-372

WASHINGTON, D.C. 20518

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MAY 12 12 03 PM '83
HHS-OS-CCC

May 12, 1983

The Honorable Margaret M. Heckler
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I am writing to request your assistance in obtaining certain information from the Center for Disease Control (CDC) in Atlanta, Georgia.

Specifically, I am requesting that the CDC provide to subcommittee staff full access to all Center personnel and to all documentation repositied in the files of the Center.

As you may be aware, a member of my subcommittee staff is currently visiting the CDC in Atlanta for the purpose of gathering information and documentation pertaining to the Center's research into the cause and treatment of Acquired Immuno-Deficiency Syndrome (AIDS). As she has encountered great difficulty in obtaining the cooperation of CDC management, I would very much appreciate your informing the agency of its responsibility and obligation to the Congress in responding to oversight inquiry.

I trust that future visits by staff will be accommodated in appropriate and responsive fashion.

Thank you for your cooperation in this matter.

Sincerely,



TED WEISS
Chairman

12 May 83 7:00 AM '83

CDC ID: D 11025
DATE: MAY 18 1983
Correspondence Unit, OD
Ext. 3322

EFO/ TELECOPIER 495:13- 5-80110:2761

62303270:4 2



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

*From: Pils Blower
5-13-83*

MAY 12 1983

The Honorable Ted Weiss
Chairman, Intergovernmental Relations
and Human Resources Subcommittee
of the Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter requesting assistance in obtaining certain information from the Centers for Disease Control. I want to assure you that we will cooperate fully with your staff in providing them access to appropriate personnel of CDC and to any documents that may be necessary or relevant to your oversight inquiry.

It is my intent to affirm and support, as we have in the past, policies and procedures which will provide all of the information you desire and request in a manner that will be the least disruptive to the important ongoing work and mission of the Department.

I'm sure you will agree that an orderly and organized process will facilitate the exchange of information between our staffs.

With respect to the individuals whom your staff desires to interview, we will need some advance notice from you of the names of the employees so that schedules may be arranged in a mutually convenient manner and they may be apprised of their responsibility to cooperate with your staff and of their individual rights. If your staff is going to be visiting an office at a particular time, advance notice of that visit will enable us to rearrange schedules accordingly in order to make available all of those individuals whom you desire to interview.

With respect to documents which you may wish to review and/or duplicate, I would ask that you give us advance notice of the subject matter of your inquiry and the category of documents or files to which you would like to have access in order that we can arrange to have those files available and to determine that they contain no information (such as

trade secrets, patient specific material or grand jury information) to which access would be restricted by law.

I am sure you appreciate the need for the fair and orderly process I have outlined. In this way, we can both be assured that we are carrying out our respective responsibilities in a manner that is productive, meets the needs of the Subcommittee, minimizes disruption of agency work and is in the public interest.

I have asked the Assistant Secretary for Legislation, Mr. Thomas R. Donnelly, Jr. to assist you in making particular arrangements as outlined above. If you or your staff have particular problems that are not addressed above, Mr. Donnelly will be pleased to meet with you or your staff to work out any necessary arrangements.

Sincerely,



Margaret M. Heckler
Secretary

NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
HUMAN RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

RAYBURN HOUSE OFFICE BUILDING, ROOM 8-372

WASHINGTON, D.C. 20515

(202) 225-2048

May 17, 1983

*Mr. Winn's reply
to Sec. Heckler*

The Honorable Margaret M. Heckler
Secretary
Department of Health and Human Services
700 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

Thank you for your letter of May 12. I appreciate your reiterating the Department's intention to cooperate fully with the subcommittee in the performance of its oversight responsibilities and share your desire to maintain the orderly and organized process of oversight investigations which this subcommittee has traditionally followed.

- In the past the subcommittee has enjoyed excellent cooperation from the Department and its personnel. Until recently, we have experienced little difficulty in obtaining the information necessary for the subcommittee's work. Unfortunately, this has not been the experience over the past few weeks, when our investigators have encountered tactics at the Food and Drug Administration, the Center for Disease Control, and numerous institutes within NIH, which have seriously impeded our oversight work.

With respect to the proposed procedure set forth in your letter, I appreciate the need to minimize disruption of agency personnel, while at the same time assuring complete and independent congressional review of Department programs and regulatory activities. In the past, it has been our practice to give advance notice of our visits whenever possible, and I welcome your assistance in the scheduling of those interviews. However, there are circumstances which do not lend themselves to pre-notification when our investigators must contact specific personnel directly to arrange appointments at a mutually convenient time. To the best of my knowledge, no case of unreasonable interference was ever brought to the attention of this subcommittee while following that procedure.

I also appreciate your suggestion that Department staff be apprised of their responsibility to cooperate with Congressional investigators and of their rights. As in the past, we will continue to apprise executive personnel that the Rules of the House permit them to have personal legal counsel in attendance during interviews or during appearances before the subcommittee to give testimony. The potential chilling effect, however, of permitting the presence of other third parties during oversight interviews is one which we cannot condone.

With respect to our review of agency files, it has been and will continue to be the practice of this subcommittee to apprise various agencies of our intention to visit and review files whenever possible, as well as to advise them of the general subject matter of our inquiry. However, I am sure that you would agree that it would be inappropriate to require advance notice of the specific matter or documents as a pre-condition to the Department's release of the files or that materials purportedly containing trade secrets, patient specific material or grand jury information be expunged prior to our examination.

I look forward to your continuing cooperation.

Sincerely,



TED WEISS
Chairman

TED WEISS, N.Y. CHAIRMAN
JOHN COVINE, JR., MICH.
SANDER H. LEVIN, MICH.
BUDNY MACKAY, S.C.
EDOUARD TOWNE, N.Y.
BEN BRIDGES, ALA.

*Info 10-1
Pending*
ANDREW S. WALKER, N.C.
ALBERT R. PAUL MCCARDLETT, CALIF.
LARRY E. CRANE, IDAHO

NINETY-EIGHTH CONGRESS
Congress of the United States
House of Representatives
INTERGOVERNMENTAL RELATIONS AND
HUMAN RESOURCES SUBCOMMITTEE
OF THE
COMMITTEE ON GOVERNMENT OPERATIONS
RAYBURN HOUSE OFFICE BUILDING, ROOM 8-372
WASHINGTON, D.C. 20518
(202) 225-2648

May 17, 1983

Dr. William H. Foegen
Director
Centers for Disease Control
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

5:41

Dear Dr. Foegen:

I am extremely surprised and distressed to learn of the serious lack of cooperation afforded my staff last week by CDC personnel.

As you know, Ms. Susan Steinmetz traveled to Atlanta at my direction to gather information and documentation pertaining to the CDC's research into the cause, treatment, and prevention of Acquired Immune Deficiency Syndrome. This followed numerous telephone communications the previous week to advise you and other agency personnel of our planned activities. Unfortunately, the continued refusal of CDC officials to grant my staff full access to personnel and documentation left me no alternative but to recall Ms. Steinmetz to Washington without having obtained the information sought by this subcommittee.

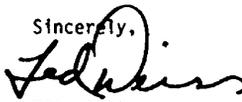
I am particularly disturbed by the procedures announced by Mr. Elvin Hilyer and Mr. James Bloom which were clearly designed to limit Congressional access to information and to interfere with the subcommittee's right and responsibility to conduct thorough oversight review of the agency's activities. Specifically, there is no justification whatsoever for: (1) CDC executive officers prohibiting direct contact with CDC personnel regarding arranging appointments for interviews that were mutually convenient; (2) restricting the questions prepared by subcommittee investigators; (3) prohibiting CDC employees from discussing plans, policies, or budget requests under development; and (4) requiring my staff to interview public employees only under the surveillance of management supervisors.

It is particularly outrageous that Mr. Hilyer attempted to instruct my staff that her visit would be terminated on May 11 and that agency personnel would no longer be made available to speak to her.

CDC ID: D <u>11042</u>
DATE: <u>MAY 18 1983</u>
Correspondence Unit, OD
Ext. 3522

The agency's blatant attempt to disrupt Congressional oversight work is a very serious matter. I sincerely hope that it will not be repeated.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ted Weiss".

TED WEISS
Chairman

XEROX TELECOPIER 495:10- 6-83: 4:07PM

B2363296;M 2

CHAIRMAN
 SEN. JAMES EASTLAND, MISSISSIPPI
 SEN. JIM BURR, SOUTH CAROLINA
 SEN. BOB DODD, ARIZONA
 SEN. DONALD W. RIEDEL, ILLINOIS
 SEN. JIM HASTINGS, CALIFORNIA
 SEN. JIM MOHR, ARIZONA
 SEN. JIM WELLS, TEXAS
 SEN. BOB WOODRUFF, ALABAMA

NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
 HUMAN RESOURCES SUBCOMMITTEE
 OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

RAYBURN HOUSE OFFICE BUILDING, ROOM 8-372
 WASHINGTON, D.C. 20516

(PH) 226-2540

ROBERT L. WALKER, PA.
 ALBERT A. HALL, SACRAMENTO, CALIF.
 LARRY A. OWEN, OREGON

6/10 sent

copies to: Foege
 Watson
 Hilyer
 Bloom
 Dowdie
 Hicks
 Berreth
 Matthews
 Crittenden
 Pickelsimer
Aznick
Owens ps

June 10, 1983

(also distributed in
 HHS and PHS by Francie
 dePeyster)

Dr. William H. Foege
 Director
 Centers for Disease Control
 1600 Clifton Road, N.E.
 Atlanta, Georgia 30333

Dear Dr. Foege:

The subcommittee is continuing an inquiry into Federal policy, coordination, and preparedness for health emergencies, especially in light of our experience in the current AIDS crisis. As part of this investigation, I am writing to request that you submit to the subcommittee the following information and documentation:

1. All memoranda or letters and/or other documents which have been circulated at CDC regarding the actions of Congressional subcommittees to files and personnel under your direction, whether or not these documents were created by you or others in the Department.

2. A listing, by category, sub-category and type, of all files and documentation pertaining to AIDS research and surveillance projects which are maintained by your office and by each of the offices and laboratories within the CDC.

3. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

(a) a listing, by name and position, of all CDC personnel assigned at CDC headquarters and in the field (designate location) to work on AIDS research and surveillance (specify whether full or part-time); and

(b) for each of these individuals, a statement of his/her function and responsibilities prior to and after having been assigned to AIDS work.

4. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

(a) a listing, and dates of initiation and termination, of all AIDS activities at CDC facilities (designate location); and

(b) the proposed and actual funding for each of these activities. Please provide all supporting documentation.

5. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

(a) a listing of each of the AIDS-related projects that has been proposed, but disapproved;

(b) the dates of proposal and disapproval;

(c) the reason(s) for disapproval;

(d) the identity of the proposer.

Please provide all supporting documentation.

6. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

(a) a detailed breakdown of funds and positions transferred from other CDC/HHS activities (please specify) to AIDS projects within CDC; and

(b) a detailed breakdown of hirings of individuals from outside of CDC/HHS to specifically work on AIDS projects and the projects to which these individuals were assigned.

7. All documents relating to proposed CDC requests for additional funding and positions for AIDS activities.

8. All documents which illustrate CDC's role and involvement in coordinating the response of the Public Health Service to the AIDS epidemic. Please include correspondence between CDC and NIH, FDA, and the Assistant Secretary for Health, as well as minutes from meetings which involved CDC and other Federal agencies.

I would appreciate receiving your response to this preliminary request, at your earliest convenience, by July 1, 1983. So as to facilitate expeditious transmittal, please provide the information and documentation on an incremental basis.

Thank you for your cooperation.

Sincerely,



TED WEISS
Chairman



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

JUN 17 1983

EYES ONLY

The Honorable Ted Weiss
 Chairman, Intergovernmental Relations and
 Human Resources Subcommittee
 U.S. House of Representatives
 Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letters of May 17 and June 10 to Dr. William H. Foege, Director of the Centers for Disease Control (CDC), regarding the visit to CDC of Ms. Susan Steimetz of your staff, and your subsequent written request for information and documentation.

As we were in the process of responding to your earlier letter to Dr. Foege, we received the latter one requesting comprehensive information on Acquired Immune Deficiency Syndrome (AIDS) from CDC. Agency personnel, including scientists involved in research on AIDS, are currently undertaking the extensive effort necessary to compile the documentation that you have requested. I must point out that the primary responsibility of these CDC personnel is, and should continue to be, to combat AIDS. We will begin to submit materials as rapidly as possible. However, we cannot meet the July 1 deadline with all materials without inordinately diverting CDC staff, currently working on laboratory and other investigations on AIDS, from their primary duties. I am sure you will agree that this would not be in the public interest.

We sincerely regret that during her visit, Ms. Steimetz seemed to perceive CDC personnel as unresponsive to her needs as a Subcommittee investigator. To my knowledge, CDC made numerous efforts to accommodate Ms. Steimetz's schedule. As you may know, these efforts were complicated by previous CDC staff commitments related to a full day scientific meeting on AIDS and blood products previously arranged for Thursday, May 12.

As you know, Secretary Heckler's policies regarding the Department's procedures for cooperating with Congressional oversight investigations have been set forth in her letter to you of May 12. CDC and all its personnel are prepared to carry out the spirit and intent of the Secretary's letter.

The objectives of this Department and your Subcommittee are the same. I thoroughly regret any misunderstandings which may exist regarding your staff's visit to CDC. Our desire is to work out any such misunderstandings so that you can obtain the information you need to carry out your Congressional responsibilities in a manner which is least disruptive of the Department's ongoing work.

Sincerely,

Thomas R. Donnelly, Jr.
 Assistant Secretary for Legislation

JUN 24 1983

The Honorable Ted Weiss
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources, Committee
on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

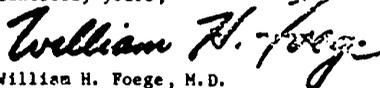
The information on Acquired Immune Deficiency Syndrome (AIDS) requested in your letter of June 10 is being forwarded in incremental packages as the information and supporting documentation are collected. The packages will be tabbed in reference to the questions in your letter.

The enclosed package contains tabbed material as follows:

- Question 1. - complete information
- Question 7. - complete information
- Question 8. - partial information, remainder later.

Subsequent increments will be supplied in like fashion.

Sincerely yours,



William H. Foege, M.D.
Assistant Surgeon General
Director

Enclosure

JUL 1 1983

The Honorable Ted Weiss
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

The enclosed material is the second incremental package providing the information on Acquired Immune Deficiency Syndrome (AIDS) requested in your letter of June 10.

The enclosed package contains tabbed material as follows:

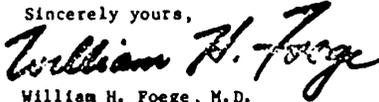
- Question 6. (b) - complete information
- Question 8. - additional information, completing this item.

The previous package contained tabbed materials as follows:

- Question 1. - complete information
- Question 7. - complete information
- Question 8. - partial information.

Subsequent increments will be supplied in like fashion.

Sincerely yours,



William H. Foege, M.D.
Assistant Surgeon General
Director

Enclosure

JUL 18 1983

The Honorable Ted Weiss
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

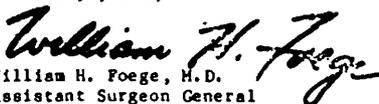
Dear Mr. Weiss:

The enclosed material is the third and final incremental package providing the information on Acquired Immune Deficiency Syndrome (AIDS) requested in your letter of June 10.

The enclosed package contains tabbed material as follows:

- Question 2. - complete information
- Question 3. - complete information
- Question 4. - complete information
- Question 5. - complete information
- Question 6(a). - complete information.

Sincerely yours,


William H. Foegen, M.D.
Assistant Surgeon General
Director

Enclosure

Question 1. All memoranda or letters and/or other documents which have been circulated at CDC regarding the access of Congressional subcommittees to files and personnel under your direction, whether or not these documents were created by you or others in the Department.

Included in this Tab are the following documents:

May 24, 1983 Memo from Dr. Brandt to PHS Agency Heads, OASH Staff Office Directors
Re: Congressional Inquiries

May 20, 1983 Memo from Anthony L. Itteilag to OPDIV Executive Officers
Re: OMB Clearance of Budgetary Information for Congressional Committees

May 17, 1983 Letter from Mr. Weiss to Secretary Heckler

May 12, 1983 Letter from Secretary Heckler to Mr. Weiss

April 29, 1983 Memo from Secretary Heckler to Operating Divisions/Staff Divisions, Regional Directors
Re: Congressional Activities

November 4, 1982 Memo from President Reagan to Heads of Executive Departments and Agencies
Re: Procedures Governing Responses to Congressional Requests for Information

July 28, 1982 General Administration Manual Issuance
Re: Disclosure of Individually Identified Records to the Congress

June 15, 1982 Correspondence Handbook, Chapter CDC 1.2 & Illustrations
Re: Congressional and Other Controlled Correspondence

March 13, 1980 Memo with attachment from Dr. Foege to Directors, Bureaus/Institutes/Offices
Re: Communications with Congressmen

February 28, 1980 Memo with attachment from Charles Miller to PHS Agency Heads, Deputy Assistant Secretaries for Health, Staff Office Directors
Re: Congressional Correspondence

August 30, 1979 Memo with attachment from Dr. Foege to All Bureau/Institute/Office Directors
Re: Communications with Members of Congress and Staff

June 22, 1979 Memo with attachment from Dr. Foege to All CDC Supervisors (to Branch level)
Re: Communications on New Legislation

March 15, 1979 Memo with attachment from Dr. Foege to All Bureau/Office/Institute Directors
Re: Congressional Contacts

Question 2. A listing, by category, sub-category and type, of all files and documentation pertaining to AIDS research and surveillance projects which are maintained by your office and by each of the offices and laboratories within the CDC.

Included in this Tab is the following document:

A listing of all files maintained at CDC which pertain to AIDS.

Question 3. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

- (a) a listing, by name and position, of all CDC personnel assigned at CDC headquarters and in the field (designate location) to work on AIDS research and surveillance (specify whether full or part-time); and
- (b) for each of these individuals, a statement of his/her function and responsibilities prior to and after having been assigned to AIDS work.

Included in this Tab is the following document:

A listing of CDC Employees Assigned to Work on Aids
Fiscal Years 81, 82, 83, & 84

- Question 4. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:
- (a) a listing, and dates of initiation and termination, of all AIDS activities at CDC facilities (designate location); and
 - (b) the proposed and actual funding for each of these activities. Please provide all supporting documentation.

Included in this Tab are the following documents:

- Summary of AIDS Activities
- Supporting Documentation
 - Epidemiological Investigations
 - Surveillance
 - Laboratory Investigations*
 - Technology Transfer/Information Dissemination
- Bibliography of CDC Published and Proposed Journal Articles

*Description of nitrite inhalent study by NIOSH not included. This information will be supplied when available.

Question 5.

For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

- (a) a listing of each of the AIDS-related projects that has been proposed, but disapproved;
- (b) the dates of proposal and disapproval;
- (c) the reason(s) for disapproval;
- (d) the identity of the proposer.

Please provide all supporting documentations.

Included in this Tab are the following documents:

Statement concerning projects

Question 6(a). For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

- (a) a detailed breakdown of funds and positions transferred from other CDC/HHS activities (please specify) to AIDS projects within CDC.

Included in this Tab are the following documents:

- Comments concerning listing
- Listing of positions and funds transferred from other CDC/HHS activities to AIDS projects within CDC
- Backup Information on CDC AIDS Resources

Question 6. For each of the fiscal years 1981, 1982, 1983, and 1984-projected, please provide:

- (b) a detailed breakdown of hirings of individuals from outside of CDC/HHS to specifically work on AIDS projects and the projects to which these individuals were assigned.

Included in this Tab are the following documents:

Explanation of listing

Listing of individuals hired outside of CDC/HHS to specifically work on AIDS projects

Question 7. All documents relating to proposed CDC requests for additional funding and positions for AIDS activities.

Included in this TAB are the following documents:

Centers for Disease Control - AID Funding History

Centers for Disease Control - Legionnaires' Disease, Toxic Shock Syndrome, and Acquired Immune Deficiency Syndrome (obligations in thousands)

Supplemental Appropriations Bill, 1982

DHHS PHS AIDS - Effect of House and Senate Action, FY 1983 Supplemental Request (HF, SC) June 1983

May 20, 1983 Letter from Thomas R. Donnelly to Mr. Gar Kaganowich with attachments - Amendment to House Full Committee Print of FY 1983 Supplemental Appropriation Bill and Draft Report Language

May 18, 1983 Letter from Dr. Brandt to Mr. Natcher with Current Level Funding, May 12 Update on AIDS, and Report on AIDS Additional FY 1983 Activities (in priority order)
Note: Dr. Brandt's letter and attachments were inserted in the Congressional Record - House, May 25, 1983, beginning on page H 3337.

May 13, 1983 Memo with attachments from Dr. Foege to Assistant Secretary for Health, Re: Additional AIDS Resource Needs

May 13, 1983 Memo with attachments from Dr. Brandt to Assistant Secretary for Management and Budget, Re: Additional AIDS Resource Needs

May 9, 1983 letter from Mr. Natcher to Dr. Brandt

FY 1984 OMB Submission

FY 1984 Appropriation Hearing - Dr. Foege's Opening Statement

FY 1984 Congressional Submission

Information from Supporting Data Book-FY 1984 Congressional Hearings

1984 Budget Appeal

Report to Congress, 6/15/83

Questions and Answers Provided at the Request of the House Appropriation Subcommittee as a Result of the FY 1984 Appropriation Hearings

Questions and Answers Provided at the Request of the Senate Appropriation Subcommittee as a Result of the FY 1984 Appropriation Hearings

Question 8. All documents which illustrate CDC's role and involvement in coordinating the response of the Public Health Service to the AIDS epidemic. Please include correspondence between CDC and NIH, FDA, and the Assistant Secretary for Health, as well as minutes from meetings which involved CDC and other Federal agencies.

Included in this Tab are the following documents:

June 17, 1983 Memo from the Assistant Secretary for Health to Director CDC, Director NIH, and Commissioner, FDA
Re: Coordinating AIDS Policy

June 15, 1983 Progress Report to the House Appropriations Committee on Acquired Immune Deficiency Syndrome

June 10, 1983 Memo from Chairperson, Public Health Service (PHS) Executive Committee on Acquired Immune Deficiency Syndrome (AIDS) to the Assistant Secretary for Health
Re: Biweekly Report on the Status of AIDS - INFORMATION

June 8, 1983 Memo from the Assistant Secretary for Health to Assistant Director for Public Health Practice, CDC/PHS
Re: Congressional Report on AIDS

June 2, 1983 Memo from Assistant Director for Public Health Practice, CDC, to the Assistant Secretary for Health
Re: Proposed Advisory Committee on Acquired Immune Deficiency Syndrome (AIDS)

May 27, 1983 Memo from Assistant Director for Public Health Practice, CDC, to Members of the PHS Executive Committee on AIDS
Re: Committee Communications

May 27, 1983 PHS AIDS Executive Committee

May 23, 1983 Memo from the Assistant Secretary for Health to PHS Agency Heads, OASH Staff Office Directors
Re: AIDS Correspondence

May 17, 1983 Memo from Chairman, PHS AIDS Executive Committee to Committee Members
Re: PHS AIDS Executive Committee Meeting

May 16, 1983 Memo from the Assistant Secretary for Health to Agency Heads, PHS, Members, PHS AIDS Executive Committee
Re: PHS Acquired Immune Deficiency Syndrome (AIDS) Executive Committee

May 16, 1983 Memo from the Assistant Secretary for Health to Members, PHS AIDS Executive Committee
Re: Formal Constitution of PHS Acquired Immune Deficiency Syndrome (AIDS) Executive Committee

February 25, 1983 Memo from the Director, Centers for Disease Control to the Assistant Secretary for Health
Re: Prevention of the Acquired Immune Deficiency Syndrome (AIDS)--ACTION

Included in this Tab are the following documents:

June 27, 1983 Memo from the Chairperson, PHS Executive Committee on AIDS, to Assistant Secretary for Health, PHS (with attachments).
Re: Biweekly Report on the Status of Aids - INFORMATION

June 17, 1983 Memo from Assistant Secretary for Health to Agency Heads and OASH Staff Offices.
Re: Acquired Immune Deficiency Syndrome

June 16, 1983 Note to Dr. Jeffrey Koplan from Assistant Secretary for Health.
Re: Memo of June 9 - briefing on AIDS

June 15, 1983 Note to Dr. Koplan from Shellie Lengel, OPA, PHS.
Re: AIDS fact sheet dated June 13, 1983

June 14, 1983 Note to Dr. Koplan, Chairman, PHS Executive Committee on AIDS, from Shellie Lengel.
Re: Draft leaflet for the public on AIDS

June 13, 1983 Memo from Assistant Secretary for Health to Director, NIH.
Re: NHLBI Proposal to Form AIDS Expert Panel

June 6, 1983 Memo from Chairperson, PHS Executive Committee on AIDS, to Assistant Secretary for Health.
Re: Biweekly Report on the Status of AIDS - INFORMATION

June 1, 1983 Note to Dr. Koplan from Jim Buchan, Office of Public Affairs, PHS.
Re: Dr. Koplan's participation on AIDS in the U.S. Conference of Mayors on June 12, 1983, in Denver

May 27, 1983 Memo from ADAMHA AIDS Representative to Chairman, PHS AIDS Executive Committee.
Re: ADAMHA AIDS Activities

May 24, 1983 Statement on AIDS by Edward N. Brandt, Jr., M.D. (for release).

May 23, 1983 Memo from Scientific Director, NIAID, NIH, to Dr. Robert Gordon, Chairman, NIH Working Group on AIDS.
Re: AIDS Research Projects in the Intramural Programs of NIH Institutes

May 19, 1983 Report prepared by the Food and Drug Administration: "Current Research and Future Needs for Study of the Acquired Immunodeficiency Syndrome (AIDS)."

May 19, 1983 Weekly report from FDA on AIDS activities - to Chairperson of PHS AIDS Executive Committee.

May 16, 1983 Memo from Director, National Institute of Allergy and Infectious Diseases, NIH, to Assistant Secretary for Health.
Re: Summary of trip to Haiti on May 3-10, 1983, in regard to AIDS - INFORMATION

May 12, 1983 Agenda and Attendees for Meeting of Outside Consultants on the Association of AIDS with Blood and Blood Products

April 21, 1983 Memo from Dr. John Killen, Head, Medicine Section, CIB, CTEP, BCT, NCI, NIH, to NIH staff.
Re: AIDS Extramural Working Group Meeting, May 6, 1983

March 24, 1983 Memo from Director, Office of Biologics, National Center for Drugs and Biologics, FDA, to All Licensed Manufacturers of Plasma Derivatives.
Re: Source Material Used to Manufacture Certain Plasma Derivatives
with enclosures listed below:

Memo from Director, Office of Biologics, FDA, to All Establishments Collecting Human Blood for Transfusion.
Re: Recommendations to Decrease the Risk of Transmitting AIDS from Blood Donors

Memo from Director, Office of Biologics, FDA, to All Establishments Collecting Source Plasma (Human), (plus attachments).
Re: Recommendations to Decrease the Risk of Transmitting AIDS from Plasma Donors

February 24, 1983 Memo from Director, AIDS Activity
Re: Meeting with Dr. Coutinho & Professional Escoal The Netherlands - 3/22/83 w/2/11/83 ltr from Dr. Coutinho

January 12, 1983 Memo from Director, CDC, to Assistant Secretary for Health, PHS.
Re: Summary Report on Workgroup to Identify Opportunities for Prevention of AIDS, January 4, 1983

August 17, 1982 Memo from Assistant Secretary for Health to Director, CDC.
Re: Report of PHS Committee on AIDS

August 6, 1982 Memo from Director, CDC, to Assistant Secretary for Health.
Re: Open Meeting of the PHS Committee on Opportunistic Infections in Patients with Hemophilia, July 27, 1982, Washington, D.C. (summary report attachment)

The accompanying table lists positions and funds transferred from other CDC/HHS activities to AIDS projects within CDC in FY 1981, 1982, and 1983.

In fiscal year 1984, it is anticipated that all personnel assigned full time to AIDS work will be permanently assigned to the AIDS project group in CID.

The activities of many other personnel who work in laboratory-related positions (as evidenced in the response to question 3) were redirected to place some priority on conducting laboratory investigations of AIDS. However, these personnel were not transferred from their original organization to the AIDS Activity.

JUL 12 1983

JOHN EDWARDS, JR., MCA
SENATOR BY LETTER FROM
BUDNY HANCOCK, FLA.
EDOUARD TOWNSE, ILL.
BAR FROM CA, ALA.

NINETY-EIGHTH CONGRESS

ROBERT S. TRALLER, PA.
ALFRED A. PAU MCCANN-JESS, CALIF.
LARRY S. CRAIG, IDAHO

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
HUMAN RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

RAYBURN HOUSE OFFICE BUILDING, ROOM 8-372

WASHINGTON, D.C. 20515

DD2 225-2548



July 6, 1983

Dr. William H. Foege
 Director
 Centers for Disease Control
 1600 Clifton Road, N.E.
 Atlanta, Georgia 30333

Dear Dr. Foege:

This is to inform you that Mr. Martin Landry of the General Accounting Office has been assigned to the staff of the Intergovernmental Relations and Human Resources Subcommittee of the Committee on Government Operations. He will assist the subcommittee in its continuing inquiry into the Federal response to the AIDS epidemic and other health emergencies. Mr. Landry has my full authorization to conduct investigations on behalf of this subcommittee. I would very much appreciate your cooperation in providing Mr. Landry with full access to any and all information, documentation, and personnel requested.

Thank you for your cooperation in this matter.

Sincerely,



TED WEISS
 Chairman

118 WEAVER ST. CHAIRMAN
 JOHN C. WEAVER, JR. MICH.
 SAMUEL W. LITTLE, MICH.
 BUDDY BRADY, ILL.
 EDOLPHUS TORRES, R.T.
 BEN TROBSON, ALA.

ROBERT S. WALKER, PA.
 ALFRED A. WELLS, CALIF.
 LARRY S. CRANE, IOWA

NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
 HUMAN RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

RAYBURN HOUSE OFFICE BUILDING, ROOM 8-322

WASHINGTON, D.C. 20518

DDO 228-2146

July 17, 1983

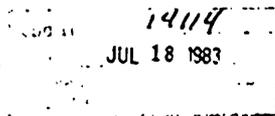
William H. Foege, M.D.
 Director
 Centers for Disease Control
 1600 Clifton Road, N.E.
 Atlanta, Georgia 30333

Dear Dr. Foege:

It again becomes necessary to reiterate the subcommittee's position regarding the conduct of our oversight investigation at CDC. It is unfortunate that you are continuing to delay the subcommittee's performance of its investigation into the Federal response to the AIDS crisis.

First, as you know, there is no legal basis for denying the subcommittee access to files maintained at the Center based either on grounds of "budget information, policy formation, or patient confidentiality." With regard to patient information, I reiterate that the subcommittee has no interest or intention of removing the names of patients from CDC files. However, we must maintain the ability to review those files directly. I am enclosing a proposed procedure for file review and duplication for the purpose of this investigation only.

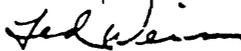
As I advised the Secretary in my May 17 letter, the Department should feel free to advise all of its employees of their right to have personal legal counsel in attendance during interviews or during appearances before the subcommittee to give testimony, and of their right to decline interviews with congressional investigators, should they so choose. Of course, the subcommittee would then have the right to call such persons before the subcommittee in Washington. Permitting the presence of other third parties during interviews could have a serious chilling effect on congressional oversight.



I want to assure you that the subcommittee's inquiry seeks to determine that CDC and other Federal agencies are receiving adequate Federal resources, in a coordinated manner, to meet this public health crisis, and that the confidentiality of AIDS victims is being maintained.

The subcommittee does not intend to allow your lack of cooperation, without legal or other justification, to interfere with this critical oversight work.

Sincerely,



TED WEISS
Chairman

Enclosure

FILE REVIEW/DUPLICATION AT CDC

1. Subcommittee staff is to be permitted to retrieve files from wherever they are usually repositied (as long as there is no interference or interruption of CDC business).

2. Staff will tab (paper clip) the materials sought for duplication in increments (file-by-file) for duplication--two copies--one for the subcommittee and one for CDC.

3. Subcommittee staff will keep their copies of documents in a lock-file cabinet provided by CDC while CDC personnel review its identical copies for patient names.

4. Those documents in which CDC finds patient names will be duplicated (one copy) and CDC will redact (blot out) the patient names from this third copy.

5. CDC will provide the redacted copies to subcommittee staff and will pull (under subcommittee supervision) the unredacted duplicates from the subcommittee staff's file cabinet for separate storage in CDC files and for future reference by subcommittee staff (should the need arise).



TED WEISS, N.Y., CHAIRMAN
JOHN CONYERS, JR., MICH.
BANDER M. LIVER, MICH.
BUDDY MACKAY, ILL.
EDOUARD TOWNE, N.Y.
BNA BRONSON, ALA.

ROBERT B. WALKER, PA.
ALFRED A. MAJ. MCCARDLE, CALIF.
LARRY S. CRAIG, IDAHO

NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
HUMAN RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

RAYBURN HOUSE OFFICE BUILDING, ROOM B-372

WASHINGTON, D.C. 20518

GD2 228-2848

July 15, 1983

William H. Foegen, M.D.
Director
Centers for Disease Control
1600 Clifton Road, N.E.
Atlanta, Georgia 30333

Dear Dr. Foegen:

I am writing to invite you to personally appear before the subcommittee on August 2 at 2:00 p.m. in hearing room 2154 of the Rayburn House Office Building.

As you know, the subcommittee has been examining the response of the Public Health Service to Acquired Immune Deficiency Syndrome (AIDS). This public hearing will provide an opportunity for the subcommittee to review public concerns about AIDS and the Federal response to the epidemic.

Will you please arrange to have 50 copies of your prepared statement delivered to the subcommittee office by no later than the close of business on Friday, ~~JULY 22, 1983~~ ~~1983~~. Such advance submission is required by the Committee Rules in order to give Members an opportunity to study your statement in advance of the hearing. If your prepared statement will require more than 10 minutes of oral presentation, please be prepared to summarize it in approximately that time. Your entire statement, regardless of its length, will be included in the printed hearing record.

If you are unable to attend, I would appreciate having your office notify the subcommittee as soon as possible. A similar invitation is being sent to Secretary Heckler by a separate letter.

I greatly appreciate your cooperation in this important matter. If you have any questions concerning the hearing, please have your staff call Susan Steinmetz at the subcommittee office.

Sincerely,

TED WEISS
Chairman

14113
JUL 18 1983
Correspondence Unit, OD
Ext. 3322

11 /

JUL 25 1983

The Honorable Ted Weiss
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

I am sorry that you believe we are delaying your investigation of the acquired immune deficiency syndrome (AIDS). We are prepared to provide you photocopies of all AIDS records with personal identifiers removed. While this would require taking people from AIDS activities temporarily, thereby interfering with our efforts to solve this desperate problem, we are more than willing to do so in order to assist the Subcommittee in their work. The delay in developing a procedure has been due to my need to verify specifically whether you are asking to see the names of patients with AIDS.

We indicated to Mr. Landry, the GAO investigator assigned to your Committee, that we were prepared to provide all information possible, as we have always done with Congressional investigations. When Mr. Landry told us in our initial meeting last week that you were interested in all information including identifiers and names, I thought it necessary to obtain written documentation of your request. Also, Mr. Landry indicated that he was instructed not to proceed even though we offered to provide AIDS information pending resolution of the access issue.

Your letter, with its attached procedural recommendations, makes it clear that you do intend for your staff to see the names of patients even though the documents which you would later receive would have the names removed. I'm sure you can appreciate the confidentiality difficulties inherent in such a procedure. We are concerned about protecting the privacy of all individuals with AIDS, but prominent public figures present a special problem if they are identified. It would be difficult for any investigator to simply ignore or forget if such an individual were included as a case.

As you may know, the investigation of AIDS is hampered by the concern of patients, physicians, and local health authorities that names given to CDC could not be safeguarded. Your request lends substance to that concern. We are now working on a procedure which would preclude CDC's receipt of names as part of its AIDS surveillance system. All documents would be identified by code. Such a procedure will obviously extract a price in the efficiency and effectiveness of this and subsequent investigations, but may be the only way to assure accurate medical information is collected from patients who are concerned about confidentiality and exposure. Your request to see

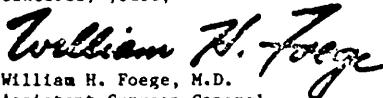
names makes it clear that we will have to pay that price in order to retain the cooperation of State and local health departments and physicians and patients. In summary, our attempts to solve the problem of AIDS will be markedly slowed by any requests for patient identification data which will undermine the accuracy or availability of future data collection.

In the meantime, I trust you will agree that there are also moral factors involved in this instance that should transcend the legal prerogatives of Congress or the Executive Branch. These patients are already suffering under a burden of physical disintegration, social ostracism, and an unknown future. I cannot add to their burden with the possibility that they will be identified to a Congressional office. I sincerely hope you will withdraw your request to see the names and identifiers of AIDS patients.

My staff is already stretched to the limit in attempting to deal with this epidemic. I hope we can develop a working procedure to provide you with the information you require and at the same time minimize any delays this might cause in solving the AIDS problem.

OMB Circular A-10, prohibits me from complying with your request for certain budget information. Once again, let me offer full access to all clinical and epidemiological information short of personal identifications.

Sincerely yours,



William H. Foegen, M.D.
Assistant Surgeon General
Director

TED STEGALL, N.Y., CHAIRMAN
 JOHN CORTNER, JR., MISS.
 DANIEL R. LEVIN, MISS.
 RUSSELL BASKET, FLA.
 EDWIN J. TORRES, N.Y.
 BOB BRIDGES, ALA.

ROBERT S. WALSH, PA.
 ALBERT A. HAI, INDIANAPOLIS, CALIF.
 LARRY E. CRAIG, TEXAS

NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives
 INTERGOVERNMENTAL RELATIONS AND
 HUMAN RESOURCES SUBCOMMITTEE

OF THE
 COMMITTEE ON GOVERNMENT OPERATIONS
 RAYBURN HOUSE OFFICE BUILDING, ROOM 8-373
 WASHINGTON, D.C. 20518
 (202) 225-2644

July 26, 1983

cc:
 Foegen
 Watson
 Bloom
 Hilyer
 Dowdle
 Matthews
 Berreth
 Koplan
 Noble

William H. Foegen, M.D.
 Director
 Centers for Disease Control
 1600 Clifton Road, N.E.
 Atlanta, Georgia 30333

Dear Dr. Foegen:

I am in receipt of your letter of July 25, 1983.

In my letter of July 15, 1983, I stated that "the subcommittee has no interest or intention of removing the names of patients from CDC files."

I am writing once again to emphatically state to you that the subcommittee, in performing oversight investigation of the Centers for Disease Control (CDC), has no wish, nor does it intend, to collect the names of patients who are suffering from acquired immune deficiency syndrome (AIDS).

However, this subcommittee is resolved to fulfill its directed responsibility to conduct thorough and comprehensive oversight investigations into the policy, procedure and practice of all Federal agencies and departments that fall within the subcommittee's jurisdiction, including the CDC, so as to determine program economy, efficiency and effectiveness. Further, it is the practice of this subcommittee to conduct such investigations without disrupting administration and program of the subject agency or department.

In order to allay your latest concern expressed in your July 25, 1983, letter regarding subcommittee staff "seeing names and identifiers" of AIDS patients, especially those of "prominent public figures," I am offering the following procedure for subcommittee staff review and duplication of CDC file materials:

1. During performance of a file search, the subcommittee staff person will be accompanied by a CDC staff person whenever necessary.
2. As the subcommittee staff person selects and retrieves file materials (with the CDC staff person present) from wherever they are usually repositied (as long as there is no interruption of CDC business), both the subcommittee and CDC staff persons will take the files to a designated room or space nearby.

3. The CDC staff person, in the presence of the subcommittee staff person, will review each of the files to determine if any of the documentation therein contain patient names and identifiers. Those that do contain patient names and identifiers will be removed from each of the files and numbered consecutively on the face of each such document by the CDC staff person (in the presence of the subcommittee staff person).

4. The balance of the records and documentation remaining in each of the files (those not containing patient names and identifiers) will be turned over immediately to the subcommittee staff person for review and photocopying (if the subcommittee staff person so chooses).

5. While the subcommittee staff person is reviewing the documentation and records that do not contain patient names and identifiers, the CDC staff person will take the consecutively numbered documents and records containing patient names and identifiers and photocopy each of them (including all attachments thereto).

6. The CDC staff person will take the photocopies and blot out all AIDS patient names and identifiers.

7. The CDC staff person will photocopy each of the documents wherein AIDS patient names have been blotted out, and will present these copies to the subcommittee staff person for review and retention (if the subcommittee staff person so chooses).

8. The CDC staff person will return the original and unredacted documents and records to the appropriate files, and the CDC will retain the first photocopy of each of the documents and records wherein AIDS patients names were blotted out.

I trust you will find this procedure to be acceptable, as it precludes any possibility of subcommittee staff seeing AIDS patient names and identifiers and as it requires the services of only one CDC staff person to assist subcommittee staff in collecting selected documentation and records in file searches that are essential to the subcommittee's investigation.

Finally, I assume that "budget" issues raised in your July 25 letter will be addressed during our meeting next week.

Sincerely,



TED WEISS
Chairman

JUL 28 1983

The Honorable Ted Weiss
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

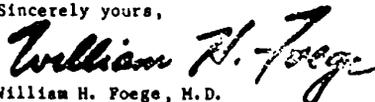
Dear Mr. Weiss:

The enclosed material is the fourth incremental package providing the information on Acquired Immune Deficiency Syndrome (AIDS) requested in your letter of June 10.

The enclosed package contains three items from our National Institute for Occupational Safety and Health (NIOSH). These items are to be inserted under Questions 2, 3, and 4, as indicated in the note attached to each.

This package completes the response to your letter of June 10.

Sincerely yours,



William H. Foege, M.D.
Assistant Surgeon General
Director

Enclosure

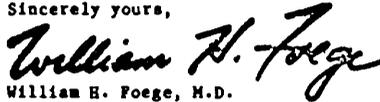
AUG 16 1983

The Honorable Ted Weiss
Chairman, Subcommittee on Intergovernmental
Relations and Human Resources
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

This is in response to your letter of July 26 outlining a method for your subcommittee staff person to review files of the Centers for Disease Control without having access to names or other identifiers. Although your proposal will require considerable time of a person on our AIDS staff to assist with the files, it is an acceptable procedure to maintain confidentiality of personal identifying information in the files, including secondary identifiers.

Sincerely yours,



William H. Foege, M.D.
Assistant Surgeon General
Director

Dr. FOEGE. I think you have made it clear from the beginning that you did not want the names of patients who had AIDS. The discrepancy has been in the procedure which would have allowed your staff to see the names but not have them. I think the proposal you made last week corrects that problem, and I think we have only minor differences now.

For instance, I think instead of talking about patient identifiers, if we talk about person identifiers, so that if a record includes the name of a contact of a case we will not have to provide that name. I think with some slight changes that we can now reach an agreement on how to proceed with the record search.

Mr. WEISS. Well, without again forgoing any of the constitutional prerogatives of the Congress or of this subcommittee, I am sure that we can indeed dispose of that as an issue.

I had occasion yesterday in the course of testimony from some of our witnesses to note with some consternation that while you were insisting on this unfounded concern about confidentiality as far as Congress was involved, you were refusing to discuss the legitimate concerns of confidentiality which the affected groups were trying to raise with you. I found that sort of perplexing. But in any event, I am pleased that we seem to have resolved that issue at this time.

Now, there are other—would you like to comment on that?

Dr. FOEGE. I really don't know what that charge is that was made yesterday. I would like to know more about it, because I think that we have worked extensively with the gay rights groups to try to solve questions. So I don't know what that is about.

Mr. WEISS. Well, they don't believe so. They point to the fact that CDC insisted on collecting names; that in some instances the recordkeeping and security of those names was so shoddy that names were sent by mistake to the New York City Department of Health, and so on.

If you like, I will get more specific information and send it to you for your comment.

Dr. FOEGE. And I would be happy, Mr. Chairman, to talk about our security procedures and how we have shared names, under what circumstances, if you would like.

[Material referred to follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date July 14, 1983

From Acting Chief, Surveillance Section, AIDS Activity

Subject Confidentiality of AIDS surveillance data: Current systems for collection and protection of data

To THE RECORD

This memorandum outlines the legal authorities for collection of AIDS surveillance data, protection from unauthorized disclosure of this data under the Freedom of Information and Privacy Acts, and the precautions being taken by the AIDS Activity to protect sensitive personal information collected through the AIDS surveillance system.

Data collected on the AIDS case report form

Data requested on the AIDS case report form used for surveillance includes name, date of birth, city and zip code, race/ethnic group, specific medical conditions, and risk factors such as sexual orientation (and sex of partners), use of drugs, country of family origin, and possible exposures or predisposing factors. Information is also asked about laboratory data, hospital where treated, and person reporting.

The following information is not requested: social security number (SSAN), street address, telephone number, names or numbers of sexual contacts or sexual practices.

Reportable diseases, surveillance by States, and reporting to CDC

Each State or local health jurisdiction is responsible for deciding whether AIDS (or any other disease or condition) will be reportable and the conditions surrounding means of reporting. If a disease is reportable, physicians, and frequently hospitals, are responsible for submitting a report regardless of the wishes of the patient. This is considered to be a public health responsibility and is not a breach of confidentiality or of the patient-physician relationship. Consent from the patient is not required for reportable diseases. Reporting from local to State health departments is established by State law. Reporting from the State health department to CDC is voluntary and is not mandated by statute or regulation. A State that has collected surveillance data about a disease may share that information with CDC without informing the patient or obtaining further consent. Further release of information by the State, either voluntarily or in response to request or subpoena, is governed by applicable State laws and regulations.

Freedom of Information Act (FOIA)

FOIA provides for release of records from a Federal government agency to the public on request. Specifically exempted from this disclosure, however, are "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

This provision has been tested in court and has been upheld without disclosure of personal or medical information or general information that would allow identification of individuals. Examples of court cases based on this principle include:

Rural Housing Allowance v. United States Department of Agriculture, 498 F.2d 73 (D.C. Cir. 1974).

Wine Hobby USA, Inc. v. United States Internal Revenue Service, 502 F.2d 133 (3rd Cir. 1974).

Rose v. Department of Air Force, 495 F.2d 261 (2nd Cir. 1974).

Most recently, release by CDC of names of individuals reported with toxic shock syndrome has been denied under court appeal.

Privacy Act

The Privacy Act prohibits the government from maintaining secret files about individuals and provides means for an individual to have access to his/her records and to amend incorrect information in the files. The CDC system of files in which records of AIDS patients are maintained is the Epidemiologic Studies and Surveillance of Disease Problems system, as described in the Federal Register, vol. 47, no. 198, October 13, 1982, pages 45494-96, and updated annually. This system provides that "Records may be disclosed to Health Departments and other public health or cooperating medical authorities in connection with program evaluations and related collaborative efforts to deal more effectively with diseases and conditions of public health significance." The system description further specifies the conditions under which release of information is justified and the precautions to be taken.

Precautions to protect data at CDC include: "24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel, i.e., designated researchers, epidemiologists, and their clerical staffs. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by each individual study or specific project. Departmental security guidelines will be followed. For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

Management of AIDS case report forms at CDC

States and cities submitting case reports of AIDS to the AIDS Activity have been asked to mail the list of names and case numbers in a separate envelope from the remainder of the case report data. We have requested that all envelopes with patient data be clearly addressed to the Surveillance Section, AIDS Activity, and be marked "To be opened by addressee only." The envelopes with the case reports are opened in Richard M. Selik's office where they are processed and stored in locked file cabinets during non-working hours. Dr. Selik's office is locked at all times he is not in the office.

After Dr. Selik has reviewed, classified, and logged in the cases, the reports are hand carried in small batches by an AIDS Activity staff person to Ann Rumph, statistical clerk, Statistical Services Branch, DVD, CID. Case reports in this office are maintained in a locked file cabinet at all times they are not being used directly. After the case data are entered on computer, the case report forms are again hand carried by a staff person back to Dr. Selik's office where they are filed in the locked file cabinets by case report number.

Medical epidemiologists and staff members at CDC working on AIDS and with a legitimate reason for needing case reports or computer summaries of reports have access to the files through Dr. Selik or another staff person in the Surveillance Section authorized to grant such access. Persons using these materials are requested to maintain them in strict confidence and to keep them in an appropriate locked file or office.

Management of computerized AIDS case data at CDC

All computer access to AIDS case data is double password protected. Currently only 5 staff people in the Statistical Services Branch, DVD, CID, know the password allowing direct access to AIDS case data. All have been informed about the need for maintaining confidentiality of patient data and procedures for guarding the data against unauthorized access or release.

Computer records of AIDS surveillance data are maintained on hard disk on the ADABASE system. Backup tapes are prepared regularly according to Computer Systems Office standard procedures; these tapes are stored in a secure area according to standard procedures. Access to CDC's mainframe computer is also carefully controlled.

Management of computer printouts and tabulations at CDC

Computer reports of summarized information without identifying data are prepared and distributed to staff members weekly and at other intervals. A single computerized line list of cases is also printed weekly and hand carried by authorized Statistical Services Branch personnel directly to Dr. Selik. Under current operating policy, this list is not xeroxed or distributed to other staff members on a regular basis; authorized persons at CDC working on AIDS are able to obtain a copy of the line list as needed for a special project from Dr. Selik. Persons with access to this list are notified of the need to keep this and all materials with names or other personal identifiers in a locked file or a locked office.

Computer summaries of cases reported by individual States and selected local health departments are prepared on a monthly basis by the Statistical Services Branch and hand carried to Dr. Selik's office. Data reports to be mailed back to the State and local health departments are prepared by AIDS staff members who xerox, collate, and stuff envelopes directly. Printouts with case data are stored in a locked office until sealed in envelopes addressed directly to the State epidemiologist or designated individual to receive the material; envelopes are marked "To be opened by addressee only." Case report material without patient names is sent in a separate envelope from the list of patients.

Case materials, computer reports, and similar information that may have patient identifying information but that are no longer needed are stored in a box in Dr. Selik's office until being taken directly for destruction. These materials are not discarded through the standard trash disposal system.

Sharing of AIDS case data with States, public health or medical authorities
A summary of ways in which AIDS case data (including computer lists or summaries of information) has been used or provided to States or other public health or medical authorities will be summarized in a separate memorandum titled Distribution and Use of AIDS Case List.



James R. Allen, M.D.

cc: James W. Curran, M.D.
Wilmon Rushing
Richard M. Selik, M.D.
E. Thomas Starcher
Dennis J. Bregman, M.S.

Doc. 0358Q



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date July 19, 1983

From Director, AIDS Activity

Subject Confidentiality of AIDS surveillance data: Proposed modification to case report system to eliminate collection of patient names

To Director, Center for Infectious Disease

Within recent months the issue of confidentiality of AIDS surveillance data has become increasingly prominent, despite assurances by AIDS Activity personnel that the names and other identifying information about patients is protected from disclosure by a specific exemption of the Freedom of Information Act and that data is collected, handled, and stored according to guidelines for the Epidemiologic Studies and Surveillance of Disease Problems system of records as required by the Privacy Act. The Centers for Disease Control receive and use on a daily basis confidential data about patients with a variety of diseases and conditions; the initial reports of patients with AIDS were treated with the same precautions accorded other diseases in which personal and medical information is shared with CDC. As AIDS cases continued to be reported, the information received and used at CDC was separated into two classes: (1) Surveillance data, usually case reports from physicians, health departments, and others that provided general information about the case; information included name, birth date, sexual orientation, and use of drugs. (2) Epidemiologic study data, usually specific, detailed, information obtained through special studies or intensive case investigations; informed consent from each patient was necessary to obtain this detailed information. Measures to protect the security of the AIDS surveillance information were reviewed and tightened in early 1983.

In spring 1983 a formal AIDS case report form was distributed to State and local health departments throughout the country and, with the exception of a few cities/counties that had already established active surveillance programs, primary responsibility for surveillance was transferred from passive data collection at CDC to the State and local health departments. The question about whether the name of a patient with AIDS should be included on the case report form was considered in a number of discussions with different groups. The primary arguments included: (a) Detecting and eliminating duplicate reports from different reporting jurisdictions (a real problem with AIDS since the disease is prolonged and a patient often is hospitalized in multiple cities and States); (b) tracking and updating disease and condition reports on patients, including mortality reports, to more fully and accurately understand the natural history of AIDS; (c) correlating laboratory specimens from patients and data from tests performed with case report information, since these often are sent independently to CDC; (d) conducting special studies that require determining through matching whether a given individual has been reported as having AIDS (examples include the study to determine whether receipt of hepatitis B vaccine during the vaccine trials increased risk of AIDS, and studies to determine probability of AIDS being transmitted through

blood transfusion). These arguments for collecting identifying information seemed cogent, and the decision was made to continue to include name and date of birth on the case report form. This decision was reviewed again by CDC program planning personnel and those responsible for clearance; the potential for problems was recognized, but the initial decision was accepted.

Coincident with the introduction of the AIDS case report form, several individuals and groups raised questions about confidentiality and the case report form, including the need for name or other identifying information, the detail of the information being reported, and the need for informed consent from the patient before a case could be reported. The importance of studying AIDS was affirmed, but there was disagreement about the need for identifying information. Part of the concern resulted from misinformation about data being sought on the case report form and misunderstanding about the difference between epidemiologic studies and surveillance--and the data collected for each. Members of the AIDS Activity met on several occasions with health department officials in New York City and Washington, D.C., and with representatives from the affected communities to listen to concerns about confidentiality, to explain reasons for collecting the names of patients, and to discuss measures being taken to protect the identity and confidentiality of individuals. Simultaneous with the surfacing of the concerns about confidentiality, we began receiving reports that some physicians treating patients with AIDS were refusing to report cases or that they were submitting incomplete or inaccurate information, including aliases or pseudonyms.

Data collected on the AIDS case report form

Data currently requested on the AIDS case report form includes name of patient, date of birth, city and county of residence at onset of illness, race/ethnic group, specific medical conditions, and risk factors such as sexual orientation (and sex of partners), use of drugs, country of family origin, and possible exposures or predisposing factors. Information is also asked about laboratory data, hospital where treated, and person reporting.

The following information is not requested on case report forms for surveillance: social security number (SSAN), street address, telephone number, names or numbers of sexual contacts or sexual practices, specific information about drug use patterns.

Proposed modifications to the AIDS surveillance (case report) system

On July 18, 1983, David J. Sencer, M.D., in a dual role as Commissioner of Health for New York City and as the representative from a group of health commissioners of large cities concerned about AIDS, met with representatives of the Surveillance Section, AIDS Activity, to continue discussions about confidentiality and concerns about reporting names of AIDS patients. After discussing alternative strategies, the following general position was proposed that should allow the AIDS Activity to continue to monitor trends and patterns in the occurrence of this disease and that is satisfactory in principle to Dr. Sencer. We propose to implement this system on a trial basis by July 25, 1983, and then to accept or modify it as soon as we determine how well the system functions, problems with it, and the reaction of the State and

Territorial epidemiologists and health officers. Target date for a final decision is August 31, 1983, with full implementation of the system by September 30, 1983.

1. State and local health departments will continue to be the primary focus for surveillance of AIDS. To perform this function efficiently, they need to continue to obtain names and selected other identifying information about patients with AIDS. These health departments are urged to take all necessary steps to protect the confidentiality of records and information in their possession.
2. Cases of AIDS will continue to be reported voluntarily to the AIDS Activity, CDC, through state and local health departments in accord with the May 1983 resolution of the Conference of State and Territorial Epidemiologists. (a) Given names or initials of the patient will not be reported; the last name (surname) will be encoded using a phonetic alpha-numeric system that consists of the first letter of the surname and 3 digits. Using this system, it is impossible to reconstruct a specific name from the encoded form. This type of phonetic alpha-numeric system is currently in use in other health related areas, including for management of sexually transmitted disease reports, and apparently has been used successfully at CDC in the past for special projects. (b) The date of birth will be provided. (c) All other information on the case report form will be reported; none of this is patient identifying information. (d) If a case of AIDS is reported to CDC in which the name is included, routine precautions already in effect will be used to protect that name until it can be encoded using the phonetic alpha-numeric system and the name deleted.
3. State and local health departments will continue to share information with each other about cases of AIDS as necessary. Situations necessitating this may include a resident from one State or area seeking treatment in another State or area and being reported to health officials in the second area, or CDC bringing to the attention of health officials in different jurisdictions that a duplicate case report may exist.
4. Special investigations involving other public health agencies or cooperating medical authorities that require matching of lists will be performed under stringent precautions to protect confidentiality, including submission of a formal protocol with review and approval of the protocol by appropriate institutional review boards (IRBs) and, where appropriate, OMB. Since CDC will not have a list of names of patients with AIDS, our involvement in approved studies may be restricted to matching of the phonetic alpha-numeric list with a similar list generated by the cooperating group.
5. Laboratory specimens from AIDS patients submitted to CDC will need to continue to be appropriately identified. For specimens or results that need to be linked to case information in the surveillance file, sufficient information to establish the link will be sought from the appropriate

physician or health department; no patient name or other identifying information will be added to the surveillance record system.

6. Epidemiologic and intensive case investigations separate from the AIDS surveillance system will be conducted as necessary by CDC, usually in collaboration with State or local health officials and other cooperating medical authorities. The proposed surveillance system for names of patients with AIDS may be used for these other investigations, but this memorandum should not be construed as restricting the design and conduct of these other studies. These investigations generally are initiated with a protocol that has been reviewed and approved through formal clearance channels and IRBs including, where appropriate, expedited clearance through OMB. In this type of study, information from individual patients is collected only after the study has been explained and they have agreed voluntarily to participate in the investigation and have signed a consent form.

Proposed changes to the AIDS surveillance data files

As soon as a final decision is made about the exact format for name/phonetic alpha-numeric code for the AIDS surveillance system, names of all cases of AIDS on the surveillance file will be converted to the new system and all names as such will be deleted from all computer files. In addition, during the trial period of the new system (July-August 1983), proposals for management of paper copies of AIDS surveillance forms will be reviewed and a decision will be reached about a means to eliminate case names from paper records. Possible methods include obliterating names from the case reports, destroying all copies of the paper case report forms, or returning all case report forms to the original reporting State or the listed State of residence of the case. A decision about a method will be reached by August 31, 1983; work on implementing this system to modify paper records will be started immediately after the decision is made and will be completed by a target date of September 30, 1983. Similarly, all existing copies of computer printouts of the AIDS case list will be destroyed as soon as the revised system is functioning.

We would appreciate your comments on our proposed modifications to the AIDS surveillance system to assist in protecting patient confidentiality and to assure individuals with this disease and their physicians of our intent to maintain the privacy of the patients.


James W. Curran, M.D., M.P.H.

cc: John V. Bennett, M.D.
Wilmon Rushing
James R. Allen, M.D.
Richard M. Selik, M.D.
E. Thomas Starcher

Doc. 0498Q

Disclosures made by CDC of Individually Identified AIDS Data

In certain situations CDC has worked with cooperating public health officials and medical authorities, including blood banks, to pursue information relating to AIDS cases. Any such disclosures were consistent with a routine use under the Privacy Act and were necessary in order to carry out epidemiologic investigations of AIDS.

Disclosures were made pursuant to the Routine Use provision [(Section 3(b)(3)] of the Privacy Act.

The published routine use is as follows:

Records may be disclosed to Health Departments and other public health or cooperating medical authorities in connection with program evaluations and related collaborative efforts to deal more effectively with diseases and conditions of public health significance.

This routine use appears in a notice entitled "Epidemiologic Studies and Surveillance of Disease Problems," HHS/CDC/CID, which is published on page 45495 of the Federal Register, Volume 47, No. 198, October 13, 1982.

Comparison of reported AIDS cases with a list of homosexual men who received experimental hepatitis B vaccine was crucial due to concerns that the vaccine might cause AIDS. Since the earliest vaccine trial was conducted among homosexual men at the New York Blood Center, the investigation had to be conducted there. Licensing and marketing of the vaccine in 1982 gave the investigation added urgency. Although the New York Blood Center had an excellent record of maintaining privacy of records during its decade of working with the gay community, extra precautions were taken. The AIDS list was hand-carried to the Blood Center, kept securely locked and hand-carried back to CDC when the investigation showed no evidence of the vaccine increasing the risk of AIDS. The AIDS list was also checked against the list of vaccine recipients in Chicago, Denver, St. Louis, San Francisco and Los Angeles. This was personally done by CDC field Public Health Advisors who immediately returned the list to CDC.

In San Francisco, a case list was provided to Dr. Selma Dritz, the physician in the Communicable Disease Division in charge of the AIDS surveillance and prevention program to assist in the investigation of transfusion related cases in the Bay Area, and to monitor the occurrence of AIDS cases in the largest cohort of gay men in the hepatitis B study. Only Dr. Dritz had access to the list. She kept it in a locked file cabinet in her office at all times she was not using it. The list has been transferred to the CDC Public Health Advisor recently assigned to San Francisco to assist with AIDS activities.

Between February 1982 and June 1983 an updated copy of the national case list was provided on approximately four occasions to Dr. David Auerbach, CDC field EIS Officer assigned to the Los Angeles County Health Department. The list of names was used in epidemiologic investigations of AIDS patients who had been sexual partners of each other and in studies of transfusion-related AIDS. The only other person to use the lists was Ms. Loren Lieb, an epidemiologist employed by the Health Department working on AIDS surveillance and epidemiologic investigations. The lists were never physically removed from the Health Department and were kept in a locked file; outdated lists were destroyed. Since Dr. Auerbach has completed his EIS assignment, the list has been transferred to the CDC Public Health Advisor recently assigned to Los Angeles to assist with AIDS activities.

Mr. WEISS. Well, whatever additional information you would like to have included in the record, we will keep the record of this hearing open for another 10 days for that purpose, without objection.

Now, there are some other questions of access that apply. I have again been absolutely dumbfounded by the insistence of CDC, under your direction, that there be third parties, management personnel, present at discussions between our staff and staff people of CDC.

Now, as a matter of policy, you know or should know that at hearings that this subcommittee holds—and, in fact, all the subcommittees of this committee—the rules provide the opportunity for witnesses to be accompanied by personal legal counsel of their own choosing, not because it is a matter of constitutional right but because the rules of the House dictate it as a policy decision that is appropriate. Our subcommittee has extended it so that if our staff people go out to conduct a field investigation or inquiry, we also provide the opportunity for people who are to be interviewed, if they so request, to have personal legal counsel of their own choosing present.

That is a far cry from allowing a Federal agency to have its management interpose itself between the staff person to be interviewed and our subcommittee staff. That is a chilling and unacceptable process. I don't know where you think you have the basis for it. I want your comment on having free and unfettered access, with prior notification as to time and place, and with no disruption of your work. I want your thoughts on having a big brother of the agency watching over the interviewing of your staff.

Dr. FOEGE. I think the request we made, Mr. Chairman, was that people who were to be interviewed would be notified of the fact that they could have a person in the interview if they cared to. I think these were the procedures that Mrs. Heckler put out in her letter.

Mr. WEISS. I am not sure where Mrs. Heckler, who should know better, gets that premise, either. As far as we are concerned, we have the opportunity to interview people informally or formally. If you want it all to be done formally, by subpoena, it seems to me that it would be a terrible disruption of your time.

So what we have done is to send our people out, after prior discussion as to whom we wanted to see and under what circumstances. For you to then suggest that not only do they have the right to have counsel but that you have the right to determine who should be present is, I think, awfully wrong.

Mr. DONNELLY. Mr. Chairman, may I try to make an effort to perhaps deal with your concerns?

Mr. WEISS. Mr. Donnelly.

Mr. DONNELLY. As you may be aware, I have had some meetings with your staff and others as we have attempted to resolve these issues. I think it is important to say at the outset that no one, certainly at this table or in the Department, is anything but very much aware of the procedures, the rights, the rules of the Congress of the United States in terms of the business that the Congress conducts.

It is my understanding——

Mr. WEISS. And the Constitution.

Mr. DONNELLY. These are constitutional rights, not only the Constitution but the statutes that the Congress has enacted, and in the policies of the House rules for the conduct of House business or the Senate, I assume, for the rules that the Senate conducts.

Clearly, I am not a lawyer, so I am speaking to you as to my understanding of these matters—counsel may differ with me, perhaps, but I believe this is essentially correct—in the matter of having the Congress conduct discussions within the executive branch, short of the subpoena power, which as you say is something that all of us would seek to avoid because it simply sharpens confrontation and polarization, the matter of how one conducts those discussions and investigations or any kind of those interactions is a matter of comity, and it is a matter—

Mr. WEISS. It is not a matter of comity. That is where you and I disagree.

Mr. DONNELLY. We may disagree on that. But it is my understanding that when you would ask people to come up here to be in executive session or to be sworn in or in any other way to appear before you in executive session or appear before this subcommittee, all of the rules of the House and all of the statutes and all of those powers certainly do apply. Where you would ask to come into the executive branch and discuss and have an interaction of material and information that would come back to you, short of that subpoena power we are trying to accommodate you.

Mr. WEISS. You have not accommodated us.

Mr. DONNELLY. All of our efforts have been to accommodate you and provide you access to the information that you require and that you request in an orderly fashion that does not interrupt the mission of the Public Health Service.

Mr. WEISS. Let's get it very clear and straight. I have a GAO investigator; I have a staff investigator. I intend to have them go out in the field to the location of the Centers for Disease Control. I intend to have those people interview previously notified staff people of your agency.

Will you, in fact, permit our staff or the GAO staff to interview those people on the premises without the presence of your management people?

Mr. DONNELLY. Will we permit that? Of course, we permit that. We have always permitted that.

Mr. WEISS. Well, you did not permit it when my staff person visited this past May.

Mr. DONNELLY. No, sir. I would disagree with you, Mr. Chairman, in one point that you made. The issue of whether or not an employee is accompanied by someone is an issue of that employee's choice and solely that employee's choice, and not of management.

Mr. WEISS. Well, it is the policy of this subcommittee that anybody who wants counsel present may have it. The subcommittee will not allow the presence of other staff or management personnel during interviews. We are not about to have employees of the Government intimidated by top level bureaucrats. OK?

Now, I would hope that, in fact, the cooperation would be genuine and not just rhetoric.

Mr. DONNELLY. Mr. Chairman, I trust that our cooperation has been genuine all along. It is my understanding that the things you

have required and needed and the exchanges we have had have been provided forthwith and promptly, as quickly as we can.

Mr. WEISS. We have an internal memo dated May 5, 1983, of minutes from the NCI executive committee. It says:

Program and intramural staff have the right to have an NCI representative be present during meetings with Congressional staff. Dr. Knipmeyer should be advised of Congressional staff requests for interviews and invited to attend.

Mr. DONNELLY. Well, Mr. Chairman, not seeing the memo you have in front of you—

Mr. WEISS. I will give you a copy.

Mr. DONNELLY. I don't know its origin or date in terms of the timing or sequence of these matters. I think as your staff has advised you, given our discussions with them and our openness to come up and discuss these matters, if that memorandum did not reflect accurately the policy of the Secretary which I just announced to you, I am sure the Department or the individual agency has, in fact, corrected that. Perhaps Dr. Henney would wish to speak to that.

But I don't believe we have that kind of problem that exists—

Mr. WEISS. Please speak to that memorandum.

Dr. HENNEY. I think the memorandum is consistent with what Mr. Donnelly was saying insofar as we were trying to give our employees a choice as to whether or not they wanted any other individual staff member to be with them. Dr. Knipmeyer was to be contacted of any meeting only in her coordinating function in terms of congressional liaison activity, so that she would know when congressional staff were at the NCI and could see to it they were accommodated in terms of a room to look through materials, proper Xeroxing facilities, that sort of thing.

Mr. WEISS. You are doing this for our benefit?

Dr. HENNEY. It was the intent to accommodate your investigation, yes.

Mr. WEISS. Do you understand now that, in fact, we consider it inappropriate to have staff people of the agency in a position where they may feel they are being intimidated by top level supervisory staff?

Dr. BRANDT. Are you suggesting that even if an employee voluntarily asks for someone else to be present with them, that you would deny them that right?

Mr. WEISS. I would permit—

Dr. BRANDT. Unless they are a lawyer.

Mr. WEISS. I would permit them to have their personal counsel present. I would not put them in a position where they might feel intimidated by your management staff; that is right.

Dr. BRANDT. Does counsel mean a lawyer, attorney only?

Mr. WEISS. Legal counsel. We don't think it is essential or necessary. There is no constitutional requirement for it. But, as a matter of policy, this subcommittee and this committee have taken those steps. I would hope that, in the future, you would follow this policy and not insist that an intermediary of your agency staff be put between us and the Federal employee who is to be interviewed.

Dr. BRANDT. Nobody is attempting to do that. However, I think that if an employee—an employee, even though they work for the

Federal Government, still has some rights as a person. And it seems to me that should they choose to have—to ask for somebody's presence with them in order to see that their rights are protected following the interview, that, it seems to me, is just sort of simple human decency or courtesy.

Mr. WEISS. Well, we have given simple human decency and legal representational rights. What we are trying to do is to protect agency employees from having big brother watching over them as they talk to a Member of Congress or to the staff of the subcommittee.

Dr. BRANDT. Nobody is forcing them to have anybody with them. Nobody is forcing them to do that.

Mr. DONNELLY. Mr. Chairman, I think it is important for all of us to understand here that what you say is precisely what we are trying to accommodate in that no employee who needs to meet with one of your investigators—and we would ask them to cooperate in every possible way—needs to feel intimidated in either event, either by your investigators or your person, who certainly have no intention of being intimidated, or by our personnel. And that is why when people come to us and request of us what should we do, how can we be cooperative with the Congress, they are advised of that right.

Mr. WEISS. That is not what this memorandum says, Mr. Donnelly.

Mr. DONNELLY. But that is what is, in fact, in place.

Mr. WEISS. Well, let me again be very clear as far as this subcommittee is concerned. You do not have the right to interpose your management people between the committee and staff.

Next area: You have a position of policy development—whatever that means—as being an area where you, Dr. Brandt, and the people under you, make a determination as to subject matters which you will not disclose to this subcommittee.

What does that mean? What does "policy development" mean?

Dr. BRANDT. The only thing that I can think of has to do with budget, sir. That is the only issue that I am aware of that has come up. We are all, as members of the executive branch, bound by OMB Circular A-10, which was first published November 12, 1976, which basically defines what our responsibilities are for disclosure with respect to the budget. That is an order that comes from the President and came from President Carter initially—I guess President Ford initially—and then reinforced by President Carter, and now by President Reagan. As far as I know, that is the only issue that I am aware of.

Mr. WEISS. So that there is no such thing as policy development as the basis for refusal of access to this subcommittee?

Dr. BRANDT. There is nothing that I am aware of. Perhaps you could give me an example of something that you are talking about, and I will try to deal with it.

Mr. WEISS. We have a memo dated May 20, 1983, from Mr. Anthony L. Itteilag to OPDIV Executive Officers. It refers to providing budgetary data to Congress.

Dr. BRANDT. Yes, sir.

Mr. WEISS. It says that:

Statements of evaluation and opinion should be omitted. In instances where Congress has requested factual data, a separate narrative section which clearly outlines the administration's position and facts to support this position must be included.

And then:

All material submitted to the Congress must evidence the Department's support of the administration's stated policies.

What does that mean?

Dr. BRANDT. I don't know, from what you have just read, what that means, sir. I don't know where that memo came from.

Mr. WEISS. This was sent to us from CDC files by Dr. Foegen.

Dr. BRANDT. We will be happy to look at it and try to determine what it means. But I don't—

Mr. WEISS. As far as budgetary items are concerned, is it your position that discussions pertaining to the fiscal 1984 budget—that is, memorandums, and all papers pertaining thereto—are matters which you are foreclosed or precluded from discussing or making available to this subcommittee?

Dr. BRANDT. Papers—the President has submitted to the Congress a budget. And the information pertinent to that budget is certainly available.

Mr. WEISS, it was just pointed out to me that in this memo you had quoted from the NCI, there is a statement at the end that perhaps ought to go in the record. It says: "Should an employee wish to meet with a congressional staffer alone, he or she is free to do so."

Mr. WEISS. Is that the position now?

Dr. BRANDT. It has always been the position. Whenever they choose to do it—

Mr. WEISS. When Ms. Steinmetz, sitting next to me, went down to Atlanta, that was not the case. She was absolutely forbidden to meet with any of your staff people unless, in fact, there was somebody from the management staff present.

Dr. BRANDT. At that point in time, we had received no advance notification, and the Secretary had not set forth the policies under which we were going to deal.

Mr. WEISS. The Secretary may not have set forth the policy. As far as advanced discussions are concerned, there were discussions with the employees who were to be seen prior to her Atlanta visit.

Dr. FOEGE. Mr. Chairman, I think the fact is, Ms. Steinmetz did talk by phone to some of the people she wanted to see. We had no indication before her arrival that she wanted to look at files. And it was at that point that we raised the problem that we would have to remove identifiers first. So that was the real problem.

We asked to get departmental help on deciding where to proceed with that. So that was the problem at that time.

Mr. WEISS. I gather from what you are saying that as of this point there should be no problem as far as access is concerned to either files or to individuals, as long as we follow the confidentiality procedure that we have agreed on.

Well, I am pleased that we have that established. We will be having further hearings. I hope that we don't have to go through this again.

Mr. Walker.

Mr. WALKER. Thank you, Mr. Chairman.

Mr. Chairman, I share your concern over our committee access to executive branch files and information; unnecessary obstructionism by executive agencies can exacerbate situations that can be more easily resolved through negotiation. Hopefully those negotiations have now come to fruition.

But I would point out that this whole matter of access to documents sometimes depends upon whose ox is being gored, too.

The chairman of the full committee of this committee is a little less than enthusiastic about giving us access to information that we have needed recently with regard to the records of this committee, public documents.

When I asked to review transcripts of what went on in this committee and in the published records of the committee, I was told that I personally would have to come and look at it, that I could not send a member of my staff to review that material. And in fact when I personally came down to look through the material and brought along a member of the staff, I had to have a member of the majority staff sit in during the period of time that I went through materials that are on the public record.

So I would say that when we exert our constitutional prerogatives here at times, we ought to be very careful that our own house is in order. In this case it is not.

Let's get back to the issue of AIDS. I think that is something that we want to get discussed.

As I sat here through the day yesterday and listened today to the testimony particularly from the leaders of the gay rights or homosexual activities groups, I had the feeling that the Department was acting in a vacuum. We were led to develop the impression that there is no interaction on the AIDS problem between HHS and a lot of these affected organizations.

First of all, is that a correct impression?

Dr. BRANDT. No, sir, it is not a correct impression.

I will let Dr. Foege begin to summarize this. But I think again, sir, I would like to point out that it clearly is not possible to interact on a frequent basis with every possible organization that may express an interest in this activity. We have, I think, made an effort to try to work with them, and indeed I might say that these groups have been very helpful to us.

For example, in setting up the hotline, Ms. Apuzzo of the National Gay Rights Task Force was very helpful to us in giving us leads and so forth. Perhaps Dr. Foege could summarize some of the interactions we have had with the various gay organizations.

Dr. FÖEGE. I think, Mr. Walker, we have actually worked quite closely with the groups and many individuals in the groups.

For instance, when the problem first came to light, we did a fairly large case control study of AIDS patients with matched controls to try to determine what the risk factors were. This was done in cooperation with the gay physicians organization in San Francisco, the Bay Area Physicians for Human Rights. These physicians actually helped to get the control groups from their own patient groups.

We have invited representatives of various gay groups to our national meetings, for instance, the meeting we had in July of 1982

when we first looked at the problem of blood transfusions. We had the same representatives attend meetings early this year to review where we were on the transmission, and what we should be advising for the donation of blood.

We have met continuously with the gay groups at their own meetings to explain what we know about AIDS. We have had their involvement, their active involvement in preparing the Public Health Service prevention statement on how to reduce the rise of AIDS.

I think we have had very close cooperation and collaboration with the gay groups.

Mr. WALKER. As I said in my opening remarks, I think what is important here is to begin to put some of this into perspective, and take a look at some of the charges made yesterday.

For example, during testimony yesterday, one gay leader made the suggestion that there had been discrimination against homosexuals and persons of color as evidenced by the treatment of persons with AIDS.

Under questioning, this individual was unable to be specific about her charges, which included, by the way, a statement to the effect that AIDS victims were being treated as "expendable." For the record, I would appreciate some response to these what I regard as reckless charges.

Dr. BRANDT. Ever since the situation with AIDS has become popular in the media at least, the issue of bias toward homosexuals influencing scientific decisionmaking and influencing responses has been repeatedly raised. It is one of those issues that you can only deny and only show that in fact we have approached this disease like we have approached virtually every other disease.

I might call your attention to the fact that in this morning's New York Times Dr. Lawrence Altmann, a very distinguished medical observer, has written a comment summary called "It Takes More than Money to Conquer Diseases Like AIDS" And he points out in there that we have followed orthodox scientific precedents as we hoped to do all the way along. At no time, to my knowledge, has any of the biases, prejudices or other negative aspects influenced our decisionmaking solely because these people were homosexual or Haitian or any other group. In fact, they are people with a disease, with a serious disease, and our principal goal is to help people who are sick.

Dr. Fauci, who is here with us, treats most of the patients at the NIH Clinical Center. I am sure that since he is a physician to many of these patients, and the charge that he is treating them as if they were expendable, he may wish to say something.

Dr. FAUCI. Well, I think that really is a most extraordinary comment and charge, Mr. Walker. I think that anyone who has anything directly or indirectly to do with my staff and the group at the NIH who are directly involved in the care, both the physical and mental care of the patients who are suffering from this extraordinary disease, will be more than happy to attest to the fact that our sensitivity to them as individuals and as patients is what one would expect of any patient with any disease, and I can say without a doubt that to my knowledge there has been absolutely no dis-

crimination in any manner or form to any patient, subpopulation, either in fact or even by inference.

Mr. WALKER. And in fact one of the AIDS victims who testified here yesterday did say precisely those kinds of things about your staff. But again, I thought it was important to have it on the record.

Dr. BRANDT. Mr. Walker, I don't know how to put this charge to rest. We have repeatedly expressed our concern—quite frankly, early on my personal outrage—at a charge that I consider to be insulting to a lot of dedicated physicians and scientists who are trying to solve a problem, and the charge is just without foundation as far as I am concerned. If in fact there are any specific instances of it, I would love to know about them.

Mr. WALKER. Another charge that has been made is that the Public Health Service has not responded promptly enough to the AIDS problem.

Now, early today we were given somewhat of a benchmark of what a prompt response might be by the people from the Public Health Service who indicated when they respond to the problem in their local areas, where there are affected populations, they responded in terms of about mid-1981.

Now, you talked a little bit about this in your testimony, I think. But I think, again for the record, could you tell us when the first AIDS cases were reported to you, when epidemiologists were sent into the field, and when NIH admitted the first AIDS patients?

Dr. BRANDT. All right.

In the period of March and April 1981 was the first time that the cases began to be reported to the CDC. These were people with pneumocystis pneumonia, and Kaposi's sarcoma, in young homosexual men. Since both of these are unusual events, CDC sent epidemiologists into the field, who began to look into this situation within a matter of days of hearing of it.

On June 5 the first publication of the MMWR, which listed these cases, we began that day to set up within CDC a surveillance of all cases. Eleven days later, on June 16, 1981, the first patient was admitted to NIH.

At the same time NIAID alerted people at its—by the way, these first five cases in Los Angeles were in fact discovered in an NIAID-supported facility, a sexually transmitted disease facility—I mean an immunological diseases facility—Center for Interdisciplinary Research and Immunologic Diseases, University of California, Davis—there. And the other persons were alerted to this problem, and work began, both within the NIH intramural program as well as grantees around the country who were competent and who had grant support already in place from the NIH, began to work on the problem.

I think it is important that everybody recognizes that there is a great deal of flexibility in our grant system. That flexibility allows grantees with the permission of the NIH, and with notification to the NIH, to begin to aim their work at serious public health problems that need solutions. So that by September 1981, roughly less than 6 months after the first cases were reported, the first workshop was held in an attempt to try to define a scientifically respon-

sible agenda to be followed. So I believe the response was as rapid as one could hope for.

Mr. WALKER. So using that mid-1981 benchmark, by mid-1981 you had become cognizant of the problem, had put epidemiologists in the field, and had admitted your first patient to an NIH facility; is that correct?

Dr. BRANDT. Yes, sir, and not only that. We already had the earliest clue that we had about this disease, which turned out not to be correct, had to do with the use of a substance, amyl nitrate which comes in a little capsule that can be broken and inhaled, called poppers on the street. And the histories from the early patients would indicate that these people used large numbers of poppers.

Now, amyl nitrate had previously been and occasionally now is used by patients with heart disease, but usually in relatively small amounts. So work had already begun to try to determine whether or not that in fact might have led to this drastic immune suppression. And it was early in the fall that that was ruled out as a real possibility.

Mr. WALKER. Mr. Chairman, I do have some additional questions.

Mr. WEISS. Thank you, Mr. Walker.

Mr. Levin?

Mr. LEVIN. Let me ask a series of questions relating to budget matters. I hope that you can answer them—regarding the Presidential memo of 1976.

What was the Department's position regarding the \$12 million supplemental for AIDS?

Dr. BRANDT. We requested, Mr. Levin, early on to transfer funds across appropriation lines—I mean, the technical term for it, I cannot tell you. I never can keep that straight.

Anyway, we have requested permission of the Appropriations Committee to transfer \$12 million from activities of lesser priority into this program. Instead, as you know, the appropriations committees of both the House and Senate put in a \$12 million supplemental.

Mr. LEVIN. In a word, the Department took the position that there should not be more money granted to the Department, but it should take money from other places within the Department's budget.

Do you oppose the addition of money for want of authority to transfer? Isn't that in simple English an accurate summation of the Department's position?

Dr. BRANDT. I guess you could say it is accurate. What we did—I would put it more positively.

We proposed a transfer of money into this problem by the Congress.

Mr. LEVIN. You took the position you did not want more money. You wanted the authority to transfer.

Dr. BRANDT. We took the position that we wanted the authority to transfer.

Mr. LEVIN. But not more money.

Dr. BRANDT. We cannot request more money.

Mr. LEVIN. Did you oppose it?

Dr. BRANDT. I don't know that we did either one.

Mr. LEVIN. All right. From what activities——

Dr. BRANDT. In any event, the President signed the bill, as you know.

Mr. LEVIN. All right. But your position on that may have some relevance as to what you see as the appropriate battle plan of the Department.

From what activities were you proposing to take the \$12 million?

Dr. BRANDT. Actually, I am going to have to provide that for the record because I really don't remember. It was not from other research programs.

But I don't remember the specific activities. I will be happy to try to provide that.

Mr. LEVIN. All right. I was looking over the budget levels for CDC. You mentioned in your testimony the various activities of CDC. These documents are always complicated.

But looking at budget authority, the figures show that the budget authority for 1982 for CDC, \$299 million, rounded off to \$300 million. For 1983, \$334 million.

The proposed budget authority for 1984, \$270 million. Could you tell me when or how with that kind of a requested level you felt that CDC and the figures are not so different for other parts of the agency, at least some of them, how CDC could carry on an adequate effort in this area in 1983 and 1984 when the administration was requesting a budget level for 1984 of \$64 million less than 1983.

Dr. BRANDT. Well, there is a very simple explanation for that, sir. There is \$80 million of the \$334 million for a block grant—in the 1984 budget, in the President's budget, that block grant has been transferred out to my office.

So to get comparable figures, you would have to subtract roughly \$84 million from the \$334 million, giving you a figure of approximately \$250 million, compared to \$270 million.

Mr. LEVIN. All right. So you are saying the figure for 1984 is \$270 million versus \$250 million for 1984, and how about for 1983 and how about for 1982?

Dr. BRANDT. I don't have the 1982 figures.

Mr. LEVIN. Let's take the National Cancer Institute. I would appreciate your supplying for the record the figures for 1982.

Dr. BRANDT. All right, sir.

[The information follows:]

Centers for Disease Control Budget Figures by Year

1. Comparable (exclude block grant)

1982 - \$231,349,000
 1983 - \$267,147,000
 1984 - \$254,423,000

2. Noncomparable (include block grant)

1982 - \$312,949,000 (including \$81,600,000 block grant)
 1983 - \$353,476,000 (including \$86,329,000 block grant)
 1984 - \$254,423,000 (excluding \$86,329,000 block grant which
 is included in ~~PHS~~ budget)

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Mr. LEVIN. When the block grant money is included in there. For the Cancer Institute, the proposed level for 1984 is \$989 million; for 1983, \$983 million; for 1982, \$986 million.

How do you fit into those budget figures a major assault on AIDS?

Dr. BRANDT. I think, sir, that the issue is an attempt to—of course, NCI is not the only institute, in the first place. Indeed, a major part of our effort will be in NIAID, because this is an infectious disease, and a sexually transmitted disease.

But it depends, I guess, upon—it is very clear that the issue with funding research is one of attempting to develop priorities. As you know, in the President's 1984 budget, as submitted to the Congress, we have recommended that moneys be transferred from some of the centers' program into the grants program.

It is through that mechanism that we would fund additional research grants.

Mr. LEVIN. The NIAID request shows \$281 million for 1984, compared with \$273 million for 1983. So if there is going to be heavy reliance on that institute, you are talking about a proposed increase of \$8 million, which I think raises dramatically the request as to your battle plan.

We have heard at the same time from several people, including people who are scientists, who presumably are very well versed in research matters, that an effort ten times what is being contemplated could be well used.

Let me ask you not only to comment on that, but more importantly, what do you think is necessary in the way of efforts by the Department, funded through the Department, to tackle this challenge?

Dr. BRANDT. Well, what we need at the present time, sir, are ideas. I mean, we need some insights, and some fresh insights, and some ideas that will allow us to get a breakthrough in this effort.

Now, I have heard those figures loosely tossed around, and, frankly, I don't know what is included in those numbers. But I can give you the following information.

This is a disease that, under our current operating plan, we believe is a virus. We believe this virus is transmitted sexually and through blood; that it has a long incubation period.

We, therefore, have our plan developed along three basic lines. The first is to attempt to further define the characteristics of those people who develop the illness, that is, those who are at risk, and appropriate blood tests and other tests to try to determine ways to obtain an early diagnosis.

The second line of attack is to identify the etiologic agent which is, we feel, a virus. As you know, three different viruses have been isolated from patients with AIDS—CM, EB virus, and the human T-cell leukemia virus.

Whether or not these are opportunistic or whether or not they play a role in the development of the disease at this point in time is not clear.

The third main line of research is towards therapy. Here, again, we have basically two, really three lines of research. One is aimed at treatment of the complicating illnesses, i.e., Kaposi's sarcoma, pneumocystis, and so forth, for which we have some treatment that is working and, therefore, we have been able to get people over that part of their disease. The second is to try to restore the immune system. That includes such things as bone marrow transplants, which have been carried out at the NIH Clinical Center. Third is to augment the immune system through the use of such things as alpha or gamma interferon, and more recently, the human trials now underway on a substance known as interleukin-2.

Now, given all of that, and given that we are headed down all of those lines, the question is what kind of research, further research, is needed. We need, we believe, additional understanding of basic virology, additional understanding of basic immunology, additional understanding of other aspects related to that.

If you take at the NIH all of the money that is currently being expended in those areas, it adds up to \$166 million in fiscal year 1982, any one of which could lead us down to a breakthrough with this illness. I am not sure, quite frankly, what further activities we could undertake at the present time in a reasonably meaningful way.

We have had, as I testified, a lot of outside consultation, a lot of competent scientists. We have advisory groups at every one of those institutes who are outstanding people in the field, who are aware of what is going on, who give us advice constantly. We have tried to follow that advice. I think we are pursuing all of the reasonable scientifically responsible pathways at the present time.

Mr. LEVIN. My time is up. Let me just give you the advice of someone quoted in the same article that you referred to in the New York Times of this morning.

Dr. Richard Krause is Director of the National Institute of Allergy and Infectious Diseases, just one of the NIH member institutes that have appealed for more AIDS researchers.

Dr. Krause says he has shifted money from other projects to finance some AIDS research because it was so pressing a problem. But he has also expressed deep concern that unless more new funds become available for AIDS, valuable projects involving other diseases might not be done.

The tragic possibility exists, he said, that, "the answer to AIDS may come from the kind of research activity in basic virology and immunology that might go unfunded."

Thank you, Mr. Chairman.

Mr. WEISS. You don't want to comment on that?

Dr. BRANDT. Well, that certainly is the quote in the paper from Dr. Krause. I have to agree with that.

Mr. WEISS. Pardon? I missed the closing words.

Dr. BRANDT. What I said was that that is certainly the quotation that is in the newspaper; yes, sir. I agree. I agree with Dr. Krause in the following sense. I think that the answer to AIDS may very well come from the kind of research activity that I think is underway. It is quite possible that one of the grants is unfunded. But we have had unfunded grants throughout history. That is not going to change.

I think we need some specific advice as to where that money might wisely be spent, what kind of research. We are, in fact, bringing in consultants who are knowledgeable and are competent. We are attempting to follow their advice.

Mr. WEISS. Mr. McCandless.

Mr. MCCANDLESS. Thank you, Mr. Chairman.

Doctor, yesterday we heard testimony which leveled certain criticisms at the Department which you represent. I would like to go over a few of these and for the record get your response.

One of the criticisms was, that to date there had been no convening of the professionals, who are responsible, on a nationwide basis, for coordinating the research program.

I found that a little difficult to understand. Would you respond to that?

Dr. BRANDT. It is absolutely not correct. That is the reason that I find it difficult to understand. It clearly means whoever said that wasn't at one of those meetings, perhaps. But we have had repeated meetings. As a matter of fact, the most recent one we had was July 19, when the Blood Products Group met to advise us about the safety and purity of factor VIII.

The National Cancer Institute's Board of Scientific Counsellors and the National Cancer Advisory Board have been involved. The National Institute of Allergy and Infectious Diseases' board of scientific counselors has repeatedly sought advice from advisory groups. We have called together ad hoc groups to deal with problems. Indeed, I have outlined a number of these in my testimony.

They have certainly been involved. We fully expect them to continue to be involved.

Mr. MCCANDLESS. Another was, that there is no overall plan of attack or direction for the purpose of ultimately arresting the disease.

Dr. BRANDT. I think that my testimony is, in fact, a recitation of the plan of attack, sir.

Mr. MCCANDLESS. I was interested in the comment that you made concerning \$166 million worth of research. In the comment you made, I was left with the impression that a lot of the research that is being done in other fields has a parallel to the research that is necessary in the field of AIDS.

Is that a correct assessment of what it was you talked about?

Dr. BRANDT. Yes. We have a disease here that is an attack on the immune system of the body.

Mr. McCANDLESS. For a reformed used car salesman turned politician can you help me a little bit.

Dr. BRANDT. Yes. The immune system—

Mr. McCANDLESS. I mean as far as the parallels are concerned with other diseases, or something that we can relate to as laymen.

Dr. BRANDT. All right, sir. We have a disease that involves the body's ability to respond to—particularly to infections, and to other stimuli.

The parallel kind of research would be to try to understand how a normal functioning system responds to infections, because once we understand that, and knowing somehow or other what the defect is, we can better deal with the defect in these people. Therefore, the whole area that is attempting to understand the body's defense systems relates, indirectly I would agree, but nevertheless, relates to AIDS.

Second is attempting to understand the particular blood cells involved. They have a name called T-cells, which is sort of a code, but nevertheless, trying to understand how those cells actually function, what destroys them, what enhances their growth, et cetera, is another area directly relevant to AIDS.

Finally, trying to understand better the way in which viruses can operate. Here we have what appears to be a virus that has some sort of direct influence on the body's defense system, and that, as far as I know, is virtually unheard of. I have a couple of virologists here who can comment on that, if you would like.

To understand better the biology of these organisms so that we can understand how they might function, it seems to me is critical.

If you add up all of that research that is going on at the NIH, that is relevant to this particular problem—admittedly, it covers a whole lot of other problems, too, and admittedly it is not directed exclusively at this disease—it adds up to be \$166 million.

Mr. McCANDLESS. I would like to get one more question in before the chairman puts the gavel down on me.

Let's take a fictitious time line for purposes of our discussion. This time line represents your Department's projected accomplishment line as to what you feel your responsibility is and what you hope to accomplish within the time, given certain parameters.

Would you say that the Department is on schedule as far as its time line is concerned? If it is, great. If it is not, what do you suggest should be done to put you back on the time line?

Dr. BRANDT. It is always difficult, I think, Mr. McCandleless, to try to estimate when you are going to discover something in science. I think it is probably better for me to talk about my personal time line.

My personal time line, we are way behind, because, in fact, I was hopeful that certainly by the end of this year that we would have the organism isolated, would be working on a treatment, and perhaps a vaccine.

We have not done that yet. The disease has turned out—I think the further we get into it—to be even more complicated every time we learn something new, it turns out to be somewhat more complex.

I think in terms of the overall research plan that we have been developing, that we are on course with respect to the directions and the types of research that we have needed. We have not at the moment obtained any additional leads that would cause us to deviate from the course that we are currently on. From that standpoint, I would say that we are on time.

From the standpoint of those people who are suffering from the illness and who are at risk of the illness, we are clearly way behind in terms of our ability to help them, and I deeply regret that. But I don't at the same time fault the scientific community that has addressed itself to this issue. The easiest thing in the world right now is to be very critical of that.

In fact, these people have devoted a great deal of their time and their effort and their brains to try to solve this problem. As long as these young men and others are suffering from this illness, we are going to solve it and we are going to solve it as soon as we possibly can.

Mr. McCANDLESS. My time is up, Mr. Chairman.

Mr. WEISS. Thank you very much, Mr. McCandless.

Dr. Brandt, you have noted that all of us on both sides of the aisle have pressed you on these budgetary issues, specifically on how much is needed, how much is being spent, how much are you requesting, and so on.

I guess you have to place that within the context of the declaration that you had made and you repeated here today, and which the Secretary, Mrs. Heckler, has made, that you consider AIDS to be the No. 1 health priority concern of your agency. That is correct?

Dr. BRANDT. That is a correct statement; yes, sir.

Mr. WEISS. Now, the question I think that we are trying to tie down, is how is that concern reflected—not in sympathy, not in compassion, not in words, not in rhetoric, but in dollars and cents research efforts expended to try to get to the bottom of this epidemic.

Now, you had responded to Mr. Levin's questions earlier about the requests that were made for the supplemental fiscal 1983 appropriation. I understand that this is not the only problem that you are concerned with, and therefore perhaps your recollection as to what transpired in the chronology of events leading to that request may have become a little bit vague. But, because you maintain that AIDS is the No. 1 priority, and because the dollars that are available have been criticized as being woefully inadequate, I want to take you back through that chronology.

I have the Congressional Record excerpt of May 25, 1983, when the House in the Committee of the Whole, discussing the supplemental appropriation on the floor, provided \$12 million in new moneys for AIDS in fiscal 1983.

One of the people who spoke in the course of that debate was Mr. Conte of Massachusetts, who is the ranking minority member on the Labor-HHS Appropriations Subcommittee, and the full Appropriations Committee. He was very chagrined.

He said—I am quoting now:

Let me inform the members of this body that concern over the funding for AIDS research was expressed by every member of the subcommittee during the hearings that the subcommittee has been conducting on the budget.

Every agency involved in the investigation and research on AIDS was asked to describe their efforts and to indicate what more they could be doing, what more could be done.

They all stated that they had adequate resources.

Then he says that he is inserting into the Record the transcript of what transpired in the subcommittee's April hearings. Here is an exchange involving Dr. Foege's testimony before that subcommittee.

After Dr. Foege had gotten through describing what was happening in relation to AIDS, the number of cases and so on—this is at page H3342 of the Congressional Record of May 25, Mr. Conte says:

That is frightening. Are you equipped now to go ahead with your work on this?

Dr. Foege said:

As we have in the past when we have a health emergency, we simply mobilize resources from other parts of the center. In 1982, we spent \$2 million on AIDS, even though we did not have a budget line item for AIDS.

This year we have \$2 million in the budget and we will probably spend about \$4.2 million, the difference again, we will mobilize from other parts of the center. If we reach a point where we cannot do that, of course, then we will come back and ask for additional funds, but at the moment that is the way we intend to handle it.

Mr. CONTE. You are equipped to go ahead with it? There is nothing that is holding you back?

Dr. FOEGE. That is the way we have operated for many years—go ahead and take funds from another part of the center when an emergency requires it.

Now, that hearing was held in April 1983. The reason that concern was expressed on the floor by the subcommittee chairman Mr. Natcher and Mr. Conte, the ranking member, was that apparently sometime around May 13, Dr. Foege sent a memorandum to the Assistant Secretary for Health, Dr. Brandt, which outlined for the first time a detailed description of resource needs for expanded projects for fiscal year 1983, the current fiscal year, the same year that was being discussed in the Appropriations Subcommittee in April.

In that memo, you talked about surveillance, Dr. Foege, for \$264,000. You spoke about epidemiologic studies, investigations, needing \$140,000. Laboratory studies, investigations, \$335,000. Restoration of funds diverted from other CDC activities in fiscal year 1983, \$1.465 million, for a total of \$2.25 million.

Now, what happened between your testimony in April before the subcommittee and the early part of May when you advised Dr. Brandt that, in fact, you could use some additional moneys to the tune of \$2.25 million?

What did you learn during that timeframe or had you known previously that, in fact, you needed these additional funds?

Dr. BRANDT. I would like to go back to 1981 for a moment to put this thing in some perspective. In testimony before and in the President's budget estimate submitted to the Congress for fiscal year 1982, the Public Health Service requested \$20 million for use in emergencies from the Congress.

This was turned down by the Congress. Instead, we were instructed to deal with emergency funding in the same way as we had always dealt with this, which was to make the expenditures

and then go back and request funding—deal with the problem and then go and request funding from the appropriation committees.

I testified on that appropriation. It was sent up as a part of the President's budget. Secretary Schweiker testified on this, and so forth.

We, therefore, have been responding to emergencies of all kinds since that time, and the Congress has always responded when we have come in and requested the money—

Mr. WEISS. Now, I would like you to answer my question. In April of 1983, in testimony before the Subcommittee on Appropriations in your area, CDC said that it didn't need any authorization for any additional money or transfers, and that Dr. Foege would spend \$4.2 million instead of the appropriated \$2 million by an internal shift of funds.

Then in May, about the 18th of May, you notified the Appropriations Committee that the Public Health Service could use a \$12 million transfer. What I am trying to determine is when was that determination made, how was that determination made, did you know it prior to April, did you discover it between April and your testimony and May 12, May 18?

Tell me about the change in position.

Dr. BRANDT. We have during that period of time and continuing to the present time almost continually evaluated where we stand on AIDS, where we stand both in terms of science and in terms of monetary needs.

I think you will notice, sir, if you read my testimony, which is not reproduced in this particular colloquy, but if you read the testimony of Dr. Foege and others, you will see that in each case they say, and I quote from Dr. Foege, "If we reach a point where we cannot do that, then we will come back and ask for additional funds."

We were reviewing this process, as I testified in the appropriations' hearings, virtually on a week—indeed, not virtually—exactly on a week-by-week basis to try to see where the leads were, where we might go.

At that point in time, indeed, we were anticipating we might get a breakthrough somewhat earlier than we did. On May 9, Mr. Natcher, chairman of our Subcommittee on Appropriations, sent me a letter requesting that I give him an analysis of the budgetary needs and so forth. We immediately then reanalyzed the whole budgetary situation. It was on that basis that I requested the memorandum that Dr. Foege and Dr. Hayes and other agency heads, review their needs.

We discussed them. The memo of May 13 that you have quoted from Dr. Foege was his response to my request—and then my letter to Congressman Natcher of May 18 was as a result of that whole thing.

The situation changes all the time, Mr. Weiss. We are dealing with a very dynamic situation with this disease. We were attempting, as we have—the Public Health Service has been set up to—handle emergencies since 1798. It is continuing to do so. We have always pulled that money from other sources, and then as the situation got to the point where we needed additional money, we have

come in and asked the Congress. That is the way the Congress has asked us to behave. That is what we do.

Mr. WEISS. Dr. Foege, I would like your response to the question. Again, let me state it. In April 1983, you appeared before the Labor HHS Appropriations Subcommittee and were pressed according to Mr. Conte by every member of that subcommittee for your description of the problem and what you needed.

You testified according to the transcript that you didn't need any more money, if you needed anything more you had enough other resources within the Agency to transfer to AIDS—and you judged that you would be spending about \$4.2 million in fiscal year 1983.

According to Dr. Brandt, on May 9, the Department received a letter from Mr. Natcher, who chairs that subcommittee, which says, "Hey, fellows, reassess, reanalyze, tell us what your needs are."

Between the 9th and the 13th, you analyze, and for the first time conclude that, indeed, within various agencies of HHS, you can, in fact, use \$12 million.

Now, does that seem to be a coordinated planned approach dealing with that disease? Was it truly the first time that you discovered, when Mr. Natcher asked HHS for a reanalysis, that instead of needing maybe \$4.5 million, you were going to need \$12 million more for the balance of this fiscal year?

Dr. FOEGE. Mr. Chairman, let me put it in perspective first. I did not request \$12 million. I requested \$2.25 million.

Mr. WEISS. For the Centers for Disease Control?

Dr. FOEGE. That is right.

Mr. WEISS. How about for the other component agencies?

Dr. BRANDT. I made a request for the whole Public Health Service, including the Centers for Disease Control. There is another thing that happened in the interim, Mr. Weiss, with respect to NIH. That is, we had put out a request for applications and we re-evaluated the worthy applications that came in.

Precisely, if you look at the justification that we sent to Mr. Natcher, and if you look at subsequent information which was made available to Chairman Waxman, all of which we would be happy to provide to you, it is precisely the funding of grants, additional grants, that came in response to our request, subject to that testimony, that we have requested the money to fund.

[Material referred to follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20208

June 10, 1983

The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Waxman:

We have been asked by your staff to provide information on our current research efforts on Acquired Immune Deficiency Syndrome (AIDS) and projections for estimated obligations and spending for the duration of FY 1983 if we receive additional funds.

As you know, on May 9, William H. Natcher, Chairman of the House Appropriations Subcommittee on Labor-HHS and Education asked Dr. Edward N. Brandt, Assistant Secretary for Health, how much in the way of additional resources for AIDS activities could be effectively used in the current fiscal year and an explanation of how those resources would be used, if provided by Congress.

Dr. Brandt responded on May 18 with a request for discretionary authority for the Secretary, Department of Health and Human Services (HHS) to transfer up to \$12 million for AIDS activities across appropriations lines of HHS. In floor action by the House on the FY 1983 supplemental, \$12 million was added to the bill for AIDS activities without granting the transfer authority. The Senate Appropriations Committee has also included the \$12 million for AIDS in its version of this bill.

In the following paragraphs, we describe current AIDS activities as well as our plans for additional funds if they become available.

National Cancer Institute (NCI)

CURRENT EFFORTS (\$4.4 million)

Extramural (\$2.8 million)

A Request for Application (RFA) process was begun in FY 1983 to support a multidisciplinary, multi-institution "Working Group" to study the etiology and treatment of AIDS and Kaposi's sarcoma. Although this RFA was originally budgeted at \$1.3 million, NCI has provided a total of \$1.8 million for this project. Awards are made as cooperative

agreements so that NCI staff can serve as a resource for information on the activities of various scientists and can act to facilitate collaboration among involved researchers. With the cooperation of the awardees, collaborative areas are identified and developed. The purpose of this Cooperative Agreement is to encourage such research by providing support to institutions with an interest in the problem, access to a population of affected patients and laboratory facilities and personnel appropriate to the conduct of such research. The intent of this award is to encourage innovative, multidisciplinary studies of this problem.

Specific research currently underway with support from this RFA includes:

- Animal studies on the immunosuppressive potential of human seminal plasma and cytomegalovirus (CMV), which causes a type of infection seen in AIDS patients. Seminal plasma and CMV have been suggested by investigators as possible causal agents for AIDS.
- Extensive virological and immunologic studies on a group of AIDS patients. The viruses to be studied include CMV, Epstein-Barr virus (EBV), and human T-cell leukemia-lymphoma virus (HTLV). EBV and HTLV have been associated with some rare cancers, but at present the association between these viruses and AIDS is uncertain.
- Immunologic and virologic studies to identify and characterize the similarities and differences of AIDS patients who belong to different groups at risk of developing the disease.
- Genetic studies of specimens from AIDS patients to look for viruses and cancer-related genes that may play a role in causing the disease.
- A three-year study of early defects in the immune function of AIDS patients that might permit early diagnosis. Laboratory studies will be conducted to see if alpha-interferon, an antiviral agent that is produced by the body, might be a diagnostic indicator for AIDS. Blood cells of AIDS patients grown in the laboratory fail to produce normal amounts of alpha-interferon for unknown reasons.
- A five-year study to develop immunologic profiles of AIDS patients and apparently healthy individuals at risk for the disease, including the occurrence of persistent lymphadenopathy as a possible precursor of AIDS.

NCI is also funding regular research project grants which have a direct relevance to AIDS. For example, currently funded grants include funds for studying the treatment of Kaposi's sarcoma and other sarcomas. The two objectives of a large NCI human cancer serology program project grant, for example, are on problems which may relate to these patients. They are: (1) serological definition and biochemical characterization of distinctive cell surface antigens of human cancers and, (2) immunovirologic analysis and biochemical characterization of human cancers of suspected viral etiology.

Since the development of Kaposi's sarcoma is thought to be related to a dysfunction of the immune system, research involving immunodeficiency, or the immune system as a whole, may hold the key to understanding the genesis and etiology of this rare malignancy. Another of NCI's comprehensive program project grants provide resources for investigating the relationship of the development of the lymphoid system and immunodeficiency diseases and human cancers. This program project will coordinate and focus the efforts of ten interrelated projects working on both clinical and fundamental perspectives.

Laboratory and technical support for NCI studies of patients with AIDS, or at risk of developing it, is being provided by portions of four contracts which were originally established to provide program-wide support for a variety of research projects in the Environmental Epidemiology Branch (EEB), Division of Cancer Cause and Prevention, NCI. The Environmental Epidemiology Branch conducts studies to define the distribution and determinants of cancer. These activities include the formulation of hypotheses using national and other data resources and the testing of these hypotheses in analytic case-control and cohort studies. Descriptive studies are conducted at whatever locales within the United States offer the greatest likelihood of producing meaningful new clues to cancer etiology. These contracts are now being employed to provide support for studies relevant to AIDS.

Intramural (\$1.6 million)

Approximately \$1.6 million of NCI's 1983 funds are devoted to AIDS intramural research.

The NCI supports a large intramural program which investigates the immune system, the dysfunction of which apparently allows the development of diseases such as Kaposi's sarcoma and other opportunistic infections associated with AIDS.

In addition, NCI is conducting research specifically devoted to AIDS. Researchers in the Laboratory of Pathology are examining tissue specimens taken from AIDS patients during surgery to examine the immunological characteristics of certain AIDS-related lymphomas. The Field Studies and Statistics Program is conducting epidemiological studies of immunological profiles of healthy homosexual men and profiles of hemophiliacs with symptoms, as well as individuals with AIDS or

members of population groups at risk of developing AIDS. Also, Division of Cancer Treatment investigators are using alpha-lymphoblastoid interferon in combination with chemotherapy to treat Kaposi's sarcoma in AIDS patients.

PROPOSED ADDITIONAL NCI FUNDS (\$3.3 million)

Extramural (\$2.8 million)

If additional funding is made available for FY 1983, NCI will fund up to 12 additional responses to the current Request for Application, for a total of about 70% of the approved applications.

The science which would be supported with the additional money includes:

- o the nature of the defective immunoregulation in AIDS;
- o etiology and immunological basis of AIDS;
- o interferon and the etiology of AIDS;
- o noninvasive diagnosis of Pneumocystis carinii in AIDS patients;
- o development of laboratory animal models for AIDS and Kaposi's Sarcoma;
- o immunodeficiency in hemophilia;
- o the role of cytomegalovirus (CMV) in AIDS.

In addition, grant proposals received through the normal peer review process will be tracked closely and the review and approval procedures will be expedited to hasten funding for research project grants which otherwise would not be awarded until FY 1984.

Intramural (\$0.5 million)

With additional funds, NCI could increase the efforts of its newly-created Task Force on AIDS, and provide a central focus and thrust for new initiatives on AIDS emphasizing the possible role of etiologic agents. Dr. Robert Gallo, whose unique expertise in the isolation of human oncogenic viruses is world renowned, will act as the Scientific Director of the Task Force effort, which will consist of intramural and contract-mediated components to deal primarily with the role of HTLV as a potential causative agent in AIDS. This expanded intramural effort at NCI locations in Bethesda and Frederick will each require renovations and equipment commensurate with increased safety requirements for both AIDS- and HTLV-containing samples. Accordingly, a portion of the additional funds will be used for renovation of a high-containment facility at Frederick. Also, several laboratory technical personnel will be added to this effort. Examination of samples of electron microscopy, fluorescence-activated cell sorting, radioimmune assays, virus isolation and concentration, and production of monoclonal antibodies will be carried out by NCI's technical support contractor with the direct input of Dr. Gallo.

In total, NCI's AIDS budget, including the proposed additional funds, would be \$5.6 million for extramural and \$2.1 million for intramural research.

National Institute of Allergy and Infectious Diseases (NIAID)

CURRENT EFFORTS (\$4.1 million)

Extramural (\$2.3 million)

Of \$1.4 million allocated for grants, approximately \$1 million has been used to fund four applications in response to the NCI RFA.

These include studies on the following:

- o potential drug treatments for Pneumocystis carinii pneumonia in an animal model;
- o the prevalence and transmission of cryptosporidiosis, a recently identified parasitic disease that can cause severe and potentially fatal diarrhea in the immunosuppressed AIDS patients;
- o the development of opportunistic infections in infants born to mothers who were sexual partners of AIDS patients; possible routes of transmission of AIDS among contacts of adult heterosexual patients;
- o evaluation of chemotherapeutic and naturally occurring substances for the treatment and prevention of AIDS, as well as the study of immunologic defects in AIDS patients and the possible relationship of cytomegalovirus to the cause of AIDS.

The remaining \$0.4 million will support research project grants not submitted in response to the RFA, including the effects of cytomegalovirus on cell-mediated immunity, plus AIDS projects at ongoing NIAID Sexually Transmitted Disease Centers and Centers for Interdisciplinary Research on Immunologic Diseases which include: a study to define the interrelationship between the "AIDS prodrome wasting syndrome" and full-blown AIDS in case control and cohort studies; a study of life style and other factors influencing occurrence and reversibility of AIDS in homosexually active young males, including association of sexual practices with altered helper/suppressor T-cell ratios; and a study analyzing T-lymphocytes of AIDS patients by molecular hybridization with specific DNA probes in order to detect and quantitate the number of genome copies of cytomegalovirus and herpes simplex virus type II DNA in these lymphocytes.

On May 9, 1983, NIAID issued an RFP ("Study of the Natural History of Acquired Immune Deficiency Syndrome (AIDS) in Homosexual Men") which will support a prospective study with the following specific objectives:

- To observe and study the natural history of the disease in enough persons who are uninfected at the outset to yield a number of cases of AIDS sufficient for meaningful estimates of risk;

immunologic evaluation of AIDS; autoimmune anti-T helper activity in AIDS patients; immunobiology of AIDS; immunoregulation in AIDS; semen-induced immunosuppression; antimicrobial immunity in AIDS patients; and immunopathology of AIDS.

- o Supplements to ongoing grants for research on the association of a number of virologic and parasitic infections and the immune dysfunction of AIDS patients.
- o Payment of additional cooperative agreements from the NCI RFA might include: AIDS and the mechanism of defective immunoregulation; pathogenesis of Acquired Immune Deficiency Syndrome; and herpes viruses and immune responses in male homosexuals.

An estimated \$2.0 million for contracts would be used as follows:

- o Supplementation of an existing contract on enteric diseases, to initiate studies on severe diarrheal problems associated with AIDS.
- o Additional funds would allow NIAID to award three additional contracts from the RFP ("Study of the Natural History of AIDS in Homosexual Men"), issued May 9, 1983, and described under NIAID's current efforts.

Intramural (\$1.0 million)

Additional resources for intramural research would permit NIAID to conduct a study of patients at risk of AIDS with collection of specimens for identification of etiologic agents and to initiate a clinical trial on the treatment of AIDS patients with alpha-interferon to correct immune defects.

Total NIAID support for AIDS with the proposed additional funds would amount to \$8.6 million in FY 1983: \$5.8 million for extramural and \$2.8 million for intramural research.

National Heart, Lung, and Blood Institute (NHLBI)

CURRENT EFFORTS (\$346,000)

Extramural (\$290,000)

The NHLBI is currently supporting extramural research on AIDS in FY 1983 as a part of the blood diseases and resources program. Specifically this support is divided among four areas:

- o Support of a conference to be held in early August, jointly sponsored with NCI and NIAID, to discuss recent developments related to the epidemiology of AIDS. NHLBI's special emphasis will be on possible transmission of the disorder by blood

- To build a repository as a national resource for specimens and data from men who traverse the entire course from well to ill; it would permit testing of hypotheses about etiologic factors, and
- To complement similar smaller but less well standardized follow-up studies performed in different places and times.

Proposals in response to the RFP are due July 8, 1983, and will be reviewed this summer and funded this fiscal year. Twenty-seven institutions have indicated their intent to submit proposals. The current FY 1983 budget includes \$900,000 funds to support one contract in response to this RFP.

Intramural (\$1.8 million)

Current FY 1983 intramural efforts involve a total estimated obligation of \$1.8 million. Patients with each of the clinical forms of AIDS are being evaluated and intensely studied to determine the mechanisms and natural history of the immunodeficiency and the consequent opportunistic infections. NIAID physicians are studying the immunoregulatory defect that occurs in patients with AIDS. This includes an evaluation of the excessive stimulation of immunoglobulin production that is seen in contrast to the profound lack of T-helper cells in patients with this syndrome. Therapeutic approaches being undertaken by NIAID physicians with AIDS patients are antiviral agents; immunological reconstitution by bone marrow transplantation or transfer of immune competent cells; and immunological enhancement by the use of factors such as interferon. An intensive effort to identify the etiologic agent of AIDS is underway. Chimpanzees have been inoculated with blood and other material from AIDS patients. Other NIAID scientists are studying the immune response following CMV infections, including the virus' ability to reverse T-helper and T-suppressor cell ratios, and the sera of AIDS patients is being evaluated for the presence of antibodies to parvoviruses.

PROPOSED ADDITIONAL NIAID FUNDS (\$4.5 million)

Extramural (\$3.5 million)

A total of \$1.5 million is proposed for grants to be allocated in priority order among:

- o Some of the 17 new research project grant applications deemed scientifically meritorious which have been received recently. These applications will be reviewed by initial peer review groups this summer and by the NIAID Advisory Council either at their next (September) meeting, or by an earlier mail ballot. These applications include the following activities: virologic and

products; the overall focus will be on epidemiologic, immunologic, virological and clinical aspects of AIDS.

- o An intra-agency agreement with the Centers for Disease Control to determine whether AIDS may be transmitted through parenteral contact with blood and blood products and whether patients with hemophilia and frequently transfused patients with sickle cell disease and thalassemia major display similar immunologic abnormalities.
- o Support of a portion of a research project which utilizes current data to study sera from homosexual men who showed elevated levels of thymosin and beta-2-microglobulin.
- o Support a study of the prevalence of immunologic abnormalities in a large group of hemophilic patients and compare the abnormalities identified with findings in hemophiliacs from other countries to determine whether this is an endemic problem within the United States.

Intramural (\$56 thousand)

NHLBI is currently supporting a study at the Clinical Center, NIH, to determine if AIDS can be transmitted to chimpanzees by infusing the animals with plasma from human AIDS patients. There are no plans to increase intramural research efforts on AIDS in FY 1983.

PROPOSED ADDITIONAL NHLBI FUNDS (\$1.0 million) -

The Institute proposes to support a prospective study of 1,500 homosexuals to measure thymosin and beta-2-microglobulin levels in an at-risk population and to determine whether there are genetic factors, such as Human Leukocyte Antigen abnormalities, involved in a predisposition to AIDS.

Total NHLBI AIDS resources for FY 1983, including the proposed additional funds would be \$1.3 million for extramural and \$56 thousand for intramural research.

National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

CURRENT EFFORTS (\$72 thousand)

Extramural (No current funding)

The NINCDS does not support any extramural research grants directly relevant to AIDS research at this time, and there are no pending grant applications.

Intramural (\$72 thousand)

In its current effort of clinical and laboratory research, the NINCDS has found that 25% of Kaposi AIDS patients have neurological complications such as central nervous system (CNS) infections-- cytomegalovirus (CMV), toxoplasmosis, and progressive multifocal leukoencephalopathy (PML). Investigations are being carried out on the interaction between viruses and the host immune-system to examine mechanisms of protection as well as disease production in the case of acute or chronic infections of the central nervous system.

The NINCDS is collaborating with the California Primate Center to study AIDS in experimental animal models by examining tissue obtained from rhesus monkeys who have Simian Acquired Immune Deficiency Syndrome, a disorder which may be similar to AIDS. In addition, our Institute staff are seeing patients admitted by the National Cancer Institute and the National Institute of Allergy and Infectious Diseases at the NIH to study the deterioration of neurological functions in patients with AIDS.

PROPOSED ADDITIONAL NINCDS FUNDS (\$545,000)

Additional funds would provide for several initiatives, including purchase of equipment and isolation facilities modifications. An increase of \$275 thousand is proposed for clinical studies of neurological findings in AIDS and Kaposi's sarcoma patients, since 25% of these patients have neurological complications such as central nervous system infections of unknown cause. Seriological and virus isolation studies using new advanced tissue culture methods would be initiated.

An additional \$200 thousand would be used to study individuals during early prodromal stages of disease before the onset of opportunistic infections which obscure the primary infecting agents.

An additional \$70 thousand would be required in anticipation of the increased need for cortical biopsies and other clinical studies in order to investigate involvement of the central nervous system.

The total FY 1983 NINCDS budget with the proposed additional funding would be \$617 thousand *For AIDS Research.*

SUMMARY

The remaining support for AIDS research at NIH for FY 1983 is provided by the Division of Research Resources (DRR), the National Institute of Dental Research (NIDR) and the National Eye Institute (NEI). Support is provided extramurally by the DRR (an estimated \$644,000 in 1983) primarily through its General Clinical Research Centers and primate centers, and intramurally at the National Institute of Dental Research (NIDR) and the National Eye Institute (NEI) within the Clinical Center at Bethesda. NIDR research, at \$25,000 in 1983, is concerned with virus isolation and with abnormalities in the interferon system of AIDS patients. The NEI, with estimated expenditures of \$45,000 in 1983, is involved with providing ocular care of AIDS patients and is studying the causes of the visual difficulties that frequently beset these patients.

With the availability of additional funds, as outlined in Dr. Brandt's letter of May 18, 1983, to Mr. Natcher, NIH funding for AIDS in FY 1983 would be nearly \$19 million. (A summary table is attached.)

With these resources, we are well positioned to provide a critical mass of resources to take advantage of the latest research opportunities involving AIDS.

Sincerely yours,



James B. Wyngaarden, M.D.
Director

Attachment

NIH RESEARCH ON AIDS IN FY 1983

<u>Institute</u>	Current		Proposed Under Supplemental Appropriations		Total
	<u>Extramural</u>	<u>Intramural</u>	<u>Extramural</u>	<u>Intramural</u>	
National Cancer Institute	2.8 million	1.6 million	2.8 million	0.5 million	7.7 million
National Institute of Allergy & Infectious Diseases	2.3 million	1.8 million	3.5 million	1.0 million	8.6 million
National Heart, Lung, and Blood Institute	290,000	56,000	1.0 million	0	1.356 million
National Institute of Neurological & Communicative Disorders & Stroke	0	72,000	0	545,000	617,000
National Institute for Dental Research	0	25,000	0	0	25,000
National Eye Institute	0	45,000	0	0	45,000
Division of Research Resources	644,000	0	0	0	644,000
NIH					18.987 million



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

MAY 18 1983

The Honorable William H. Natcher
Chairman
Subcommittee on Labor, Health and
Human Services, Education
and Related Agencies
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

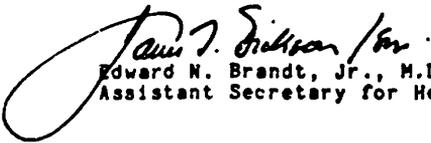
I am responding to your letter of May 9, 1983, regarding Acquired Immune Deficiency Syndrome (AIDS). The enclosed status report (Enclosure 1), prepared by the Public Health Service (PHS) on AIDS, updates information provided to you by Departmental witnesses at the recently completed 1983 appropriations hearings. I am glad to have this opportunity to assure you that resources allocated to the campaign against AIDS are substantial, as indicated by the budget summary table, and the Department is committed to taking necessary actions.

You also asked whether additional resources could effectively be used in the current fiscal year. As with any situation as dynamic and critical as that of AIDS, funding requirements can change rapidly. Enclosure 2 is a description of additional efforts which could be accomplished now and in future months.

While we are not requesting additional budget authority for these items, we would not oppose Congress giving the Secretary of Health and Human Services discretionary authority to transfer up to \$12.0 million for AIDS activities across appropriation lines of HHS. We are currently requesting authority from the Office of Management and Budget for this purpose.

I want to assure you that the problem of AIDS is indeed of major concern and interest to the Public Health Service.

Sincerely yours,


Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health

Enclosures

UPDATE ON ACQUIRED IMMUNE DEFICIENCY SYNDROME

May 12, 1983

Identified AIDS cases:	1,410
Case rate per million:	6.3
Mortality rate/2 yrs. diagnosis:	77%

The cause of this immune dysfunction is unknown, however, the occurrence of these disorders among the high risk groups suggests that the cause is probably an infectious agent transmitted sexually, or through blood or blood products. To date, no person to person transmission has been identified other than through intimate contact or blood transfusion. Studies have reported the following transmission patterns, paralleling the hepatitis B virus:

- o sexually-transmitted among homosexual or bisexual men,
- o heterosexual transmission among women who are steady sexual partners of men with AIDS or of men in high risk groups,
- o in vitro or perinatal transmissions in infants born to mothers from high risk groups,
- o transmission through blood or blood components such as hemophilia patients requiring clotting factor replacement, drug abusers sharing contaminated needles, and blood products or blood transfusions.
- o no AIDS cases have been reported among health care or laboratory personnel caring for AIDS patients or processing laboratory specimens.
- o very little is known about risk factors for Haitians with AIDS.

Since only a small percentage of high risk group members have AIDS, a laboratory test is clearly needed to identify those with AIDS or those at highest risk of acquiring AIDS. Identification of a cause is hindered by latent periods of several months to 2 years between exposure and recognizable illness. Work conducted by the Public Health Service has produced the following results:

- Nitrite inhalants are probably not the cause of AIDS; substance is rarely used by heterosexual cases and does not cause immunosuppression in mice.
- Marmosets and chimpanzees inoculated with patient materials have remained well, to date, though followup is less than eight months.
- Immunological parameters of AIDS cases have been defined, including identifying a cellular immune deficiency related to T-cell function.

- Relationship of AIDS and cytomegalovirus (CMV) has been clarified; CMV is likely an opportunistic infection in AIDS cases and not the cause.
- Testing of blood products used by hemophiliacs (Factor VIII concentrate and cryoprecipitate) have thus far been negative for etiologic agents, using available laboratory technology.
- Other virologic and pathologic laboratory examinations of patient materials (blood, lymph nodes, autopsy specimen) have not detected the cause, although many such examinations are underway.

Although the cause of AIDS remains unknown, the PHS recommends the following preliminary preventive actions:

1. Sexual contact should be avoided with individuals known or suspected to have AIDS. Multiple partners increase the possibility of developing AIDS.
2. As a temporary measure, members of risk groups should refrain from donating plasma and/or blood. Collection centers should inform potential donors.
3. Studies should be conducted to evaluate screening procedures for their effectiveness in identifying and excluding plasma and blood with a high probability of transmitting AIDS. These procedures should include specific laboratory tests as well as careful histories and physical exams.
4. Physicians should adhere to medical indications for transfusions, and autologous blood transfusions are encouraged.
5. Work should continue towards the development of safer blood products for use by hemophilia patients.

ONGOING PHS ACTIVITIES

The objectives of the PHS activities are to determine the pathogenesis of AIDS, and how it is transmitted and, finally to develop methods of prevention and control. When the AIDS problem was recognized in early 1981, close liaison was established among the Public Health Service agencies with major responsibilities, each emphasizing its primary mission: the Centers for Disease Control (CDC), surveillance and investigations; the National Institutes of Health (NIH), research into fundamental causes and clinical aspects of AIDS; and the Food and Drug Administration (FDA), preventive measures related to blood collection and its use. CDC meets weekly to provide updates on the status of laboratory investigations and research activities. When necessary, outside consultants and NIH and FDA personnel are invited to consult with and advise CDC on AIDS activities. An Inter-Institute NIE Working Group, with active participation by CDC and FDA scientists, was established in July 1982 to foster exchange of scientific findings and to provide a ready channel to make current data available. A complementary working group coordinates information

collection and dissemination. In addition, two major meetings have been held with representatives of the PHS agencies and a variety of outside scientists and representatives of concerned groups. A meeting on July 27, 1982 led to the recommendation to intensify surveillance of AIDS patients with hemophilia, and to improve the quality of Factor VIII concentrate to decrease infectious risk. A similar meeting was held on January 4, 1983 in which a detailed set of approaches to prevention was discussed. This led to the publishing of PHS guidelines for the prevention of AIDS.

CENTERS FOR DISEASE CONTROL

The major responsibilities of CDC in the AIDS investigation are to conduct surveillance, epidemiologic studies and investigations, and laboratory investigations. The top priority of the investigation is to find the cause of AIDS.

A. Surveillance

A surveillance system has been implemented to receive case reports from physicians, hemophilia treatment centers, and State and local health Departments. A cooperative agreement has been established with the New York City Health Department to improve surveillance activities in the New York City metropolitan area.

B. Epidemiologic Studies

Epidemiologic studies to identify risk factors for AIDS in homosexual populations include a national case-control study and an analysis of clusters of sexually related cases which support the hypothesis of sexual transmission of an infectious agent.

Epidemiologic studies and investigations are also being done of cases occurring among four other groups: (1) heterosexuals and their frequent sex partners, (2) Haitians, (3) intravenous drug abusers, and (4) hemophiliacs, as well as homosexual men with chronic unexplained lymphadenopathy, and "sub-clinical immunosuppression". More than 100 AIDS cases and 200 controls have been interviewed by CDC epidemiologists. Results of investigations of hemophilia patients and intravenous drug abusers suggest transmission through blood and blood products.

C. Laboratory Investigations

Laboratory investigations into the cause of AIDS include intensive virologic, pathologic, and immunologic studies. Inoculations of tissue from patients into cell cultures and laboratory animals, observation of these cultures and animals, and prolonged immunologic and pathologic follow up of the animals are underway. Extensive laboratory investigation of patient materials (blood, lymph nodes, autopsy specimens) are being conducted using highly sophisticated methods.

NATIONAL INSTITUTES OF HEALTH**A. Extramural Activities**

The National Cancer Institute (NCI) has initiated a Clinical Cooperative Research Awards project on etiologic studies to support clinical research into the causes and prevention of AIDS. NCI has also given high priority to grant-supported studies of Kaposi sarcoma and similar malignant tumors related to AIDS.

The National Institute of Allergies and Infectious Diseases (NIAID) is supporting research on cellular immunology and regulation of the immune system; on deficiencies in the immune system; and on cytomegalovirus.

The National Heart, Lung, and Blood Institute (NHLBI) is studying the effect of AIDS patients' blood plasma and other bodily fluids as administered to chimpanzees with the hope of identifying a causative agent. The Institute is expanding a study of blood recipients and plans to initiate studies of "surrogate tests" for AIDS, which may lead to a method for screening blood prior to transfusion.

Other components of NIH are also active in AIDS research. The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is conducting research into neurological aspects of AIDS, and the Division of Research Resources (DRR) is seeking to develop animal models for AIDS.

B. Intramural Activities

Concurrent with the external research assault on AIDS, NIH's intramural laboratory and clinical scientists mounted a multidisciplinary attack on the syndrome. The continuing internal collaboration at the Bethesda location involves at least 25 investigators and their teams in a dozen laboratories, including those working directly with patients in the Clinical Center and the newly activated Ambulatory Care Research Facility (ACRF).

At NCI: Researchers in the Laboratory of Pathology are examining tissue specimens taken from AIDS patients during surgery to examine the immunological characteristics of certain AIDS-related lymphomas. The Field Studies and Statistics Program is conducting epidemiological studies of immunological profiles of healthy homosexual men and profiles of hemophiliacs without symptoms, as well as individuals with AIDS or members of population groups at risk of developing AIDS. Division of Cancer Treatment investigators are using alpha-lymphoblastoid interferon in combination with chemotherapy to treat Kaposi sarcoma in AIDS patients.

At NIDR: The roles of viruses and interferon in the human immune system disorders are being studied. The studies indicate that the AIDS patients examined have abnormalities in their interferon systems. These abnormalities are seen as a defect in the ability of the

lymphocytes to produce interferon (usually of the gamma type), or as a significant increase in circulating interferon (usually of the alpha type).

At NINCDS: The Infectious Diseases Branch is conducting clinical and laboratory research on AIDS. The Institute is collaborating with the California Regional Primate Research Center on the examination of tissue obtained from rhesus monkey who have Simian Acquired Immune Deficiency Syndrome--a disorder which may be similar to AIDS.

At NIAID: Intramural scientists are searching for an infectious agent or agents that might trigger AIDS and are conducting immunologic studies. Several scientists are examining the immunoregulatory defect that occurs in these patients. In the Laboratory of Clinical Investigation, an evaluation of the role of herpes infections and Epstein-Barr virus in relation to AIDS is under way. The Laboratory of Infectious Diseases is investigating the role of hepatitis in AIDS because virtually all AIDS patients have had hepatitis. NIAID scientists are also evaluating AIDS patients for parvoviruses, a group of DNA viruses.

At NEI: Clinical Branch scientists are studying ocular lesions that occur in patients with AIDS. These studies have the dual purpose of determining whether there are distinctive ocular signs that might help in recognizing AIDS victims and in obtaining new clues to the role of the immune system in eye disease.

At NHLBI: Scientists are examining plasma specimens in an attempt to transfer a causative agent or agents taken from AIDS patients in the Clinical Center to chimpanzees. The goal is to isolate a transmissible, infectious agent.

C. Information Dissemination and Scientific Workshops

Because of the multiple approaches to the mystery of AIDS, mechanisms have been established to coordinate and expedite research and information exchange among agencies involved, within the national scientific community, and throughout internal research efforts. The Office of the Scientific Director of NIAID has compiled a comprehensive bibliography of articles in the scientific literature on AIDS and related disorders which is updated periodically. The NIAID Office is also planning a "Memorandum" to be published periodically for rapid dissemination of information within the scientific community on findings and developments in AIDS research.

Since the problems of AIDS surfaced, NIM has convened three major scientific workshops on the syndrome--by DRR on animal models for AIDS, by NHLBI to gain suggestions for future studies on prevention of transmission of AIDS in blood and blood products, and by NIAID to stimulate research in search of a causative agent. All meetings were open to the press and public.

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
Public Health Service Current Level of Effort
(Dollars in thousands)

	<u>1982</u> <u>Actual</u>	<u>1983</u> <u>Current</u> <u>Level</u>
Centers for Disease Control:	\$2,000	\$4,600
Food and Drug Administration:	150	350
National Institutes of Health:		
NCI.....	2,400	4,400
NHBLI.....	5	346
NIDR.....	25	25
NINCDS.....	31	72
NIAID.....	297	4,050
NEI.....	33	45
DRR.....	564	644
Subtotal, NIH.....	<u>3,355</u>	<u>9,582</u>
Alcohol, Drug Abuse and Mental Health Administration:	<u>---</u>	<u>---</u>
Total, PHS.....	\$5,505	\$14,532

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Additional FY 1983 Activities
(in priority order)

.(Dollars in thousands)

Agency	1983		
	Current	Increment	Revised
A. Additional Activities			
1. Centers for Disease Control	\$4,600	+\$2,225	\$5,360 <u>1/</u>
2. National Cancer Institute....	4,400	+3,300	7,700
3. National Institute of Allergy and Infectious Diseases.....	4,050	+4,500	8,550
4. National Heart, Lung and Blood Institute.....	346	+1,030	1,376
5. National Institute of Neurological and Communicative Disorders and Stroke.....	72	+545	617
6. Alcohol, Drug Abuse and Mental Health Administration	---	+400	400
Subtotal.....	\$13,468	\$12,000	\$24,003 <u>1/</u>
B. Other Continuing AIDS Activities			
1. National Institute of Dental Research.....	\$ 25	--	\$ 25
2. National Eye Institute.....	45	--	45
3. Division of Research Resources.	644	--	644
4. Food and Drug Administration...	350	--	350
Total, PHS.....	\$14,532	\$12,000	\$25,067 <u>1/</u>

1/ Does not include \$1,465,000 which was used from a variety of other CDC activities to respond on a timely basis to AIDS needs.

Dr. BRANDT. So that in fact a number of events had occurred.

You are making it appear like we just suddenly woke up one day. In fact, we had a number of things occurring during this period of time. We are trying to be responsive. We are trying to do the job. And it seems like what we did is a perfectly reasonable thing to do if you are going to try to be responsive.

Mr. WEISS. Now, let me ask you to look at a memo dated March 25, 1983, from the Director of the National Cancer Institute to the Director of the National Institutes of Health. Would you have that handy?

Dr. BRANDT. No, sir, I don't have it handy.

Mr. WEISS. We will get it to you in just a moment. This was written prior to the Public Health Service officials' testimony before the Appropriations Subcommittee. It says, "NCI has already funded four applications"—in response to the August AIDS RFA "totaling \$369,000."

I am going to rush through the first couple of lines.

NCI and NIAID jointly are prepared to fund six additional grants. This will require a total of \$1.8 million from NCI, and \$1,011,942 from NIAID. Money will be reprogrammed within the NCI budget to enable us to fund this high quality science since our original set-aside is exceeded by approximately \$600,000.

And then this line, "With this plan we will be able to fund 30 percent of all approved applications for AIDS research," approved applications.

That is as of March 25, 1983, prior to Dr. Foege's testimony before the subcommittee that you don't really need authorization for any new money.

Dr. BRANDT. Of course, Dr. Foege does not represent the NIH or NCI. He represents only the CDC; that is the agency he is Director of. So actually, Dr. Foege couldn't have commented on that.

Mr. WEISS. But your testimony, Dr. Brandt, is that the reason for the change, for the request for \$12 million, was the new application requests that came in to NIH. Now, did you need Mr. Natcher's letter of May 9 to point that out to you?

Dr. BRANDT. Well, certainly Mr. Natcher's letter to me requested of course a great deal of information. But it gave me an opportunity to make our situation known to the subcommittee.

Dr. FOEGE. Mr. Chairman?

Mr. WEISS. Yes, Dr. Foege.

Dr. FOEGE. If I try to explain the CDC portion of this and not try to explain any other—I pointed in my testimony that when we are in an emergency situation, where we do not have funding, we do in fact use money from other parts of CDC, and that in 1983 it was my estimate that while we would have \$2 million appropriated, we would be spending at least that much extra from other parts of CDC.

My request then a month later made an increase really from about \$4 million plus to ask for an additional three-quarters of a million dollars for AIDS activity, and the remainder would be pay-back of what we had borrowed. So it was a fairly small increment of less than 20 percent. At the same time, during that period of time there were things happening that were causing us great concern.

No. 1, we simply had no leads on an agent and we had been hoping that the extensive effort would provide some idea of the etiology.

No. 2, the numbers, instead of plateauing, were increasing, as you noted this morning, at a rate that was doubling about every 6 months. But there were two other things in that period of time that caused us concern. One was whether this problem was much bigger in terms of what we were then seeing in lymphadenopathy in people who did not have AIDS, and we had to do some extensive investigations to determine if this was a prodromal phase of AIDS, a midphase of AIDS, or totally unrelated to AIDS?

Finally, the fourth thing that was concerning us at that time, the conviction that this was probably a virus, and, if so that it could be bloodborne. And we had in mind at that time that we might have to launch surveillance systems looking for cases. In fact, we talked about the possibility of hemophiliacs being at risk before we ever had the first case of AIDS in a hemophiliac.

All of those things were happening in that time period. Because of that, I asked for an increase of less than 20 percent in the budget, because I did not think we could continue to borrow more from other parts of CDC.

Mr. WEISS. I understand that. You must understand that my expression of concern is not that you asked for too much money. Quite the contrary. What I am suggesting is that either there was an unwillingness to know, or in fact you did not know how much money you needed, that there seemed to be no comprehensive approach to this problem, and that you were reacting almost on a day-to-day kind of basis, as Dr. Brandt said, rather than having planned and plotted out your work to see what in fact your needs were going to be.

I think that coming back and asking for a modest increase, having been pushed by the House to a great extent, was perfectly genuine and legitimate on your part. The question that I raise is why the discovery only when Mr. Natcher wrote to Dr. Brandt on May 9 and said, hey, reanalyze your position, and you say, OK, maybe we can use an extra \$12 million at that.

Dr. BRANDT. I must admit the way you paint the picture, it doesn't sound very good. I have to agree with you, sir, in that respect. But, I don't think we were reacting on a day-to-day basis. What I said was, we were reviewing and analyzing on a week-by-week basis attempting to determine where we were.

Things were happening at that time, narrowing in on the virus. We thought, therefore, we needed to take advantage of the opportunity. Congressman Natcher gave us that opportunity to do so.

Mr. WEISS. Let me touch on another aspect of what we have just been talking about.

There have been suggestions from the representative of the American Public Health Association, research physicians: Dr. Conant, and Dr. Voeller; and from affected communities that one of the problems seems to be that in fact there has been no effort to pull together the best scientific minds in this country, and with their cooperation, determine what a comprehensive approach ought to be.

Your responses here this morning have suggested a series of sporadic kinds of meetings and the attitude, if you will pardon my paraphrasing, that "We know what we are doing. We know what is best. We don't really need anybody else from the outside to be pulled into this situation."

If in fact your base of knowledge is as limited as you acknowledge it is, why not reach out, bring the best scientific and medical brains in, and set up a comprehensive approach to dealing with this crisis over the next year, the next 5 years. Or, leave out a timeframe and just discern what steps ought to be taken.

Dr. BRANDT. The issue, sir, is that we are doing that. That is the whole point that we have been bringing outstanding scientists in. Now the question of who is the best in terms of brains, perhaps Dr. Conant and I might disagree on who that is. But they are certainly brains that are capable of dealing with this problem that are outside the Government.

I mean these are people that have been brought in, and to whom we have gone to look at these areas. This is a complex problem. There is no one human being or no one scientist that is going to be able to look at the total picture from dealing with intricacies of blood to intricacies of virology. Therefore, we have brought in groups to address them, to develop these research agendas. We have outlined a lot of these.

I am sorry that Dr. Conant does not think those people are competent. That is obviously his own opinion. I don't happen to share that. But we will continue to involve people that are competent. We have regular standing advisory committees; we have groups that are brought in specifically to deal with this problem. We will continue to do it.

Mr. McCANDLESS. Will the chairman yield?

May I offer a suggestion for purposes of the record?

In your answer to my question, you gave certain specific instances which you analogized to the question of bringing people together for the common purpose.

With your permission, Mr. Chairman, I would like to have submitted for the record, whenever it is possible for Dr. Brandt, a list of these various meetings and who attended. I think it would directly answer the question that you are asking and which I presented earlier.

Mr. WEISS. An excellent suggestion.

Dr. BRANDT. We will be more than delighted. I have tried to outline them in my testimony. We will be more than delighted to send you all the names of the people who attended and let somebody determine whether or not they are qualified to give us advice.

[Material referred to follows:]

FDA*August 2, 1983*

Blood Products Advisory Committee Meetings

September 23-24, 1982

December 3-4, 1982

February 8, 1983

March 1-2, 1983

July 19, 1983

BLOOD PRODUCTS ADVISORY COMMITTEE

Chairman

Bove, Joseph R., M.D.
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Executive Secretary

Tourault, Mary Ann
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Blood Products Advisory Committee

Office of Biologics
National Center for Drugs and Biologics
Food and Drug Administration
September 23-24, 1982
Bethesda, MD

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James W. Mosley
John W. Suttie
James G. White
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Ronald D. Miller
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Executive Secretary

Clay Sisk'

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John Finlayson
Joseph Fratantoni
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Blood Products Advisory Committee
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 National Center for Drugs and Biologics
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 Place: NIH, Bldg. 29, Room 115

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 Joan Maher, American Association of Blood Banks
 Charla Issitt, American Dade
 Aaron Kellner, New York Blood Center
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Non-specific methods of detecting infectious agents in donated blood was one of the topics of discussion at the meeting.

Blood Products Advisory Committee
 Office of Biologics
 National Center for Drugs and Biologics
 Food and Drug Administration
 July 19, 1983
 Bethesda, MD

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 Atlanta, Georgia

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AIDS and Blood and Blood Products Meeting
May 12, 1983

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National Institute of Mental Health

MENTAL HEALTH ASPECTS OF AIDS

RESEARCH PLANNING WORKSHOP

August 1, 1983

Conference Room B, Parklawn Building

9:00 A.M. - 4:30 P.M.

PARTICIPANTS

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MENTAL HEALTH AND BEHAVIORAL ASPECTS OF AIDS
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August 3, 1983

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AIDS Technical Review Meeting
July 25
9-5

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SUMMARY OF THE WORKSHOP ON KAPOSI'S SARCOMA

Sponsored by:

Division of Cancer Treatment and
Division of Cancer Cause and Prevention
National Cancer Institute
and
Center for Disease Control

National Institutes of Health
Bethesda, Maryland

September 15, 1981

WORKSHOP ON KAPOSI'S SARCOMA

ATTENDEES

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Dr. Robert Bolan
Dr. Samuel Broder
Dr. Bruce Chabner
Dr. Jose Costa
Dr. James Curran
Dr. William DeWys
Dr. Lawrence Drew
Dr. Hans Enzinger
Dr. Max Essex
Dr. Henry Falk
Dr. Joseph F. Fraumeni
Dr. A. E. Friedman-Kien
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Committee to Coordinate Environmental and Related

Programs Meeting on AIDS

Mount Sinai Medical Center

New York, New York

July 13, 1982

Sponsored by NIEHS

OBJECTIVE

The program for the July 1992 meeting included detailed reviews of information concerning Acquired Immunodeficiency Disease including clinical syndromes recently evident in New York City, San Francisco, Los Angeles and other cities in the United States, and in other countries. Leading investigators in the field reviewed current studies.

SCIENTISTS THAT PARTICIPATED IN THE MEETING

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*Sponsored by NIEHS

Acquired Immunodeficiency Syndrome (A.I.D.S.) and Kaposi's Sarcoma
 Banbury Center, Cold Spring Harbor Laboratory, 6-8 February 1983

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Workshop on Acquired Immunodeficiency Syndrome In Nonhuman Primates

Masur Auditorium
NIH Clinical Ctr.
National Institutes of Health
Bethesda, Maryland 20205

Supported by the Division of Research Resources, NIH

March 2, 1983

8:45 a.m.	Welcome Dr. Betty Pickett, Director, DRR, NIH		
Session I	Comparative Medical Aspects Of Aids Chairman - Dr. John L. Sever, NINCDS, NIH	Session II	Differential Diagnosis, Epidemiology, and Biosafety Aspects Chairman - Dr. William I. Gay, DRR, NIH
8:50 a.m.	<i>Acquired Immune Deficiency Syndrome in Man - An Overview</i> Dr. H. Clifford Lane, NIAID, NIH	1:30 p.m.	Identification of AIDS and Related Diseases in the Nonhuman Primate - California Regional Primate Research Center <i>Epidemiological Aspects of an Outbreak of Acquired Immunodeficiency Syndrome in Rhesus Macaques at the California Primate Research Center</i> - Dr. Roy V. Henrickson
9:15 a.m.	Discussion		<i>Unique Mortality Pattern Associated With Acquired Immunodeficiency Syndrome in Rhesus Macaques at the California Primate Research Center</i> - Dr. Donald H. Maul
9:25 a.m.	Aids in the Nonhuman Primate - Clinical, Pathological, and Immunological Aspects - New England Regional Primate Research Center <i>A Clinicopathologic Study of Macaques with an Acquired Immunodeficiency Syndrome (AIDS)</i> - Dr. Norman L. Letvin, Dr. Ronald C. Desrosiers, and Dr. Norval W. King, Jr.	2:00 p.m.	Identification of AIDS and Related Diseases in the Nonhuman Primate - New England Regional Primate Research Center <i>A Transmissible Lymphoma in Macaques: Is It Related To Macaque AIDS?</i> - Dr. Ronald D. Hunt, Dr. Edward P. Gelman, and Dr. Normal L. Letvin
10:10 a.m.	Discussion	2:45 p.m.	Discussion
10:25 a.m.	Coffee Break	3:00 p.m.	Coffee Break
10:45 a.m.	Aids in the Nonhuman Primate - Clinical, Pathological, and Immunological Aspects - California Regional Primate Research Center <i>Epizootics of Acquired Immunodeficiency Syndrome in Rhesus Macaques at the California Primate Research Center</i> - Dr. Roy V. Henrickson*, Dr. Donald H. Maul, and Dr. Murray B. Gardner <i>Clinical Summary of Acquired Immunodeficiency Syndrome in Rhesus Macaques at the California Primate Research Center</i> - Dr. Donald H. Maul*, Dr. Roy V. Henrickson, and Dr. Murray B. Gardner <i>Cellular and Humoral Immunity of Monkeys with Simian Acquired Immunodeficiency Syndrome (SAIDS)</i> - Dr. David L. Madden, NINCDS, NIH <i>The Pathology of an Epizootic of Acquired Immunodeficiency Syndrome in Rhesus Macaques at the California Primate Research Center</i> - Dr. Murry B. Gardner*, Dr. Donald H. Maul, Dr. Roy V. Henrickson, Dr. Kent G. Osborn, Dr. Srinivasa Prahalada, and Dr. Linda J. Lowenstine	Panel Epidemiology and Biosafety Chairman - Dr. Kenneth Sell, NIAID, NIH	
11:45 a.m.	Discussion	3:20 p.m.	<i>Probable Transmission of AIDS and Potential Risk to Laboratory Personnel</i> - Dr. Donald P. Francis, Centers for Disease Control
12:00 p.m.	Summary of Comparative Medical Aspects - Dr. Sheldon Wolf, Tufts University	3:40 p.m.	Epidemiology and Biosafety - Panel Dr. Donald Francis, Centers for Disease Control Dr. Roy V. Henrickson, California Regional Primate Research Center Dr. Donald H. Maul, California Regional Primate Research Center Dr. Norman L. Letvin, New England Regional Primate Research Center Dr. Norval W. King, New England Regional Primate Research Center
12:30 p.m.	Lunch	4:30 p.m.	Summary of Differential Diagnosis, Epidemiology and Biosafety Aspects - Dr. John L. Sever, NINCDS, NIH
		5:00 p.m.	Adjournment

*Indicates person presenting paper.

LIST OF ATTENDEES

<u>Name</u>	<u>Institution</u>
Dr. Cladd E. Stevens	The New York Blood Center
Dr. John A. Hansen	Puget Sound Blood Center
Dr. Richard B. Counts	Puget Sound Blood Center
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Dr. Michael Lederman	Dept. Med., Case Western Reserve University
Dr. Jay Menitove	Blood Center of SE Wisconsin
Dr. Jonathan C. Goldsmith	Univ. of Iowa College of Medicine
Dr. Leon W. Hoyer	Univ. of Connecticut Health Center
Dr. Sergio Piomeilli	Columbia University
Dr. Paul R. McCurdy	ARC Blood Services, Washington Region
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Dr. Amoz Chernoff	Division of Blood Diseases & Resources
Dr. William Bayer	Community Blood Center of Kansas City
Dr. Paul Naylor	George Washington University
Dr. Roger Dodd	American Red Cross
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Dr. Robert Gordon	OD/National Institutes of Health
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Dr. Alan Levine	Division of Blood Diseases and Resources
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NIAID WORKSHOP

"Search for Etiological Agents in Acquired Immune Deficiency Syndrome"

PROGRAM

Building 31, Conf. Rm. 10

April 5-6, 1983

April 5, 1983

- 8:30-8:45 a.m. Welcome - Dr. Richard Krause (Director, NIAID)
- 8:45-9:15 a.m. Epidemiological Overview of Acquired Immune Deficiency Syndrome (AIDS)
Dr. James W. Curran (CDC)
- 9:15-9:30 a.m. New viral agents and the problem of AIDS
Dr. Kenneth W. Sell (NIAID)
- 9:30-9:45 a.m. Discussion
- Session I: Review of known agents: Detection, cultivation, and possible role of etiological agents in AIDS.
- Moderator: Dr. Robert M. Chanock (NIAID)
- 9:45-10:05 a.m. Cytomegalovirus
Dr. Gerald Quinnan (BoB)
- 10:05-10:20 a.m. Epstein-Barr Virus
Dr. Joseph Pagano (University of North Carolina)
- 10:20-10:35 a.m. Break
- 10:35-11:00 a.m. Herpes Simplex Virus
Dr. William Summers (Yale Medical School)
Dr. Priscilla Schaffer (Harvard Medical School)
- 11:00-11:15 a.m. Adenoviruses
Dr. Stephen E. Straus (NIAID)
- 11:15-11:45 a.m. Hepatitis Viruses
Dr. Robert Purcell (NIAID)
- 11:45-12:15 p.m. Retroviruses
Dr. Robert Gallo (NCI)
Dr. Malcolm Martin (NIAID)

- 12:15-1:15 p.m. Lunch
- 1:15-2:30 p.m. Parvoviruses
- A. Adeno-associated Viruses
Dr. James A. Rose (NIAID)
 - B. Minute Virus of Mice
Dr. Gary MacMaster (Hoffmann-La Roche, Basel)
 - C. Aleutian Disease Virus
Dr. David Porter (University of California)
 - D. Canine Parvovirus
Dr. L. E. Carmichael (Cornell University)
 - E. Parvovirus-like Virus of Aplastic Anemia
Dr. Philip Mortimer (Central Public Health Laboratory, London)
- 2:30-2:45 p.m. Enteric viruses: Diagnosis by Immune Electron Microscopy
Dr. Albert Z. Kapikian (NIAID)
- 2:45-3:00 p.m. Reoviruses
Dr. Bernard Fields (Harvard Medical School)
- 3:00-3:15 p.m. Arboviruses
Dr. Philip Russell (Walter Reed Army Institute of Research)
- 3:15-3:30 p.m. Break
- 3:30-3:45 p.m. Papilloma Viruses
Dr. Maurice Green (St. Louis University)
- 3:45-4:00 p.m. Slow Viruses
Dr. Clarence J. Gibbs, Jr. (NINCDS)
- 4:00-4:15 p.m. Rubeola and SSPE
Dr. Ashley Haase (VA Hospital, San Francisco)
- 4:15 p.m. General Discussion
- 5:00 p.m. Reception at Dr. Krause's residence on NIH campus
(For Invited Participants)

April 6, 1983

8:30-8:50 a.m. Epidemiology of Transmission in AIDS
Dr. Michael Marmor (New York University)

8:50-9:00 a.m. Discussion

Session II: Current efforts to recover potential etiological agents from patients with AIDS.

Moderator: Dr. Bernard Fields (Harvard Medical School)

9:00-12 Noon

Dr. Gary Noble (CDC, Atlanta)

Dr. Cirilo Cabradilla (CDC, Atlanta)

Dr. Donald Francis (CDC, Phoenix)

Dr. Edward Gelmann (NCI)

Dr. Thomas Quinn (Johns Hopkins University)

Dr. Lata Nerurkar, Dr. David Madden (NINCDS)

Dr. Kenneth Takemoto (NIAID)

Dr. John Hooks (NIDR)

Dr. Anthony Fauci (NIAID)

Dr. Marshall Horwitz (Albert Einstein)

Dr. Lawrence Drew (Mt. Zion Hospital)

Dr. Jorg Eichberg (Southwest Foundation for Research and Education,
San Antonio, Texas)

Dr. Robert Purcell (NIAID)

Dr. John Sever (NINCDS)

12 Noon-1:30 p.m.

Lunch

1:30-3:00 p.m.

General Discussion and Development of Research Opportunities

Dr. Kenneth W. Sell (NIAID)

Suggested topics to be considered:

1. Most likely etiologic agents
2. Adequacy of current technology employed
3. Need for resource sharing (reagents, nonhuman primates)
4. New proposed hypotheses to be tested
5. Biological containment

2:45 p.m.

NIH Grant Support in the Search for an AIDS Agent
Dr. Richard Adamson (NCI)

3:00 p.m.

Summary: Dr. Albert Sabin

4:00 p.m., Bldg. 31, Conf. Rm. 10

Press Briefing

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EXTRAMURAL AIDS WORKING GROUP MEETING PARTICIPANTS -- 5/6/83

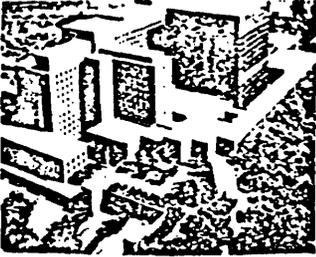
DR. JOHN FAHEY	UCLA
DR. MICHAEL GOTTLIEB	UCLA
DR. EVAN HERSH	M.D. ANDERSON
DR. MARTIN HIRSCH	MASS. GENERAL
DR. JOHN HUGHES	OHIO STATE
DR. WALTER HUGHES	ST. JUDE'S
DR. WARREN JOHNSON	CORNELL
DR. PEARL MA	ST. VINCENT'S, N.Y.
DR. JAMES MULLINS	HARVARD
DR. ARYE RUBENSTEIN	ALBERT EINSTEIN
DR. BIJAN SAFAI	MEMORIAL SLOAN-KETTERING
DR. FREDERICK SIEGAL	MT. SINAI, N.Y.
DR. GREGORY SISKIND	CORNELL
DR. FREDERICK VALENTINE	N.Y.U.
DR. PAUL VOLBERDING	U.C.S.F.

CENTERS FOR DISEASE CONTROL

DR. JAMES CURRAN

NIH STAFF

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DR. FAYE AUSTIN	NCI
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DR. ROBERT BIGGAR	NCI
DR. SAMUEL BRODER	NCI
DR. BRUCE CHABNER	NCI
DR. AMOZ CHERKOFF	NHLBI
DR. JOHN COUPER	NCI
DR. GENROSE CUPLEY	NCI
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DR. PETER FISCHINGER	NCI
DR. JOSEPH FRAUMENI	NCI
DR. ED GELMAN	NCI
DR. ROBERT GORDON	NIH
DR. JACK GRUBER	NCI
DR. BERGE HAMPAN	NCI
DR. JACK KILLEN	NCI
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DR. ALAN RABSON	NCI
DR. PREM SARKIN	NCI
DR. KENNETH SELL	NIHID
DR. BERNARD TALBOT	NIHID
DR. JACK WHITESCARYER	NIHID
DR. ROBERT WITTES	NCI
DR. RICHARD WYATT	NIHID



Conference of the

Combined Clinical Staffs

National Institutes of Health
Bethesda, Maryland 20205

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Public Health Service
National Institutes of Health

Thursday, June 23, 1983
Masur Auditorium
3-5 PM

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Anthony S. Fauci, M.D., Moderator
Chief, Laboratory of Immunoregulation
National Institute of Allergy and Infectious Diseases

Introduction, Epidemiology and Clinical Syndromes
Anthony S. Fauci, M.D.

Infections in AIDS
Abe M. Macher, M.D., Staff Fellow, Microbiology Service
Department of Clinical Pathology, Clinical Center

Kaposi's Sarcoma and other Neoplasms in AIDS
Dan L. Longo, M.D., Head, Experimental Immunology Section
Medicine Branch, National Cancer Institute

Immunology of AIDS
H. Clifford Lane, M.D., Senior Investigator,
Laboratory of Immunoregulation
National Institute of Allergy and Infectious Diseases

Treatment of AIDS - Infections and Immune Defects
Henry Masur, M.D.
Deputy Chief, Critical Care Medicine Department
Clinical Center

Host Defenses Against viral Infections in AIDS
Atain H. Rook, M.D.
Research Investigator, Division of Virology
National Center for Drugs and Biologics

Search For AIDS Agent - Possible Role of Retroviruses
Edward P. Gelman, M.D., Senior Investigator
Medicine Branch, National Cancer Institute

Summary and Future Directions
Anthony S. Fauci, M.D.

CONFIDENTIAL STATE DOCUMENT

Date June 23, 1983, Thursday

Director Dr. Anthony S. Fauci, NIAID

Title: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

3:00 p.m. - 5:00 p.m.

REGISTRARS

- | | |
|--|-----------------------------|
| 1. I. TORLONI (Brazil) | 26. M. Rodrigues |
| 2. James T. Mapp (Georgetown Univ) | 27. Gail Katz |
| 3. J. F. ROSENSTOCK (Navy Hosp) | 28. V. Hubbard NIAID/DC |
| 4. P. Beebe NIAID/DC | 29. M. P. ... LVD |
| 5. Charles F. Repetti American Medical | 30. John W. Ames |
| 6. H. Shivaishi (C.S. Blood) | 31. Terri Schlessinger |
| 7. James R. ... cc/Pharmacy | 32. Ed Yarnall (NCC) |
| 8. Charlotte Kenton NIAID | 33. ... mm |
| 9. R. ... NIAID/DC | 34. ... NCI |
| 10. G. DAVIS, NIAID/DC | 35. Kristin Klase SW |
| 11. HOWARD DRUCE, NIAID | 36. Moses Schaeffer, FDA |
| 12. Susan Goss, RN NIAID/DC | 37. Jim ... NIAID/DC |
| 13. Cathy H. McMillan, NEI | 38. Gloria E. Babilonia NCI |
| 14. Sandra Levis, OD, News Branch | 39. _____ |
| 15. James ... LI, NIAID | 40. _____ |
| 16. ... MI, NIAID | 41. _____ |
| 17. P. K. Naranga, Pharmacy | 42. _____ |
| 18. Julie Heller, NIDK | 43. _____ |
| 19. Debra Waller | 44. _____ |
| 20. Sharon Otto - Social Work | 45. _____ |
| 21. Kerry ... (Ameth) | 46. _____ |
| 22. ... (CCBS) | 47. _____ |
| 23. Jayasree Nath (NIAID/DC) | 48. _____ |
| 24. C. V. Castro (CPD-Micro) | 49. _____ |
| | 50. _____ |

CONFIDENTIAL FEDERAL STATE CONFERENCE

Date June 23, 1983, Thursday

Mod. rator Dr. Anthony S. Fauci, NIAID

Title: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

3:00 p.m. - 5:00 p.m.

REGISTRANTS

- | | |
|---|-----------------------------------|
| 1. John D. Decker MADDK | 26. James Ruppore |
| 2. Albert Cor. Bess, M.D. | 27. Concetta Long |
| 3. in vacuo | 28. John Angelos Keyes |
| 4. Naina Mustrop, RN CS | 29. Anne Novak |
| 5. Virginia Johnson M.D. | 30. Bernice Maynard, RN OR |
| 6. Umanu Madzwicki, N.E.I. | 31. Raymond P. Chen NIMBI |
| 7. Michael Ho NIAID | 32. _____ |
| 8. Jim Rose NIAID | 33. _____ |
| 9. John. Ferris, D.S. | 34. _____ |
| 10. Harold Kucumski M.D. NCI | 35. _____ |
| 11. Marie Papancolas | 36. _____ |
| 12. W. Gordon OD/NIAH | 37. _____ |
| 13. Jay Zupka M.D./CR | 38. _____ |
| 14. Paul V. Holland PhD/CC | 39. _____ |
| 15. Marsha Lambert C.A. Ph.D. | 40. _____ |
| 16. Linda Sony | 41. _____ |
| 17. Martha D. Koster NIAID | 42. _____ |
| 18. Mark Butler | 43. _____ |
| 19. Jack Jensen | 44. _____ |
| 20. Richard F. Fink | 45. _____ |
| 21. Raymond B. Hines | 46. _____ |
| 22. Jean M. Bennett | 47. _____ |
| 23. Mark Joseph | 48. _____ |
| 24. Helene Kozil | 49. _____ |
| | 50. _____ |

CONFIDENTIAL STATE CONFERENCE

Date June 23, 1983, Thursday

Mod.ator Dr. Anthony S. Fauci, NIAID

Title: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

3:00 p.m. - 5:00 p.m.

REGISTRARS

- | | | | |
|-----|-----------------------------|-----|-------|
| 1. | <i>Norma Wetzel</i> | 26. | _____ |
| 2. | <i>B. Di Pietro</i> | 27. | _____ |
| 3. | <i>Jimm Myers</i> | 28. | _____ |
| 4. | <i>J. H. Hines</i> | 29. | _____ |
| 5. | _____ | 30. | _____ |
| 6. | <i>John O. Bunt</i> | 31. | _____ |
| 7. | <i>Ernest</i> | 32. | _____ |
| 8. | <i>[Signature]</i> | 33. | _____ |
| 9. | <i>[Signature]</i> | 34. | _____ |
| 10. | <i>ZVI MAREN</i> | 35. | _____ |
| 11. | <i>[Signature]</i> | 36. | _____ |
| 12. | <i>Clifford P. M. H. H.</i> | 37. | _____ |
| 13. | <i>A. J. Casper BBID</i> | 38. | _____ |
| 14. | <i>[Signature]</i> | 39. | _____ |
| 15. | <i>Thomas C. Capporelli</i> | 40. | _____ |
| 16. | <i>[Signature]</i> | 41. | _____ |
| 17. | <i>[Signature]</i> | 42. | _____ |
| 18. | <i>Angela N. Hill, M.D.</i> | 43. | _____ |
| 19. | _____ | 44. | _____ |
| 20. | _____ | 45. | _____ |
| 21. | _____ | 46. | _____ |
| 22. | _____ | 47. | _____ |
| 23. | _____ | 48. | _____ |
| 24. | _____ | 49. | _____ |
| | | 50. | _____ |

CENTRO FEDERAL STATE UNIVERSITY

Date: June 23, 1983, Thursday

Moderator: Dr. Anthony S. Fauci, NIAID

Title: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

3:00 p.m. - 5:00 p.m.

REGISTRARS

- | | |
|---|---------------------------|
| 1. d. Puchlich NIAID | 26. Kathy Hagg Tachbasi |
| 2. Jon MD | 27. J. R. Rient |
| 3. Jeffrey Orr, Dallas NINCDS | 28. Carol Fobke EN NINCDS |
| 4. DAVID GROUND'S ATCC | 29. Patricia J. Col |
| 5. Rendo Ruyosana NIDIB | 30. Irene Chu |
| 6. Max Shepard | 31. James Zee |
| 7. Arnold M. Schwartz GWU ^{Medicine} _{Genetics} | 32. Serrill J. |
| 8. Marion Peters ADOX | 33. Demetrius Albanes |
| 9. Gita Goutal MD | 34. [Signature] |
| 10. Jeanne Wagoner | 35. B. L. Chan MD |
| 11. Jacquen Viment | 36. M. M. Zunder, M.D. |
| 12. Frank J. Salbo (Science News) | 37. Yoshiki Sakurai M.D. |
| 13. J. A. Morris Galley Park | 38. J. Hicks M.D. |
| 14. Virginia F. Frost DCCP, NCI | 39. Nancy B. Antin MD |
| 15. [Signature] | 40. [Signature] |
| 16. Ted McPherson | 41. [Signature] |
| 17. Anne O. Anderson MD PLM | 42. C. Restrepo Jr. |
| 18. Susan Mary Murray Dept. | 43. Franki Takatsu MD |
| 19. Dale Tenner Nuclear Med. | 44. Robert Gurdron, MD |
| 20. Jan Paluch " " | 45. _____ |
| 21. Liz Grady Miller " " | 46. _____ |
| 22. Wadley Malariu | 47. _____ |
| 23. K. Hillson NCI | 48. _____ |
| 24. Mary H. Bredford | 49. _____ |
| 25. Mary Ann Russell | 50. _____ |

COMBINED CLINICAL STAFF CONFERENCE

Date June 23, 1983, Thursday

Moderator Dr. Anthony S. Fauci, NIAID

Title: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

3:00 p.m. - 5:00 p.m.

REGISTRANTS

- | | |
|---------------------------------------|--|
| 1. Ric S. Martin, D | 26. John Kastakia |
| 2. James Leonard / Jun | 27. Mary J. J. J. NIAID |
| 3. Ann Korman | 28. Wendy E. G. Nelson, Ed |
| 4. Sheila Sherlock | 29. Wendy E. G. Nelson |
| 5. Ben Roy, M.D. | 30. Janice / Longfield, MD. USUHS |
| 6. Gail Water / M.D. | 31. Patricia Charles, MPH |
| 7. H. P. S. on / Kas, M.D. | 32. Gray Altman, RPH |
| 8. Ann V. Kuhlhoff, MD | 33. Tom Santoro, MD |
| 9. William Steiner (NIAID) | 34. V. Robert M.D. |
| 10. Jose G. Condeelis, FDA | 35. J. G. L. MD |
| 11. Philip Cohen, GWU | 36. Gay Charles |
| 12. Jennifer K. Mistack, BRI | 37. Rodlyn E. Epps, GCS |
| 13. S. D. Gole, M.D. | 38. Norm Marshall |
| 14. Robert Hoffman | 39. Ellen Skuta, OT |
| 15. Katrina Boverman, Soc. Work | 40. Bobby Kern |
| 16. Lu S. J. Lan, NIAID | 41. Robert M.D. |
| 17. Diane J. G. J. NIAID | 42. Anthony Rayner, SB NCI |
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| 24. Robert J. J. NIAID | 49. Timothy Kern |

NCI AIDS TASK FORCE ADVISORY GROUP MEETING

NCI - Bld. 37

July 18, 1983

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REGIONAL MEETING ON AIDS
August 8-9, 1983

NIAID Sponsored Participants

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Associated with Department of Medicine
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"Haitian Study Group on Kaposi's Sarcoma and
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Dr. Bislam Mahabir
Senior Medical Office (STD)
Ministry of Health
Port-of-Spain, Trinidad

Dr. Carlos Mulhraise
Medical Health Officer
Ministry of Health
Nassau, Bahamas, W.I.

Dr. Moliere Pamphile
Epidemiologist and Chief
Division of Public Hygiene
Département de la Santé Publique
et de la Population
Port-au-Prince, Haiti

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Other Participants

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Dr. G. Causse
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World Health Organization
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Dr. A. Clayton
Director
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Ottawa, Canada

Dr. Alma Dyer
Principal Medical Officer
Ministry of Health
Kingston, Jamaica

Dr. R. Edelman
Chief, Clinical and Epidemiology Studies Branch
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National Institutes of Health
Bethesda, Maryland

Dr. R. Gordon
Office of the Director
National Institute of Health
Bethesda, Maryland

Dr. H. Jaffe
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Atlanta, Georgia

Dr. Joyce Johnson
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Director
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National Institutes of Health
Bethesda, Maryland 20014

Dr. T. Quinn
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Baltimore, Maryland 21205

Dr. Arturo Romero
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Pan American Health Organization
Washington, D.C.

Dr. R. St. John
Coordinator
Epidemiology Unit
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Washington, D.C.

Dr. Hector Terry Molinert
Vice Minister
La Habana, Cuba

Dr. K. Western
Assistant Director for International Research
National Institute of Allergy and Infectious Diseases
National Institutes of Health
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Observers

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Gueldy Parisien Rene
Port-au-Prince, Haiti

Mr. WEISS. Mr. McCandless' question reminded me that in reading through your testimony before the hearing, and in following it this morning as you read it, one of the problems that I have is understanding how much money has been spent on AIDS research. You stated today that a total of \$167 million is one way or another being directed toward some aspect of the AIDS problem, although not necessarily to fund research specifically initiated for dealing with the AIDS problem. However, there is no way of segregating from your testimony which of those programs in fact were initiated to deal with the AIDS problem, which of them have been in effect and directed toward basic research, separate and apart from AIDS, when they began and how much is being expended on those programs.

It appears to be a morass. I would appreciate if you can have somebody go through your testimony and try to identify specific programs, dates of initiation, and dollar values for each so that the subcommittee can determine how much indeed is being spent to deal with this crisis.

[Material referred to follows:]

Budget Figures Describing
Support for Science Base Research Related to AIDS

The NIH has a solid foundation of ongoing research in the fields of cellular immunity and infectious diseases which has provided and will continue to provide technological developments and the conceptual base for research on AIDS. To evaluate the extent of this support, we established a series of descriptors which relate directly to the areas of current AIDS research. The broad categorical headings are cellular immunity, interferon, key viruses, sexually transmitted diseases and opportunistic infections. A series of more specific descriptors was provided for each category. The accompanying table shows the categories and specific descriptors.

The budget office of each BID which directly supports AIDS research was provided FY 1982 figures for research funding in the area of each of the descriptors on the table. The Institute budget offices worked in conjunction with their planning offices to generate the figures. The Division of Financial Management put the responses into tabular form using the major categorical headings.

FY 1982
SCIENCE BASE RESEARCH RELATED TO AIDS

Cellular Immunity:

- o immunoregulation
 - physiologic
 - unresponsive
- o suppressor cells, helpers, other T cell functions
- o immunodeficiency
 - cellular
 - congenital
- o immunosuppression

Interferon

- not including production Lymphokines

Key viruses:

- o Hepatitis B, nonA-nonB hepatitis
- o cytomegalovirus
- o herpes virus
- o EB Virus

Sexually Transmitted Diseases

- o sexual behavior

Opportunistic Infections:

- o Kaposi's sarcoma
- o Pneumocystis carinii
- o Toxoplasma gondii
- o Cryptococcus neoformans
- o Mycobacterium avium-intra cellulare
- o Cryptosporidium
- o candidiasis
- o amoebiasis (Entamoeba histolytica)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

FY 1982 ACTUALS
SCIENCE BASE RESEARCH RELATED TO ACQUIRED IMMUNE DEFICIENCY SYNDROME
(Dollars in thousands)

	<u>Cellular Immunity</u>	<u>Interferon</u>	<u>Key Viruses</u>	<u>STDs</u>	<u>Opportunistic Infections</u>	<u>Total</u>
NCI	\$63,826	\$8,316	\$13,575	\$700	\$426	\$86,843
NHLBI	3,273	97	1,250	---	---	4,620
NIDR	---	---	25	---	---	25
NIADOK	8,980	703	660	---	---	10,343
NINCDS	4,605	544	1,290	33	66	6,538
NIAID	17,447	3,398	7,569	1,485	6,577	36,506
NIGMS	---	---	---	---	---	---
NICHD	1,387	221	1,202	569	51	3,430
NEI	4,451	610	2,913	---	205	8,179
NIEHS	---	---	---	---	---	---
NIA	407	---	136	---	---	543
DRR	<u>6,907</u>	<u>630</u>	<u>1,553</u>	<u>198</u>	<u>564</u>	<u>9,852</u>
TOTAL, NIH	111,313	14,519	30,173	2,985	7,889	166,879

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NIH/ADA/DFM/BFPB
June 30, 1983

Dr. BRANDT. We will be delighted to do that, but I think I have to point out honestly to you, if you put two competent scientists together and ask them to go through and address each research grant and say to what extent is this directed to AIDS, you will get differences of opinion. I am perfectly willing to give you what our view of that is, and that is the best we can do.

Mr. WEISS. Well, certainly, Dr. Brandt, you would have to I think—

Dr. BRANDT. We have a couple of competent scientists at the NIH.

Mr. WEISS. I believe you. In fact, you have a great many. But, I think that you would acknowledge that moneys which were committed prior to the onset of AIDS as a known and recognized syndrome cannot legitimately now be counted as moneys which the Department is, in fact, focusing on the AIDS crisis.

Do you acknowledge that?

Dr. BRANDT. I would agree with you up to a point, sir, and that is, if we allocate a grant in 1980 to a sexually transmitted disease center, and in 1981, in response to this crisis, we permitted them to direct their research toward it, that is a legitimate expenditure of funds to be counted in this battle. We have not counted them. None of these numbers include that. The numbers I have given you are for grants and programs that came about in response.

It is only the tip of the iceberg, and, frankly, I personally think that we are going to waste more time and money trying to go out and determine the exact dollars and cents that have been spent, but we will be happy to do it.

Mr. WEISS. One of the areas that was addressed by witnesses yesterday dealt with finding an animal model for AIDS.

Dr. BRANDT. Yes, sir.

Mr. WEISS. Will you tell us what the Department or the various agencies have done in attempting to find an animal model?

Dr. BRANDT. Well, I will turn it over to the scientists at this point, and let them tell you what they are doing.

I think it is important that we do have a spontaneous disease that looks like AIDS that occurs in simians, that has been reported both at the University of California at Davis at their NIH-funded primate center, and at the Boston Harvard NIH-funded primate center. But perhaps we can begin with Dr. Foege, where they have been trying to develop an animal model.

Dr. FOEGE. Mr. Chairman, we have attempted to inoculate various animals with body fluids of all types from AIDS patients, and we have literally done hundreds and thousands of tests, but we realize that the incubation period of this disease in humans may mean that we have to wait many months or even years before we would find the disease in the animal, even if the animal is susceptible and even if the agent is in the material that we injected; so this is a very time-consuming process.

Dr. Fauci, you might want to comment on the NIH experiments.

Dr. FAUCI. That is really quite similar, Mr. Chairman, in that it involves predominantly taking materials, either secretions or specimens, for example, suspected involved lymph nodes and lymph node tissue which we feel is a very highly suspect target organ of

this putative agent and try to induce the expression of this in a number of animal models.

There are a number of difficulties with that approach predominantly being the very long incubation period as well as the fact we are not sure that this particular virus, as it were, which we are presuming it is, has not adapted itself just to the human model and may not be able to be expressed in the animal model.

Therefore, the spontaneous models of the diseases, the monkey colonies, appears to be a good model to study, perhaps at least an analogous situation, but even in that we are not sure whether we are dealing with something which is the animal counterpart of AIDS, strictly speaking.

Dr. BRANDT. However, I must say that at the present time, we are behaving as if that is an animal model, because, in fact, it does show similar disease characteristics and we are following up on it.

We have not been able to induce a model, but again we are dealing with an illness that has a very long incubation period. In humans we can document from 7 months to 3 years that incubation period. Mainly, we document that on the basis of exposure through blood or other mechanisms, and in animals it may very well be longer than that.

Right now, we are in the 13th month, if my arithmetic is correct, but I think that we have what might be an ongoing animal model of an AIDS-like syndrome spontaneously occurring in animals that is being studied in some detail at two different universities.

Mr. WEISS. Again, I am not a scientist, and so you have to bear with me.

Are you telling me that you have the traditional animal model development program in effect that would be used to test the various body fluids on the various primates, or are you telling me that you have found that in one instance that an AIDS-like syndrome has developed, and you worked backwards from that and concluded that that is an animal model?

Dr. BRANDT. The answer to both of your questions is yes. We have a system set up to try to develop an animal model involving nonhuman primates.

We do have at the same time, a spontaneous illness developed in two monkey colonies that we are currently studying to determine whether or not it is an animal model; so, we have two routes going, but I think until proven otherwise, that we ought to look upon that one as an analogous disease in animals. We do have—both at CDC and at NIH—a program underway to try to develop an animal model in the classical sense of that.

Mr. WEISS. Those bells indicate that we now have a series of votes which will take probably in totality around 45 minutes; so, with the permission of my colleagues and the witnesses, I think this is an appropriate time to break for lunch. We will return at 2 o'clock, probably for no more than an hour, because by that time we will be back on substantive legislation on the floor.

The subcommittee stands in recess.

[Whereupon, at 12:55 p.m., the subcommittee recessed, to reconvene at 2 p.m. the same day.]

AFTERNOON SESSION

Mr. WEISS. The subcommittee will come to order.

Would the witnesses please resume their places?

The affirmation or oath which was taken at the beginning of the panel's testimony is still in effect.

Dr. Brandt, we were discussing at the time that we broke for our recess the question of animal models.

Because we have a limited amount of time remaining, and because I am still somewhat confused on the subject, we will submit some of our questions to you in writing, if we don't get a chance to get back to this subject before we complete our hearing this afternoon.

Dr. BRANDT. That will be fine, sir.

Mr. WEISS. I believe that you now have had a chance to review the March 25, 1983, memo from Dr. DeVita, Director of the NCI, stating the estimated costs for the approved grants was \$7,565,622. Is that correct?

Dr. BRANDT. Correct.

Mr. WEISS. That memo states that they could only fund 30 percent of these grants with available funds.

Could you tell the subcommittee at this point, as of August 2, how many of the remaining 70 percent of the approved grants, if any, have been funded?

Dr. BRANDT. We have funded a total of 9 by the NCI and 4 by the NIAID, a total of 13; and with the funds from the supplemental we will fund an additional number. I don't know precisely that number yet, because, since that RFA, there will have to be a little bit of negotiation with the grantees.

Mr. WEISS. That is a total of 13 funded out of a universe of how many? Thirty-three were approved and 10 disapproved, so it is 13 funded out of the 33 approved; is that correct?

Dr. HENNEY. There were 45 applications received. Ten were disapproved. Thirty-three were approved, and two were re-reviewed. One of those has since been approved and funded, and the other one is undergoing another site visit this month for possible funding.

Mr. WEISS. And those remaining 20 or so, a number of them may be funded before the end of this fiscal year. Is that correct?

Dr. BRANDT. That is correct. I cannot tell you precisely how many of them at this point in time, because it depends a little bit on the money situation and any changes that may have occurred, but I would guess we will fund most of them.

Mr. WEISS. It is my understanding, and you correct me or give me the accurate information, that the NCI first planned to issue this request for application, that is the RFA, sometime in November of 1981. Is that correct?

Dr. HENNEY. We had an RFA under consideration at that time.

It was not passed for concept review by the appropriate Board of Scientific Advisers, I don't believe, until the first of the year.

Mr. WEISS. Of 1982?

Dr. HENNEY. Yes.

Mr. WEISS. And the proposal was finally published in August of 1982?

Dr. HENNEY. Yes; that is correct.

Mr. WEISS. And the bulk of the money is being spent for those grants in the summer of 1983. Is that correct?

Dr. HENNEY. Yes, the bulk of it actually was awarded this spring.

Mr. WEISS. OK.

Now, can we hope for anything better in terms of expediting this process at NIH when we have what is acknowledged by everyone on all sides to be an emergency situation?

Why that kind of delay, and why can't we do better?

Dr. HENNEY. Actually, the average time for RFA development issuance to time of award is usually 18 months, and we did cut that down by a considerable amount, down to 14 months.

However, some of the delay in the whole process was the site visits that were conducted. In order to give those applicants with large, complex proposals every fair chance at getting funded, the peer review committee recommended that we proceed to have actual site visits of some of the grants or grantees that had submitted applications.

That did take a little bit more time than we had originally planned for and delayed some of our funding of those grants. It did, by that process, make some grant applications that might possibly be disapproved or not receive funding eligible for funding.

Dr. BRANDT. Actually, the deadline for the receipt of those applications, Mr. Chairman, was October 22, 1982, and awards were made in May 1983.

October 22, 1982, and awards were made in May, so we are talking about 7 months. The time from August to October was to allow the scientists to develop their proposals to respond to the application.

Again, I need to remind you, sir, that this is a very complicated disease. This is not something that you can sit down and slap a proposal together over a weekend. This takes some time.

Mr. WEISS. But why would you have the gap from November of 1981 or the beginning of 1982, if you will, until August of 1982, before the publication takes place?

Dr. BRANDT. You mean from the time that the Board approved it until it was published?

Mr. WEISS. You have a 6- to 8-month gap.

Dr. BRANDT. Actually, closer to 6 months, because it was in January when the National Cancer Advisory Board met and, under the law, the Board has to approve those kinds of actions before we move on them.

Mr. WEISS. I think that the point that both the scientific witnesses, as well as the organizational representatives, were making is that you have an acknowledged emergency. You have a situation which has now been designated as the No. 1 public health priority.

Would you not think it appropriate—never mind what happened last year or the year before that designation—would you not think it appropriate now to try to provide for some formalized expedited process so that you do not have a continuation of these time gaps from the approval through the publication, through the funding?

Dr. BRANDT. We will expedite all of the steps except the scientific review. Under no circumstances would I be a party to shortcutting the scientific review of these things.

The last thing we need in this problem is lousy science.

Mr. WEISS. I agree with you, but we have an indication here that long after you got scientific approval, you have these seemingly unavoidable or nonconstructive delays.

Dr. BRANDT. I seriously doubt that you can cut down the review period less than the time that was used in this, namely, about 6 months.

Certainly the steps that went on before, we are, in fact, decreasing the time. We are going now with mail and telephone balloting, not waiting for regularly scheduled council meetings, and other steps are being taken. But once you begin to make site visits of these institutions, pull together the outside consultants who come in and advise us on these issues and who, in fact, make decisions and determine the scientific quality of these things; I think it is very difficult to do that in less than 6 months. We will try. No question about that, but I think again that we have to continue to insist upon thorough review for scientific merit.

Mr. WEISS. Again, we have no disagreement.

My concern, and everybody else's concern, is that for the No. 1 health priority, there ought to be a recognition of urgency in those areas where urgency can, in fact, be applied.

Dr. BRANDT. We are in agreement. There is no question about that. We are in agreement, and we are doing it.

Mr. WEISS. When did the Department scientists first come to the realization that an infectious agent might be the cause of AIDS?

Dr. BRANDT. It was in the fall of 1981, early 1982, that I think we all came to the conclusion that that was the most likely explanation. However, we were a little bit further along in the year before we were all convinced that we could begin to focus our efforts there, and no longer pursue chemical and other possibilities.

Mr. WEISS. It is my understanding that the first request for proposal on the etiology of the disorder, emphasizing the search for an agent was issued in May 1983. Again, why did that request for proposal take so long?

Dr. BRANDT. Because up until that time, we had been getting requests spontaneously. See, there are basically two parallel mechanisms going on.

We have the investigator-initiated grants program, where these grants come in year round, and the RFP's, and RFA's, and RFC's that we send out are only done in those instances where it is felt that the investigator-initiated grant proposals are not covering the entire waterfront that we feel is important; so it was not necessary to develop one until it became clear that there were certain areas that were not, in fact, being covered by investigator-initiated grants.

The backbone of the NIH and the scientific progress that has been made in this country has been the so-called RO-1's.

In general, the scientific community figures out the problem as fast as all of the rest of us do, and they come in on their own, and those grants have been funded right along; so there has never been any delay in that program.

Mr. WEISS. Well—

Dr. BRANDT. But that is a judgment call, clearly, and reasonable people will differ on the timing of it.

Mr. WEISS. There is a problem, besides the delay that I see. You keep on saying that, in fact, there is some comprehensive approach to this crisis and yet sitting where I am, what occurs to me is that the process you just described is sort of hit and miss as to whether, in fact, all of the gaps will be filled in and whether, in fact, you do have a comprehensive approach. It seems to me that when you are not in an emergency situation, investigator-originated research is fine; but when you have an emergency that you are trying to solve, you really ought to have a comprehensive plan which at least sets out all the areas that ought to be covered. That way, if an investigator does not spontaneously come forward with a request for proposal, you can go out and see if an institution or individual would be interested or be in a position to undertake that kind of research.

Doesn't that make some sense?

Dr. BRANDT. Yes, sir, but I would like to point out an apparent discrepancy in the whole process, and that is, we have been criticized yesterday, and I gather earlier today, for not having a comprehensive plan and for not having sought outside advice; by the way, a criticism that I have rejected and still reject.

One of the best ways to obtain outside advice is through the investigator-initiated grant program. After all, they are people on the frontline of science. They are the scientific talent of this country. Their response and their coming in for grants is the best kind of advice we can get as to the direction of modern science, and as to the way in which problems should be solved.

We, therefore, would prefer to look at what they come in with, and then determine whether or not there are some areas that are being missed rather than go the other way around, and try to tell them, the scientific talent of the country. If we do what you are suggesting that we do, I think we would be exactly guilty of what we were accused of yesterday, and instead, it is—rather than a hit and miss—it is, in fact, a way, and a very effective way—and a way that has been in effect for 50 years, and I might say quite successfully—of getting the kinds of advice from the scientific community that we need. I happen to believe in it as the way to go.

Mr. WEISS. Well, I am pleased that you believe in it. At least you are not doing something that you don't believe in, but, when do you think the time will arrive when you will have received sufficient investigatory-originated proposals so that you can look to see where the gaps are? Has that time arrived yet?

Dr. BRANDT. Well, obviously we have done that. We have put out this RFA you are talking about on the etiology aspect, because we felt there were gaps, and those RFA's are quite specific as to the kinds of places we are soliciting proposals. They were not coming in through the standard mechanism, and we do this at every round of grants to try to determine where there are holes and which way to go.

Mr. WEISS. Has that RFA been funded yet?

Dr. BRANDT. No. It is—right now the grants are under review; they are scheduled to be funded out of 1984 dollars, and were all along. The RFA was released in May.

What is the deadline? The deadline is this month, so we will review the grants when they come in. I think it is August 1.

Mr. WEISS. Here we have a request for proposal on the etiology of the disorder. The determination that an infectious agent is involved was made by you or one of your people sometime toward the latter part of 1981, and the research proposals will be reviewed and funded in fiscal year 1984, a gap of approximately 2 years?

Dr. BRANDT. The first award was made in April 1983, sir, which is roughly 5 months after the deadline.

Mr. WEISS. I am talking now about the etiology of the disorder.

Dr. BRANDT. The date of issue, May 1983, and we anticipate awarding the first dollars in November 1983, which is, yes, November 1983, which is fiscal year 1984 dollars, which is roughly again 6 months.

Mr. WEISS. That is right, but didn't you say that you first determined that you needed to do this, in the fall of 1981?

Dr. BRANDT. No, sir, I didn't say that. If I said that, I certainly made a mistake. What I said was, that it was after the determination by the virologists and particularly the people at the NIAID and NCI, their group of scientists, that one was needed, and it was put out in May 1983.

Mr. WEISS. I am sorry; you had said that the realization that an infectious agent might be the cause of AIDS occurred sometime in the fall, November 1981?

Dr. BRANDT. Yes, sir, the realization of that, but work was underway at that time. We already had work underway looking at that.

We have not waited until 1983 to begin to look at it.

After all, viruses have now been isolated and work is underway with great rigor, if you will pardon the expression, in trying to identify the specific one, so that this RFA is to fill in the kind of gaps that we see present. It is not the first time we looked at it, and let me ask Dr. Fauci when, for example, his institute began to work on the infectious etiology.

Dr. FAUCI. We were involved in admitting the first patient to the clinical center in collaboration with the National Cancer Institute in studying the infectious and immunological aspects.

I would imagine it would have been a matter of just months, sir, after that when the epidemiological data began coming in from the CDC about the various risk groups, and it became likely that this was an infectious agent, and it was at that point in the intramural program, bringing us to the very beginning of 1982, we began a series of studies looking at the particular cells that we suspected were being infected from this agent.

We were directly involved in investigations, concrete investigations, early in 1982, within the first month or two of 1982.

Mr. WEISS. Again, so I understand this, would it be unfair or incorrect to state that although as of this moment we still do not know what causes AIDS, research funded in response to an RFA on etiology of the disorder has not yet begun?

Dr. BRANDT. No, sir, that is wrong. The August of 1982, RFA included work on the etiology; so that in terms of—well, let me—

Mr. WEISS. Who is doing that, and where is that being done?

Dr. HENNEY. We don't have specific individuals for you, but in our original RFA that we released, one of the specific areas that we wanted to look at was possible etiologic agents of which viruses were a potential part. It became clear in reviewing both those ap-

plications that came in response to the RFA and the general results that were coming out of the scientific community, that it was more likely that there a viral agent was involved.

Many people already working in the whole area of viral research turned their focus toward looking for such—to identifying such—an agent, and we at the same time began the development of the second RFA, of which you are speaking, that would again clearly signal the scientific community that we were most interested in seeing more applications for work in this area.

So we have ongoing efforts in that regard, and we also are trying to stimulate more.

We have on at least two, and I think possibly three, occasions during the last several months, brought all of the investigators together that are in our extramural community that are specifically working on defining the etiological agent, together with representatives from NIAID and FDA, and so forth, to discuss this very matter. So there is much work going on in that regard.

Dr. BRANDT. Dr. Quinnan might have some comments about it, also.

Dr. QUINNAN. I think we have to go back to the consideration that ongoing programs are not AIDS-related research programs, or at least the claim that that was so, and both in our own laboratories at FDA and NIH laboratories and laboratories around the country, since before the first cases of AIDS were recognized as being part of a new syndrome, there has been intensive study going on in viral infections in homosexual men. Those studies have continued in all of those laboratories, including our own, and the first patient that we studied with AIDS to try to find the virus was a patient admitted in June of 1981 to the clinical center at the NIH.

There is a great deal of information available now, and most of it has been developed prior to or on the basis of grants funded prior to the time that AIDS was recognized, but because the grants were awarded for types of studies that were applicable to AIDS patients.

Dr. BRANDT. I think, Mr. Chairman, if I might, that it is important to state that there are at least four mechanisms under which the Public Health Service funds research, in response to emergencies or anything else, but particularly in response to emergencies.

One is that we have in place roughly right now 16,000 grants. I don't know how many cooperative agreements and other things are out there; a large pool of scientific talent that is available.

As soon as this disease was described in June of 1981, and certainly during that summer, calls were made by the NIAID, NCI, and others, letting them know of this activity, and some of the grantees, themselves, called and said they would like to begin to work more specifically in this area, and that was permitted, and they started right away. Most of this group were in an NIH-funded center program.

A second activity is the investigator-initiated grants which go on. The investigator-initiated program is the standard grant pool, and it is investigator-initiated and draws upon that great pool of talent outside of the Federal Government that this country depends upon. They submit grants and largely dictate the direction of scientific effort in this country.

Third, the requests that we send out, where it is determined by the NIH or the FDA, or whomever, that there are specific areas that are not being covered through the first two mechanisms, and this is used, then, for that mechanism.

The fourth is, of course, the intramural research program. We have been criticized as being slow, but largely that evidence is built only upon one of those four mechanisms, namely, the request for proposals and requests for applications.

If one judges only by that, admittedly the response was slow, but all other mechanisms were in place within a few months of the determination that this disease occurred, so that the response was quick and fast, and was determined, in large part, by the scientists out in the field as well as the intramural scientists. The fact that RFA's were not put out until a year later is just because at that point in time the work was being done, and so putting the RFA's out, I think, is a distortion of what really happened.

Mr. WEISS. Can you tell us what statistics you have as to the number and the dollar value of the investigator-initiated grants?

Dr. BRANDT. We can supply you with that list; yes, sir.

Mr. WEISS. I would appreciate that. Since you have focused on these, it would also be important to know how many investigator-initiated proposals were approved and then not funded.

Dr. BRANDT. I think we can; I am sure we can supply that to you. I am guessing we can.

Mr. WEISS. We would appreciate that.

[The information follows:]

INVESTIGATOR INITIATED RESEARCH PROJECT GRANTS

The following table provides, as of August 1, 1983, the number and amount of research project grants devoted to AIDS research funded by the National Institutes of Health in fiscal year 1983.

(Amounts in thousands of dollars)

	<u>No.</u>	<u>Amount</u>
NCI.....	12	\$2,868
NHLBI.....	2	128
NIAID.....	7	1,254
Total.....	21	\$4,250

Additional research project grants have been approved for funding and will be awarded later this fiscal year. The precise number that may go unfunded cannot be predicted at this time.

It should be noted that the NIH supports additional AIDS research through other funding mechanisms, including research centers, research and development contracts, and the intramural program.

Dr. BRANDT. The one thing I can't supply you, though, is how many people who already had grants out there who shifted their direction in response to this emergency, because that I don't know, and I certainly can't put dollar values on it.

I guess we could go back and query the 16,000 people, and try to determine that, but it seems to me that is not in our best interests or theirs.

Mr. WEISS. When did the CDC first learn about AIDS cases in hemophiliacs?

Dr. FOEGE. The first publication that we made was in July of 1982, listing three cases, and I would have to look back at the dates, but we had been for some weeks before that dealing with two cases, and both of them had problems with: were they really AIDS or not?

One of the people had died, and this was retrospective information that the patient might have AIDS.

The first two cases were hard to decipher. When the third case was reported, we immediately put a publication out to say that we had these three cases.

Mr. WEISS. Is it accurate that the first request for research proposals, specifically to look at this possible carrier state in blood, was issued on July 15 of this year?

Dr. BRANDT. I don't know the answer to that, who issued it. Dr. Chernoff?

Dr. CHERNOFF. The National Heart, Lung, and Blood Institute did issue an RFA July 15 to cover the area of identifying possible contaminated blood or blood substances. However, a great deal of research had already been going on before that RFA, directed to the general problem of hemophilia and the question of whether there was transmission of AIDS through blood products.

Efforts had been initiated as far back as September or October of 1982 through an intra-agency agreement with the CDC to examine patients with hemophilia and determine their immunologic status to try to determine if there was some relationship between the clinical situation and hemophilia and the receipt of blood products.

Mr. WEISS. Is that an epidemiological study that you mentioned?

Dr. CHERNOFF. That was a study dealing with the situation at one point in time. It is our intent to do a prospective epidemiologic study in the immediate future, and an RFP to that effect is in the process of being developed and will be issued shortly.

Mr. WEISS. Again, are you telling me that there has been no extramural research grant approved and funded that is specifically aimed at the possible carrier state in blood?

Dr. CHERNOFF. There has been no specific grant funded relative to the carrier state of AIDS. However, there has been work not specifically related to a specific grant that has covered this area.

The CDC, itself, has looked at the various tests of blood and blood serum to see whether there is a connection between some chemical abnormality or some virologic abnormality in the AIDS state. Not knowing what the infectious agent or what the agent involved in AIDS is, it is difficult to develop a specific test directed toward this purpose.

Mr. WEISS. Well, I would again appreciate for the record as much detail in this area as you can give me, because what I gather, and my impression may not be absolutely correct, is that precious little research specifically aimed at an AIDS carrier state in blood was done.

Dr. BRANDT. Let me be sure that I understand what you mean by an AIDS carrier state in blood, because that is not clear to me.

Mr. WEISS. Well, I am talking about—

Dr. BRANDT. Yes.

Mr. WEISS [continuing]. Some scientific or biological or chemical research, as distinguished from an epidemiological kind of research which Dr. Chernoff seemed to be talking about in our discussion.

Dr. BRANDT. Are you concerned about trying to isolate a virus from the blood, or are you interested in trying to identify antibodies in the blood?

Mr. WEISS. I want to know what it is that you fellows have done. There is talk about blood being one of the carriers. It seems to me that if that is one of the genuine concerns, that somebody would have posthaste gotten on the stick and decided to fund some research grants to tie down whether, in fact, this is or is not transmitted through blood.

As of now, as I try to follow you through the morass of response I get, what I sense is that, in fact, there has been little such research done.

Dr. BRANDT. Let me then disabuse you of that idea by calling on Dr. Quinnan, from the FDA, where this is done.

Dr. QUINNAN. There has been a tremendous amount of research done in this area. One type of work that has been done is to screen various types of blood products, to test them in every way possible to try and identify an infectious agent, and that work has been done in part at FDA, and a lot of work was done in CDC and in other parts of the PHS.

Other types of work that have been done is to try and apply various tests that are candidates for screening tests, all of which have been identified beforehand as having various shortcomings, but being the best available.

There is research being done at least at a couple of the major blood centers around the country, applying a number of potential screening tests.

The biggest part of the work in this general area, though, is not in the immediate application. The problem is that we don't have a test right now, and what we need to do is to understand the disease better so that we do have a test, and there has been a tremendous effort devoted toward finding characteristics of the disease that are diagnostic, and a tremendous amount of progress has been made in understanding the etiology, and—I am sorry—in understanding the immunology.

There has also been progress in understanding the etiology to the extent that there are many, many, many viruses and other infectious agents and chemicals that can now be discounted, and a list of potential causes is being narrowed down quite rapidly.

So, we don't have an answer yet, but there has been an intense amount of investigation ongoing since the beginning.

Mr. WEISS. I read from a release dated July 15, 1983, request for research grant applications: RFA, assay methods to detect the carrier state of acquired immuno-deficiency syndrome—AIDS.

Application receipt date, October 17, 1983.

Purpose: It invites grant applications for the development of tests to identify the carrier state of acquired immuno-deficiency

syndrome—AIDS—and to evaluate the sensitivity and specificity of these tests.

The major purpose of this special grant program is to determine whether there are markers made that could be used to rapidly, simply and specifically identify individuals who are asymptomatic carriers of AIDS.

Has the research along the lines just described in that paragraph been undertaken by anyone under the auspices of either the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, CDC, NIH? Anybody?

Dr. CHERNOFF. This particular RFA has just been issued within the past few weeks, and obviously we will not have responses until October 17, 1983.

Mr. WEISS. I appreciate that. Has there been research done in the exact area that the paragraph I just read describes?

Dr. CHERNOFF. There have been a number of activities over the past year that have dealt with this problem. The CDC, in the summer of last year, published or presented information on a great many indirect or surrogate tests that could be related to the presence of the AIDS situation.

Other groups have followed up on this, and, in our own institute, a number of program projects going on in different blood centers in the country have dealt with the problem of trying to identify tests that may be related to this particular condition.

They have included such esoteric things as beta-2-microglobulins and special kinds of interferon that are known to occur in populations with the AIDS problem.

Unfortunately, these tests are quite nonspecific and appear in a number of other populations which may show no evidence of AIDS and not be members of any high-risk group. So there has been considerable activity going on in the past.

Dr. BRANDT. The answer, I think, Mr. Chairman, to your question is, yes, there has been research underway on this, because early on, when the issue came up about whether or not this disease could be transmitted by blood or blood products, the question came up as to whether we could determine by some screening test the safety of blood and blood products in particular.

There have been six such tests proposed, at least six, but six that have been proposed that have hit the public media of one kind or another, been latched onto by one group or another, and all six of those have been evaluated; and as far as we are concerned, we are in agreement with Dr. Chernoff that they are nonspecific; that they do not specifically identify AIDS, and are not useful tests.

Now, what we are trying to do is to carry this one step further, and that is the reason for the RFA.

Mr. WEISS. OK. I think we are going to have to break at that point.

The bells have rung for a vote on the floor.

We will be submitting questions to you in writing, and we hope that you will get responses to us within the timeframe that we set, so that we can have the transcript of the hearings compiled, and collated.

Finally, let me express my appreciation to you for your participation here today, and Mr. Donnelly, Dr. Brandt, we look forward to

the new cooperative effort between the subcommittee and the Department and its various agencies.

Thank you so much.

[Whereupon, at 2:55 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIXES

APPENDIX 1.—HHS RESPONSE TO SUBCOMMITTEE QUESTIONS

TERMINAL
JOHN F. O'NEILL, JR. M.D.
SUNSHINE HOSPITAL
SUITE 800
1800 W. 15th St.
MIAMI, FLA.
33135

ALFRED S. JACOBSON, M.D.
LARRY E. CARL, M.D.

NINETY-EIGHTH CONGRESS

Congress of the United States

House of Representatives

INTERGOVERNMENTAL RELATIONS AND
HUMAN RESOURCES SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

RAYBURN HOUSE OFFICE BUILDING, ROOM 3-372

WASHINGTON, D.C. 20515

(202) 225-2848

August 24, 1983

Honorable Edward Brandt, Jr.
Assistant Secretary for Health Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Brandt:

I am writing to ask your cooperation in completing the record on the subcommittee's August 2 hearing on the Federal response to the AIDS crisis.

I will greatly appreciate receiving for inclusion in the record the Department's response to the enclosed questions, including all relevant documentation and budget data, by no later than Friday, September 16, 1983.

If there are any questions concerning this request, please have your staff contact Susan Steinmetz at the subcommittee office.

Thank you for your continuing cooperation.

Sincerely,


TED WEISS
Chairman

Enclosure

(487)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

SEP 23 1983

The Honorable Ted Weiss
Chairman, Intergovernmental Relations
and Human Resources Subcommittee
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

Enclosed is a partial response to your letter of August 24 to Dr. Brandt requesting responses to 49 follow-up questions for the record on the Subcommittee's August 2 hearing on AIDS. As agreed to with your staff the remaining responses to questions 17 and 21 will be transmitted as soon as these are available. The operational plan mentioned in question #8 that was outlined in Dr. Brandt's testimony is being further refined and will be completed soon.

Please let me know if I can be of further assistance.

Sincerely,

Cynthia C. Root
Deputy Assistant Secretary
for Legislation (Health)

Enclosures



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

SEP 30 1983

The Honorable Ted Weiss
Chairman, Intergovernmental Relations
and Human Resources Subcommittee
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

Enclosed are responses to NIH questions 17 and 21 as requested
in your letter of August 24 to Dr. Brandt.

The only remaining item is the AIDS operational plan, which should
be available soon.

Sincerely,

Cynthia C. Root
Deputy Assistant Secretary
for Legislation (Health)

Enclosures

1. Please outline the Department's policy regarding congressional access to information. Specifically, what restrictions, if any, apply to congressional oversight information or interview requests. If there are any restrictions, please delineate each and cite the relevant statutory authority for each restriction.
- A. The Department's policy regarding Congressional access to information and interview requests are set forth in the Secretary's letter to Congressman Weiss dated May 12, 1983.

The statutory restrictions on release of information are:

18 U.S.C. 1905 — Trade Secrets

Food, Drug, and Cosmetic Act, Section 301(j),
21 U.S.C 331(j)

Public Health Service Act, Section 303(a),
42 U.S.C. 242a(a) — Mental Health Research

Public Health Service Act, Section 308 (d),
42 U.S.C 242m(d) — Health Research and
Statistical Activities

Comprehensive Alcohol Abuse and Alcoholism
Prevention, Treatment, and Rehabilitation Act
of 1970, Section 333, 42 U.S.C. 4582

Drug Abuse Prevention, Treatment and Rehabilitation
Act, Section 21 U.S.C. 1175

2. Please specify exactly what budget information the Department believes may be withheld from a congressional oversight committee pursuant to OMB Circular A-10 and cite the statutory authority for the Circular.
-
- A. OMB Circular A-10 authorizes the withholding of all budgetary information prior to transmittal by the President of the material to which it pertains. Under A-10, budgetary information includes, but is not limited to "agency [budget] submission, requests, recommendations, supporting material and similar communications...." OMB Circular A-10 refers to the statutory restrictions in 31 U.S.C. 1105, et seq. (formerly 31 U.S.C. 11 and 15).

3A. Question: The Department has revised its FY 1984 budget request for AIDS research from \$17.6 million to approximately \$40 million. Please provide a complete breakdown of how the \$40 million will be spent and from which programs the additional \$22 million will be transferred under this proposal.

Answer: Since the AIDS problem was first reported in June 1981, the Public Health Service has centered its activities in this area around three major objectives --

To determine the pathogenesis (the process of the development of a disease) of AIDS.

To determine how AIDS is transmitted.

To develop methods of treatment, control and prevention.

The Department's FY 1984 revised budget request of \$39,827,000 for AIDS will be used to continue and expand the specific PHS activities directed at achieving these three objectives. Implicit in this request is the assumption that by FY 1984 a causative agent will have been identified and a screening test developed for AIDS. Four agencies of the Public Health Service are involved in AIDS activities. The allocation of the FY 1984 revised budget request and the AIDS activities which will be carried out by these agencies is as follows:

CENTERS FOR DISEASE CONTROL

<u>ACTIVITIES</u>	<u>FY 1984 Revised Budget Request</u>
1. Surveillance.....	\$ 1,946,600
2. Epidemiologic Studies/ Investigations.....	\$ 3,374,000
3. Laboratory Studies/ Investigations.....	\$5, 710,000
4. Technology Transfer, Training, and Dissemination of Information.....	\$ 570,000
Total - CDC	\$11,600,000

Some activities to be supported by CDC in FY 1984 are:

- o Continue and institute additional surveillance activities in order to monitor adequately morbidity and mortality trends and to identify emerging risk-groups.

- o Expand and continue the studies of risk factors among Haitians, intravenous drug abusers, blood products and homosexual men screened for hepatitis B.
- o Continue to serve as the National repository and reference diagnostic center for AIDS laboratory specimens.
- o Train laboratory personnel as well as develop training and informational materials related to the laboratory aspects of isolating and identifying the causative organism of AIDS.

NATIONAL INSTITUTES OF HEALTH

<u>Activities</u>	<u>FY 1984 Revised Budget Request</u>
1. Research Project Grants.....	\$13,958,000
2. Research Centers.....	1,371,000
3. Research Contracts.....	4,765,000
4. Intramural Research.....	<u>7,233,000</u>
Total - NIH	\$27,327,000

Examples of the broad range of activities which would be funded by the NIH's FY 1984 revised budget level are:

- o Continuation of the AIDS extramural and intramural research initiated in 1983 in order to expand the knowledge base on AIDS treatment and cure.
- o Studies of the biology and molecular biology of the causative agent of AIDS.
- o Research on blood donors.
- o Research, development and testing of a vaccine for treating AIDS.

ALCOHOL, DRUG ABUSE AND
MENTAL HEALTH ADMINISTRATION

<u>Activities</u>	<u>FY 1984 Revised Budget Request</u>
Grants and Contracts.....	\$500,000
o ADAMHA will continue to support research into the cause of AIDS and risk factors associated with intravenous drug abusers who have succumbed to AIDS.	

FOOD AND DRUG ADMINISTRATION

<u>Activities</u>	<u>FY 1984 Budget Request</u>
Research.....	\$400,000
o FDA will continue to evaluate blood products and blood sterilization methods to increase safety of use and prevent transmission of AIDS to recipients of plasma, blood and blood products.	

The additional \$22.2 million proposed for AIDS activities in FY 1984 would be derived from transfers from two DHHS programs. Of this amount, \$12.5 million represents a decrease in the amount budgeted in FY 1984 for the National Health Service Corps. Current estimates predict that more private practice physicians rather than Federal staff physicians will be employed in FY 1984 which results in substantial Federal dollar savings. The other \$9.7 million needed for increased AIDS activities in FY 1984 would be available from the Rural Development Loan Fund.

3B. Question: The Department has revised its FY 1984 budget request for AIDS research from \$17.6 million to approximately \$40 million. Please provide a projected timetable for obligating these funds.

Answer: It is not possible at this time to provide a projected timetable for obligating the FY 1984 revised budget request for AIDS activities. An FY 1984 spending plan will be developed by each agency after its FY 1984 appropriations level is determined. In addition, the process for obligating funds varies according to the type of award to be made by the Public Health Service. For instance, new research grants which will be awarded in FY 1984 by NIH and ADAMHA are subject to the peer review system. Each NIH and ADAMHA Institute establishes a schedule for convening its advisory councils which review and score the applications for research grants. Also, a record of the FY 1983 research awards and date for their FY 1984 continuation is not compiled until the end of a fiscal year. However, as was the case for FY 1983 funding, the Committee can be assured that these funds will be obligated promptly.

3C. Question: The Department has revised its FY 1984 budget request for AIDS research from \$17.6 million to approximately \$40 million. Please provide all budget estimates, funding proposals or requests, or other information used to arrive at the revised budget request.

Answer: The Secretary requested a budget amendment of \$22.2 million based on extensive discussion between the Secretary and the Assistant Secretary for Health. This amount is sufficient to fund the highest priority activities in combatting AIDS. The appropriate materials reflecting this decision are attached. (For further information, see answer to Question 4A).



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

August 19, 1983

The Honorable David A. Stockman
Director
Office of Management and Budget
Washington, D.C. 20503

Dear Mr. Stockman:

I am writing to request your approval of a 1984 budget amendment to further the Department's research and surveillance activities on Acquired Immune Deficiency Syndrome (AIDS).

In my speech before the U.S. Conference of Mayors in June, I officially recognized AIDS as the Department's highest priority emergency health problem which we are anxiously and aggressively seeking to resolve. This condition attacks young, productive people by destroying the body's ability to fight infection. There is no known path of recovery once the immune system has been attacked.

In the past two years, the Centers for Disease Control (CDC) has received reports of over 2,000 persons who have AIDS and of these, about 38 percent have died so far. The number of reported AIDS cases has nearly doubled every six months. The mortality rate for AIDS victims diagnosed two years ago is about 80 percent.

While the incidence of this disease is relatively low, it is a priority concern because of the suffering of AIDS victims with its extremely high fatality rate and the enormous cost of the necessary intensive use of hospital facilities and personnel. Also, after two years of intensive efforts by government and non-government scientists, the cause of this immune dysfunction remains unknown.

With the additional funds provided by the 1983 Supplemental Appropriations Act (P.L. 98-63), the Department will spend \$25.1 million on AIDS research and surveillance activities in 1983. There are sufficient numbers of worthy AIDS research project proposals ready for immediate funding in FY 1983 so that we will not need to take advantage of the extended funding availability the Congress provided for in the Supplemental. The FY 1984 President's budget includes \$17.6 million for AIDS.

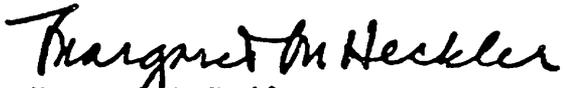
I am now proposing the Administration seize the initiative with respect to AIDS in FY 1984 and propose an increase of \$22 million and up to 61 FTE to the pending budget request. These funds will allow us to continue the efforts begun with the 1983 Supplemental and, through the initiation of additional projects, to search for ways to control and prevent this tragic disease.

A summary listing of these proposed additional expenditures is enclosed. A more detailed description of these activities will be provided to your staff within the next two days.

To offset these increases for AIDS, I have identified \$22.2 million not necessary for the purposes budgeted. Of this amount, \$12.5 million represents a decrease in the amount budgeted in FY 1984 for the National Health Service Corps because we now predict that more private practice physicians (rather than Federal staff physicians) will be employed, as compared to our budget plan. Hence a dollar savings results. In addition, there is \$9.7 million available in the Rural Development Loan Fund which is not needed to carry out either the loan program or the transfers for pay raise directed in the Supplemental Act.

I have publicly pledged to leave no stone unturned to pursue an answer to AIDS and consider this amendment essential to that goal. Should you or your staff have additional questions on our proposal, please let me know.

Sincerely,


Margaret M. Heckler
Secretary

Enclosure

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

FY 1984 Budget Amendment

(Dollars in millions)

FY 1983 Appropriation.....	\$25.1
FY 1984 President's Budget.....	\$17.6
Proposed Budget Amendment.....	+22.2
o Continuation of program activities included in FY 1983 Supplemental:	
-- National Institutes of Health (NIH).....	(+10.8)
-- Centers for Disease Control (CDC).....	(+3.1)
Subtotal.....	<u>(+13.9)</u>
o New AIDS program activities for CDC and NIH.....	(+8.3)
New Total, FY 1984 AIDS activities.....	<u>539.8</u>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

AUG 24 1983

NOTE TO DAVID KLEINBERG

FROM : John P. Scully *JPS* Acting Deputy
Assistant Secretary for Budget

SUBJECT : Detailed Description of AIDS
FY 1984 Budget Amendment

As promised in the Secretary's August 19 letter to OMB Director Stockman, I am forwarding a more detailed description of the activities proposed to be funded with the requested FY 1984 budget amendment for Acquired Immune Deficiency Syndrome (AIDS). Also, attached is revised appropriation language for the AIDS budget amendment. The FTE identified in the attached will be addressed for FY 1984 in the Department's FY 1985 budget request.

Attachments

A handwritten signature or mark, possibly "JPS", written in ink.

National Institutes of Health

Additional FY 1984 Needs for the Study of
Acquired Immune Deficiency Syndrome (AIDS)

The proposed FY 1984 budget amendment of \$14.9 million for NIH consists of:

o Continuation of FY 1983 Research

\$10.8 million would provide continuation costs of research efforts funded by the FY 1983 supplemental appropriation for AIDS. Such research includes studies on the nature of the defective regulators of immunity in AIDS, the epidemiology and natural history of the disease, the treatment of AIDS patients, investigations regarding the possible involvement of genetic factors in a predisposition to AIDS, and studies of neurological findings in AIDS patients. Continuation of these activities will expand our knowledge base on AIDS treatment and cure with important implications for other conditions affecting the immune system.

o New Activities

Assuming that a causative agent is identified and a reliable screening test developed, NIH would direct \$4.1 million toward the following:

NIAID - An additional \$2.6 million would support study of the biology and molecular biology of the causative agent and research, development and testing of a vaccine through grant funds, R&D contracts and expansion of the intramural program. In addition, research efforts would focus on modes of transmission, restoration of immune functions and new modes of treatment for opportunistic infections. Research on the abnormalities seen in the interferon system of AIDS patients would be expanded.

NHLBI - Supplemental funding of \$1.0 million in FY 1984 would be directed to research efforts focused on blood donors. Specifically, research will focus on whether blood donors are carriers of AIDS, whether they transmit the disorders, and determination and validation of appropriate screening tests for donors and blood products.

DRR - The addition of \$.5 million would provide immunological studies at the Primate Research Centers to provide baseline clinical and laboratory information of potential value to human AIDS research. In addition, funds would be available for patient care resources for NIH funded research at General Clinical Research Centers.

CENTER FOR DISEASE CONTROL

Additional FY 1984 Needs for Study of the
Acquired Immune Deficiency Syndrome (AIDS)

The following list of proposed activities is based on the assumptions that an AIDS causative agent will have been identified, and that a reliable screening test will have been developed.

- o Surveillance (6 FTE) \$1,276,000

Additional resources will allow the continued expansion of surveillance activities in order to adequately monitor morbidity and mortality trends. Special efforts to survey unexplained immuno-deficiency in infants, lymphadenopathy syndrome and other "pre-AIDS" conditions will be instituted. Active serologic surveillance for AIDS in the States or cities with moderate to low incidence will begin.

- o Epidemiologic Studies and Investigations (12 FTE) \$2,484,000

Additional resources will be used to continue to assess risk factors among Haitians, intravenous drug abusers, blood products and homosexual men screened for hepatitis B. Given an availability of diagnostic markers for AIDS, CDC will be providing additional epidemic assistance to State and local health departments.

- o Laboratory Study and Investigations (20 FTE) \$3,120,000

In 1984, CDC will continue to serve as the National repository and reference diagnostic center for AIDS laboratory specimens. CDC will produce advanced diagnostic reagents, evaluate commercially available reagents and test kits, if developed, used to detect antibody or antigen to the AIDS agent. In addition, resources will provide support for the development of alternative diagnostic tests with special attention to enhanced specificity and sensitivity that can be used in any routine diagnostic laboratory.

- o Technical Transfer, Training and Dissemination of Information (3 FTE) \$420,000

— Train laboratory personnel. Develop training and informational materials related to the laboratory aspects of isolating and identifying the causative organism of AIDS. Prepare a training package consisting of manuals, audiovisuals, and test kits. Implement training courses in field locations.

- Maintain a flow of information on AIDS to the medical, scientific, and public health committees.
- Convene an International Conference to disseminate AIDS information on surveillance, epidemiologic studies, and laboratory investigations through the medical and scientific community.

Additional Resources Required:	<u>Funds</u>	<u>FTE</u>
1983 Supplemental		
Continuation Costs.....	\$3,100,000	20
New Activities.....	4,200,000	21
Total.....	<u>\$7,300,000</u>	<u>41</u>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

<u>Budget Appendix Page</u>	<u>Heading</u>	<u>1984 Request Pending</u>	<u>1984 Proposed Amendment</u>	<u>1984 Revised Request</u>
	<u>Health Resources and Services Administration</u>			
I-K3	Health Resources and Services....	\$292,444,000	-\$12,500,000	\$279,944,000
	<u>Human Development Services</u>			
I-K49	Rural Development Loan Fund.....			
	(Capital transfer to general fund).	9,824,000	-9,700,000	124,000
	<u>Centers for Disease Control</u>			
I-K10	Disease Control...	270,023,000.	7,300,000	277,323,000
	<u>National Institutes of Health</u>			
I-K11	National Cancer Institute.....	989,263,000	3,500,000	992,763,000
I-K12	National Heart, Lung and Blood Institute.....	628,028,000	2,036,000	630,064,000
I-K13	National Institute of Neurological and Communicative Disorders and Stroke.....	301,022,000	1,560,000	302,582,000
I-K14	National Institute of Allergy and Infectious Diseases.....	281,405,000	7,270,000	288,675,000
I-K18	Research Resources	228,542,000	500,000	229,042,000

4A. Question: Please specify when Dr. Brandt first became aware of the need for additional FY 1984 funds and who alerted him to this need.

Answer: Given the dynamic nature of AIDS, the Assistant Secretary for Health established the PHS Executive Committee to apprise him of the PHS operational plan on a weekly basis. In addition, the Boards of Scientific Advisors at each research institute within the National Institutes of Health provide highly technical scientific consultation on current activities by NIH scientists, university and private investigators. Several workshops and conferences have been held to evaluate our current knowledge and our future needs to control and prevent AIDS.

While the May 9th correspondence from Representative Natcher was limited to FY 1983 AIDS activities, the Assistant Secretary for Health took this opportunity to comprehensively review and reassess planned PHS activities for both FY 1983 and FY 1984. He requested the PHS agency directors to conduct a thorough evaluation of ongoing requirements as requested by Mr. Natcher, and to identify additional resource requirements for FY 1984 based on the assumptions that the causative agent will have been identified and a screening test will have been developed.

The Directors of the Centers for Disease Control, the Food and Drug Administration and the National Institutes of Health responded by identifying a need for an additional \$35 million for the following activities:

- o Food and Drug Administration (+\$2.0 million and +20 FTEs)
Additional resources would support the testing of AIDS treatment products, the development of methods to assure the safety and efficacy of a vaccine, and the expansion of measures to assure blood product safety.
- o Centers for Disease Control (+\$9.6 million and +41 FTEs)
This request would support the expansion of surveillance, epidemiologic studies and information dissemination, additional laboratory studies of AIDS specimens, development of diagnostic tests and additional training of laboratory and field personnel.
- o National Institutes of Health (+\$23.4 million)
Additional funds would support expanded intramural and extramural research activities in the Cancer, Heart, Neurology, Dental, Eye, and Allergy Institutes and the Division of Research Resources.

4B. Question: When was a decision made to request additional FY 1984 funds by the Assistant Secretary for Health?

Answer: The Assistant Secretary for Health decided to request additional FY 1984 funding in mid-May. His decision was based upon the review and reassessment of AIDS activities conducted by the PHS agencies. Following normal budgeting procedures, the proposed FY 1984 budget amendment was incorporated into the PHS FY 1985 budget submission to the Secretary. This request was formally submitted to the Secretary on June 23rd.

A subsequent decision was made by the Secretary, acting on Dr. Brandt's recommendation, to submit the FY 1984 budget amendment to OMB prior to the scheduled deadline for the DHHS FY 1985 budget. Dr. Brandt recommended this accelerated submission on July 26 since an earlier submission of a FY 1984 budget amendment would allow the House and Senate Appropriations Committees to consider the proposal in conjunction with their deliberations on the overall FY 1984 PBS appropriations.

4C. Question: When was this request approved by the Secretary?

Answer: The request for the FY 1984 budget amendment of \$22.2 million was approved by the Secretary on August 10th.

4D. Question: When was this request submitted to OMB? Please provide the original request that was sent to OMB.

Answer: The request was transmitted verbally to OMB by the Assistant Secretary for Management and Budget. An agreement was subsequently reached at the staff level to immediately request a budget amendment of \$22.2 million. On August 19th, a letter was submitted formally by the Secretary proposing \$22.2 million for AIDS activities. These activities would be financed by redirecting funds from the National Health Service Corps and the Rural Development Fund. Further programmatic information was provided to OMB on August 23rd.

4E. Question: When did OMB approve the request?

Answer: On September 15th, the President transmitted a formal FY 1984 budget amendment requesting additional support for AIDS-related activities.

4F. Question: When was the approval transmitted to the Secretary's office?

Answer: The Department was informed on September 16th. On September 14th, the Office of Management and Budget authorized the Department to transmit to the Congress, materials justifying the need for the proposed FY 1984 budget amendment of \$22.2 million for additional AIDS activities.

4G. Question: When was this request forwarded to House and Senate appropriations committees?

Answer: On September 15th, the President transmitted a formal FY 1984 budget amendment requesting additional support for AIDS-related activities as a message to Congress.

June 23, 1983, Preliminary Budget Submission to DHHS, Fiscal Year 1985, Public Health Service (PHS Summary Volume)

The following is a description of the proposed FY 1985 Budget for all the PHS agencies. In addition, it contains a description of the proposed FY 1984 budget amendment for additional AIDS activities. The following quotation contains the relevant information on the AIDS proposal:

"1984 Budget Amendments

The 1984 current estimate includes funding for several high priority activities which were not included in the 1984 President's Budget. These budget amendments are being requested to increase PHS efforts to combat Acquired Immune Deficiency Syndrome (AIDS)... The details of each of these amendments follows:

Acquired Immune Deficiency Syndrome

A total of \$35.0 million is included in the 1984 current estimate for additional CDC, FDA, and NIH activities related to AIDS. The request for each of these agencies is based on the assumptions that by 1984, a causative agent will have been identified and a reliable screening test will have been developed.

The CDC portion of the amendment (\$9.6 million and 41 FTE's) would be used for increased surveillance of AIDS morbidity and mortality trends, expansion of epidemiological studies to assess risk factors related to the disease, additional laboratory studies of AIDS specimens, training of laboratory personnel, and the dissemination of the most recent information on AIDS to the medical, scientific and public health communities.

The FDA portion of the AIDS amendment is \$2.0 million and 20 FTE's. These resources would be used to test products to treat AIDS (such as different interferons or other immune modulators) and to exercise general preventative measures to assure the safety of blood products. More specific FDA activities would include studies of the biological properties of the AIDS causative agent, development of methods for producing a live vaccine, and coordination of extensive regulatory review activities.

The \$23.4 million request for NIH would support additional intramural and extramural research on AIDS in the Cancer, Heart, Neurology, Dental, Eye, and Allergy Institutes, and the Division of Research Resources. Research project grants, research center grants and contracts are expected to be funded. Included would be research on the occurrence of cancer and the impact of lifestyle, the characterization of the infectious agent, and the identification of the antigen that stimulates protective immunity."

July 26, 1983 Memo from Dr. Brandt to Secretary Heckler
"FY 1984 Budget Amendment Request for the Public
Health Service"

On July 26, 1983 Dr. Brandt recommended the submission of the proposed FY 1984 AIDS budget amendment to the Office of Management and Budget on an accelerated basis. The attached memorandum contains those portions of the memorandum which are relevant to the AIDS budget amendment.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 26 1983

Memorandum

Date

Edward N. Brandt, Jr., M.D.

From

Assistant Secretary for Health *E. Brandt*

Subject: FY 1984 Budget Amendment Request for the Public Health Service

To

The Secretary

Through: US _____
ES _____

I am requesting your approval to submit three FY 1984 budget amendment proposals to the Office of Management and Budget (OMB). Although each of these amendments was submitted as part of our FY 1983 budget submission, I am recommending that they be submitted to OMB on an accelerated basis. The three budget amendments would provide additional funding for: Acquired Immune Deficiency Syndrome (AIDS), Orphan Drug Research, and the Indian Health Service. Each of these proposals addresses a critical health need which is receiving increased public attention and congressional scrutiny. At the same time, these three items are appropriate areas of Federal involvement in which the Department should continue its leadership role.

Although the attachments to this memorandum provide revised appropriation language (Tab A) and detailed narrative descriptions (Tab B) for each proposed budget amendment, I would like to summarize briefly the three proposals and stress their importance.

The FY 1984 budget amendment for AIDS would provide an increase of \$35.0 million over the FY 1984 President's budget. These funds will continue the efforts obtained with the 1983 supplemental appropriation of \$12.0 million and will allow the initiation of additional projects.

This \$35.0 million includes \$2.0 million for the Food and Drug Administration (FDA), \$9.6 million for the Centers for Disease Control (CDC), and \$23.4 million for the National Institutes of Health (NIH). The request for each of these agencies assumes that by FY 1984 a causative agent will have been isolated and a reliable screening test will have been developed. Highlights of planned initiatives for each agency include the following:

o Food and Drug Administration (+\$2.0 million and +20 FTEs)

The additional resources requested for FDA will be used primarily to test products for treating AIDS, to develop methods to assure the safety and effectiveness of a vaccine against AIDS, and to continue measures to assure the safety of blood products.

o Centers for Disease Control (+ \$9.6 million and +41 FTEs)

The request for CDC would support a variety of important AIDS-related activities such as continued expansion of surveillance activities to monitor morbidity and mortality trends, expansion of epidemiological studies to assess risk factors for differing populations, additional laboratory studies of AIDS specimens, development of diagnostic tests, training of laboratory and field personnel, and continuing dissemination of the most recent information on AIDS to the medical, scientific, and public health communities.

o National Institutes of Health (+\$23.4 million)

The \$23.4 million requested for NIH would support additional intramural and extramural AIDS research in the Cancer, Heart, Neurology, Dental, Eye, and Allergy Institutes, and the Division of Research Resources. This amendment would fund additional project grants, research center grants, and contracts for studies on AIDS. For example, the National Cancer Institute will study immunodeficiency in hemophilia, the National Institute of Allergy and Infectious Diseases will support research to develop a vaccine, and the National Heart, Lung, and Blood Institute will investigate the relationship between AIDS and blood donorship.

Food and Drug Administration

Justification of FY 1984 AIDS Budget Amendment

With the presumption that a causative agent has been identified and a reliable screening test has been developed, FDA would support the following research totaling \$2 million:

National Center for Drugs and Biologics: 20 Positions - 15 FTE - \$900,000

- o Studies of the laboratory biology of AIDS agent including methods to propagate it in vitro, and definition of its physical and chemical characteristics.
- o Definition of the proteins of the agent, determination of which proteins are important in immunity, and purification of them in intact form.
- o Studies of the biologic properties of the agent which relate to its ability to cause immunosuppression and induce malignant transformation. These issues are likely to be crucial to vaccine development.
- o Studies of the molecular biology of the agent including genetic mapping, identification of unique enzyme functions and cloning of important genes by recombinant DNA technology. Gene cloning should be relevant to vaccine development and development of diagnostic tests.
- o Development of methods for producing live, attenuated vaccine, for engineering a genetically altered agent that lacks the ability to cause malignancy or immunosuppression, and to produce sufficient amounts of the inactivated agent or selected proteins that could be used for production of an inactivated vaccine.
- o Development of specific immune globulins which may have clinical applications, but are also needed for evaluating animal models and for testing inactivation of the agent in blood products.
- o Development of physical, chemical, and immunological methods for inactivation of the agent in blood products.
- o Basic research to define potential applications of immune modulators, develop methods for standardization, safety, and potency testing; clinical studies of immune modulators. Similar studies pertaining to application of antiviral drugs.

National Center for Toxicological Research (NCTR): 7 positions - 5 FTE - \$300,000

- o Development of a system to directly define, in human tissue, the etiology of AIDS in order to better evaluate the therapeutic modalities and potential immunotoxicants involving AIDS. Additionally NCTR will use this model to evaluate the potential multifactorial nature of AIDS relative to potential predisposing agents.

Contract Research..... \$800,000

- o FDA has recently approved procedures intended to decrease the infectivity of Factor VIII when transfused to hemophiliacs such as may be involved in AIDS. The continued administration of these products to the hemophiliac results in continuing exposure, not only to potentially infectious agents, but also foreign protein. The contract proposed would allow the establishment of an ongoing system of evaluation of the health of the hemophiliac for the purpose of interpreting the benefit of these new manufacturing procedures and including the potential of eliminating AIDS as a complication of their therapy.

CENTERS FOR DISEASE CONTROL

Justification of FY 1984 AIDS Budget Amendment

The following list of proposed activities is based on the assumptions that an AIDS causative agent will have been identified, and that a reliable screening test will have been developed.

o Surveillance 7 positions/6 FTEs \$1,276,000

Additional resources will allow the continued expansion of surveillance activities in order to adequately monitor morbidity and mortality trends. Special efforts to survey unexplained immunodeficiency in infants, lymphadenopathy syndrome and other "pre-AIDS" conditions will be instituted. Active serologic surveillance for AIDS in States or cities with moderate to low incidence will begin.

o Epidemiologic Studies and investigations 14 positions/12 FTEs \$2,484,000

Additional resources will be used to continue to assess risk factors among Haitians, intravenous drug abusers, blood products and homosexual men screened for hepatitis B. Given an availability of diagnostic markers for AIDS, CDC will be providing additional epidemic assistance to State and local health departments.

o Laboratory Study and Investigations 23 positions/20 FTEs \$3,120,000

In 1984, CDC will continue to serve as the National repository and reference diagnostic center for AIDS laboratory specimens. CDC will produce advanced diagnostic reagents, evaluate commercially available reagents and test kits, if developed, used to detect antibody or antigen to the AIDS agent. In addition, resources will provide support for the development of alternative diagnostic tests with special attention to enhanced specificity and sensitivity that can be used in any routine diagnostic laboratory.

o Technical Transfer, Training and Dissemination of Information 4 positions/3 FTEs \$420,000

Assuming the identification of a causative agent, the additional funds in FY 1984 will support the following activities:

- Train laboratory personnel. Develop training and informational materials related to the laboratory aspects of isolating and identifying the causative organism of AIDS. Prepare a training package consisting of manuals, audiovisuals, and test kits. Implement training courses in field locations.

- Maintain a program to assure that information on AIDS is provided on a timely basis to the medical, scientific, public health communities, and the general public.
- Convene an International Conference to disseminate AIDS information on surveillance, epidemiologic studies, and laboratory investigations throughout the medical and scientific community.

o Restoration of Diverted Resources \$2,300,600

Additional funds will allow the restoration of funds that otherwise will be diverted from several CDC budget activities including Venereal Disease, Chronic and Environmental Disease Prevention, Epidemic Services, and Infectious Diseases to support AIDS and AIDS related activities in FY 1984.

Summary of CDC Resources
(dollars in thousands)

	<u>Funds</u>	<u>Positions</u>	<u>FTEs</u>
FY 1984 Base.....	\$4,300	25	25
Budget Amendment:			
New Activities.....	7,300	48	41
Restoration of diverted funds.....	<u>(2,300)</u>	<u>(---)</u>	<u>(---)</u>
Amendment Subtotal.....	(9,600)	(48)	(41)
 FY 1984 Total.....	 <u>\$11,600</u>	 <u>73</u>	 <u>66</u>

National Institutes of Health

Justification of FY 1984 AIDS Budget Amendment

With the presumption that a causative agent has been identified and a reliable screening test has been developed, NIH would support the following research totalling \$23 million.

National Cancer Institute \$3,500,000

Studies would continue on the relationship of viral etiology in the occurrence of cancer and the impact of lifestyle on the propensity to cancer. Specific research would include a study of immunodeficiency in hemophilia, study of retroviruses and immune response, and epidemiological and immunologic investigations of AIDS.

National Heart, Lung and Blood Institute \$3,886,000

Research efforts would include validation of the sensitivity and specificity of the screening test in the blood donor population. Other research would be supported to determine whether blood donors are carriers of AIDS, whether they transmit the disorders, and whether donors and blood products should be routinely screened.

National Institute of Dental Research \$30,000

Research on the abnormalities seen in the interferon system of AIDS patients would be expanded.

National Institute of Neurological and Communicative Disorders and Stroke \$1,695,000

Funds would be directed toward characterization of the agent; continued study of an animal model; seeking underlying mechanisms of infection; development of rapid diagnostic procedures; and eventual development of an effective therapeutic regimen and/or immunoprophylactic measures to prevent the disease. In addition, the Institute would perform clinical studies on the neurological findings in AIDS and Kaposi's sarcoma patients compared to homosexuals; serological studies of cytomegaloviruses and other viruses; and tests to determine predisposing factors, immune response, and development of treatment modalities. An increased need is anticipated for coritcal biopsies and other clinical investigations in order to diagnose central nervous system involvement and evaluate the tissue for pathogens.

National Institute of Allergy and Infectious Diseases \$12,670,000

Additional grant funds would support studies of the biology and molecular biology of the causative agent; to identify and isolate the antigen(s) that stimulate protective immunity and those useful

for serodiagnosis and seroepidemiology; and to support research on vaccine development. The Institute would also support R&D contracts for vaccine development including pre-phase I testing such as toxicity testing and protective trials in animals; seroepidemiologic studies on the natural history of subclinical and clinical AIDS, modes of transmission, and identification of high-risk patients; and development of antimicrobial drugs for treatment of the causative agent, development of new modes of treatment of opportunistic infections, and the treatment to reconstitute the immunodeficiency. Intramural activities would be expanded to focus on microbiology studies and molecular biology studies to fully characterize the infective agent and identify the antigen responsible for raising protective antibodies as well as mechanisms for restoring immune function.

National Eye Institute \$40,000

The funds would provide for expanded ocular care of AIDS patients and studies of the causes of the visual difficulties that beset these patients.

Division of Research Resources \$1,550,000

Immunological and transmission studies of Simian AIDS would be conducted at the Primate Research Centers to provide baseline clinical and laboratory information of value to human AIDS research. Funds for the General Clinical Research Centers would provide patient care resources for AIDS research by investigators supported by through the NIH grant mechanisms.

(dollars in thousands)

Research Project	FY 84	FY 1984 Budget Amendment						Amendment	AIDS	
	Base	NCI	NHLBI	NIDR	NINCDS	NIAID	NEI	DRR	Subtotal	Total
Grants.....	\$6,342	\$3,000	\$1,786	---	---	\$3,580	---	---	\$8,366	\$14,708
Research Centers.	851	---	---	---	---	20	---	1,550	1,570	2,421
Contracts.....	1,040	---	2,100	---	---	6,125	---	---	8,225	9,265
Intramural										
Research.....	4,228	500	---	30	1,695	2,945	40	---	5,210	9,438
Total.....	\$12,461	\$3,500	\$3,886	\$30	\$1,695	\$12,670	\$40	\$1,550	\$23,371	\$35,832

5. Question: When did the need for additional funds for FY 1983 come to Dr. Brandt's attention? Please provide supporting documentation.

Answer: In early May, the Director of the Centers for Disease Control (CDC), discussed the need for additional resources for AIDS activities with the Assistant Secretary for Health. A memo outlining various funding options was submitted on May 6th. This proposal was based on the current knowledge of the disease. The Director, CDC, was requested to develop another proposal based on the assumptions that the causative agent would be found and a screening test would be developed.

In response to Dr. Foege's concerns and a request from the Chairman of the House Appropriations Committee on FY 1983 AIDS requirements, the Assistant Secretary for Health requested the PHS agency Directors to conduct a thorough review of their program needs. During the week of May 9th, the Directors of the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), the Centers for Disease Control (CDC), and the National Institutes of Health (NIH) each recommended additional funds totaling \$12 million. Funds would be used to expand efforts in surveillance, laboratory investigations, biomedical research and intravenous drug abuse studies. After discussions with the Secretary and the Office of Management and Budget, the Assistant Secretary for Health responded on May 18th to the Chairman's request. This letter contained a status report on the incidence of AIDS, PHS activities and a request for discretionary authority to transfer up to \$12 million for AIDS activities across appropriation lines of the Department of Health and Human Services.

Attached: May 6, 1983 Memo from Dr. Foege (CDC) to Dr. Brandt
regarding AIDS funding.
May 18, 1983 Letter from Dr. Brandt to the Chairman, House
Appropriations Committee.

May 6, 1983 Memo from Dr. Foege, Director of CDC, to Dr. Brandt
regarding "AIDS Funding"

The attached memorandum was submitted to the Assistant Secretary for Health on May 6th. This memorandum was withdrawn when the Director was requested to re-evaluate funding needs based on the assumptions that the causative agent will have been identified and a screening test will have been developed.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date MAY - 6 1983

From Director
Centers for Disease Control

Subject AIDS Funding

To The Assistant Secretary for Health
Through: ES/PHS _____

Will discuss

As a result of our discussions about the AIDS problem, I promised to give you an analysis of CDC's funding needs. This has taken a bit longer than I had anticipated because we have had to build into our plans appropriate followup on the recent HTLV lead. We have attempted to display our funding and position requirements in a comprehensive manner in order to provide the information that would be needed depending upon the funding solution that is chosen. We have felt that we could not afford to wait to begin working on followup of HTLV. Thus, I have temporarily diverted \$300,000 of VD contract funds to the AIDS Task Force. This, together with a later projection, increases our estimated funding of AIDS for fiscal year 1983 to \$4.6 instead of \$4.2 million, as we had recently reported.

CDC is being pressed from many different sides for information about its resource needs related to the AIDS problem. The questions are coming from gay groups, Congressional committees, individual Congressmen's staffs, and even the Library of Congress. This heightened interest and concern has been stimulated by the recently held appropriations hearings, media coverage of the HTLV lead, and demonstrations by interested groups.

We understand that various proposals to increase both 1983 and 1984 funding for AIDS are being considered in Congress. This puts both PHS and CDC in the frustrating position of once again playing "catch up" in regards to AIDS funding. For example, I have attached a copy of information that we provided in response to Congressional inquiries concerning our 1983 funding for AIDS (this information previously has been provided to your staff).

Clearly, we can effectively use additional funds and positions this year and definitely should be expanding our efforts in 1984. In fairness, I must point out that our plans and our resource estimates are based on what we now know about AIDS. We have not included estimates of resource needs

Page 2 - The Assistant Secretary for Health

beyond this first phase of the investigation. I anticipate that once we have identified an agent, our efforts will change direction, intensify, and our needs will escalate. I am prepared to discuss this package with you in our meeting on Monday, May 9.

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William H. Foegen, M.D.
Assistant Surgeon General

Attachments:

- Tab A - Summary of Resource Needs 1983-84
- Tab B - Summary of New or Expanded Projects or Activities
- Tab C - Response to Representative Roybal's Questions
- Tab D - Description of the VD Projects That Have Been Postponed in Order to Provide AIDS Funding
- Tab E - Funding Options

TAB A

Centers For Disease Control Acquired Immune Deficiency Syndrome
Resource Needs Summary

I. Currently Available

	1983		1984	
	FTE	AMT.	FTE	AMT.
Laboratory Investigations	53.1	\$3.18	57.2	\$2.65
Epi Studies/Investigations	10.9	.83	12.7	.94
Surveillance	5.9	.59	6.8	.71
Total	69.9	\$4.60	76.7	\$4.30

Source of Funds:

Earmarked by Congress:	\$2.0	Requested by HHS	\$2.0
Diversion from within CDC:	\$2.6	Diversion from within CDC:	\$2.3

II. Additional Needs

A. 1983 Needs:

1. If funds are reallocated within PHS and no positions or FTE's are provided, then \$695,000 could be used for additional or expanded AIDS projects and \$1,340,000 could be used for payback of monies and positions diverted from within CDC in FY83. (New and expanded projects would require positions and funds for continuation in 1984).
2. If funds are reallocated within PHS and FTE's are provided, then 8 positions and \$760,000 could be used for additional or expanded AIDS projects and \$1,465,000 (23 new positions) could be used for payback of monies and positions diverted from within CDC in FY83. (New and expanded projects would require positions and funds for continuation in 1984).
3. If a supplemental is passed by June 1 making both positions and funds available then, the same numbers in 2 above will apply.

B. 1984 Needs:

If additional funds and positions are made available in 1984 then CDC could effectively use 27 positions and \$2.5 million for new or expanded AIDS activities; and 70 positions and \$2.3 million to cover funds and positions diverted from other activities within CDC.

III. Summary of Resource Requirements

A. 1983 AIDS Resource Requirements

	Without Additional Positions/FTE		With Additional Positions/FTE	
	<u>Pos./FTE</u>	<u>Amt.</u>	<u>Pos./FTE</u>	<u>Amt.</u>
Current Activities	69.9	\$4.6	69.9	\$4.6
New or Expanded Activities	-	\$.695	8.0	\$.760
	69.9	\$5.295	77.9	\$5.360

B. 1984 AIDS Resource Requirements

	<u>Pos./FTE</u>	<u>Amt.</u>
Current Plans	76.7	\$4.3
New or Expanded Activities	<u>27.0</u>	<u>2.5</u>
	103.7	\$6.8

The amount of additional resources needed will depend upon whether or not CDC is expected to continue to divert more than \$2 million for other CDC activities.

TAB B

New and/or Expanded Project Resource Needs

	<u>Funds without Positions</u>	<u>Positions</u>	<u>Funds with Positions</u>
Fiscal Year 83			
Laboratory Investigations	\$ 320,000	4	\$ 355,000
Epidemiologic Studies	125,000	2	141,000
Surveillance	<u>250,000</u>	<u>2</u>	<u>264,000</u>
	\$ 695,000	8	\$ 760,000
Fiscal Year 84			
Laboratory Investigations		17	\$1,360,000
Epidemiologic Studies		7	420,000
Surveillance and Prevention		<u>3</u>	<u>720,000</u>
		27	\$2,500,000

Summary of New and/or Expanded AIDS Projects

Fiscal Year 1983

Laboratory Investigations to Identify Etiologic Agent - \$320,000

- o Expanded capability to obtain, process, and store AIDS-related laboratory specimens

Intensive virologic and animal studies will require extensive collection of a variety of specimens from each AIDS risk group and a variety of control groups. More extensive collaboration with laboratories outside CDC can be facilitated by sharing these well-characterized specimens if they are available in sufficient quantities. Additional funds are needed to cover expenses of obtaining and shipping specimens as well as enhancing the safe storage of them.

- o Expansion of Diagnostic Immunology Testing

Experiments have shown that laser nephelometry is an effective method to determine immunoglobulins; acquisition of semi-automated instrumentation would increase progress significantly. With the availability of more monoclonal antibodies and second/third generation cell sorters, further identification and isolation of lymphocyte subsets needs to be investigated with respect to predictive value for immune deficiency states. Studies of enzyme linked immunoassays versus radioimmunoassays also are needed in an attempt to find an optimal combination of tests with maximal predictive capability of immune deficiency states.

Epidemiologic Studies - \$125,000

- o Study of Risk Factors Among Haitians

From the beginning of the AIDS investigation, it was recognized that Haitian emigres constitute a special high risk group. Little is known about the risk factors or the incidence of AIDS among the Haitian population in this country or in Haiti. Since the Haitian patients with AIDS do not appear to share risk factors with other groups, important clues to the etiology and transmissibility of the disease may be discovered through collaborative epidemiologic studies of AIDS in this population. Since relatively few living Haitian patients exist in the U.S., it may be necessary to extend this study into Haiti.

- o Blood Related Investigations

Epidemiologic investigations of AIDS cases associated with prior receipt of blood or blood products including evaluation of their donors need to be intensified. Evaluation of appropriate control recipients and donors as well as cohort followup of recipients of blood products from AIDS patients and appropriate controls.

Surveillance Activities - \$250,000

- o Define Trends and Identify Risk Groups, Clarify the Natural History of AIDS and Expand Epidemiologic Studies Among High Risk Groups

Active surveillance methods need to be expanded into several major metropolitan areas in order to adequately monitor morbidity and mortality trends and to identify emerging risk groups. These methods include hospital-based case identification and reporting systems. This information is necessary to fully define the extent of the problem and to target epidemiologic and laboratory investigations to high risk groups. Extensive active surveillance for cases in children with AIDS-like illnesses is required in at least 2-3 metropolitan areas. Active surveillance is crucial for accurate determination of factors influencing mortality among reported cases. Additional studies of homosexual men and other high risk groups to further define risk factors and incidence trends are needed.

Note: If additional positions are available in FY 83, 8 positions and \$65,000 could be used this fiscal year for further expansion of the above activities. Without additional positions, activities above would be limited to procurement of equipment and supplies, travel funds, and contracts/cooperative agreements.

Fiscal Year 1984

Laboratory Investigation to Identify an Etiologic Agent - \$1,360,000 and 27 positions

- o Maintain the Expanded Virology & Molecular Biology Capabilities from FY 83

AIDS in humans is similar to illnesses in a variety of animal species caused by retroviruses. Human T-cell leukemia virus, a T-helper cell tropic agent, is the first retrovirus isolated from man and it causes T-cell leukemia lymphoma. There is preliminary evidence that antibody to HTLV is more commonly detected among homosexual men with AIDS or lymphadenopathy than controls. The etiologic importance of this infection remains to be determined. CDC is collaborating with Dr. Essex's laboratory at Harvard and Dr. Gallo's laboratory at NIH to delineate HTLV's role in AIDS. If HTLV does not prove to be the AIDS agent, the association of this test appears to be sufficiently strong to pursue as a surrogate test for AIDS. This expanded capability will enhance the search for other groups of viruses and subviral agents.

(Assumes beginning of project in FY 83 including equipment purchases)

- o Maintain Expanded Animal Inoculation Studies

Current experiments have proven that the etiologic agent for AIDS have not been readily cultivated in conventional in vitro systems or laboratory animals. As with hepatitis viruses, an animal model would appear to be crucial for isolation of the agent, confirmation of the etiology, and full characterization of the disease. Chimpanzees and rhesus monkeys are the animals most likely to prove successful; rodents, rabbits and other species also will be tested. Several primates have been inoculated at CDC and NIH, but larger numbers are likely to be required for further definition of the agent, especially if the degree of infectivity is low. The possibility of incubation periods in excess of one or two years adds complexity to the experiments. The costs of animals and their housing costs will be handled through a contract arrangement.

(Assumes beginning of project in FY 83 including contracts for animals)

- o Maintain and Expand the National Storage Bank for AIDS-related Laboratory Specimens

Intensive virologic and animal studies will require extensive collection and maintenance of a variety of specimens from each AIDS risk group and a variety of control groups. More extensive collaboration with laboratories outside CDC can be facilitated by sharing these well-characterized specimens if they are available in sufficient quantities. Additional funds are needed to cover expenses of obtaining and shipping specimens.

(Assumes beginning of project in FY 83 including equipment purchases)

- o Continue and Expand Diagnostic Immunology Testing and Studies

With the availability of state-of-the-art equipment purchased in FY 83, further identification and isolation of lymphocyte subsets can be investigated with respect to predictive value for immune deficiency states. Studies of enzyme linked immunoassays versus radioimmunoassays will attempt to find an optimal combination of tests with maximal predictive capability of immune deficiency states.

(Assumes equipment purchases in FY 83)

Epidemiologic Studies - \$420,000 and 7 positions

- o Study of Risk Factors Among Haitians (an expansion of studies begun in FY 83 if funds available)

- o Blood Related Investigation

Epidemiologic investigations of AIDS cases associated with prior receipt of blood or blood products including evaluation of their donors need to be intensified. Evaluation of appropriate control recipients and donors as well as cohort followup of recipients of blood products from AIDS patients and appropriate controls.

Surveillance & Prevention - \$720,000 and 3 positions

- o **Continued Expansion of Surveillance Activities mentioned in FY 83 summaries**

Active surveillance methods need to be expanded into several major metropolitan areas in order to adequately monitor morbidity and mortality trends and to identify emerging risk groups. These methods include hospital-based case identification and reporting systems. This information is necessary to fully define the extent of the problem and to target epidemiologic and laboratory investigations to high risk groups. Extensive active surveillance for cases in children with AIDS-like illnesses is required in at least 2-3 metropolitan areas. Active surveillance is crucial for accurate determination of factors influencing mortality among reported cases. Additional studies of homosexual men and other high risk groups to further define risk factors and incidence trends are needed. It is anticipated that additional public health advisor field positions will be required to conduct surveillance and epidemiologic activities.

- o **Plan & Convene an International Conference on AIDS**

CDC will convene an International Conference to disseminate AIDS information on surveillance, epidemiologic studies, and laboratory investigations throughout the medical and scientific community.

INFORMATION REGARDING IMPACT OF FUNDING OF THE AIDS
INVESTIGATION ON CDC ONGOING ACTIVITIES

During FY 1983 CDC will spend an estimated \$4.5 million on the investigation of the epidemic of Acquired Immune Deficiency Syndrome in the U.S. This includes \$2.0 million appropriated by Congress specifically for AIDS in its continuing resolution. The remaining \$2.5 million has been diverted from other program activities in order to respond to the continuing AIDS problem.

I. Q. From what budget activities have funds and positions been diverted for support of the AIDS investigations?

A. The funds have come from several CDC budget activities including Venereal Diseases (\$500,000), Control of Chronic Conditions (\$100,000), Epidemic Services (\$700,000), and Technology Development & Application (\$1,200,000) affecting virtually all of CDC's programs. Specific impact has been greatest on the Center for Infectious Diseases, Center for Prevention Services, and the Epidemiology Program Office. Physicians, laboratory scientists, public health advisors, statisticians, and support personnel have been reassigned from ongoing activities to assist in conducting the AIDS investigations.

II. Q. What has been the impact of those diversions on other CDC programs?

A. A number of research, technology development, and service activities have been postponed, deleted, or severely curtailed:

- o Funding of cooperative agreements and contracts to obtain surveillance data on the prevalence of hepatitis in the United States has been eliminated.
- o Work on rabies has been slowed including collaborative studies with Virginia Polytechnic Institute on raccoon rabies ecology and a study on rabies epidemiology with the National Park Service and University of the District of Columbia. In addition, CDC has been unable to support a collaborative project with Johns Hopkins to study the raccoon rabies problem in the Eastern Atlantic States and a National Conference on rabies ecology.
- o Influenza vaccine efficacy studies in high-risk elderly populations have been postponed.
- o Studies in monkeys of Lassa Fever virus pathophysiology and immunology have been cancelled. Such studies are important to understanding the potential value of plasma therapy of human patients infected with Lassa Fever virus one of the deadly class IV agents.

- o Studies of Korean Hemorrhagic Fever (KHF) virus have been delayed, including collaborative studies to characterize the animal reservoirs of KHF in the United States and the structure and biochemical/genetic properties of KHF.
 - o The development of immunoassays for the detection of influenza-specific IgM and IgA have been delayed affecting the identification of recent influenza or varicella zoster virus infections in patients with Reye Syndrome. This work is important to current and proposed studies of the relationship between aspirin ingestion and the development of Reye Syndrome.
 - o Progress in the application of DNA recombinant technology, e.g. hybridization with labelled DNA probes, in rapid diagnosis of influenza, polio, rabies, herpes viruses, CMV, and many other viruses has been delayed.
 - o Development of monoclonal antibodies for use in rapid viral diagnosis of influenza, rickettsial diseases, rabies, herpes simplex viruses, cytomegalovirus, varicella zoster, Korean Hemorrhagic Virus and African Hemorrhagic Fever Viruses has been delayed.
 - o Projects to assess the role of Sexually Transmitted Diseases (STD) in infertility were postponed.
 - o Important epidemiologic studies of chlamydial infections could not be undertaken.
 - o Monitoring of domestic gonococcal resistance was reduced to an inappropriately low level.
 - o Completion and distribution of "Quality Assurance Guidelines for STD Clinics" was delayed.
 - o Efficiency of tuberculosis consultation provided to State and local health agencies was diminished.
 - o Procurement of important laboratory reagents, glassware, and other support materials has been reduced thus reducing stocks of these supplies to dangerously low levels.
 - o Procurement of important freezers both mechanical and liquid nitrogen has been delayed.
 - o Electronic equipment for use in laboratory automation necessary to efficiently produce laboratory data has not been purchased.
- III. Q. Assuming a supplemental appropriation bill is passed in early June what dollars and positions could CDC use effectively to repay their diversions?

- A.o Award contracts/cooperative agreements for surveillance of hepatitis. \$265,000
- o Purchase essential laboratory supplies including reagents, glassware, chemicals and diagnostic kits. \$250,000
- o Purchase of electronic equipment to speed up and increase the efficiency of laboratory investigations. \$425,000
- o Award contracts to study the risk factors for influenza and the efficacy of influenza vaccine in high risk populations and to study the effectiveness of rimantadine in the prophylaxis and/or treatment of influenza among nursing home residents. \$100,000
- o CDC is redirecting the efforts of more than 85 employees during FY 1983 (the equivalent of more than 60 person years). Of these CDC would be able to hire 23 new personnel to carryout eliminated work on viral diseases and host factors. \$125,000
- TOTAL 23 positions \$1,165,000

- IV. Q. What activities have needed to be carried out that caused the expenditures for AIDS to rise from \$2.0 million to the current estimate of \$4.2 million?
- A. As the AIDS problem has increased and new risk groups and hypotheses have been identified, it has been necessary to expand and intensify surveillance activities, epidemiologic studies, and laboratory investigations to respond to this highly fatal syndrome.

Surveillance

There has been a need to expand surveillance activities to respond to newly emerging risk groups in additional urban areas. Since the end of fiscal year 1982, the number of AIDS cases have doubled.

Epidemiology Studies/Investigations

New risk groups have emerged since last fiscal year that have required epidemiologic investigations including recipients of blood products and children of reported cases.

Laboratory Investigations

The major increase in cost has come in this area. There has been a need to pursue expensive laboratory technology in an attempt to find an etiologic agent for AIDS including animal studies, and other sophisticated and expensive immunologic, pathologic, and virologic studies.

- V. Q. What are some of the additional activities that we would like to undertake in the AIDS investigation which are precluded due to lack of resources?

- A. Additional surveillance activities, epidemiologic studies, and laboratory investigations are needed.

Surveillance

Active surveillance methods need to be expanded into several major metropolitan areas in order to adequately monitor morbidity and mortality trends and to identify emerging risk groups. These methods include hospital-based case identification and reporting systems. This information is necessary to fully define the extent of the problem and to target epidemiologic and laboratory investigations to high risk groups. Funds are needed to implement surveillance systems in metropolitan areas that are likely to have a high prevalence of AIDS; including San Francisco, Los Angeles, Miami, Newark, Chicago, Houston, and Boston.

Epidemiologic Investigations

From the beginning of the AIDS investigation, it was recognized that Haitian emigres constitute a special high risk group. Little is known about the risk factors or the incidence of AIDS among the Haitian population in this country or in Haiti. Although this investigation has received lower priority because of the shortage of funds, the key to the etiology of the disease may well lie in the understanding of the natural history of the disease in this population.

In addition, opportunities are numerous for indepth epidemiological investigations leading to a better definition of disease risk factors. These opportunities include prospective studies of high risk population and long term followup of hepatitis B vaccinees, blood recipients, and cohorts of AIDS cases. Studies of these risk groups include homosexual men, intravenous drug users, children, and recipients of blood products.

Laboratory Investigations

Current experiments have proven that the etiologic agent for AIDS cannot be readily cultivated in conventional in vitro systems or laboratory animals. As with hepatitis A and B viruses, an animal model would appear to be crucial for isolation of the agent, confirmation of the etiology, and full characterization of the disease. Chimpanzees are the animals most likely to prove successful. Several chimpanzees have been inoculated but larger numbers are required if the period of infectivity of the agent is brief, or if the degree of infectivity is low. The possibility of incubation periods in excess of one or two years adds complexity to the experiments. There is also a need to establish laboratory proficiency in studying retroviruses which may prove to be important in finding the AIDS etiologic agent. Other virologic, immunologic, and pathologic studies are also needed.

**GC/CHLAMYDIAL PID/INFERTILITY STUDY PLANS TO BE
CANCELLED BY DVDC LOSS OF \$300,000**

In 1982, CDC formulated a set of comprehensive Sexually Transmitted Diseases Treatment Guidelines. These guidelines were developed in consultation with a group of distinguished scientists selected from a cross-section of medical and public health disciplines. Although background papers were drafted by CDC staff that summarized all available treatment data, experts were forced to recommend regimens for some STD which have not been evaluated through clinical trials.

One such regimen is a combination of amoxicillin or ampicillin, plus tetracycline for treatment of uncomplicated gonococcal infections. Concerns which lead to the development of this theoretically effective regimen include: (1) Coexisting gonococcal and chlamydial infection rates of up to 45% in patients for whom adequate chlamydial cultures are done; (2) patient compliance problems with multiple - day tetracycline regimens for gonococcal infections; and (3) potential selection of tetracycline - resistant gonococcal isolates when incomplete doses of tetracycline alone are taken.

The first of two RFC's to be affected by the DVDC loss of \$300,000, "Clinical Therapy Trial of Regimens for Uncomplicated Gonococcal Infections and Coexistent Gonococcal and Chlamydial Genital Infections," proposes to: (1) Compare the efficacy of tetracycline vs. amoxicillin/ampicillin plus tetracycline in the treatment of uncomplicated gonococcal infections; (2) evaluate the side effects/toxicity of the combination regimen of amoxicillin/ampicillin plus tetracycline; and (3) compare efficacy of tetracycline vs. combination regimen for treating coexisting gonococcal and chlamydial infections.

As more practitioners recognize the importance of chlamydial infections and their coexistence with gonococcal infections, the combination regimen will be more widely used. Consequently, there is an urgent need to evaluate the efficacy and toxicity of this untested regimen.

Pelvic inflammatory disease (PID) is one of the most serious complications caused by sexually transmitted diseases (STD). More than 1,000,000 cases of PID are diagnosed and treated each year. These pelvic infections may jeopardize a woman's reproductive health by placing her at increased risk for repeated PID, ectopic pregnancy and infertility. Infertility related to STD, usually results from delayed or ineffective management of PID. To study STD related infertility, an evaluation of treatment practices for PID must be conducted in concert with surveillance of PID and long-term follow-up of patients to determine efficacy of regimens used and associated infertility rates.

The purpose of the second RFC, "Surveillance System for Pelvic Inflammatory Disease Epidemiology and Therapy," is to fund the first phase of the prospective observational study to: (1) provide high quality surveillance of PID epidemiology (trends), (2) assess modes of therapy used in the community; and (3) determine short-term complication rates of PID.

This letter RFC is in response to the partial restoration of \$1.754 million for needed research to evaluate the role of PID in infertility. Subsequent phases of this study would then permit the ongoing evaluation of these patients, their recurrent episodes of PID, and the relationship of their complications to subsequent infertility status.

Funding Options
1983 and 1984

1983

- Option 1: Seek additional funds, but no positions/FTE's for New or expanded projects.
+ \$695,000.
- Option 2: Seek additional funds and positions/FTE's for New or Expanded Projects.
+8 pos + \$760,000
- Option 3: Seek additional funds, but no positions/FTE's for New or Expanded Projects and restore a portion of "diverted" funds.
+ \$2,035,000
- Option 4: Seek additional funds and positions/FTE's for New or Expanded Projects and restore a portion of "diverted" funds.
+31 pos. + \$2,225,000

1984

- Option 1: Seek additional resources for New or Expanded Projects.
+27 pos. + \$2,500,000
- Option 2: Seek additional resources for New or Expanded Projects and restore "diverted" FTE's and funds.
+97 pos. + \$4,800,000



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 18 1983

Office of the Assistant Secretary
for Health
Washington DC 20201

The Honorable William H. Natcher
Chairman
Subcommittee on Labor, Health and
Human Services, Education
and Related Agencies
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

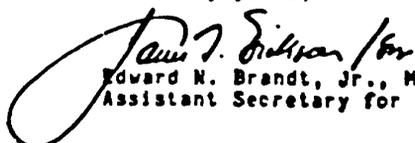
I am responding to your letter of May 9, 1983, regarding Acquired Immune Deficiency Syndrome (AIDS). The enclosed status report (Enclosure 1), prepared by the Public Health Service (PHS) on AIDS, updates information provided to you by Departmental witnesses at the recently completed 1983 appropriations hearings. I am glad to have this opportunity to assure you that resources allocated to the campaign against AIDS are substantial, as indicated by the budget summary table, and the Department is committed to taking necessary actions.

You also asked whether additional resources could effectively be used in the current fiscal year. As with any situation as dynamic and critical as that of AIDS, funding requirements can change rapidly. Enclosure 2 is a description of additional efforts which could be accomplished now and in future months.

While we are not requesting additional budget authority for these items, we would not oppose Congress giving the Secretary of Health and Human Services discretionary authority to transfer up to \$12.0 million for AIDS activities across appropriation lines of HHS. We are currently requesting authority from the Office of Management and Budget for this purpose.

I want to assure you that the problem of AIDS is indeed of major concern and interest to the Public Health Service.

Sincerely yours,


Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health

Enclosures

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
Public Health Service Current Level of Effort
(Dollars in thousands)

	<u>1982 Actual</u>	<u>1983 Current Level</u>
Centers for Disease Control:	\$2,000	\$4,600
Food and Drug Administration:	150	350
National Institutes of Health:		
NCI.....	2,400	4,400
NHBLI.....	5	346
NIDR.....	25	25
NINCDS.....	31	72
NIAID.....	297	4,050
NEI.....	33	45
DRR.....	564	644
Subtotal, NIH.....	<u>3,355</u>	<u>9,582</u>
Alcohol, Drug Abuse and Mental Health Administration:	<u>---</u>	<u>---</u>
Total, PHS.....	\$5,505	\$14,532

QUESTION 6:

- a. When did Dr. Foege and Dr. Wyngaarden first learn that the original FY'83 levels were insufficient for AIDS activities?
- b. When was that information first communicated to the Assistant Secretary's office?
- c. Please provide all supporting documentation.

ANSWER

Please refer to the response to question 5.

7. Question: Please provide a specific timetable for obligating the \$12 million in the supplemental appropriations. How much of the \$12 million will be spent in FY 1983? How much of this supplemental money will be deferred until FY 1984?

Answer: The Supplemental Appropriations Act, 1983 (P.L. 98-63) was signed into law by the President on July 30, 1983. Since that time, the three PHS agencies -- the Centers for Disease Control, the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration -- which were allocated funds from the \$12 million supplemental appropriations for AIDS have moved as quickly as possible to obligate these funds in FY 1983. The specific amounts received and the timetable for obligations are as follows:

<u>Agency</u>	<u>FY 1983 Supplemental Appropriations</u>	<u>Amount and Date of Obligations</u>
Centers for Disease Control	\$2,225,000	total to be obligated by 9/30/83
National Institutes of Health		
NIAID	4,500,000	total to be obligated by 9/30/83
NCI	3,300,000	total to be obligated by 9/30/83
NHLBI	1,000,000	\$814,000 to be obligated by 9/30/83
NINCDS	500,000	total to be obligated by 9/30/83
Alcohol, Drug Abuse and Mental Health Administration	400,000	total to be obligated by 9/30/83
PHS Total:	\$12,000,000	\$11,814,000 to be obligated by 9/30/83

Thus, it is anticipated that only \$186,000 of the total \$12 million will be deferred until FY 1984. These remaining funds will be obligated in the first quarter of Fiscal Year 1984 by the National Heart, Lung and Blood Institute and will support grants approved in response to the Institute's Request for Applications which was issued in July 1983.

8. Dr. Brandt frequently referred to the Department's comprehensive plan or "plan of attack" during his testimony (transcript pages 112, 115, 130 and 146).

a. Please supply for inclusion in the record a copy of this plan and all related budget documents.

A: As noted in the transcript, Dr. Brandt referred to his testimony as a recitation of the plan of attack on AIDS. A copy of his testimony is attached, along with a copy of a memorandum describing "Current and Future Strategies with Respect to AIDS," and a copy of the PHS AIDS Operational Plan *will follow*.

b. When was the plan first developed?

A: Planning began in June of 1981 with the first epidemiologic evidence of a disease involving immunodeficiency.

c. Who participated in the development of the plan?

A: In close coordination with the Assistant Secretary of Health, the first agencies to participate in planning a response to what was then described as an outbreak of Pneumocystis carinii pneumonia (PCP) and Kaposi's sarcoma (KS) were CDC and NIH. The FDA, NIDA, and ADAMHA became involved as evidence developed reflecting the role of blood, blood-products, and intravenous drug abuse in the transmission of AIDS.

July 29, 1983

Chairperson, Public Health Service (PHS)
Executive Committee on AIDS

Future Strategies with Respect to AIDS

The Assistant Secretary for Health

Attached is a report on "Current and Future Strategies with Respect to AIDS" as requested in your memorandum of July 18.

Jeffrey P. Koplan
Jeffrey P. Koplan, M.D.

Attachment

cct
OD
CDC/W
OPA/OD/CDC
CID

CDC:OD:JPKoplan:mc 7/27/83
Doc. 0127R

CURRENT AND FUTURE STRATEGIES WITH RESPECT TO AIDS
Centers for Disease Control

I. EPIDEMIOLOGY AND IDENTIFICATION OF RISK FACTORS

A. Surveillance

- Passive Surveillance will continue and will be aided by efforts in most States to make AIDS a notifiable disease. We will continue to provide encouragement and surveillance guidelines to States.
- Active surveillance will be established in specific geographic areas.
 - a. We provide financial support to local health departments (New York City and San Francisco)
 - b. We assign Public Health Advisors to selected high incidence cities (New York City, San Francisco, Los Angeles, and Miami).
 - c. As needed, we supply public health staff to local and State health departments to assist in AIDS investigations.

B. Epidemiologic Studies

- Analyses of data gathered by studies already completed or underway will help identify risk factors, characterize risk groups (homosexual men, hemophiliacs, sexual partners, infants born to high risk mothers).
- Studies are being planned for other risk groups identified by surveillance (Haitians, IV drug users, blood transfusion-associated cases, hospital workers exposed to AIDS occupationally).
- Epidemiologic studies are being developed to identify possible etiologic factors in affected patients or in individuals with prodromal conditions.
- We plan to study an existing cohort in San Francisco with unique baseline data to help ascertain true incidence of AIDS and other factors.
- Thorough investigation of any additional clusters of cases will be undertaken, should they occur.

II. IDENTIFICATION OF AN ETIOLOGIC AGENT

- Field studies will continue to provide access to specimens from clinically and epidemiologically characterized cases and controls that can be used to forward laboratory searches for an etiologic agent.
- Specimens will be collected prospectively for a national repository in anticipation of microbiologic and immunologic studies.
- Identification of agents recovered from AIDS patients will be undertaken through a wide variety of laboratory techniques.
- Efforts are being made to create an animal model for AIDS.
- In the search for agents that, in theory, could produce the clinical syndrome of AIDS, retroviruses are the candidate agents of greatest interest.

III. THERAPY

A. Immune Defect

- NIH will continue to search for effective treatment for AIDS using immune replacement approaches and other methods.

B. Opportunistic Infections

- CDC will continue to distribute drugs for PCD (pentamidine), and M. avium-intracellulare (ansamycin).
- CDC will continue to consult on treatment of opportunistic infections (cryptosporidiosis, CNS toxoplasmosis, etc.)

C. Kaposi's sarcoma

- Interferon and other agents will be tested for their therapeutic value.

IV. DIAGNOSTIC TESTS

- Such a test would be very desirable, but none is available as yet. As progress is made in identifying agent, serologic and/or culture tests may be feasible.
- To date, surrogate tests have not proved sufficiently sensitive or specific for AIDS to be useful. However, prospective studies are underway to assess tests of immune function that might be predictive or diagnostic of AIDS.

- Diagnosis is now based on epidemiologic criteria but lab confirmation is desirable. Diagnostic tests await identification of the cause of AIDS.
- Intensification of pathologic evaluation of AIDS patient tissues may result in characterization of "vesicular rosettes" and other unique microscopic formations seen thus far.

V. SAFETY OF BLOOD PRODUCTS AND BLOOD

- Existing surveillance systems should serve to identify AIDS cases should they occur in blood product consumers other than those already known (e.g. hypogammaglobulinemia patients, Heptavax recipients).
- Epidemiologic investigations of cases in blood recipients continue.
- Blood and blood product consumers would be among the first to benefit from development of screening test(s) for AIDS.

VI. OTHER ISSUES

A. Public Health Service Coordination of AIDS Efforts

- The PHS will continue to coordinate AIDS research, control, prevention, and education activities among its agencies and with other government, health, and consumer groups.

B. Information to Public and Private Health Professionals and the General Public

- The PHS will continue to disseminate information to health professionals and the general public via the Morbidity and Mortality Weekly Report (MMWR), other bulletins, journal articles, media interviews, and correspondence.

C. Safety in Workplaces

- CDC will work with hospitals, laboratories, health departments, medical and dental associations, unions representing all categories of health care providers and workers to develop guidelines for prevention of AIDS and other infections in the workplace.
- Continued distribution of guidelines that already exist; updating of these as new conclusions are reached.

D. Prevention of AIDS

- Disseminate these recommendations based on most recent information to appropriate risk groups or general public as indicated.
- Develop more prevention guidelines as above mentioned studies are completed.
- Educate health professionals about AIDS and its prevention.
- Work with special interest groups (AAPHR, Haitian Physicians Abroad, Hemophilia Foundation, etc.) to keep lines of communication open between PHS and AIDS risk groups.

E. What to Do After Agent is Identified

- Characterize agent microbiologically.
- If vaccine is feasible, start R and D at once.
- Begin tests for candidate therapeutic agents.
- Develop laboratory animal model for treatment and vaccine studies.
- Develop practically useful screening and diagnostic tests (culture, serology, etc.)
- Disseminate information on the findings to public and private health professionals and researchers in this country, WHO, etc.
- Transfer technology to other labs (e.g., as in Legionnaire's Disease).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

October 25, 1983

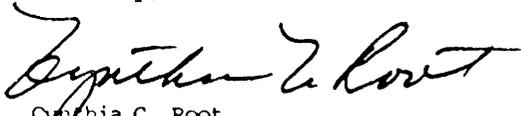
The Honorable Ted Weiss
Chairman, Intergovernmental Relations
and Human Resources Subcommittee
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Weiss:

Attached is the remaining response to question #8 of your letter of August 24 to Dr. Brandt. The enclosed is a copy of the Public Health Service AIDS Operational Plan.

Please let me know if we can be of further assistance.

Sincerely,



Cynthia C. Root
Deputy Assistant Secretary
for Legislation/Health

Attachment

PUBLIC HEALTH SERVICE AIDS OPERATIONAL PLAN

BACKGROUND

Acquired Immunodeficiency Syndrome (AIDS), a newly recognized health problem, is characterized by a severe and persistent breakdown in the immune system. The subsequent crippling of immune functions in AIDS patients is accompanied by opportunistic infection and/or cancer. There is no known underlying cause for the deficiency nor for the reduced resistance reportedly associated with AIDS. Persons with AIDS are susceptible to certain cancers, such as Kaposi's sarcoma and B-cell lymphomas, plus numerous life-threatening infections, most commonly Pneumocystis carinii pneumonia. The case fatality rate among AIDS patients is high, approximately 40 percent. There has been no case of AIDS in which the immune system has returned to normal.

From June 1981 through September 1983, 2,374 diagnosed cases of AIDS were reported to the Centers for Disease Control (CDC). More than 60 percent of these cases were reported from New York City, San Francisco, and Los Angeles. The average number of cases reported each day has increased from 2 to 7 during the past year.

Eighty-nine percent of AIDS patients can be placed in groups that suggest a possible means of disease acquisition: 71 percent are homosexual or bisexual men; 17 percent have a history of intravenous drug abuse; and 1 percent are hemophiliacs. Of the remaining 11 percent of the cases, means of disease acquisition is less clear, but in none of these cases does casual contact appear to be involved. All of these cases are the subjects of intensive investigation. This group includes cases for whom information about risk factors is either absent or incomplete (3 percent of the total number of cases) and patients who were born in Haiti but have lived in the United States since 1978 (5 percent of the total number of cases). Also under investigation are sexual partners of persons with AIDS or increased risk of AIDS (1 percent) and those receiving blood transfusions (1 percent). Some cases belong to none of the above groups (1 percent of the total number of cases).

THE PUBLIC HEALTH SERVICE (PHS) RESPONSE

The PHS recognition of AIDS began in June 1981 with a report in the CDC's Morbidity and Mortality Weekly Report (MMWR) of the first five cases in Los Angeles. Epidemiologists from CDC investigated these and other newly identified cases in New York City and San Francisco. The first AIDS patient was admitted to the Clinical Center at the National Institutes of Health (NIH) in the same month. The Food and Drug Administration (FDA) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) subsequently became involved in the study of AIDS. The PHS has undertaken a variety of approaches to study and solve this problem that involve many medical disciplines and methodologies. Research priorities have been established and basic science researchers have shifted the foci of their studies onto AIDS.

The PHS Agencies have characterized the disease epidemiologically and clinically. Therapeutic regimens have been evaluated and new ones studied. Health care providers and other groups have been provided with the most up-to-date information regarding the treatment and prevention of the disease. In March 1983, the PHS published guidelines on the prevention of AIDS (a copy of these guidelines is attached). These guidelines were widely disseminated. Attempts have been made to keep the public and specific risk groups well informed with the latest accurate medical information, including guidelines for prevention. The PHS strategy has been multifaceted and coordinated. Physicians, epidemiologists, social scientists, communications specialists, and basic science researchers have combined their efforts in working on various aspects of this syndrome. In May 1983, a PHS Executive Committee on AIDS was established to coordinate the PHS efforts to solve the public health, research and clinical problems associated with AIDS. Our strategy and its results thus far are described in the following sections. Efforts in each of these areas is continuing.

FUNDING

In response to the AIDS problem, CDC, NIH, and FDA spent \$5.5 million for AIDS-related work including research in Fiscal Year 1982. Expenditures were approximately \$25.2 million in Fiscal Year 1983 including \$12 million in supplemental funds made available in a bill signed by the President on July 30, 1983. Expenditures are anticipated to be at least \$17.7 million in Fiscal Year 1984 (including projected expenditures by ADAMHA) and an additional \$22.2 million has been requested by the Department of Health and Human Services (HHS) for the Fiscal Year 1984 AIDS budget. At this time, Congressional action on the HHS Fiscal Year 1984 budget is pending.

EPIDEMIOLOGY AND SURVEILLANCE

AIDS has presented a unique problem. Epidemiologic and surveillance studies are necessary to describe accurately the scope of the AIDS epidemic by time, place, and person. By clearly identifying these parameters, health officials can develop intervention and prevention strategies as well as avenues for further research. The CDC-coordinated disease surveillance system relies upon the voluntary disease reports from State and local health departments and individual physicians. These case reports form the basis of the national listing of AIDS cases.

CDC has assigned Federal public health advisors to the health departments in New York City, Miami, Los Angeles, and San Francisco where AIDS is most prevalent. CDC has funded cooperative agreements with the New York City, San Francisco, Los Angeles, Boston, Florida, New Jersey, and New York State health departments to strengthen AIDS case surveillance.

Special epidemiologic studies to identify risk factors and modes of transmission, to characterize risk groups, and to identify possible etiologic factors have been undertaken. A national AIDS case-control study among homosexual men was conducted by CDC in the fall of 1981, and published results show that AIDS cases occurred most frequently in

those groups of homosexuals with large numbers of sex partners. Further evidence of sexual transmission and probable infectious etiology was found from the investigation of a cluster of male AIDS patients who were linked by sexual contact. Other investigations have found evidence of AIDS in individuals with hemophilia who have received clotting factor concentrates.

Investigations now being conducted include a study of risk factors in Haitians living in New York and Miami, a cohort study of 7,000 homosexual men living in San Francisco, a study of AIDS transmission in intravenous drug abusers, a study of the risk of AIDS to health care workers, special investigations of AIDS patients not belonging to known risk groups, and investigations of possible transfusion-acquired AIDS. On September 30, 1983, the NIH awarded five new grants for epidemiologic studies. These projects will permit more precise delineation of the course of this illness.

As data and information on this illness accumulate indicating new avenues for investigation, new epidemiologic studies will be initiated.

IDENTIFICATION OF AN ETIOLOGIC AGENT

CDC, FDA, and NIH are supporting a wide variety of AIDS research activities designed to identify the etiologic agent(s) of AIDS. In addition, over 40 intramural research projects are under way at NIH; FDA, and CDC involving studies on the nature of the immune deficiency, the isolation of etiologic agents, treatment, and attempts to transmit the disease to nonhuman primates. Studies are using various DNA hybridization, isolation, and serologic techniques to identify microbial agents. Research emphasis is being placed on various agents including retroviruses (such as the human T-cell leukemia virus), adenoviruses, cytomegaloviruses, Epstein-Barr virus, various parvoviruses, rickettsia, and chlamydia. A search is being made for the presence of a "slow virus" in brains of AIDS patients who develop dementia. Funds have been awarded to the California Regional Primate Center to expand its study of simian AIDS, an AIDS-like illness seen in monkey colonies. In addition, NIH has funded AIDS research proposals from hospitals and universities to encourage studies on the search and the isolation of the biological agent which may be the primary causative factor in AIDS. Over 50 grants, contracts, and cooperative agreements have been awarded to researchers in 46 institutions to do AIDS research.

Finding the cause of AIDS will mark the beginning of a second phase of AIDS research. Identification of the etiologic agent will hasten the development of specialized diagnostic tests, the discovery of animal infection models, and the search for specific drugs and treatments that will neutralize the agent. A major PHS priority will be the transfer of this technology to health departments and medical practitioners where it will be used in the identification and treatment of the disease.

DIAGNOSTIC TESTS AND THERAPY

At present, there currently is no satisfactory diagnostic test for AIDS. Several tests are under evaluation, including T cell ratios, alpha-thymosin, hepatitis B core antibody, and beta-2 microglobulins.

The discovery of a specific diagnostic test for AIDS, like the identification of the AIDS causative agent, will herald intensified medical research efforts to delineate AIDS epidemiology, to improve treatment therapies, and to develop specific AIDS prevention strategies. A specific diagnostic test will be critical in the identification of a possible pre-illness test for AIDS and recommendations that will aid in the prevention of the disease.

NIH scientists have been involved in treating 69 AIDS patients at the NIH Clinical Center. Scientists both within NIH and at other medical centers have been developing and evaluating strategies to treat the opportunistic infections and Kaposi's sarcoma. These strategies have included interferon therapy, use of experimental drugs, chemotherapy regimens that involve cytotoxic drugs, and radiation therapy procedures to treat skin lesions. Attempts have been made to restore the patient's immune system by using purified interleukin-2. Some of these strategies appear promising but their clinical usefulness has yet to be developed or established.

SAFETY OF BLOOD PRODUCTS AND BLOOD

In 1982, the development of AIDS in people with hemophilia and others who had received transfusions of blood and/or blood products and who had no other risk factors raised questions as to the safety of the blood supply. Accordingly, guidelines for the prevention of AIDS, for blood donation and for the use of blood and blood products were developed and distributed in March 1983 (see attachment).

Through a series of workshops and conferences, FDA has had close contact with the scientific and manufacturing community and with the various organizations of the blood service complex. In addition, FDA has recently approved a new heat process that is now being used in the manufacture of clotting factor concentrates. This is expected to increase this product's safety.

PUBLIC INFORMATION AND EDUCATION

The PHS has produced materials and undertaken many projects and activities for providing information about AIDS to health professionals and certain other occupations, the populations at risk for contracting AIDS, and the public. Information for professionals has been disseminated via the MMWR, journal articles, bulletins, media interviews, and numerous PHS sponsored meetings, conferences, and workshops on AIDS attended by outside consultants, organizations, and the public. Approximately 40,000 copies of the MMWR -- which has carried articles on AIDS epidemiology and etiology, PHS recommendations, and precautions for health workers -- are regularly distributed to the health community. In addition, reprints of these articles have been distributed to community health centers, to other health facilities, and to drug treatment centers. AIDS information

has also been circulated to all practicing physicians through the FDA Drug Bulletin. CDC has distributed slides showing Kaposi's sarcoma to requesting physicians for help in diagnosis. The National Library of Medicine provides bibliographic AIDS information to requesting scientists. Videotapes are being prepared on AIDS for primary care physicians to be distributed through medical societies and appropriate organizations. Another videotape is being prepared for nurses who care for AIDS patients, in addition to tapes for other health workers. These will also be distributed through professional organizations and the National Medical Audiovisual Center. A videotape on AIDS findings has been prepared by CDC and distributed to State health officials and requesting health facilities. A videotape for correctional officers is under development, as is a booklet outlining precautions that all laboratory and clinical workers should observe.

Extensive information efforts are under way for the populations at risk. A basic information bulletin has been distributed by homosexual organizations. Cards describing symptoms and prevention precautions are being printed for distribution by these groups. News media, including the gay press, have carried articles based on the PHS-provided information about AIDS and promoted a national AIDS toll-free telephone hotline (800-342-AIDS), staffed by PHS professional employees. The hotline is available to the public for AIDS information and has received over 5,000 calls per day, most of them from individuals in the populations at risk. The National Institute of Drug Abuse has directed materials about AIDS to drug users through drug treatment centers. A mailing of AIDS information has been made to Haitian organizations, and an effort is under way to develop an education program for this group, possibly through publications, distributed through such channels as social organizations, health facilities, and churches, as well as through the news media. PHS has also been working with organizations representing hemophiliacs to provide information to that group.

The general public has been informed through the news media, with whom the PHS has conducted numerous interviews, briefings and press conferences, in addition to providing printed and videotaped material. Information materials are now being prepared to assure the public that persons outside the identified risk groups are at very low risk of acquiring the disease and that casual contact with persons in the risk groups poses no danger to the public health. These materials also help allay public concerns regarding the safety of donating blood or receiving blood transfusions. A videotape and slide talk on AIDS are being produced for showing to general audiences, including basic information about the syndrome which places the risk factors in perspective. Additional publications are also being developed for traditional channels of health information distribution. Basic information about the syndrome has already been made available to the public through a monthly PHS AIDS Fact Sheet and through the national hotline, and through effective articles in the press and by appearances of knowledgeable health officials on television and radio interviews. The Secretary of Health and Human Services and the

Assistant Secretary for Health addressed the Washington Press Club in September 1983 to emphasize the need for the media to provide additional, accurate information to the public without provoking needless fears.

COORDINATION

An effective mechanism for coordination has been developed under the direct supervision of the Assistant Secretary for Health (ASH). There are three components to this mechanism. First, there is a PHS Executive Committee which includes members from all PHS agencies involved in AIDS research and public health activities. This Committee meets weekly to review AIDS activities within the PHS and to coordinate PHS research and public health strategies. This Committee makes recommendations to the ASH regarding the overall PHS AIDS strategy. Second, within each agency there is a committee to oversee and coordinate AIDS activities within that agency. The chairmen of these agency committees serve on the PHS Executive Committee. Third, public and professional education and information campaigns are carried out by the PHS Office of Public Affairs under direct supervision of the ASH.

CONCLUSION

The unprecedented research, public health, and clinical efforts to identify, characterize, and treat AIDS have helped us learn a great deal about the syndrome in a short period of time. Epidemiological studies indicate that the syndrome is transmitted through sexual contact or direct exposure to blood or contaminated needles. Ninety percent of the AIDS cases have been in patient groups defined by identified risk factors. There is no evidence suggesting that AIDS is transmissible through casual contact with persons in AIDS risk groups or AIDS patients. No health worker has contracted AIDS as a result of taking care of an AIDS patient. Basic medical research is narrowing the search for an etiologic agent which most believe to be a virus.

Immunological research has greatly improved our knowledge of the workings of the immune system. The discovery of simian AIDS will provide further clues to the transmission and therapy for the syndrome. Experience in treating AIDS has led to the development of several promising therapies for opportunistic infections that plague not only AIDS patients but also other patients with compromised immune systems.

AIDS continues to be a major public health problem, but our research and public health and clinical knowledge are continually expanding. These efforts will be essential in finding a solution to AIDS.

September 30, 1983

Question 11:

Dr. Brandt testified (transcript pages 144 and 146) that NIH monitors ROI's to determine if additional RFA's or RFP's should be issued to assure that all needed research on AIDS is being conducted.

Question 11a:

Specifically who monitors the ROI's on AIDS?

Answer 11a:

The responsibility for monitoring ROI's to determine if additional RFA's or RFP's should be issued for AIDS research lies with staff members of those Institutes having AIDS extramural activities as listed below:

NIAID

NIAID staff in the Microbiology and Infectious Diseases Program (MIDP) and Immunology, Allergic and Immunologic Diseases Program (IAIDP) monitor research grants. The decision to issue new RFA's and/or RFP's is made by the NIAID AIDS Working Group in conjunction with the NIAID Executive Committee which includes representatives from each program area.

NHLBI

Staff of the Blood Resources Branch, Division of Blood Diseases and Resources, are directly responsible for monitoring grants, contracts, and intra-agency agreements on AIDS.

NCI

Monitoring of the ROI's on AIDS at NCI is performed by three lead program personnel, each responsible for ROI's funded by the respective scientific Division. Their evaluations are forwarded in turn to each Division Director and to the NCI-wide Director for coordination of AIDS activities. Grants administration also supplies computerized information designating the functional and fiscal status of the activity. Division Directors then interact with their Board of Scientific Counselors to determine whether areas of AIDS research exist which need further reinforcement by recommending further RFP's and RFA's.

Question 11b:

Provide all reports of R01 monitoring.

Answer 11b:

No formal written reports exist for the NIAID. All reports to date have been verbal and have been made to both the NIAID AIDS Working Group and the NIAID Executive Committee. The AIDS program at the NHLBI is a relatively new program and reports of these activities are not yet available.

Attached are two documents* that the NCI considers to be examples of written monitoring. The September 1981 report led to the 1982 supplements for AIDS. The May 1983 report is an example of monitoring by continually updating and summarizing NCI research efforts.

Question 11c:

Provide documentation of recommendations for RFA's or RFP's that directly resulted from this monitoring process.

Answer 11c:

The NIAID decided as a result of the monitoring process to fund grants in response to the NCI RFA on "Studies on Acquired Immunodeficiency Syndrome (Kaposi's Sarcoma and Opportunistic Infections)." Further monitoring resulted in the decision of the NIAID to co-sponsor with NCI the RFA "Infectious Etiology of Acquired Immunodeficiency Syndrome (AIDS) and Kaposi's Sarcoma," and to issue an NIAID RFP on "The Natural History of Acquired Immune Deficiency Syndrome (AIDS) in Homosexual Men."

The extramural AIDS program of the NHLBI is still in its early stage, consequently the monitoring process had not yielded any concrete recommendations for additional RFA's or RFP's on AIDS research.

The monitoring process at the NCI led to the decision to supplement ongoing projects (September 1982), develop the RFA on "Studies on Acquired Immunodeficiency Syndrome," and to co-sponsor the RFA "Infectious Etiology of Acquired Immunodeficiency Syndrome (AIDS) Kaposi's Sarcoma." Monitoring of extramural projects also assists the NCI in determining intramural priorities.

*Documents available in Subcommittee files

12. Please provide a list and brief description of all PHS funded research activities designed to find a diagnostic test and/or surrogate marker for AIDS. (Please include chief investigator, agency or institute if intramural, university or hospital if extramural, cost, approximate date on which research commenced, and results.)

A:						
<u>Study</u>	<u>Brief Description</u>	<u>PI</u>	<u>Agency/ Collaborators</u>	<u>Costs</u>	<u>Estimated Beginning</u>	<u>Results</u>
1) Infectious agents in AIDS	Study AIDS patients and controls for markers of known infectious agents	Dr. Noble	CDC	± 75,000	Aug 81	Both infected with many agents; no etiologic agent identified.
2) Intensive study for viruses	Using virus culture techniques attempt to isolate a virus	Dr. Noble	CDC/Memorial Sloan Kettering Hospital	150,000	May 82	CMV and adeno viruses isolated. No etiologic agent
3) Primate inoculations	(See question #17)		CDC		Aug 82	No etiologic agent
4) Microscopic examination of AIDS tissues	Using light and electron microscopes search tissue sections for microbial agents	Drs. Chandler, Ewing and Palmer	CDC	150,000	Jan 82	VR particles visualized other virus-like particles seen
5) Surrogate testing	Evaluate usefulness of various surrogate tests for predicting AIDS	Dr. Spira	CDC and others	70,000	Jan 82	Several possibilities - study expanded
6) HTLV Anti-body prevalence	Measure HTLV antibodies in AIDS patients and high risk populations	Drs. Francis and Essex	CDC/Harvard/MCI	50,000	Nov 82	Moderate prevalence of HTLV anti-bodies in AIDS patients

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7)	HTLV/ hemo- philiacs	Test hemophilic patients for HTLV anti- bodies,	Dr. Evatt	CDC/Harvard	50,000	Feb 83	Moderate prevalence in hemophiliacs
8)	Virus particles	Examine factor VIII for viruses	Dr. Evatt	CDC	25,000	Dec 82	Same particles seen as No. 4 above.
9)	Isolation of human retro- viruses	Culture cells from AIDS patients - examine for retro-viruses	Dr. Feorino	CDC/Memorial Sloan Kettering	100,000	Apr 83	Pending
10)	HTLV-post- transfusion	Test for HTLV antibodies in donors to AIDS patients	Drs. Francis and Essex	CDC/Harvard/NCI	50,000	May 83	Commonly found
11)	Prospective studies	Follow those at high risk for AIDS, take periodic specimens	Lymphadenopathy Dr. Spria Homosexuals (SF) Dr. Francis Hemophiliacs (GA) Dr. Evatt Haitians (NY, FL) Drs. Jaffe and Johnson	CDC	300,000	May 83	Pending

Question 12:

Please provide a list and brief description of all PHS funded research activities designed to find a diagnostic test and/or surrogate marker for AIDS. (Please include chief investigator, agency or institute if intramural, university or hospital if extramural, cost, approximate date on which research commenced, and results.)

Answer #12

The following list, by Institute, provides details on all NIH funded research activities designed to find a diagnostic test and/or surrogate marker for AIDS.

NIAID

Extramural Research Activities:

Arye Rubinstein--Yeshiva University--U01-AI-20671-01. Date of award 4/19/83. Results on the following studies are pending: (1) a newly discovered, possibly unique lymphocyte surface marker on AIDS cells, and (2) analysis of circulating immune complexes using their newly developed, complement-binding assay on Raji cells.

John Fahey--UCLA--U01-AI-20672-01. Date of award 4/19/83. Results to date have shown that a major immune system change detected by serial testing of AIDS and lymphadenopathy syndrome patients is a decrease in T helper levels.

RFP-NIH-NIAID-MIDP-83-11, "Study of The Natural History of Acquired Immunodeficiency Syndrome in Homosexual Men." Approximate start date 9/30/83. Contractors will test a variety of new diagnostic or surrogate markers for AIDS in over 5,000 at-risk homosexual men repeatedly examined over 2-1/2 years.

Intramural Research Activities:

Although various projects in the intramural program could have applications toward development of diagnostic tests of identification of surrogate markers, the following are specifically identified for that purpose.

1. B-cell activation studies in chimpanzees and AIDS patients as a marker for early AIDS detection.

Principal Investigator: Dr. Thomas Folks
Date Started: July 1983
Results: No results at present time

2. Prospective collection of blood, semen, and fecal specimens for detection of etiologic agents of acquired immune deficiency syndrome (AIDS). The stored specimens from those individuals who develop AIDS will then be examined for possible markers of disease.

Principal Investigators: Dr. Louis M. Baker, NYBC
Dr. Jonathan Gold, MSKCC

Date Started: August, 1983

Results: No results available at this time.

3. Evaluation of B₂-microglobulin levels in chimpanzees inoculated with materials from AIDS patients. The serum samples from chimpanzees inoculated with materials from AIDS patients will be examined to determine if this serum component is predictive of disease.

Principal Investigator: Dr. Thomas Folks

Date Started: May, 1983

Results: Preliminary results do not confirm or disprove the role of B₂-microglobulin as a predictor of disease.

NHLBI

On July 15, 1983, the NHLBI issued an RFA entitled, "Assay Methods to Detect the Carrier State of Acquired Immunodeficiency Syndrome (AIDS)" which encourages the development of a test to detect the carrier state or prodromal stage of AIDS. Information regarding research grants awarded under this RFA will be available April, 1984.

In addition, Dr. Cladd Stevens, as part of the supplement to the program project grant application from the New York Blood Center, will be studying B-thymosin levels in homosexual men. Support of this work is pending approval by the NHLBAC.

NCI

The NCI is supporting both extramural and intramural studies that relate to the discovery of a diagnostic test and/or surrogate marker for AIDS.

Extramural Research Activities

A number of the projects funded under the original NCI RFA contain components which could ultimately have application as markers for AIDS or AIDS-related conditions.

- R. G. Douglas--Cornell Medical Center--U01-CA-35018, (5/1/83)
- A. Friedman-Kien--New York University--U01-CA-35982 (7/15/83)
- B. Safai--Memorial Sloan Kettering Cancer Center--U01-CA-34995 (6/1/83)

These components all involve studies attempting to further define the development and the nature of the immunologic defect present in AIDS patients. Workers at Cornell, as well as investigators at New York University (Friedman-Kien), and Memorial Sloan Kettering (Safai) are investigating circulating immune complexes in the blood of AIDS patients. The N.Y.U. investigators also are involved in work attempting to define the etiologic role of antibodies directed at sperm and lymphocytes.

All of these involve material which could eventually be useful as a marker for AIDS. The thrust of the research, however, is toward a further understanding of the etiology and pathogenesis of the disease and is consistent with the original scope of the RFA.

Intramural Research Activities

All of the NCI's epidemiological studies in response to the questions concerning AIDS have involved, or will involve, the collection of biologic specimens for laboratory analysis, and for banking efforts so that they will be available as new tests are developed. Intramural efforts to find a diagnostic test or marker began in December, 1981, and are continuing. Recently, the NCI published the results of one of these investigations among hemophilic AIDS patients, which indicated the possible utility of acid labile alpha interferon as a marker. Similar evaluations for the following suspect markers have been conducted: beta₂-microglobulin, alpha₁-thymosin, and T-cell helper: suppressor ratios. All of these markers now are being prospectively evaluated in NCI cohorts for their applicability as potential screening tools. Another factor that the institute is beginning to look at is HTLV positive tests. The presence of antibodies/antigens in blood samples may prove to be a diagnostic test, although it is likely to not become standard because of the very sophisticated laboratories that are needed to conduct such tests.

Question 13:

Documents indicate that an NCI RFA on AIDS was being drafted in November 1981, but was not published until August 1982. To what does NCI attribute this 10-month delay?

Answer 13:

The 10-month period represents an expedited form of the normal cooperative agreement process and does not represent a delay. It should be noted that new leads regarding the etiology of AIDS were being discussed and redrafting occurred continuously as the science changed.

Question 14:

The NIAID Microbiology and Infectious Diseases Program (MIDP) annual report for FY 1982, which states that, "it is regrettable that within NIH no extramural mechanism exists to permit a rapid response to such research opportunities" (referring to AIDS). In addition, participants of the July 1982 PHS meeting on opportunistic infections in patients with hemophilia concluded that, "The existing federal grants and contracts mechanisms are not responsive to rapid funding of urgent problems." Please comment on these statements and provide PHS recommendation on how this process might be expedited.

Answer 14:

The statements quoted above were primarily referring to the time involved in funding new research grants. This time includes: time for the scientist to write the grant application; time for the peer reviewers to read the proposal and meet to assign it a priority score; time for the required secondary review and approval by the Institutes' Advisory Councils; and time for staff to process the papers to make the award. Although the entire process involves a considerable amount of time, the NIH has taken steps to expedite those portions of the process which fall within NIH control. The NIH will continue to investigate other approaches that will ensure a rapid response to urgent problems such as AIDS.

The NIAID and NHLBI have attempted a number of approaches that would expedite the review process but at the same time ensure that the quality of review is not jeopardized. These efforts are detailed as follows:

NIAID

The NIAID has addressed this problem by shortening the time of the last two steps in the review process, Council review and actual award. Council review has been accomplished by mail ballot rather than waiting for the next regularly scheduled Council meeting (which occurs in January, May, and September each year). The time from Council approval to actual award has been shortened by placing the highest priority on AIDS applications and processing them ahead of other non-AIDS applications.

NHLBI

It is the experience of the NHLBI that urgent public health problems can be responded to quickly. The recently released RFA on assay methods to detect AIDS serves as an excellent example of such a response. The concept for the RFA was developed in March, approved by the NHLB Advisory Council in May, and published in July. Awards are expected to be made in April. This entire process, which normally takes 18-20 months, will be completed in 13 months or less because of the urgency of the problem. In addition, NHLBI, through the use of interagency agreements and as a result of special actions by its Council, has been able to implement several programs in an expedited manner.

15. Question: In 1981, both former Secretary Schweiker and Assistant Secretary Brandt proposed a health emergency fund to allow PHS to better respond to urgent health problems (transcript pages 119-120 of Dr. Brandt's testimony). Then, in April 1983, Dr. Brandt testified against this same idea before the Health Subcommittee. When and why did the Department change its position? Please supply all supporting documentation.

Answer: Under Sections 301 and 311 of the Public Health Service Act, the PHS has the authority to provide prompt and effective assistance to States and other Federal agencies in emergency situations which pose an immediate threat to the public health. In Fiscal Year 1982, the Administration requested a special appropriation to establish a Public Health Service Emergency Response Fund which would permit PHS to carry out this authority in a prompt and effective manner. This contingency emergency fund was designed to:

- o allow the support of critical emergency activities that were not anticipated during the development of annual budgets;
- o provide a financial mechanism for absorbing the costs of emergency services and special studies without disrupting other priority programs; and
- o permit the initiation of special studies, where necessary, to expedite determination of the health effects of emergencies.

However, this appropriations' request was not funded in the FY 1982 Continuing Resolution. In fact, the House labor/HHS Appropriations Subcommittee specifically denied the Administration's request and stated in their report that "if emergencies arise, funds can either be appropriated in a special bill or be reprogrammed as in the past." (House Report No. 97-251, p.66).

On May 9, 1983 Dr. Brandt testified on a recently introduced bill, H.R. 2713, which would authorize appropriations for research on the cause, treatment, and prevention of public health emergencies. The testimony was not intended to reverse the Department's position on a health emergency fund but rather to point out that

- 1) the Public Health service has adequate authority under Sections 301 and 311 of the Public Health Service to conduct the research activities that this bill would authorize, and
- 2) the PHS would fund these emergency-related activities according to the directives set forth by the Appropriations Committee in Fiscal Year 1982.

Dr. Brandt's testimony also presented the Administration's request for an FY 1983 supplemental appropriations to establish a separate emergency fund for Food and Drug Administration activities because of the large number of emergencies, each of which involved relatively minor amounts. Separately requesting supplementals for each of these events would be inconvenient to the Congressional Appropriations Committees. A contingency fund of \$1 million for FY 1983 was approved by the Congress for FDA to be used for activities in response to emergencies.

16. Why does the Department believe that it is important to find an animal model for AIDS?

A: An animal model would:

- a) permit the identification of an infectious agent as the cause
- b) provide material to isolate and identify the agent
- c) enable studies on methods of transmission, treatment and prevention.

Question 17:

Please describe the AIDS primate experiments that have been undertaken by the PHS to find an animal model. Include the number and type of animals inoculated, types of tissue or fluid inoculated, names of investigators, costs of experiments, and results.

Answer 17:

<u>Institute</u>	<u>Animal/No.</u>	<u>Inoculum</u>	<u>Investigator(s)</u>	<u>Est. Cost</u>	<u>Results</u>
NIAID	Chimpanzees/22	Blood, cells, other materials from an AIDS patient.	NIH intramural scientists--Dr. Sell, Watt, Tyeryar, and Purcell.	\$15,000 for 2 chimpanzees for approx. 6 months	To date, neither of the two chimpanzees inoculated has developed AIDS. Other chimpanzees are being pretested for inoculation of other materials from AIDS patients.
MHLBI	Chimpanzees/4	Plasma from AIDS patients at the NIH Clinical Center.	Intra-agency agreement with NIH Clinical Center. Animals inoculated at MHLBI chimpanzee colony in San Antonio, Texas.	\$115,583 (2-year study)	Results not yet available.
DRR/NINCDS	Macaque monkeys/50	Tissue extracts, whole blood, filtered plasma from SAIDS-affected macaques.	California Primate Center--Drs. Henrickson, Gardner, Osborn, Maul, Anderson, Lowensteine. New England Primate Center--Drs. Letvin, King, Hunt, Desrosiers. NINCDS collaborators--Drs. Sever, Maddon, London, Ellingsworth.	\$100,000	Results not yet available.
NCI	Baboons/3 Chimpanzees/1	Cells and other specimens from AIDS patients.	Dr. P. Volderding (Animal project is one component of a larger study on AIDS.)	Primates--No charge to NCI.	To date, none of these animals has developed AIDS.
	Mice, guinea pigs/12-20,000			\$43,000	

- (CDC)
17. Please describe the AIDS primate experiments that have been undertaken by the PHS to find an animal model. Include the number and type of animals inoculated, types of tissue or fluid inoculated, names of investigators, costs of experiments, and results.

A: Primate experiments:

<u>Animal</u>	<u>Inoculum</u>	<u>Investigator</u>	<u>Estimated Cost</u>	<u>Results</u>
Marmosets (4)	Plasma/lymphocytes	Dr. Francis	50,000/yr	Healthy since Aug 82
Chimpanzees (2)	Plasma/lymphocytes	Drs. Broderon and Francis	50,000/yr	Healthy since Feb 83
Rhesus (12)	Plasma/lymphocytes lymphnode tissue	Drs. Broderon and Francis	65,000/yr	Healthy since June 83
Chimpanzees (12)	Just beginning	Drs. Broderon and Francis	120,000	----

18. The FY'84 supporting data book for CDC's testimony before the appropriations Committee includes the following statement:

"As with hepatitis A and B viruses, an animal model would appear to be crucial for isolation of the agent, confirmation of the etiology, and full characterization of the disease. . . Several chimpanzees have been inoculated but larger numbers are likely to be required. . . These animals studies are estimated to require \$1 million."

a) Was this information presented to Congress as a request for supplemental funds for FY'83? If not, why not?

A: Primate experiments, including chimpanzee experiments, were a part of the '83 supplemental request.

b) What is the effect, if any, of delaying the start-up date for these inoculations until sometime in FY'84?

A: Since outcome cannot be predicted, the exact impact is unknown.

19. Have any other NIH or CDC research proposals involving a search for an animal model gone unfunded to date? If so, please provide the proposals.

A: None

NIH Response to question 19:

Have any other NIH or CDC research proposals involving a search for an animal model gone unfunded to date? If so, please provide the proposals.

Answer 19:NIAID/NHLBI

No research proposals received by NIAID to work on animal models of AIDS went unfunded through FY 1983. The NIAID currently has some projects under review for potential funding in FY 1984. Research proposals on the development of an animal model for AIDS are not referred to the NHLBI. Nevertheless, two such activities are being supported by the NHLBI: the research described in #17 above and a project on simian AIDS which is pending final action on approval of an intra-agency agreement.

NCI

As of September 15, 1983, the NCI had four unfunded animal model proposals. Four are responses to the RFA "Studies of Acquired Immunodeficiency Syndrome (Kaposi's Sarcoma and Opportunistic Infections)," and two of the proposals will be funded with FY 1983 supplemental funds. The remaining two are not being considered for funding at this date. The following is a listing and brief description of each.

AIDS: CURRENTLY UNFUNDED ANIMAL MODEL PROPOSALS*

<u>Institution</u>	<u>UOI CA/AI</u>	<u>Approx. % Involving Model</u>
Tulane "A Study of Immunodeficiency in Hemophilia"	34977	30%
Sidney Farber "Animal Models of AIDS"	34979	70%
Ohio State "Development of Laboratory Models for AIDS & KS"	35000	100%
U.C. San Diego "An Immunodeficient Animal Model for Kaposi's Sarcoma"	34983	100%

SUMMARIES

- 1) Tulane In addition to clinical studies, these investigators propose attempting to develop an animal model for the AIDS associated with hemophilia by administering cryoprecipitate and factor VII to rhesus monkeys;
- 2) Sidney Farber A portion of this proposal involves study of an apparent immunologic disease in macaque monkeys which is similar to the human AIDS. This disease arose spontaneously in a colony of animals maintained at the Sidney Farber Cancer Institute in Boston. The animals develop unusual tumors and a variety of opportunistic infections;
- 3) Ohio State Homosexual behavior is common between both male and female hogs housed in communal facilities. Researchers of Ohio State have observed the spontaneous development of a tumor with pathologic similarities to Kaposi's sarcoma in a single boar so maintained. Unfortunately, no data documenting concomitant immunosuppression exist for this particular animal, and data from other animals (who have not developed tumors) are quite weak;
- 4) U.C. San Diego U.C. San Diego researchers found that specially treated cells from a dog kidney cell culture, when injected into nude (thymus deficient) mice, produced tumors microscopically similar to Kaposi's sarcoma. They proposed further study and characterization of this "model." Subsequent information has shown, however, that the lesions were of canine (dog) origin, essentially negating the validity of this model.

*We know that the Committee understands that details on unfunded grant proposals constitute confidential information. Any release or publication of this information would be a violation of the provisions of the Privacy Act on unfunded grant proposals.

20. One research scenario for finding an animal model involves testing six species of primates with each of the six body tissues and fluids currently thought to be possible carriers for AIDS. The cost for such an effort was presented to the subcommittee as \$200 million based on CDC figures of approximately \$100 per day to raise primates. (See attached testimony.) Please comment on the need for this kind of undertaking and the accuracy of the cost estimates.

A: The need for an animal model is evident and the PHS has given this a high priority. In any setting resources are ultimately limited and experiments must be staggered and prioritized. The idea behind the experiments proposed is reasonable, and although somewhat varied in design and degree, similar experiments are being conducted.

The cost per day to "house and to care for" animals is not \$100 per day as quoted in the testimony attached to your questions. CDC's most recent experience in obtaining maintenance and feeding of animals by contract ranges from \$14 to \$26 per day cost. There are, of course, costs involved in raising primates over a period of time to have them available for such experimentation. However, these costs normally are not included in the direct costs of studies and the development of an animal model is not expected to approach the costs cited in the testimony attached to your questions.

Question 21:

Please describe each of the major protocols that have been used in the treatment of AIDS patients at the NIH Clinical Center, including numbers of patients tested, cost of treatment, results, numbers of patients and funds needed to complete each of the protocols, and FY 1984 projections for NIH activity in this area.

Answer 21:

The major protocols that have been used in the treatment of AIDS patients at the Clinical Center are the following:

1. Phase 1 trial of immune (gamma) interferon in the treatment of AIDS

Seven patients have been entered into this dose escalation trial. Thus far, patients have exhibited some decline in immunologic function. There has been some evidence that the drug may exhibit direct anti-viral and anti-proliferative effects; however, at present these seem to be of minimal clinical significance.

2. Attempted immune reconstitution in the acquired immune deficiency syndrome utilizing a pair of identical twins.

A one-year effort was devoted to reconstituting the immune system of an AIDS patient utilizing the peripheral blood lymphocytes and bone marrow of a healthy heterosexual twin of an AIDS patient. This study was able to effect marked clinical and immunological recovery; however, we were unable to fully reconstitute the diseased twin who died of pneumonia in early August 1983.

3. Phase 1 trial of interleukin 2 (IL-2) in patients with AIDS

Six patients have been entered into this single dose toxicity and dose escalation trial. Thus far, utilizing a purified natural product, dose limiting toxicity has been encountered at a dose of 25,000 units daily. This is presumably due to contaminants in the mixture and not the IL-2 itself. In spite of this, some immunologic improvement has been seen, but no clinical improvement. In all likelihood, additional testing will be necessary involving cloned products as well as natural products before the usefulness of this project can be ascertained.

4. Open trial of plasma exchange in patients with AIDS

This protocol has just been initiated based upon laboratory findings of the presence of a suppressor substance in the plasma of AIDS patients. One patient has been entered into the study, and it is too early to make any statements as to the efficacy of the procedure.

5. Combination Chemotherapy

A regimen of adriamycin, vinblastine, DTIC, and actinomycin D has yielded interesting and clinically significant results. First, it has been learned that AIDS/KS patients can generally tolerate the administration of this cytotoxic regimen without a detectably increased risk of opportunistic infections. To date, observations of ten patients show that 20% of the KS patients have become complete responders and another 20% have partial

responses. Significant responses have been seen in both skin and visceral tumors. The underlying acquired immunodeficiency does not improve clinically, even when significant regression of tumor is seen. Investigators are currently seeking to extend their research in the use of combination chemotherapy; however, they believe that in AIDS with an aggressive form of KS, they would recommend that combination chemotherapy be considered as the therapy of first choice.

6. Phase I trial of total skin electron beam therapy

The rationale for the use of total skin electron beam therapy is based on the view that KS originates in the skin and may be multi-centric even at a time when lesions cannot be widely detected. As a hypothesis of clinical research, extension to the viscera may occur after cutaneous involvement--and could be prevented by completely clearing the skin before the tumor has spread by delivering electrons that deliver ionizing radiation to a limited depth of skin--and have negligible effects on the rest of the body, thereby sparing the patient from a possible further deterioration of whatever immune capacity might still remain. It should be emphasized that these concepts are supported by clinical observations, but they are presented as hypotheses to be tested in a clinical trial now underway in the program. The first portion of this trial was to do a Phase I (dose-seeking) study of electrons delivered by way of a linear accelerator to defined lesions in six patients with Kaposi's Sarcoma. The initial doses started at 50R and there was a controlled increment of dose until 1500R was reached. The latter dose was noted to routinely induce complete regressions of targeted tumors within the electron beam field, without complications. Consequently, 1500R has been selected as the dose for the second portion of the study involving total skin irradiation. Two patients have now entered this portion, which is the actual hypothesis-testing element of the study. It is believed that this is a scientifically innovative study, and much enthusiasm exists about its use in patients with early KS lesions.

7. Phase II trial of human lymphoblastoid interferon

The current lymphoblastoid interferon (high dose) trial is now closed awaiting complete follow-up data on patients already entered. Although there are reports of some successes in treating patients with KS using genetically engineered forms of interferon, evidence of partial responses using the lymphoblastoid form has been seen. However, it is not believed that the preparation and doses of interferon used in this trial have shown a high level of promise. Other forms and other doses of interferon will be explored in the future. There are currently sixteen patients on protocol.

8. Phase I trial of purified interleukin II (TCGF) from Du Pont

Through an excellent process of collaboration between intramural scientists and the private sector, NIH has embarked upon a unique trial using an exceedingly pure preparation of human interleukin II. There are in vitro data suggesting that interleukin II can increase the ability of T cells (and perhaps other host defense cells) to mount immune responses to viruses which are thought to be pathogenic in patients with AIDS. This phase I trial has accrued three patients (as of August 30); we will try to make this a very high priority for patients who have failed chemotherapy. Because purified interleukin II has become available for clinical use only during the past few weeks, it is too early to provide a meaningful summary.

22. a) What system, if any, exists for researchers at CDC, NIH, FDA, or private institutions to obtain, process, or store AIDS related specimens?
- A: In collaboration with private and government researchers, CDC has established an AIDS specimen bank with systematic and random collections of materials. These specimens are systematically catalogued and stored and are shared with government and private researchers.
- b) What methods are used to allocate specimens and to advise researchers of their availability?
- A: Specimen requests are reviewed by senior scientists involved in AIDS at CDC, and a decision is made based on their advice regarding the appropriateness of fulfilling a request. Researchers learn of the availability through several sources:
- 1) published manuscripts describing specimens
 - 2) discussions by phones or at meetings with PHS researchers
 - 3) discussions with other scientists.
- c) Are there plans to set up a government-sponsored specimen bank? If so, supply details on cost, locations, and date of its establishment.
- A: As described, such banks are already established at CDC and NIH.

NIH Response to Question 22:

- A. What system, if any, exists for researchers at CDC, NIH, FDA, or private institutions to obtain, process, or store AIDS related specimens?
- B. What methods are used to allocate specimens and to advise researchers of their availability?
- C. Are there plans to set up a government-sponsored specimen bank? If so, supply details on cost, locations, and date of its establishment.

Answer to 22a:NIAID

In response to the need for AIDS related specimens, a research contract was awarded to the New York Blood Center and Memorial Sloan-Kettering Cancer Center to collect specimens in a prospective fashion from 325 homosexual males. NIAID expects to enter the first specimens into the system in September-October, 1983. Specimens from five additional NIAID contracts will be collected as a part of studies of the natural history of AIDS; these specimens will also be deposited in the same NIAID repository. The cost of expanding this repository to include the storage and cataloging of AIDS-related specimens has been approximately \$70,000 in FY'83 and is anticipated to be approximately \$200,000 in FY'84.

NCI

No one system exists within the NCI for the collection, processing or storage of AIDS related specimens for the entirety of the research community. Those investigators now supported under the cooperative agreement mechanism meet with NCI and NIAID staff as a continuing "working group". One major function of this group is to exchange information on the availability of specimens and epidemiologic information, and facilitate their exchange. Such an arrangement is also specified in the currently advertised RFA and will attempt to serve the same purpose.

Dr. Robert Gallo at the NCI has an extensive storage system at the Frederick Cancer Research Facility. Samples are available to all NCI personnel.

Answer 22b:NIAID

Methods to allocate specimens, now being developed, will be based on scientific review of projects in which their use is proposed. Availability of specimens will be advised through the NIAID AIDS Memorandum.

NCI

Biological material and epidemiologic information from high risk patients collected during studies performed under a recently awarded contract, will be catalogued and stored in a single repository. The contents of the repository will be advertised and made available to all qualified investigators.

Answer to 22c:NIAID

The NIAID specimen repository represents a government-sponsored specimen bank. The cost of expanding this repository to include the storage and cataloging of AIDS-related specimens has been approximately \$70,000 in FY'83 and is anticipated to be approximately \$200,000 in FY'84.

NHLBI

The NHLBI REP entitled, "Association of Blood Product Use with Immune Function Changes: Relation to Acquired Immunodeficiency Syndrome (AIDS) A Prospective Study," requires that a serum and cell repository be established for use in future scientific studies. This repository will catalog and store frozen specimens from all patients and controls participating in the study. This resource will be government property.

NCI

The NCI is not planning on setting up an independent bank of material or information. The Institute will continue to cooperate with NIAID in the banking activity described above, and make any material to which it has access available to investigators as needed.

23. Specifically define the term passive surveillance as used by CDC.
- A: Surveillance is the collection of information about a disease problem. Passive surveillance relies on reports being submitted voluntarily by physicians to State and local health departments and then being forwarded to CDC.
24. Specifically define the term active surveillance as used by CDC.
- A: Active surveillance implies active attempts to identify cases and enhance reporting of the disease under investigation. It may range from intensive efforts at educating and encouraging physicians and health departments to cooperate with reporting; to the personnel-intensive approaches of reviewing death certificates, tumor registries, hospital discharge summaries, or pathology reports; setting up specific reporting procedures through key hospitals; and directly contacting physicians likely to see cases.

25. For FY'81, FY'82, and FY'83, please specify to what extent CDC surveillance of AIDS was active or passive and why. Please provide supporting documentation.

A: During the summer of 1981, an active surveillance system was used to identify cases retrospectively by reviewing selected tumor registries and directly contacting selected physicians in 18 major metropolitan areas. During the remainder of 1981 and through 1982, local health departments in New York, San Francisco, and Los Angeles conducted partially active surveillance, although most surveillance efforts at CDC were passive, relying on direct telephone reporting from physicians to CDC. At that time, the numbers of cases were relatively small and mostly concentrated in the large cities already conducting extensive surveillance. By late 1982 it became apparent that a more active surveillance program was necessary and a cooperative agreement was awarded to the New York City Department of Health to establish an active surveillance system; this was accomplished during early 1983 and is currently operating successfully. Simultaneously, health departments around the country were provided with the new case report form, the case definition, and information about surveillance for AIDS. We have worked closely with State and local health departments throughout this year to help them establish effective surveillance programs, many of which are active.

CDC, in one sense, has continuously conducted active surveillance through the intensive followup of requests for pentamidine, an investigational drug for pneumocystis pneumonia available only by request from CDC. Approximately 20 percent of cases of AIDS come from such followup.

26. a. Is it true that CDC's surveillance figures undercount the number of AIDS cases? If so, to what extent?

A: The basis of virtually all disease surveillance systems is the willingness of physicians seeing the patients to cooperate with reporting, and then for the local and State health officials to process and forward the reports to CDC. With AIDS, some physicians have not wanted to cooperate with reporting for a variety of reasons; we have been working with State and local health officials to try to resolve these problems. In addition, AIDS is a new disease without an identified cause; even today, two years after the recognition of the problem, the full clinical and immunologic parameters of the disease are not well understood and no laboratory test is available as a standard for whether or not a patient has AIDS. The surveillance definition of AIDS developed by CDC and used nationally is conservative and strictly defined; it is, in other words, highly specific but not highly sensitive, and may result in undercounting of cases. The converse, a relatively non-specific definition that would result in cases that are not AIDS meeting the definition and being counted, would over-estimate the problem and lead to misinterpretation of it. The degree of under-reporting of AIDS varies from area to area, but our best estimate from discussions with State and local health officials is that under-reporting is not a major problem today in most areas. The current surveillance system, even though it could result in some undercounting of cases, is stable, broadly-based, and provides reliable current data for estimating the true trends and distribution of AIDS meeting the case definition. In doing so, it satisfies general criteria for a good surveillance system. Conversely, a system that concentrated primarily on 100% reporting (i.e., a case registry) would be unwieldy and unable to provide timely information about trends; the model for this type of system is a cancer registry for which full reporting is not expected for a year or more after cases have been diagnosed.

26. b. Please specify what steps could be taken to improve accuracy of the surveillance system.

A: Establishing additional cooperative agreements with State and local health departments, as is currently being done, will provide the health departments with resources at the local level to conduct more thorough and active surveillance. In addition, we are simplifying the case report form to make it easier for physicians to complete and submit, and we will be working with selected areas to establish surveillance for the AIDS-Related Complex (sometimes called chronic lymphadenopathy or mild or early AIDS).

27. CDC distributed a national case report form for surveillance to all State and territorial epidemiologists on March 16, 1983.

a. Was this the first time that CDC disseminated to all States a standard mechanism for uniform national reporting of AIDS? If not, please provide a description of the uniform system that CDC used prior to March, 1983.

A: Before March 1983 a provisional AIDS Case Report Form had been developed and was in use at CDC. This had undergone numerous revisions necessitated by our rapidly changing knowledge about the complex new disease. During this period, information about the form had not been disseminated widely to State health departments, although detailed information had been shared with public health personnel in New York City, San Francisco, Los Angeles, and selected other large cities or States that had reported more than a few cases of AIDS. Those cities that had implemented surveillance systems either had developed their own case report form that was very similar to CDC's Case Report Form or had obtained copies of the provisional CDC case report form and had reproduced it for their own use. Most reports about cases of AIDS occurring in areas outside of those with concentrated activity were telephoned to CDC and the data entered directly onto the CDC provisional case report form.

27. b. What effect has the new form had on CDC's ability to accurately track this epidemic?

A: The AIDS case report form developed by CDC has provided a means for uniform reporting of data about AIDS and has provided CDC with a means to directly involve State health departments across the country in surveillance for this problem. To the extent that State health departments are involved in monitoring and reporting cases in a cooperative effort with CDC, our ability to track the problem nationally has been significantly strengthened.

28. Documents provided to the subcommittee by CDC indicate that uniform guidelines for surveillance have not yet been sent out to the States.

a. When will these guidelines be distributed?

A: The surveillance recommendations should be distributed by the end of September 1983.

b. For what reasons has CDC not issued guidelines sooner?

A: Through the end of December 1982 there were less than 1,000 AIDS cases reported nationwide. Over eighty percent of cases had been reported from four States: New York, California, Florida, and New Jersey. CDC has been working closely with these areas regarding surveillance procedures. As the syndrome became more widespread, it was felt that written surveillance recommendations could better reach the increasing number of affected areas. Personnel from the AIDS Activity have been working with the surveillance committee of the Conference of State and Territorial Epidemiologists this summer to write a set of useful recommendations.

29. When did CDC and the medical community recognize the possibility of a prodromal state of AIDS (lymphadenopathy, etc.)?

A: As attention was focused during late 1981 on a variety of medical conditions affecting male homosexuals, cases of persistent, generalized lymphadenopathy not attributable to an identified cause began to be reported to CDC by physicians in several major metropolitan areas in the U.S. Subsequently, in February and March 1982, CDC collaborated with other medical investigators in a special study of this problem; results were published in the May 21, 1982, issue of the MMWR (copy attached). These anecdotal reports and studies suggested there may be an association between lymphadenopathy and AIDS, but this was not confirmed. CDC subsequently participated in a large retrospective epidemiologic study of lymphadenopathy in New York City that strengthened this assumption.

29. a. When did CDC officials first propose that these cases be monitored? Please provide all documentation.

A: Discussions about establishing a formal surveillance program for the condition now being called "AIDS-Related Complex" (formerly called chronic generalized lymphadenopathy and other names) have occurred a number of times during late 1982 and the first half of 1983. A number of investigators in New York and San Francisco have been studying the problem independently from a clinical perspective, but there was little support either by clinicians or local health department personnel to establish surveillance for the poorly defined and highly variable complex of signs, symptoms, and abnormal laboratory tests that would need to be monitored to provide meaningful data about the condition. Based on these responses, it was decided not to pursue the issue further at that time; we are currently reconsidering the issue.

29. b. When will CDC institute a national surveillance system for lymphadenopathy and other "pre-AIDS" conditions?

A: CDC is obligating \$400,000 by the end of fiscal year 1983 for surveillance of AIDS through cooperative agreements awarded on a competitive basis with selected State and local health departments. One criterion that could be used to fulfill requirements for being selected is documentation of cases of AIDS-Related Complex (ARC). The RFP has clearly stated that support will be available for those health departments that wish to conduct surveillance for AIDS-Related Complex as part of their total proposal. During FY 1984 we would like to work intensively with selected States or major metropolitan areas to assist them in establishing model surveillance programs for AIDS-Related Complex. As these become established and experience is gained, an informed decision can be made about establishing a national surveillance program for AIDS-Related Complex. At this time, because of the nonspecific nature of ARC symptoms, it is likely that meaningful national surveillance data would require the availability of a specific diagnostic test for AIDS.

30. What action has CDC taken to clarify, disseminate, and evaluate the CDC AIDS case definition. Please supply supporting documentation.

A: CDC's definition of AIDS is intended only to provide a uniform definition for cases reported through the surveillance system; it is not intended to restrict clinical understanding of the condition as further information continues to be obtained. The definition was developed with the assistance of clinicians and health department personnel in New York City, San Francisco, and Los Angeles and after review of the medical literature to document the validity of the criteria selected to indicate loss of cellular immune function. The definition has been well accepted by personnel at health departments throughout the country familiar with surveillance systems, and we believe that the definition continues to be useful and reliable. With the exception of the conditions covered by the AIDS-Related Complex, the surveillance definition parallels closely the clinical problems affecting most patients believed to have AIDS. Only with the availability of a specific and sensitive laboratory test will we be able to modify the case definition to allow inclusion of patients manifesting any of the wide range of clinical conditions probably associated with this disease. The AIDS case definition has been disseminated widely in direct mailings to State and local health departments, in publications in the MMWR and medical literature, and in numerous lectures, seminars and presentations made to medical groups throughout the country.

Attached:*

Article from the New England Journal of Medicine, January, 1982

Article from MMWR, September, 1982

Letter to State Epidemiologists, March, 1983.

Editorial from New England Journal of Medicine, September 1983

* Documents available in Subcommittee files

31. a. Please explain how CDC's cooperative agreement with New York City improves AIDS surveillance and/or epidemiological study.

A: The cooperative agreement with New York City has allowed hiring of additional staff persons by the City Health Department to contact the physicians and hospitals directly, to complete and review case report forms, and to conduct all of the wide range of activities included in their active surveillance program. In the months following implementation of the active surveillance program in New York City, the numbers of cases of AIDS detected per month per hospital more than doubled; many of these cases had been diagnosed months previously but had never been reported to the health department.

31. b. Please specify when CDC will grant cooperative agreements to other affected cities and include cost of each agreement.

A: CDC plans to award cooperative agreements to 4-8 cities and States before the end of the 1983 fiscal year. Individual awards are expected to range from \$50,000 to \$100,000.

32. a. Describe CDC's plans for assigning additional health officers to affected cities in FY'84. Specify targeted cities, timetable for assignments, and costs.
- A: Since the Epidemic Intelligence Service (EIS) began in 1951, EIS officers have assisted various State, local and other health agencies in improving the nation's health. When assigned to the field, EIS officers function at the direction of the local health official. Some health officials have chosen to have these EIS officers work part or full time on the AIDS problem depending on the perceived need. CDC will continue to assign EIS officers to be used at the discretion of the State, local, or other health officials.
32. b. Is CDC aware of any additional cities that are in need of assistance for AIDS surveillance work?
- A: CDC is aware of additional cities that are in need of assistance for AIDS surveillance work. This awareness is the basis for proposed surveillance cooperative agreements to be awarded to cities and States before the end of FY 1983.
32. c. Why were public health advisors first sent to Miami, San Francisco, and Los Angeles in June of 1983 to work specifically on AIDS?
- A: Public Health Advisors (PHA) were sent to Miami, San Francisco and Los Angeles in June 1983 because these three major metropolitan areas, next to New York City, had the largest number of reported AIDS cases in the U.S. New York, the city with the largest number of reported cases, has had PHA assistance over the past 2 years.
32. d. What effect, if any, has the absence of full time CDC public health advisors had in these cities during the past two years?
- A: Until the past 6-12 months, when the increase in AIDS cases became so great in these cities, the absence of PHA's probably had only minor effects. More recently, with the increased number of cases, the absence of PHA's has probably slowed the development and implementation of active surveillance programs.

33. CDC completed a national case-control study of homosexual AIDS patients in the fall of 1981.

a. To what journals was this study submitted for publication?

A: The national case-control study of AIDS in homosexual men was submitted to and published in the August 1983 issue of Annals of Internal Medicine.

b. For what reasons has this study not been scheduled for publication until this month?

A: This study was not published until August 1983 because of the complex nature of the data analysis, including newly developed statistical approaches and the unexpected changes in statistical staff, and delays inherent in publication of studies in peer-reviewed medical journals.

In addition, the study completed in 1981 was to be published jointly with related laboratory investigations which were conducted after the interviews and completed several months later.

The results of the case control study were, however, presented at major scientific meetings in April and October, 1982, well in advance of the publication date. The press also reported the results of this study.

c. What follow-up case control studies has CDC undertaken to verify or refine this early data? Please supply documentation.

A: A follow-up case control study of AIDS among homosexual men residing outside New York City and California was begun in April 1982. Data analysis from this study is complete and a manuscript is in preparation. An additional followup will be provided in the cohort study of homosexual men in San Francisco. (See 33c, 2 attachments: Acquired Immune Deficiency Syndrome in a Cohort of Homosexual Male Clinic Patients; and Case Control Study--Interview Form Project No. 2.) *

*Documents available in Subcommittee files

34. CDC reported Haitians as an AIDS risk group in July 1982.

a. Has CDC completed either a case control study for this population or a protocol for a major epidemiological study of Haitians?

A: The CDC, in collaboration with investigators at the University of Miami School of Medicine and the Downstate Medical Center of the State University of New York, has prepared a draft protocol for an epidemiologic study of AIDS among Haitians.

b. If so, please provide a copy of the study or protocol, dates of implementation and completion, and cost of study. If not, explain why.

A: This study will begin in the fall of 1983 and continue for a 1-year period. The estimated cost is \$200,000. (See 34b. attachment: Identifying Risk Factors for Acquiring AIDS Among Haitians Residing in the U.S.) *

* Document available in Subcommittee files

35. Since at least September of 1981, various researchers have recommended that funds be made available for long term prospective studies of gay men in order to define AIDS risk factors, track the development of the disease, etc. CDC is now finalizing a cooperative agreement with San Francisco for this type of study.

a. For what reasons has CDC delayed the implementation of such a study?

A: CDC epidemiologists felt that a prospective study of homosexual men would be most useful in a setting where a defined cohort of men was found to be at increased risk for AIDS. CDC and the San Francisco Health Department will begin a prospective study of this cohort in October 1983.

b. In which other cities are similar studies planned? When will they begin?

A: Any decision to begin additional prospective studies will depend on an analysis of the preliminary findings from the San Francisco Study.

36. The PHS June 15, 1983, report to Congress states that "epidemiological studies and investigations have been completed of cases occurring . . . among heterosexuals and their frequent sex partners, children with AIDS-like illnesses, prisoners, IV drug users, and hemophiliacs."

a. Please document the scope of each of these studies or investigations, the size of the populations studied, the date of completion of each study, cost of each study, and published findings for each undertaking.

A: Studies relating to IV drug users and their sexual partners are addressed in question 37. Regarding the other groups described:

(1) Heterosexuals and their frequent sexual partners

Between October 1981 and June 1982, the CDC conducted an interview study of 33 heterosexual AIDS patients. Heterosexual patients continue to be interviewed as part of ongoing studies of patients not reported to belong to known risk groups. The CDC collaborated with investigators at Montefiore Hospital, Bronx, New York in studies of the sex partners of heterosexual AIDS patients. (See 36a. attachment: Heterosexual and Homosexual Cases of AIDS.) *

(2) Children

The CDC became aware of the occurrence of AIDS-like illnesses in children in the fall of 1982. At that time, CDC investigators traveled to New York City, Newark, and San Francisco to review clinical and laboratory records on approximately 20 such children. Subsequently, attempts were made to locate, examine and test the parents of these children. As new cases are reported, these efforts are repeated. (See 36a. attachment: MMWR, December 17, 1982.) *

(3) Prisoners

The CDC became aware of the occurrence of AIDS among prisoners in the spring of 1982. At that time, CDC physicians based in Atlanta assisted a CDC EIS officer assigned to the New York State Health Department in interviewing three prisoners with AIDS in New York State correctional facilities. This investigation was continued by the EIS officer; thus far information on risk factors has been obtained from 44 prison cases. (See 36a. attachment: MMWR, January 7, 1983 and Acquired Immunodeficiency in Male Prisoners.) *

(4) Hemophiliacs

In October 1982, the CDC in collaboration with the National Hemophilia Foundation, began a survey to determine the prevalence of AIDS and AIDS-related illnesses among hemophiliacs. Data collection was completed by March 1983, at which time information was available on approximately 7,600 patients with hemophilia. (See 36a. attachment: MMWR, July 16, 1982 and Survey for AIDS Among Patients Attending Hemophilia Treatment Centers.) *

Between November and December 1982, the CDC conducted a study of the prevalence of immunologic abnormalities in hemophiliacs from Georgia. Forty-seven hemophiliacs and 94 control patients were studied. A similar study is now underway in New York City; thus far, 48 hemophiliacs have been studied. (See 36a. attachment: MMWR, December 10, 1982 and Hemophilia Acquired Immunodeficiency Epidemic Survey--States of Georgia and North Carolina.) *

- 36b. What follow-up studies, if any, are necessary, to identify AIDS risk factors for each of these groups?
- c. Please indicate if any of these follow-up studies are being conducted. Please supply all documentation.
- d. Indicate if any of these studies are planned for FY'84.

Answers to b, c and d:

The need for follow-up studies in these groups is currently being assessed. Such studies are being considered along with other AIDS projects which would be funded under the FY 1984 budget.

* Documents available in Subcommittee files

AIDS Activity - Epidemiologic Studies

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	<u>Date Started</u>	<u>Date Completed*</u>	<u>Principal Investigator</u>	<u>Written Protocol</u>	<u>Questionnaire</u>	<u>Number Participants</u>	<u>Status</u>
1. Preliminary interviews of homosexual cases	7/81	8/81	Jaffe	No	Yes	35	Data used to design case-control study
2. Survey of nitrite inhalant use	8/81	9/81	Darrow	No	Yes	420	Data included in published report (NEJM 306:251, 1982)
3. Case-control study in homosexual men	10/81	12/81	Jaffe	Yes	Yes	212	Published (Ann Intern Med 99:143, 1983)
4. Investigation of heterosexual AIDS patients	10/81	6/82	Guinan	No	Yes	35	Submitted for publication
5. Therapy for Pneumocystis pneumonia	2/82	9/82	Haverkos	Yes	Yes	338	Manuscript in preparation
6. Cases with no known risks	3/82	ongoing	Castro	No	Yes	120	Manuscript in preparation (M. Chamberland)
7. Case-control study of homosexual cases outside of NYC and Calif.	4/82	7/82	Haverkos	No	Yes	46	Manuscript in preparation
8. Investigation of clusters of AIDS cases	4/82	10/82	Auerbach	No	Yes	76	Submitted for publication
9. Follow-up of control patients from NYC	6/82	9/82	Thomas	Yes	Yes	71	Manuscript in preparation
10. Survey of AIDS in homosexuals	10/82	3/83	Lawrence	Yes	Yes	7600	Manuscript in preparation
11. Transfusion-related cases	12/82	ongoing	Haverkos	Yes	Yes	25	Manuscript in preparation
12. San Francisco cohort study	10/83	—	Darrow	Yes	Yes	830	Awaiting protocol approval
13. Haitian case-control	10/83	—	Johnson	Yes	Yes	350	Protocol in preparation

*In studies where interviews were done, date refers to completion of interviews

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- 37a. When did CDC first identify intravenous drug users as a risk group for AIDS?
- A: The CDC received its first report of an IV drug user with AIDS on August 31, 1981. It was not entirely clear that IV drug users were a "risk group" until early 1982.
- b. Has either CDC or ADAMHA conducted an epidemiological study of this risk group? If so, please provide a copy for the record.
- A: As part of the previously noted CDC study of heterosexual AIDS patients, 22 IV drug users were interviewed. In addition, the CDC has collaborated with investigators at Montefiore Hospital, Bronx, New York, in several studies of AIDS among IV drug users. In one study, sexual partners of IV drug users with AIDS were interviewed and examined for evidence of disease. In another study, the role of needle-sharing as a risk factor was examined. Specifically, the collaboration involved the assistance of a CDC research sociologist and a federal public health advisor, assigned to the New York City Health Department, in designing and conducting patient interviews. (See 37a. attachments: MMWR, January 7, 1983; New England Journal of Medicine Article, May 19, 1983; and Abstracts of the 1983 ICAAC-Needle Sharing.)*
- c. Please describe any additional studies on IV drug users and AIDS planned for FY'84 and provide supporting documentation.
- A: AIDS research projects to be funded by the FY 1984 budget are now under consideration. Additional studies of AIDS among IV drug abusers are being considered among these projects.
- d. Provide budget information on all completed and planned studies mentioned above.
- A: Intramural epidemiologic investigations of these types are not generally conducted as individually budgeted studies, but involve the resources of CDC as necessary.

*Documents available in Subcommittee files

Question 37b

Has ADAMHA conducted an epidemiological study of this risk group (i.v. drug users)?

Answer

ADAMHA has not conducted an epidemiological study of AIDS in i.v. drug users. Such a study is planned in FY 1984 and as part of this effort, a technical meeting was held on July 25 to develop a standardized survey questionnaire.

Question 37c

Please describe any additional studies on i.v. drug users and AIDS planned for FY'84 and provide supporting documentation.

Answer

Our top priority will be studies of potential predisposition to AIDS due to drug-induced alteration of the immune response. Laboratory studies have indicated that some abused drugs impair immune defenses and may interfere with a normal response to viral challenge. While it appears that AIDS is caused by a microbiological organism, further study is required to determine whether AIDS itself is an "opportunistic infection" attacking predominantly those with an altered immune system.

A. Epidemiological studies:

1. Case-control studies of intravenous drug abusers--to gather basic information about the immune status of intravenous drug abusers and to try to develop techniques for predicting the development of AIDS in this group; to describe the character of the disease in this group and its potential relationship to such life-style factors as nutrition, sanitary conditions, and overall socio-economic conditions.
2. Studies of children of intravenous drug abusers--there have been reports of AIDS-like disease in the children of some intravenous drug abusers. Further study of this is warranted to determine if these are true AIDS cases. If so, then it is important to discover whether the mode of transmission is directly related to the immediate and intimate presence of an intravenous drug abuser or other life-style factor indicated above.
3. Studies of potential synergy between homosexual life-style and intravenous drug abuse in predisposing to AIDS.

B. Laboratory studies:

Effects of abused drugs on the immune system as well as other potentially relevant organ systems, i.e., hepatic, hemopoietic, central nervous, etc.

- 38a. Please list studies underway or planned for other potentially affected groups such as prisoners, health care workers, servicemen, prostitutes, sexual partners of AIDS patients, and blood recipients.
- b. Provide specifics regarding the scope of each study, investigator, cost of study, projected startup and completion dates, and size of population studied.
- A: For the potentially affected populations listed, the only study not already mentioned in responses to preceding questions but underway is a study of health care workers who are exposed to the blood of AIDS patients through needle-stick injuries. This study is being coordinated through the Hospital Infections Program, CDC. Because there is no scientific evidence that prostitutes and servicemen are specifically at high risk for AIDS, studies of these population groups have been accorded lower priority. (See 38a. attachment: Prospective Evaluation of Hospital Personnel. Also, see response to Question 36.) *
- c. Does PHS have a plan or set of guidelines that are used to set priorities for studying these or other groups affected by AIDS? If so, please supply relevant documentation.
- A: Investigative priorities have been based upon surveillance data and epidemiologic evidence that a new group may appear to be at risk for AIDS. Accordingly, investigations have been conducted of AIDS in homosexuals, intravenous drug abusers, hemophiliacs, children, heterosexually exposed and transfusion-related cases. Recent epidemiologic investigations have concerned 4 health workers.

*Documents available in Subcommittee files

NIH Response to Question 38:

- A. Please list studies underway or planned for other potentially affected groups such as prisoners, health care workers, servicemen, prostitutes, sexual partners of AIDS patients, and blood recipients.
- B. Provide specifics regarding the scope of each study, investigator, cost of study, projected startup and completion dates, and size of population studied.
- C. Does PHS have a plan or set of guidelines that are used to set priorities for studying these or other groups affected by AIDS? If so, please supply relevant documentation.

Answer 38A and B:

NIAID

An NIAID grantee, Dr. Arye Rubinstein (Yeshiva University, New York, U01-AI-20671) as one part of his large cooperative agreement, is studying health care workers exposed to needle sticks at Montefiore Hospital in the Bronx. This open ended project involves epidemiological, clinical, immunological, and virological components.

NIAID staff plans to begin a study of health care workers at the NIH Clinical Center in early FY '84. The study will include workers exposed to AIDS materials and AIDS patients. The workers will be followed every six months with blood tests and medical questionnaires, and their serum will be stored. This is an open-ended study and is expected to cost more than \$40,000.

NIAID presently has under review a few investigator initiated research proposals which include work on special groups. These are for potential funding in FY '84 but the final disposition of these applications is not known at this time.

NHLBI

The NHLBI RFP on association of blood product use with immune function changes will support studies to examine the natural history of alterations in immune function and other physiologic functions in heavily transfused patients.

The objective of this RFP are:

- o Characterize alterations in immune function and other physiologic functions in heavily transfused patients, specifically those repeatedly exposed to large doses of alloantigens, and determine the possible relation of these alterations to AIDS.

- o Determine the sequence of physiologic alterations over a period of time in heavily transfused patients, especially in those developing certain signs and symptoms such as the immunoregulatory defects invariably associated with AIDS.
- o Establish and maintain a serum and cell repository from the study cohort for use in future scientific studies.

It is estimated that, overall, 4,000 individuals should be included in this study so that causal linkages may be examined. The number of individuals in each study group should be sufficient to provide data that can be evaluated statistically.

The proposed starting date for this project is May, 1984, with a total cost of \$24,600,000 for a period of 6 years.

NCI

Epidemiological Studies

The intramural epidemiology research program at NCI has been quite active over the past two years in the epidemiologic investigation of the AIDS problem. The following are the studies under way or planned for the next two years.

1. Population Surveys of High-Risk Groups. Over the past two years the Environmental Epidemiology Branch (EEB) has engaged in immunoepidemiologic surveys of gay populations in New York City, Washington, D.C., and two cities in Denmark. In addition, an extensive immuno-epidemiologic investigation of hemophilic patients also has been conducted. Over the next two years, the NCI intends to continue to monitor the clinical and laboratory status of the populations already surveyed, in order to identify individuals who convert from relatively normal to some index of abnormality, and the Institute will then attempt to relate the risk of such a conversion to a variety of risk factors and biologic agents currently under suspicion. In addition, two new populations will be similarly surveyed; Asian gay men living in Hawaii, and, patients who have undergone hemodialysis in close proximity to a man with AIDS will be evaluated with clinical and immunologic parameters to evaluate the potential spread and/or isolation of aids by hemodialysis.
2. Case Control Studies of AIDS-Related Diseases. NCI Staff currently are in the planning and protocol development phase for a variety of case-control studies of both "CDC-definition" AIDS cases and lymphadenopathy cases that are developing in various high-risk groups. The specific high-risk groups for which such studies are planned include gays, IV drug users, and hemophiliacs.
3. Studies of Contacts of AIDS Patients. NCI Staff also are in the protocol development phase for a study which will attempt to evaluate a variety of laboratory immunologic measures in household and sexual contacts of heterosexual IV-drug using AIDS patients and in a sample of similar

contacts of normal IV-drug users. This will be an attempt to assess directly the potential for heterosexual transmission of an "AIDS agent".

4. National Cohort Study of Homosexual Men. NCI Staff are in the early planning stages of a study in which the Institute hopes to obtain lifestyle, clinical, and demographic information and serum from up to 10,000 homosexual men in cities where AIDS is common and where AIDS is uncommon.
5. While not specifically targeted towards the AIDS question, a number of studies developed by NCI epidemiologists have been designed to assess the potential human carcinogenicity of the suspect virus HTLV.

Immunological Studies

The Intramural Immunology Program at the NCI also has been active in the investigation of the AIDS problem. The following are the studies under way or planned for the next two years.

Studies Underway: Homosexual men without AIDS, including sexual partners of AIDS patients and laboratory workers possibly exposed to AIDS.

Studies Planned: Prisoners (mainly drug abusers) and blood recipients (thalassemia patients).

The NCI Extramural Immunology Program also plans to evaluate population groups at risk for AIDS. These studies are described in the answer to question 38b as are several other extramural studies.

Answer 38b:

NCI

The following are estimates of the startup and completion dates, costs, and population sizes for the studies outlined above in the answer from question 38a.

Epidemiological studies

1. The populations of gays surveyed in New York, Washington, and Denmark total approximately 350. The hemophiliacs surveyed in Hershey, Pennsylvania, total 49. To date, the estimated cost of these studies has been \$300,000, and we project over the course of the next two years that the cost will be approximately \$800,000. The new high-risk population survey to be done in Hawaiian Oriental gays will involve approximately 200 men. Contingent on appropriate peer-review and approval, this study should commence in about six months and the first results should be available approximately one year later. The estimated cost for the study is \$300,000. The new survey of dialysis patients, about 50 in number, should commence in about one month, and the first results should be available approximately one year later. The estimated cost for the study is \$100,000.

2. The case-control investigations of various potential manifestations of the AIDS syndrome are all currently under a protocol development. Contingent upon peer-review and the development of appropriate collaborative ties, these investigations should also commence in approximately six months and we would anticipate results approximately 18 months to two years after startup. While precise estimates of the numbers to be involved have not yet been determined, the following are reasonable approximations - 100 "CDC-definition" AIDS cases and approximately 100 lymphadenopathy cases. It is our intent to choose approximately two controls for each of these cases for a total sample size for all case control studies in the high-risk groups of approximately 600. The current estimates of the costs of these investigations range between \$300,000 and \$600,000.
3. The investigation of the household and sexual contact of heterosexual IV-drug using cases will be conducted simultaneously with the case-control studies among this high-risk group outlined above. The number of case and control sexual contacts currently anticipated are approximately 200. The total cost of this study is currently estimated at \$300,000.
4. The cohort study to bank serum and information on gay men in several geographic areas will total 5,000 to 10,000 subjects. The study may be initiated in about six months, with each subject being re-evaluated again after 1-2 years. Independent of any laboratory testing, the current estimate for this study is \$300,000.
5. There is currently a multi-million dollar program of HTLV research currently being conducted by the NCI. While it would be inappropriate to target any particular populations or dollar amount from these studies to the AIDS effort, clearly relevant information concerning this potential risk factor for AIDS will be emerging from these studies over the course of the next three years.

Immunological Studies

Intramural immunological studies are estimated to cost \$60,000-\$80,000 per year. The specifics are given below for the groups listed above:

Studies underway: Homosexual men and laboratory workers - This is a prospective study that has been in progress for 11 months and is planned for a total of 3 years. It is planned that donors who exhibit interesting immunological profiles (e.g., immune suppression) will be investigated more intensively and will be carefully followed to determine if any develops AIDS. Personnel from this laboratory who work with these donors are also tested for these parameters as controls and as possible "at risk" individuals.

Studies planned: Prisoners and blood recipients - Prisoners (many of whom are drug abusers) and thalassemia patients (who receive multiple blood transfusions) also will be studied using the same immunological parameters being used in the homosexual men and laboratory worker study. It is hoped that these studies can begin before January 1984. It is also planned that healthy aged donors (not known to be at risk for AIDS) will be tested for some of the same immunological parameters, since older individuals may be somewhat

immune-compromised and more susceptible to AIDS than younger healthy individuals.

The following two extramural immunological studies plan to evaluate population groups at risk for AIDS:

1. - David Purtilo - U. of Nebraska

"Immunopathology of X-Linked Lymphoproliferative Syndrome"

This grant will include immunopathologic studies of prostitutes. The size of the study population has not yet been determined.

2. - Stanley Schwartz - U. of Michigan

"Suppressor Cells in Cancer and Immunodeficiencies"

This study will look for immunologic parameters and immunosuppressor factors in the peripheral blood of prisoners in the Michigan state prison system. The size of the population has not yet been determined.

Other Extramural Studies on Potentially Affected Groups

Underway

1. Principal Investigator: Dr. M. Essex
 Institution: Harvard School of Public Health
 Total Cost: \$140,000
 Project Period: 09/01/82 - 08/31/84
 Population Size: 196
 Subject: HTLV Sero-epidemiology and possible relationship to AIDS
 Affected Population: Blood recipients
2. Principal Investigator: Dr. P. Volberding
 Institution: University of California at San Francisco
 Total Cost: \$126,000
 Project Period: 05/01/83 - 04/30/86
 Population Size: 100
 Subject: Determination of AIDS risk factors and immunological parameters which may be significant for early detection of AIDS
 Affected Population: Sexual partners of AIDS patients

Planned

Of the 58 grant applications received to the RFA "Infectious Etiology of AIDS and Kaposi's sarcoma; 19 are related to the specific risk-groups listed in questions 38 a and b. It is anticipated that a number of these will be fundable.

39. Dr. Brandt testified that six percent of AIDS patients who have not been placed in any risk group are the subject of "intensive investigation."

a. Please explain what intensive investigation entails.

A: Whenever the CDC receives a report of an AIDS patient who does not appear to belong to a "risk group", a CDC epidemiologist contacts the local health department. If the health department is unaware of risk factors for the case, the primary physician involved in the care of the patient is contacted. If the primary physician cannot identify a risk factor, and if the patient is still alive, permission to interview the patient is requested. If such permission is given, a representative of the health department or the CDC interviews the patient, using a standard questionnaire developed by the CDC. If indicated, specimens for laboratory testing are also obtained. In special circumstances, e.g., the occurrence of AIDS in a health care worker, friends or relatives of a deceased patient may also be interviewed.

b. How does this differ from investigations done for other affected populations?

A: For other affected populations, detailed interviews are not done unless the patient is part of an ongoing study.

c. As of August 2, CDC has reported 113 cases that have not been placed in any of the identified risk groups, although Dr. Brandt testified that information has been obtained for only 61 of these patients. Please explain why the PHS has no or insufficient information on the remaining 52 cases.

--What "information" does this refer to?

--How can CDC determine risk group without such "information"?

--What caused the delay in receiving information on the 52 remaining cases?

A: The "information" sought from patients not placed in "risk groups" concerns sexual orientation, history of drug abuse, contact with members of "risk groups," and transfusion history. Although a transfusion history can often be obtained from the attending physician, the other "information" can usually be obtained only from the patient. If a patient declines an interview or has died before the case is reported, this sensitive information usually cannot be obtained. For these reasons, information concerning risk factors could not be fully developed in 52 cases.

40. Have guidelines or other information materials been developed for, and distributed to, groups such as health care workers, paramedics, correctional personnel, and morticians (in addition to the November 1982 MMWR)?

A: Yes.

a. If so, please specify when this information became available and provide a copy of the written materials for the record.

A: Additional CDC guidelines for prevention of AIDS transmission to and from hospital personnel were published in the July/August 1983 issue of Infection Control. Precautions for dental-care personnel, pathologists and morticians were published in the September 2, 1983 issue of MMWR. (See 40. attachments: MMWR, September 2, 1983 and Infection Control.) *

*Documents available in Subcommittee's files

41. Between August 1981 and May 1982 when no MMWR reports were issued on AIDS, what means did the Public Health Service use to systematically disseminate information about AIDS to the medical community, public health officials, and affected communities? Please provide all documentation.
- A: Between August 1981 and May 1982 the PHS disseminated important information on AIDS to medical and public health professionals and, through them, to the affected communities. During that time period, the national case control study mentioned at the end of the August 28, 1981 MMWR article was carried out. PHS physicians consulted with outside clinicians, cared for patients, and prepared professional reports. The very first articles published in the medical literature on AIDS appeared in the New England Journal of Medicine (NEJM) of December 10, 1981. PHS physicians wrote one of these often-cited articles. The CDC Task Force on Kaposi's Sarcoma and Opportunistic Infections prepared a Special Report on the Epidemiologic Aspects of the Current Outbreak of Kaposi's Sarcoma and Opportunistic Infections. This was published in the NEJM January 28, 1982. These publications established what was later to be termed AIDS as an important clinical entity and they served to notify virtually the entire medical community of the appearance of the outbreak and the salient presentation and pathophysiology of the syndrome.

PHS physicians consulted with Dr. Bernard Liataud and his colleagues in Port-au-Prince, Haiti in late 1981 and early 1982. That group described the first cases of AIDS among Haitians. They presented their findings in Port-au-Prince in April 1982 and acknowledged the help of PHS physicians in carrying out their investigations.

CDC has communicated openly with the Gay Men's Health Crisis (GMHC) and other organizations. The first GMHC newsletter published in July 1982 contains an extensive "view from the Centers for Disease Control."

In addition to the above, several "routine" activities of the PHS served to disseminate AIDS information between August 1981 and May 1982. These include interviews with reporters, writers, and "talk show" hosts, consultations with public and professional persons by telephone and letter and speaking before professional groups. Additionally, PHS officials testified before the April 13, 1982 hearing of Congressman Waxman's Health and Environment subcommittee which convened at the Gay and Lesbian Community Service Center in Los Angeles. This hearing was widely publicized and covered in the media.

42. The PHS AIDS Information Bulletin states that the PHS is "responsible for providing up-to-date information on AIDS to high risk groups and to the general public."

Question (a): When did the PHS assume this role for AIDS?

Answer: The Public Health Service assumed the role for providing up-to-date information about AIDS to high risk groups and to the general public in June of 1981 when an article about the first case of pneumocystis pneumonia among young homosexual men ran in the Morbidity and Mortality Weekly Report (MMWR) June 5. Individual cases were first brought to the attention of the Public Health Service in April of 1981. The first cases of Kaposi's sarcoma were reported in the MMWR of July 3, 1981 and another update followed in August. Between June 1981 and September 1983, 25 AIDS-related articles have appeared in the MMWR. These articles have been regularly described by the print and electronic media to the general public. PHS investigators have also published articles in scientific journals, spoken at medical and scientific meetings and public forums and been available to the media at press briefings and for personal interviews. Since early summer, information activities have been stepped up.

Question (b): Beginning in January 1982, please detail month by month actions taken by the Department to fulfill this goal.

Answer: Month-by-month activities from January 1982:

1. Meetings with state and local health officials to exchange information and to identify other cases to determine extent of the first two illnesses reported, Pneumocystis carinii pneumonia and Kaposi's sarcoma. (ongoing)

2. Contacts--personal and by telephone--with practicing physicians to exchange information about surveillance for diseases and clinical information about courses of illness in new population groups subject to the diseases, previously seen primarily in older men or patients with clinically induced immune suppression because of other illnesses, eg. cancer, organ transplants, genetic deficiencies. (ongoing)

3. Conferences and meetings with academic and research specialists to discover and exchange new information about risk factors, questions about immune status, tracing historic patterns of incidence for Kaposi's sarcoma, pneumocystis pneumonia; and determining geographic patterns for the diseases. (ongoing)

4. Meetings with representatives of high risk groups to inform them about findings; to plan for epidemiologic studies; to answer questions about risk factors and to determine patterns of diseases. Also to exchange information about lifestyle connections and scientific findings. (ongoing)
5. Individual conversations, between scientists and public affairs people, with representatives of the public media to inform them of findings and to encourage media attention to outbreaks of Kaposi's and Pneumocystis pneumonia. (ongoing)
6. Surveillance reports on AIDS with numerical tabulations of cases by risk group, geographic location, age, race/ethnicity and disease frequency are available and updated periodically. They are used as basic information for answering requests from the public, particularly high risk group members, and from the media. (ongoing)
7. News releases about grants available from PHS agencies for research or surveillance projects related to high risk areas have been released periodically since PHS investigation of AIDS began in 1981. These have been used widely throughout the country and have helped give visibility to AIDS projects in private research institutions as well as federal research efforts. Other news releases have described AIDS activities of other kinds and have been distributed and used widely. (ongoing)
8. The first reports of cases of opportunistic infections and Kaposi's sarcoma among Haitians in the U.S. were reported in late 1981 and contact was made with the Haitian community to exchange information. Reports of these cases were published in the MMWR of July 9, 1982 and were followed by scientific articles published in medical journals in the U.S. and abroad. (July 1982)
9. In 1982 reports of pneumocystis pneumonia in hemophilia patients were published in the MMWR of July 16. Journal articles followed and at this time the mass media became interested in the subject and numerous articles appeared in print. PHS scientists and public affairs people provided much of the information for these articles. (July 1982)
10. In July of 1982 Public Health Service Agencies and representatives of high risk groups, blood banking and processing organizations, the National Hemophilia Foundation and others met to discuss ramifications of blood donations as related to the need of hemophilia patients for Factor VIII. From that meeting began the dialogue which resulted in PHS recommendations for prevention of AIDS. Coverage of that meeting resulted in eventual articles about AIDS

throughout the mass media; among these were cover articles in Science: 83; Time; Newsweek; the major daily newspapers and all the major television networks. PHS agencies reprinted some of these articles and distributed them with packages of information which included reprints of all MMWR articles related to AIDS, several scientific papers, the Question and Answer sheet and similar materials to anyone requesting information about AIDS. (July 1982 and ongoing)

11. Similarly, the electronic media began programming segments featuring officials and scientists of the Public Health Service and its agencies as well as patients and representatives of risk groups. By fall of 1982, the emerging illness was named Acquired Immune Deficiency Syndrome (AIDS) by the Public Health Service. (September 1982)

12. On March 4, 1983, Dr. Edward N. Brandt, Jr., Assistant Secretary for Health announced interim recommendations to the public designed to reduce the risk of acquiring AIDS. These were released to the press, printed in the MMWR and in other journals from which they were picked up and given wider distribution by the gay press, the mass media, public health publications and specialty reports. Following announcement of those precautions, additional information was provided to all establishments collecting blood and plasma to guide them in steps to prevent the spread of AIDS, particularly to hemophiliacs. (March 1983)

13. Appointment of a Public Health Service Executive Committee on AIDS to formalize coordination of the response of these agencies to the AIDS problem. Dr. Edward N. Brandt, Jr., Assistant Secretary for Health, DHHS. (May 1983)

14. In May, the Assistant Secretary for Health held a press briefing at HHS to inform the working press about PHS concern for AIDS and to assure the public on transmission facts. (May 1983)

15. In June, the Secretary of HHS addressed the Conference of Mayors with a similar message. (June 1983)

16. The Public Health Service began publication and distribution of Facts About AIDS (updated periodically) and a bi-weekly information package for the general public in July, 1983. About 100,000 copies of the material have been distributed since then. Interested groups are reprinting and distributing the material. The State Department is distributing Facts internationally. (June 1983)

17. The Public Health Service has distributed slides showing Kaposi's sarcoma to requesting physicians for help in diagnosis. The National Library of Medicine also provides AIDS information to requesting scientists. (June 1983)

18. To address growing public concern in 1983, the Public Health Service has established a national AIDS-hotline. Information is available on a 24-hour basis. As many as 5,000 - 10,000 calls have been received per day on the hotline since its inception, July 1. Members of risk groups and others of the public use the hotline as a source of information--many calling periodically to obtain updated information. (July 1983)

19. AIDS information circulated to all practicing physicians through FDA Drug Bulletin. (July 1983)

20. On September 14, Dr. Brandt and the Secretary addressed the Washington Press Club on AIDS and the Media. (September 1983)

Question (c): What additional activities does PHS intend to implement in FY '84 to disseminate information on AIDS?

Answer: Videotapes are being prepared on AIDS for primary care physicians to be distributed through medical societies and appropriate organizations. Another videotape is being prepared for nurses who care for AIDS patients, in addition to tapes for other health workers. These will also be distributed through professional organizations and the National Audiovisual Center. A videotape on AIDS findings has also been prepared by CDC and distributed to state health officials and requesting health facilities. Another for correctional officers is under development, as is a booklet outlining precautions that all laboratory and clinical works should observe.

Extensive information efforts are underway for the populations at risk. A basic information bulletin has been distributed via homosexual organizations, and cards describing symptoms and precautions for risk groups are being printed for distribution by those groups. News media, including the gay press, have carried articles based on information provided by the PHS about AIDS and promoting a national AIDS toll-free telephone hotline (800-342-AIDS), staffed by PHS professional employees. The hotline is available to the public for individual AIDS information and has answered as many as 5,000 - 10,000 calls per day, most of them from the at risk population. The National Institute of Drug Abuse has directed materials about AIDS to drug users through drug treatment centers. A mailing of AIDS information has been made to Haitian organizations and an effort is underway to develop an education program for this group, possibly through simple publications, distributed

through such channels as social organizations, health facilities, and churches, as well as through the news media. PHS has also been working with organizations representing hemophiliacs to provide information to that group.

The general public has been informed primarily through the news media, with whom the PHS has conducted numerous interviews, briefings and press conferences, in addition to providing printed and videotaped material. Based on studies conducted to date, information materials are now being prepared to assure the public that the syndrome is difficult to contract outside the identified risk groups and that casual (nonsexual) contact with persons in the risk groups poses no danger to public health. The materials are also to allay public concerns regarding the safety of donating blood or receiving blood transfusions. Basic information about the syndrome has already been made available to the public through an AIDS Fact Sheet and through the national hotline, but most effective have been articles in the press and appearances by knowledgeable health officials on television interviews. The Secretary of Health and Human Services and the Assistant Secretary for Health addressed the Washington Press Club this month to emphasize the need for providing additional, accurate information to the public without provoking needless fears. A videotape and slide talk on AIDS are being produced for showing to general audiences, including basic information about the syndrome and placing the risk factors in perspective. Additional publications are also being developed for traditional channels of health information distribution.

Training courses for health professionals in research diagnosis, counselling, and treatment of AIDS patients will be funded during the coming year by several PHS agencies.

Question (d): Please supply information on the costs of these activities and the number of FTE's they require.

Answer: The information and education activities on AIDS have been done in FY '83 for a total cost exceeding \$500,000. In FY '84, at least \$1 million will be devoted to information activities on AIDS.

In both years, PHS public affairs personnel (and other professional staff) have paid special attention to AIDS activities as part of their regular duties. A public affairs AIDS task force (guided by the director of PHS public affairs) oversees coordination of the national information and education program.

43a. Please provide a list of major scientific meetings that PHS has organized and include the participants, minutes or summary report from each meeting, date, location, recommendations agreed to at each meeting, and documentation of PHS follow-up to these recommendations.

A: Centers for Disease Control personnel, on many occasions, have met and consulted with various individuals and groups including outside scientists, gay organizations, National Hemophilia Foundation, Haitians, blood banking organizations, other federal agencies and their scientists, and State and local governmental units concerning the AIDS problem.

In addition, the following scientific meetings have been held at the Centers for Disease Control in Atlanta, Georgia and the National Institutes of Health in Washington, D. C.:

1. March 3, 1982 (CDC)

PHS interagency meeting where CDC, NIH, ADA/HA, and FDA representatives met to determine the type of investigations to be undertaken and responsibilities of each agency in these investigations. (List of attendees attached: see 43a.) *

2. July 27, 1982 (NIH)

Meeting of PHS agencies, National Hemophilia Foundation, American National Red Cross, various blood banking organizations, National Gay Task Force, New York City Health Department and New York Inter-Hospital Study Group on AIDS to discuss the significance of the occurrence of opportunistic infections in three patients with hemophilia. (Summary report, list of invitees and memorandum to PHS agencies from the ASH attached: see 43a.) *

3. January 4, 1983 (CDC)

Meeting of PHS agencies, blood banking officials, and representatives of the National Hemophilia Foundation, National Gay Task Force, and manufacturers of blood products to discuss the possible transfusion of AIDS through blood or blood products, and appropriate prevention measures. The results of this meeting led to the development and publication of PHS prevention recommendations in the MMWR and the Journal of the American Medical Association. (Recommendations and list of invitees attached: see 43a.) *

4. May 12, 1983 (CDC)

CDC asked a group of expert consultants to review current data on AIDS cases among hemophilia patients and suspected transfusion-associated AIDS cases. The consultants provided a scientific evaluation of the data, presented suggested standard criteria for inclusion as cases, and advised CDC on further investigations of such cases. A paper is in preparation which will be submitted to a scientific journal. (Summary report and list of attendees attached: see 43a.) *

On numerous other occasions, the FDA, NIH, and CDC have communicated with representatives of the National Hemophilia Foundation, blood bank organizations as new information became available.

*Documents available in Subcommittee's files

43b. Explain how PHS communicates information exchanged at these meetings with the larger medical and scientific community.

A: Various methods have been used to communicate this type of information to the medical and scientific community including publications in the CDC Morbidity and Mortality Weekly Report (MMWR) and scientific journals and presentations at major scientific meetings throughout the Nation. Prevention recommendations resulting from the January 4, 1983, meeting were published in the MMWR, the Journal of the American Medical Association, and were sent to each practicing physician in the United States.

NIH Response to question 43a:

Please provide a list of major scientific meetings that PHS has organized and include the participants, minutes or summary report from each meeting, date, location recommendations agreed to at each meeting, and documentation of PHS follow-up to these recommendations.

Answer 43a:

The list of major scientific meetings that were sponsored and/or supported by NIH was provided to the Committee with the earlier submission of corrections to the transcript of the August 1-2, 1983 hearing. Included here are follow-up recommendations to these meetings not included previously.

NIAID

Follow up to April 5-6, 1983, Workshop, "Search for the Etiological Agents in Acquired Immune Deficiency Syndrome" was release of RFA NIH-NCI-DCCP-BCB-83-3, "Infectious Etiology of Acquired Immune Deficiency Syndrome (AIDS) and Kaposi's Sarcoma" in the NIH Guide to Grants and Contracts on May 20, 1983.

Follow up to the May 6, "NCI/NIAID Extramural Working Group" has been further conference calls among participants at the May 6 meeting toward development of common definitions for certain subsets of AIDS patients.

Follow up to the peer review group meetings mentioned in the memo attached to the meetings list, has been the award and/or imminent award of AIDS grants and contracts.

NHLBI

In addition to the meetings described in previous responses to inquiries related to this testimony, NHLBI is co-sponsoring a Workshop on the Epidemiology of AIDS which will be held on September 12-13, 1983. The agenda for this workshop is appended.

DRR

The Animal Resources Program, DRR, sponsored a workshop on March 2, 1983, at the National Institutes of Health (Masur Auditorium, Building 10) concerning acquired immunodeficiency syndrome in nonhuman primates (later termed SAIOS). The purpose of this workshop, which was attended by approximately 300 scientists, was to discuss clinical, pathological, and immunological findings related to recent disease outbreaks with high mortality rates in macaque species (*M. mulatta* and *M. cyclopis*) at the California and New England Regional Primate Research Centers. Comparative medical aspects of this nonhuman primate disease at these Centers and the human AIDS condition were discussed. Sessions on differential diagnosis, epidemiology, and biosafety aspects of the disease were included. Although certain characteristics of the

nonhuman primate disease differ from those of human AIDS, it was determined that many characteristics including lymphadenopathy, wasting, diarrhea, anemia, and severe opportunistic infections in the nonhuman primates are so similar that affected nonhuman primates may be useful models for studies on human AIDS. It was concluded that these investigations should continue and that other nonhuman primate colonies should be evaluated to determine the possible occurrence of this disease.

Question 43b:

Explain how PHS communicates information exchanged at these meetings with the larger medical and scientific community.

Answer 43b:

NIAID

In addition to disseminating information through publications in the scientific literature, the NIAID Intramural Program published the AIDS Bibliography and the AIDS Memorandum (Attachment 43b). The AIDS Bibliography is mailed to individuals who have expressed an interest in literature references to AIDS research appearing in the scientific and lay literature. This bibliography was first published in early 1983 and is updated periodically. The mailing list at present has 690 names. The AIDS Memorandum is published for distribution to scientists working in the field of AIDS research and is designed for rapid dissemination of research results whether positive or negative. Participants in the memorandum project must agree to contribute one article per year to remain on the mailing list. The mailing list currently contains 340 names; the first edition of the AIDS Memorandum was published in August 1983. *

DRR

Abstracts of presentations made at the workshop have been provided to interested individuals, including members of the scientific community. Also, research findings are being published in scientific journals.

The NHLBI has been delegated the responsibility to support studies to evaluate screening procedures, including laboratory tests, for their effectiveness in identifying and excluding blood and blood products from donors at increased risk for AIDS. The NHLBI is also responsible for the support of studies to determine the association of blood and blood product use with AIDS. Epidemiologic surveillance or tracking of suspected transfusion-related cases, relative to such studies, could occur, however, the responsibility for national surveillance of the AIDS epidemic rests with the CDC.

* Attached documents available in Subcommittee files

QUESTION 43

2. Please provide a list of major scientific meetings that PHS has organized and include the participants, minutes or summary report from each meeting, date, location, recommendations agreed to at each meeting, and documentation of PHS follow-up to these recommendations.

ANSWER

The FDA conducted a number of meetings at which the subject of AIDS was discussed. Information on these meetings was previously provided to the Subcommittee for inclusion in the August 2 hearing record.

The major scientific meeting organized by the FDA was the Blood Products Advisory Committee meeting to discuss the safety and purity of plasma derivatives on July 19, 1983. The list of participants, summary minutes, recommendations, and documentation of followup are attached. *

*Documents available in Subcommittee's files

QUESTION 43

- b. Explain how PHS communicates information exchanged at these meetings with the larger medical and scientific community.

ANSWER

In addition to the dissemination of information by FDA to licensed facilities, as documented in response to 43.a., the major blood bank organizations report the information in their publications such as the weekly Newsletter of the Council of Community Blood Centers and the monthly newsletters of the American Association of Blood Banks and the American Red Cross. Biomedical science reporters of several the medical and news magazines were present and reported the content of the meeting.

Question 44

In addition to the mechanisms discussed in question 42, what methods does the PHS use to disseminate information to the medical community, blood banking organizations, affected communities, and the public regarding the status of cases that potentially link blood transfusions with AIDS? Please provide documentation.

Answer

Direct communication with the involved medical personnel and blood banking organizations is the primary method used by FDA for obtaining and disseminating information on the status of cases that potentially link blood transfusions with AIDS.

CDC Response

44. In addition to the mechanisms discussed in question 42, what methods does the PHS use to disseminate information to the medical community, blood banking organizations, affected communities, and the public regarding the status of cases that potentially link blood transfusions with AIDS? Please provide documentation.

A: The primary problem with dissemination of information that potentially links blood transfusion with AIDS is the danger of over interpretation on the part of the public resulting in excessive caution. This has the potential, at least, to cause the blood-donating population to refrain from donating on one hand and the patient population to refuse necessary blood transfusions on the other. PHS sets an example by supporting blood drives, most visibly by Secretary Heckler who donated blood herself. PHS has supported the voluntary blood collection agencies by supplying data, information, and safety guidelines.

As indicated previously, the MMWR and scientific/medical journals have been used to communicate this information to the medical and scientific community including blood banking organizations. The public has been provided this information through the PHS Fact Sheet on AIDS, a periodically updated AIDS information packet, and by news releases on this problem. PHS scientists have granted numerous interviews to the media including the gay press about this issue. In addition, CDC and FDA personnel have frequent and ongoing communication with the blood banking organizations about this problem.

45. Has any information been disseminated to the medical community, blood banks, affected communities, or the public, regarding the findings of the panel called together on May 12, 1983, by CDC to review all transfusion related AIDS cases? If so, please describe how this information has been distributed and provide copies for the record.

A: Because members of the blood banking community were invited as consultants to review these data, these individuals were able to immediately share the data with their colleagues, respective organizations, and communities. As a result of the meeting, a paper which summarizes the data is in preparation. This paper will be submitted to a scientific journal for publication. In addition, a summary report of the May 12, 1983, meeting has been sent to the consultants who represent the various blood banking agencies.

A copy of the summary report has been provided under question 43a.

46. Please delineate the respective responsibilities of the FDA, NHLBI, and CDC in tracking possible blood related AIDS cases.
- A: The CDC works with State and local health departments, physicians reporting such cases, and blood banks to identify and confirm possible blood related cases and identify, interview, and examine the individuals who have donated blood to these cases. The results of each case is analyzed to determine the likelihood of the cases acquiring AIDS through the blood transfusion.

Question 46:

Please delineate the respective responsibilities of the FDA, NHLBI, and CDC in tracking possible blood related AIDS cases.

Answer 46:

The NHLBI has been delegated the responsibility to support studies to evaluate screening procedures, including laboratory tests, for their effectiveness in identifying and excluding blood and blood products from donors at increased risk for AIDS. The NHLBI is also responsible for the support of studies to determine the association of blood and blood products use with AIDS. Epidemiological surveillance or tracking of suspected transfusion-related cases, relative to such studies, could occur, however, the responsibility for national surveillance of the AIDS epidemic rests with the CDC.

Question 46

Please delineate the respective responsibilities of the FDA, NHLBI, and CDC in tracking possible blood related AIDS cases.

Answer

FDA has established donor eligibility requirements for blood donation, and has authority to inspect donor records if it becomes necessary during the course of an epidemiologic investigation of a possible blood-related AIDS case which is being conducted by the CDC. Blood banks are required by FDA to maintain a record of assigned donor numbers which can be used to trace each unit from donor to recipient.

47. What is the Public Health Service's position regarding the need to establish an independent expert panel to review all suspected blood transfusions related cases?

A: The Public Health Service does not believe formal establishment of such a panel is needed. In May 1983 a group of expert consultants met at CDC to review suspected transfusion related AIDS cases. Some of these individuals agreed to continue in a consultative role, and contact has been maintained by mail and telephone. In June, Dr. Brandt requested Dr. Jeffrey Koplan, Chairman of the PHS Executive Committee on AIDS, to review the need for establishment of such an independent expert committee on AIDS. Dr. Koplan recommended that such a committee not be established because of the existence of the PHS Executive Committee, the ability of participating agencies to call upon existing expert committees, and the ability to communicate with individual experts on an as needed basis. Dr. Brandt concurred with this recommendation. CDC will continue to seek independent expert advice as needed.

Question 48a.

Since March 1983, which office in PHS has monitored the impact of the PHS guidelines on the nation's blood supply?

Answer

In an effort to determine the impact of the PHS guidelines on the nation's blood and plasma supply, FDA has made contact with selected blood and plasma facilities. The FDA has a close working relationship with the blood banking community which allows us to continue to assess the results of these guidelines. In addition, the impact of the guidelines has also been discussed at several Blood Products Advisory Committee meetings.

Question 48b

Please provide the findings that have resulted from the monitoring process. Please supply all documentation.

Answer

The information obtained by FDA was qualitative verbal information which is undocumented. The net impression, however, from those discussions was that there has not been a significant adverse effect on the availability of blood or plasma.

49a. Does the Department currently provide any locality with funds for public education activities or for treatment of AIDS patients? Please specify the nature of the assistance, if any, and provide budget information.

A: No.

b. Does the Department plan to provide funds for treatment or public education to cities or States affected by AIDS in FY '84? If so, please provide details and budget estimates.

A: Although the total amount of funds available for fiscal year 1984 is unknown, CDC is currently determining the projects with high priority in fiscal year 1984. The highest priority will continue to be directed to finding the cause of AIDS and determining appropriate prevention measures. CDC is considering the priority use of funds for competitive awards to health departments and other organizations for public education activities. These activities would be directed to high risk communities and individuals in an effort to reduce the risk of acquiring AIDS. The NIH has funded several studies to evaluate the efficacy of treatment for AIDS and Kaposi's Sarcoma. In addition, the CDC provides pentamidine isethionate for the treatment of Pneumocystis carinii pneumonia and an experimental drug for the treatment of atypical mycobacterial infections. These infections are two of the most common causes of deaths in patients with AIDS.

CDC has assigned an individual to the New York City Health Department to work full-time in the area of public and professional education.

APPENDIX 2.—MATERIAL SUBMITTED FOR THE RECORD

STATEMENT BY REP. SALA BURTON
FOR SUBCOMMITTEE ON INTERGOVERNMENTAL RELATIONS
AND HUMAN RESOURCES

REP. TED WEISS, CHAIRMAN

AUGUST 1, 1983

AS A REPRESENTATIVE IN THE CONGRESS OF ONE OF THE CITIES MOST AFFECTED BY THE EPIDEMIC OF AIDS, I WANT TO THANK CONGRESSMAN WEISS AND THE SUBCOMMITTEE FOR HOLDING THIS CRITICAL OVERSIGHT HEARING ON THE ROLE OF THE FEDERAL GOVERNMENT IN THIS HEALTH CRISIS.

IN SAN FRANCISCO, AND ELSEWHERE IN THIS COUNTRY, WE HAVE ALREADY LOST MORE PREVIOUSLY HEALTHY, PRODUCTIVE YOUNG MEN TO THIS DISEASE THAN ANY OF US COULD HAVE -- JUST A FEW YEARS AGO -- EVER IMAGINED.

BUT THE DEATHS WE HAVE SUFFERED, THE ANGUISH OUR PEOPLE HAVE ENDURED, ARE MADE EVEN MORE HORRIBLE BY THE CERTAIN KNOWLEDGE THAT THIS EPIDEMIC CONTINUES AND SHOWS EVERY SIGN OF CONTINUING AND GROWING WORSE. THE GEOMETRIC PROGRESSION OF AIDS HAS BEEN A TERRIBLE REALITY OF OUR LIVES FOR MORE THAN TWO YEARS.

THE FEAR, THE ANXIETY WHICH THE SPECTRE OF DEADLY EPIDEMIC HAS CREATED IN THIS COUNTRY CAN ONLY BE DIMINISHED AND ULTIMATELY OVERCOME WHEN THIS DISEASE HAS BEEN CONQUERED AND THE SUFFERING HAS BEGUN TO RECEDE.

THE PEOPLE I REPRESENT, AND ALL THE PEOPLE IN THIS COUNTRY, HAVE A RIGHT TO EXPECT THAT THEIR GOVERNMENT - AT ALL LEVELS - WILL DO EVERYTHING POSSIBLE TO PROTECT THEIR LIVES AND END THIS EPIDEMIC. FOR SOME OF THEM, IT IS, QUITE LITERALLY, A MATTER OF LIFE AND DEATH.

WE HAVE, IN THE LAST SEVERAL MONTHS, REACHED A POINT IN THE STRUGGLE AGAINST AIDS WHERE OUR FEDERAL HEALTH OFFICIALS HAVE RECOGNIZED - IN THEIR WORDS - THE GRAVITY OF THIS CRISIS. THE AIDS EPIDEMIC HAS BEEN CALLED OUR "NUMBER ONE PRIORITY."

BUT HAS THE REALITY MATCHED THE RHETORIC? I WOULD LIKE TO OFFER THE SUBCOMMITTEE A FEW FUNDAMENTAL QUESTIONS CONCERNING THIS EPIDEMIC:

1) FEDERAL FUNDING. ARE THE CURRENT LEVELS OF FEDERAL FUNDING ADEQUATE? DOES TALK OF A REALLOCATION OF \$12 MILLION REPRESENT A REAL SENSE OF PRIORITY? CAN ANYONE BELIEVE THAT A SUCCESSFUL ASSAULT ON A MAJOR EPIDEMIC CAN BE LAUNCHED WITH SUMS OF MONEY SO SMALL? WHY HAS IT TAKEN SO LONG FOR ANY SIGNIFICANT AMOUNT OF EXTRAMURAL RESEARCH MONEY TO REACH THE RESEARCHERS WHO ARE WORKING TO UNDERSTAND THIS DISEASE? IF THIS IS OUR NUMBER ONE PRIORITY, WHEN CAN WE EXPECT A GENERAL CALL FOR RESEARCH PROPOSALS, BACKED UP BY LEVELS OF FUNDING SUFFICIENT TO CONVINCING THE MEDICAL COMMUNITY THAT OUR GOVERNMENT IS INDEED SERIOUS, AND TO STIMULATE THE IDEAS WHICH MAY WORK TO CONQUER THIS DISEASE?

2) FEDERAL RESPONSE STRUCTURE. WHY, MORE THAN TWO YEARS INTO THIS EPIDEMIC, IS THERE NO FEDERAL AIDS COORDINATOR, WITH CLEAR AND SPECIFIC RESPONSIBILITY TO OVERSEE ALL AIDS ACTIVITY? DOES THE FEDERAL GOVERNMENT HAVE A PLAN OR A PROGRAM TO DEAL WITH THIS EPIDEMIC? WHAT STEPS HAVE BEEN TAKEN IN THIS MEDICAL EMERGENCY TO SPEED UP THE PEER REVIEW PROCESS SO THAT RESEARCH MONIES WILL NOT BE HELD UP FOR MONTHS AND MONTHS WHILE THE EPIDEMIC CONTINUES TO SPREAD AT ITS NIGHTMARE PACE?

3) FEDERAL RESEARCH. WHOSE RESPONSIBILITY IS IT TO DETERMINE, FIRST, WHAT AIDS-RELATED RESEARCH IS UNDERWAY, WHAT HAS BEEN PROPOSED, WHICH RESEARCH IS A PRIORITY, AND WHICH RESEARCH REMAINS TO BE DONE?

WHY, WHEN THE LIVES OF HUNDREDS OF THOUSANDS OF PEOPLE ARE AT GRAVE RISK, HAS THE FEDERAL GOVERNMENT NOT UNDERTAKEN THE KIND OF SUBSTANTIAL EPIDEMIOLOGICAL RESEARCH WHICH CAN DETERMINE MORE PRECISELY HOW HIGH-RISK POPULATIONS CAN REDUCE THEIR RISK, HOW AIDS IS SPREAD, HOW LONG THE INCUBATION PERIOD IS, ETC? I CAN ASSURE YOU THAT THE ANSWERS TO THESE QUESTIONS ARE OF THE MOST FUNDAMENTAL CONCERN TO THE PEOPLE OF MY CITY AND THAT IT IS INCONCEIVABLE TO ME THAT WE WILL ADD TO THEIR BURDEN BY NOT MAKING A GREATER ATTEMPT TO ANSWER THESE QUESTIONS.

IF WE ARE CONCERNED ABOUT THE THREAT OF THIS DISEASE TO OUR NATIONS' BLOOD SUPPLY, WHEN WILL WE LAUNCH A CRASH PROGRAM TO IDENTIFY AN AIDS MARKER IN THE BLOOD? IN VIEW OF THE POTENTIAL CONSEQUENCES OF OUR LACK OF KNOWLEDGE IN THIS AREA, AND OF THE GREAT PUBLIC CONCERN ABOUT IT, CAN THE FEDERAL GOVERNMENT'S REMARKABLY TIMID EFFORTS IN THIS REGARD BE JUSTIFIED?

4) OTHER AREAS OF CONCERN. WHAT STEPS ARE CONTEMPLATED TO PROVIDE ONE OF THE ESSENTIAL INGREDIENTS FOR THE PROTECTION OF THE PUBLIC HEALTH IN AN EPIDEMIC: MASSIVE, SUSTAINED, AND COORDINATED PUBLIC EDUCATION? WHAT HAS BEEN DONE TO EDUCATE THOSE AT HIGH RISK ABOUT HOW TO PROTECT THEMSELVES? WHAT HAS BEEN DONE TO EDUCATE THE GENERAL POPULATION, TO ALLAY UNNECESSARY FEARS AND PAIN-STRICKEN REACTIONS WHICH CAN ONLY BE EXPECTED TO INCREASE AS THE EPIDEMIC WORSENS UNLESS ACCURATE INFORMATION IS WIDELY DISSEMINATED? WHAT STEPS ARE CONT-

EMPLATED TO PROTECT THE CONFIDENTIALITY OF PATIENTS (ALL TOO MANY OF WHOM, PARTICULARLY IN THE GAY AND HAITIAN COMMUNITIES, HAVE REASON TO FEAR THE INTRUSION OF GOVERNMENT INTO THEIR LIVES) WHILE PERMITTING THE FULL EPIDEMIOLOGICAL RESEARCH WHICH IS NECESSARY? FINALLY, WHAT EFFORT IS THE FEDERAL GOVERNMENT PREPARED TO MAKE TO ASSIST THE COMMUNITIES SO HEAVILY IMPACTED BY THIS EPIDEMIC, FOR WHOM AIDS IS A FINANCIAL AS WELL AS A HEALTH AND HUMAN DISASTER?

THESE QUESTIONS, AND MORE, MUST BE ANSWERED BY OUR HEALTH OFFICIALS BEFORE WE ESTABLISH THAT THIS "NUMBER ONE PRIORITY" HEALTH CONCERN IS INDEED BEING TREATED AS SUCH.

AS DR. MARCUS CONANT, THE DIRECTOR OF S.F.'S AIDS/KS FOUNDATION IS PREPARED TO TESTIFY TODAY, MEDICAL AUTHORITIES BELIEVE THAT AN INTENSIVE RESEARCH PROGRAM CAN PRODUCE THE ABILITY TO STOP THE SPREAD OF AIDS.

IT IS CLEAR THAT, WHATEVER MAY OR MAY NOT HAVE BEEN DONE IN THE PAST, IT IS NOW TIME TO DO MORE - MUCH MORE. IN MY CITY, AND IN TOO MANY OTHERS, THIS IS A MATTER OF THE MOST FUNDAMENTAL CONCERN.

WHAT OUR GOVERNMENT DOES TODAY WILL LARGELY DETERMINE WHETHER OUR TRAGEDY WILL BECOME THE TRAGEDY OF OTHER CITIES TOMORROW AND NEXT YEAR AND THE YEAR AFTER.

IT IS TIME TO ANSWER THE QUESTIONS AND TO ACT - DRAMATICALLY - WITH A TRUE SENSE OF PRIORITY AND WITH THE LEVEL OF FUNDING NECESSARY TO WIN THE STRUGGLE AGAINST THIS TERRIBLE EPIDEMIC.



AMERICAN ASSOCIATION OF BLOOD BANKS

National Office Suite 600, 1117 North 19th Street, Arlington, Virginia 22209 (703) 528-8200

August 15, 1983

The Honorable Ted Weiss
Chairman, Intergovernmental Relations
and Human Resources Subcommittee
Committee on Government Operations
Rayburn House Office Building
Room B-373
Washington, D.C. 20515

Dear Congressman Weiss:

On behalf of the AABB membership, we sincerely thank you for the opportunity to share the Association's views regarding the AIDS crisis as it relates to the quality of the nation's blood supply.

Dr. Bove's testimony summarizes our views.

It is our understanding we have been afforded the opportunity to input further on this very important concern.

Kindly include the enclosures behind Dr. Bove's written testimony to the Oversight Committee in the Congressional Record.

If we can be of further assistance with your investigations please do not hesitate to call.

We are most appreciative of your efforts to enlighten your colleagues and general public on this most important matter.

Best personal regards.

Sincerely,

A handwritten signature in cursive script that reads "Edward Carr".

Edward Carr, MT(ASCP)SBB
President

EC/ch
encl.

**AMERICAN ASSOCIATION OF BLOOD BANKS**

National Office Suite 600, 1117 North 19th Street, Arlington, Virginia 22209 (703) 528-8200

June 23, 1983

Memorandum

TO: AABB Institutional and Associate Institutional Members

FROM: Edward O. Carr, MT(ASCP)SBB, President

RE: Joint Statement on Directed Donations

The recent publicity regarding acquired immune deficiency syndrome (AIDS) has resulted in increased concern about the quality of the nation's blood supply and demands for directed donations by patients requiring transfusions. In response to these concerns, the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers have issued the attached joint statement and press release. We hope that these documents will be helpful in dealing with the AIDS problem. You are encouraged to make the press release available to your local media.

JOINT STATEMENT ON DIRECTED DONATIONS AND AIDS

The current epidemic of acquired immune deficiency syndrome (AIDS) and attendant publicity has led to concerns that AIDS may be transmitted by blood transfusion to persons not in one of the recognized high risk groups. Of 1,601 cases of AIDS reported to the CDC, 94 percent have occurred in people belonging to four groups: homosexual or bisexual males with multiple sex partners; intravenous drug abusers, recent entrants from Haiti, and persons with hemophilia. Only one newborn infant and 14 adult recipients of blood transfusions have been identified as cases of possible transfusion-associated AIDS. More than 10 million persons were transfused in the United States during the three-year period that these cases were reported and, therefore, it appears at this time that the risk of possible transfusion-associated AIDS is on the order of one case per million patients transfused.

On March 25, 1983, in response to the potential risk of transfusion-associated AIDS, we pledged compliance with the Recommendations on AIDS by the Office of Biologics, FDA, and jointly implemented a nationwide program to inform all blood donors of AIDS risk groups and provided means for individuals in high risk groups to be excluded as blood donors. We concur with Secretary of Health and Human Services Margaret M. Heckler's statement of June 14, 1983, that "...all of us might also be confronted with an unnecessary and unjustified level of fear, if misunderstanding of AIDS is allowed to grow. Such a level of fear could actually impede us in our real tasks...."

One consequence of the understandable, but excessive, concern for transfusion-associated AIDS has been requests by patients and their physicians to have blood donors selected from family members, friends, coworkers, and even newly formed private donor clubs. There is no evidence to support this notion that these "directed donations" are safer than those available through the community blood bank.

The concept that family members, friends, coworkers, church members or other selected groups are sure to provide safer blood is unrealistic. These same individuals are and have been the nation's volunteer blood donors who have, in the past, given freely for all patients rather than for a particular individual. There is no reason to think that segregating these individuals into selected donor panels will provide safety over and above the level provided by current arrangements. In addition, a system

of directed donation may create intense pressures on family and friends who may therefore be untruthful about their ability to meet donor requirements. It is possible that the administrative and operational complexity that will be part of any widespread application of directed donations may lead to a significant increase in clerical errors and, in this way, reduce the safety of transfusion.

Finally, there is the risk that widespread attempts to direct donations, while not increasing the safety of transfusions, will seriously disrupt the nation's blood donor system. Voluntary donation is essential for meeting our nation's needs for blood and blood products. There is a real concern that donors may refrain from routine blood donations while awaiting requests to provide directed donations and, thereby, could disrupt the blood supply to the point that routine and even some emergency needs for transfusions may go unmet.

Given these considerations, we strongly recommend that "directed donation" programs not be conducted. We reaffirm our commitment to a safe blood supply for all recipients, to maintaining the highest standards possible for selecting volunteer donors, and to strict compliance with pertinent recommendations by the United States Public Health Service and other federal regulatory bodies.

American Red Cross

American Association of Blood Banks

Council of Community Blood Centers

June 22, 1983

Joint News Release

June 22, 1983

American Red Cross

American Association of Blood Banks

Council of Community Blood Centers

Contacts: Virginia Pfa

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Lorry Rose

American Association of Blood Banks

(703) 528-8200

Robert Huitt

Council of Community Blood Centers

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The nation's voluntary blood service organizations today announced they do not advocate "directed donation," an unconventional practice whereby patients needing transfusions select their own blood donors. The American Red Cross, American Association of Blood Banks and Council of Community Blood Centers agreed that existing arrangements with volunteer donors and donor groups are the best way of assuring a safe supply of blood for all patients needing transfusions.

Publicity about the current AIDS epidemic has led to widespread concerns about the possibility of transmitting AIDS through blood transfusion. The facts do not justify these concerns: data accumulated over the last three years indicate that the possible occurrence of AIDS in transfusion recipients is on the order of one case per million patients transfused. Still, as a consequence of misleading reports, some patients have demanded that blood for their transfusions be donated by specially selected family members, friends or co-workers.

The three organizations emphasize there is no scientific basis for the assumption that blood from donors selected by patients is safer than that available from volunteers at community blood banks. In fact, such a practice may be hazardous because it could pressure selected donors to be untruthful about their ability to meet donor eligibility requirements.

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(over)

ARC, AABB and CCBC all agree that the altruistic volunteer donor who is free from coercion or expectation of gain is the safest blood donor. As a further precaution, blood centers across the country have recently adopted even stricter requirements for blood donation to assure that high risk donors are excluded.

Adopting a policy of patient-directed donations would create an illusion of additional protection where none exists and, by disrupting existing volunteer donor systems, could result in inability to supply blood to patients who need it. The blood collecting organizations are also concerned that the logistical complexities of patient-directed donation could lead to serious errors in donor and patient identification.

ARC, AABB and CCBC represent some 2500 community and regional blood centers, hospital blood banks and transfusion services which collect and transfuse over 98% of the nation's blood supply.

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AMERICAN ASSOCIATION OF BLOOD BANKS

National Office Suite 800, 1117 North 19th Street, Arlington, Virginia 22209 (703) 528-8200
 April 4, 1983

TO: AABB Institutional and Associate Institutional Members
 FROM: Edward O. Carr, MT(ASCP)SBB, President
 RE: STANDARD OPERATING PROCEDURES FOR ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Final recommendations on acquired immune deficiency syndrome (AIDS) were released by the Food and Drug Administration on March 24. A copy has been forwarded from the FDA to all establishments collecting human blood for transfusion; all establishments collecting source plasma (human); and all licensed manufacturers of plasma derivatives.

The recommendations call for blood banks and plasma collection facilities to implement educational programs to inform persons at increased risk of AIDS that they should refrain from donation; instruct blood and plasma center personnel on the use of medical history questions to detect AIDS symptoms or exposure to AIDS patients; and establish procedures for handling and disposing of blood and plasma collected from known or suspected AIDS patients. Any blood bank which has not received a copy of the recommendations should contact: Dennis M. Donohue, MD, Director, Division of Blood and Blood Products, Office of Biologics, HFN-830, 8800 Rockville Pike, Bethesda, MD 20205, (301)496-4396.

The Public Health Service has stated that these recommendations are intended to serve as interim measures until specific laboratory tests have been developed to screen for AIDS.

The documents state that "approved procedures developed by one of the major organizations such as the American Association of Blood Banks, the American Red Cross, the Council of Community Blood Centers and the American Blood Resources Association may be referenced in the licensed establishments' standard operating procedures without individual submission to the Office of Biologics. Alternatively, licensed establishments should develop their own procedures and should submit them directly to the Office of Biologics for approval concurrent with implementation."

Attached are standard operating procedures (SOPs) developed by the AABB to meet FDA recommendations. These procedures have been approved by the Office of Biologics and can be used by blood banks and transfusion services to comply with the March 24, 1983, "Recommendations to decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Blood Donors." Should blood banks choose to develop their own donor education piece instead of using the one developed by the AABB and approved as part of its SOP, it will be necessary to

(over)

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submit the substitute piece to the Office of Biologics for approval.

The donor education piece approved by the OoB will be available in brochure form in approximately 2½ weeks. An order form is attached.

The AABB's legal counsel advises blood banks to obtain verification that donors have read the educational materials, although this does not appear to be required by the Office of Biologics. Verification can be obtained through use of a donor acknowledgement form (such as that sent to Institutional members on March 7), or a statement verifying that donors have read the provided materials can be incorporated into the donor questionnaire. Such a statement can read: "I have read the literature provided by the blood bank concerning acquired immune deficiency syndrome (AIDS), and understand that members of groups at increased risk have been asked to refrain from donating blood at this time."

We anticipate that the AABB Standards for Blood Banks and Transfusion Services and Inspection and Accreditation requirements will be modified to encompass these new procedures.

AN IMPORTANT MESSAGE TO ALL BLOOD DONORS

WHAT IS AIDS?

AIDS or acquired immune deficiency syndrome is a condition in which the body's normal defense mechanisms against certain diseases or conditions are reduced. As a result, patients often develop unusual infections such as Pneumocystis pneumonia or a rare form of skin cancer, Kaposi's sarcoma. There is no known cause, preventative measure, laboratory test, or treatment for AIDS.

WHO IS AT RISK?

It is known, however, that certain groups are at an increased risk of contracting the disease. These include:

- *those with symptoms and signs suggestive of AIDS;
- *sexually active homosexual or bisexual men with multiple partners;
- *Haitian entrants to the United States;*
- *present or past abusers of intravenous drugs; and
- *sexual partners of individuals at increased risk of AIDS.

WHAT DOES AIDS HAVE TO DO WITH GIVING BLOOD?

While extensive research is still ongoing and no final conclusions have been reached regarding the cause of AIDS and its transmission, there is a suggestion that occasionally the disease may have been spread through the transfusion of blood products. Because of this suggestion, your blood bank is asking that you voluntarily refrain from donating at this time if you are in any of the currently identified at risk groups. Although the majority of members of these groups are not carriers, there is presently no means of detection and thus no mechanism to identify those few who may be at risk.

We appreciate the time and effort involved in making a trip to the blood bank, and hope that all donors will recognize the necessity of the voluntary screening procedures which have been instituted.

*The Office of Biologics has defined Haitian entrants as those persons who have come from Haiti during the past three years. Visitors to Haiti should be considered the same as individuals traveling to a malaria endemic area.

Developed by the American Association of Blood Banks in response to Public Health Service recommendations.

4/4/83

AMERICAN ASSOCIATION OF BLOOD BANKS

STANDARD OPERATING PROCEDURES RELATING TO ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

1. Educational materials should be available informing donors of blood intended for transfusion that persons at increased risk of AIDS should refrain from donating blood. These materials must be directed to the individual donor; thus, a sign in the donor room will not suffice; each donor should be given literature to read. The educational information developed by the AABB and approved by the Office of Biologics is attached. Each donor should receive educational materials to read prior to signing the donor consent form.

Groups at increased risk for AIDS have been defined by the Public Health Service as:

-Persons with symptoms and signs suggestive of AIDS
-Sexually active homosexual or bisexual men with multiple partners
-Haitian entrants to the United States*
-Present or past abusers of intravenous drugs
-Sexual partners of individuals at increased risk of AIDS

2. Donor screening should elicit the following:

-A history of night sweats
-A history of unexplained fevers
-Unexplained weight loss
-Signs of swollen lymph nodes
-Signs of Kaposi's sarcoma, which include pink to purple flat or raised blotches or bumps occurring anywhere on the skin or mucous membranes
-Exposure to a patient with AIDS

All positive or suggestive answers should be evaluated by a physician or suitably trained person before donation.

3. Blood inadvertently collected from AIDS patients or suspected AIDS patients should be considered potentially infectious and handled, quarantined, and destroyed accordingly. The standard operating procedures used in your blood bank for hepatitis B surface antigen positive blood should be followed.

*The Office of Biologics has defined Haitian entrants as those persons who have come from Haiti during the past three years. Visitors to Haiti should be considered the same as individuals traveling to a malaria endemic area.

Developed by the American Association of Blood Banks
in response to Public Health Service Recommendations.

4/4/83



AMERICAN ASSOCIATION OF BLOOD BANKS

National Office Suite 600, 1117 North 19th Street, Arlington, Virginia 22209 (703) 528-8200

March 7, 1983

TO: AABB Institutional and Associate Institutional Members

FROM: Edward O. Carr, MT(ASCP)SBB, President

RE: ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

On March 4, the Public Health Service (PHS) issued a statement in Morbidity and Mortality Weekly Report on Acquired Immune Deficiency Syndrome (AIDS) from the Centers for Disease Control, Food and Drug Administration, and the National Institutes of Health. The statement is attached in its entirety. Also attached is a joint statement from the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers, which contains highlights of the federal statement.

The PHS statement refers to new FDA recommendations which will be forthcoming in the near future for manufacturers of plasma derivatives and for establishments collecting plasma or blood. Although we cannot provide specific information until these new recommendations have been issued, it is anticipated that blood banks will be expected to respond in two areas:

1. Provide to donors educational materials on AIDS describing the disease and identifying the high risk groups, and ask that all donors sign an acknowledgement card stating that they have read the educational materials. Blood banks can use the attached "Important Message to All Blood Donors" and "Donor Acknowledgement" to provide this information, or may choose to produce their own materials. (The National Office is currently developing an attractive information brochure and donor acknowledgement card which will be made available to blood banks at a nominal cost.)
2. Expand donor interview questions to identify potential donors who have early signs or symptoms of AIDS. Donors should be asked about night sweats, unexplained fever, unexpected weight loss, and lymphadenopathy (swollen glands). Donors should also be questioned about skin lesions that might be Kaposi's sarcoma. These include pink to purple flat or raised blotches or bumps occurring anywhere on the skin or mucous membranes. They are persistent and often firmer than the surrounding skin. Donors should be asked about exposure to AIDS patients and deferred if they have had close contact with cases or suspected cases.

We expect the incorporation of the attached donor materials and the expansion of donor interview questions to satisfy the new federal regulations for blood collecting agencies when they are issued. There may be additional guidelines for facilities collecting Source Plasma (Human). If modifications are needed, further information will be sent. Finally, blood banks should treat blood inadvertently collected from AIDS patients or suspected AIDS patients as potentially infectious and should handle, quarantine, and destroy it accordingly.

JOINT STATEMENT ON PREVENTION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME
RELATED TO TRANSFUSION

A Public Health Service Report of Inter-Agency Recommendations on Prevention of Acquired Immune Deficiency Syndrome (AIDS) was published in the Morbidity and Mortality Weekly Report on March 4, 1983. In addressing AIDS in blood transfusion recipients, the statement notes that

"The possibility of acquiring AIDS through blood transfusion is suggested by several recent cases in persons with no known risk factors who have received blood or blood products within 3 years of AIDS diagnosis. These cases are currently under investigation."

In consideration of this possibility, the Public Health Service recommended:

"As an interim measure, members of groups at increased risk for AIDS should refrain from donating blood and/or plasma. This recommendation includes all individuals belonging to such groups, even though many individuals may be at little risk of AIDS. Centers collecting blood and/or plasma should inform potential donors of this recommendation. The Food and Drug Administration (FDA) is preparing new recommendations for manufacturers of plasma derivatives for establishments collecting blood or plasma. This is an interim measure to protect recipients of blood and blood products until specific laboratory tests are available."

This report defined persons at increased risk for AIDS as:

"...those with symptoms and signs suggestive of AIDS; sexual partners of AIDS patients; sexually active homosexual or bisexual men with multiple partners; Haitian entrants to the United States; present or past abusers of IV drugs; patients with hemophilia; and sexual partners of individuals at increased risk of AIDS."

The new FDA recommendations are not yet available, but are expected to require informing donors about AIDS, and about groups at increased risk for AIDS so that individuals in such groups will refrain from donating blood and/or plasma. It is likely that requirements for donor screening will be modified to include questions designed to identify possible early signs and symptoms of AIDS.

The blood banking organizations published a joint statement on January 14 containing recommendations similar but not identical with the Public Health Service recommendations published today. These were widely distributed to our members, and many blood banks have already begun implementing them. We are confident that the specific recommendations from FDA, once available, will provide our members with further guidance in developing procedures that will assure a continued safe blood supply for the nation.

American Red Cross

American Association of Blood Banks

Council of Community Blood Centers

CENTERS FOR DISEASE CONTROL

M M M M R

MORBIDITY AND MORTALITY WEEKLY REPORT

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Current Trends

Prevention of Acquired Immune Deficiency Syndrome (AIDS): Report of Inter-Agency Recommendations

Since June 1981, over 1,200 cases of acquired immune deficiency syndrome (AIDS) have been reported to CDC from 34 states, the District of Columbia, and 15 countries. Reported cases of AIDS include persons with Kaposi's sarcoma who are under age 60 years and/or persons with life-threatening opportunistic infections with no known underlying cause for immune deficiency. Over 450 persons have died from AIDS, and the case-fatality rate exceeds 60% for cases first diagnosed over 1 year previously (1,2). Reports have gradually increased in number. An average of one case per day was reported during 1981, compared with three to four daily in late 1982 and early 1983. Current epidemiologic evidence identifies several groups in the United States at increased risk for developing AIDS (3-7). Most cases have been reported among homosexual men with multiple sexual partners, abusers of intravenous (IV) drugs, and Haitians, especially those who have entered the country within the past few years. However, each group contains many persons who probably have little risk of acquiring AIDS. Recently, 11 cases of unexplained, life-threatening opportunistic infections and cellular immune deficiency have been diagnosed in patients with hemophilia. Available data suggest that the severe disorder of immune regulation underlying AIDS is caused by a transmissible agent.

A national case-control study and an investigation of a cluster of cases among homosexual men in California indicate that AIDS may be sexually transmitted among homosexual or bisexual men (8,9). AIDS cases were recently reported among women who were steady sexual partners of men with AIDS or of men in high-risk groups, suggesting the possibility of heterosexual transmission (10). Recent reports of unexplained cellular immunodeficiencies and opportunistic infections in infants born to mothers from groups at high risk for AIDS have raised concerns about in utero or perinatal transmission of AIDS (11). Very little is known about risk factors for Haitians with AIDS.

The distribution of AIDS cases parallels that of hepatitis B virus infection, which is transmitted sexually and parenterally. Blood products or blood appear responsible for AIDS among hemophilia patients who require clotting factor replacement. The likelihood of blood transmission is supported by the occurrence of AIDS among IV drug abusers. Many drug abusers share contaminated needles, exposing themselves to blood-borne agents, such as hepatitis B virus. Recently, an infant developed severe immune deficiency and an opportunistic infection several months after receiving a transfusion of platelets derived from the blood of a man subsequently found to have AIDS (12). The possibility of acquiring AIDS through blood components or blood is further suggested by several cases in persons with no known risk factors who have received blood products or blood within 3 years of AIDS diagnosis (2). These cases are currently under investigation.

No AIDS cases have been documented among health care or laboratory personnel caring

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES / PUBLIC HEALTH SERVICE

AIDS Continued

for AIDS patients or processing laboratory specimens. To date, no person-to-person transmission has been identified other than through intimate contact or blood transfusion.

Several factors indicate that individuals at risk for transmitting AIDS may be difficult to identify. A New York City study showed that a significant proportion of homosexual men who were asymptomatic or who had nonspecific symptoms or signs (such as generalized lymphadenopathy) had altered immune functions demonstrated by *in vitro* tests (2, 13, 14). Similar findings have been reported among patients with hemophilia (2, 15, 16). Although the significance of these immunologic alterations is not yet clear, their occurrence in at least two groups at high risk for AIDS suggests that the pool of persons potentially capable of transmitting an AIDS agent may be considerably larger than the presently known number of AIDS cases. Furthermore, the California cluster investigation and other epidemiologic findings suggest a "latent period" of several months to 2 years between exposure and recognizable clinical illness and imply that transmissibility may precede recognizable illness. Thus, careful histories and physical examinations alone will not identify all persons capable of transmitting AIDS but should be useful in identifying persons with definite AIDS diagnoses or related symptoms, such as generalized lymphadenopathy, unexplained weight loss, and thrush. Since only a small percentage of members of high-risk groups actually has AIDS, a laboratory test is clearly needed to identify those with AIDS or those at highest risk of acquiring AIDS. For the above reasons, persons who may be considered at increased risk of AIDS include those with symptoms and signs suggestive of AIDS; sexual partners of AIDS patients; sexually active homosexual or bisexual men with multiple partners; Italian entrants to the United States; present or past abusers of IV drugs; patients with hemophilia; and sexual partners of individuals at increased risk for AIDS.

Statements on prevention and control of AIDS have been issued by the National Gay Task Force, the National Hemophilia Foundation, the American Red Cross, the American Association of Blood Banks, the Council of Community Blood Centers, the American Association of Physicians for Human Rights, and others. These groups agree that steps should be implemented to reduce the potential risk of transmitting AIDS through blood products, but differ in the methods proposed to accomplish this goal. Public health agencies, community organizations, and medical organizations and groups share the responsibility to rapidly disseminate information on AIDS and recommended precautions.

Although the cause of AIDS remains unknown, the Public Health Service recommends the following actions:

1. Sexual contact should be avoided with persons known or suspected to have AIDS. Members of high risk groups should be aware that multiple sexual partners increase the probability of developing AIDS.
2. As a temporary measure, members of groups at increased risk for AIDS should refrain from donating plasma and/or blood. This recommendation includes all individuals belonging to such groups, even though many individuals are at little risk of AIDS. Centers collecting plasma and/or blood should inform potential donors of this recommendation. The Food and Drug Administration (FDA) is preparing new recommendations for manufacturers of plasma derivatives and for establishments collecting plasma or blood. This is an interim measure to protect recipients of blood products and blood until specific laboratory tests are available.
3. Studies should be conducted to evaluate screening procedures for their effectiveness in identifying and excluding plasma and blood with a high probability of transmitting AIDS. These procedures should include specific laboratory tests as well as careful histories and physical examinations.

AIDS — Continued

4. Physicians should adhere strictly to medical indications for transfusions, and autologous blood transfusions are encouraged.
5. Work should continue toward development of safer blood products for use by hemophilia patients.

The National Hemophilia Foundation has made specific recommendations for management of patients with hemophilia (17).

The interim recommendation requesting that high-risk persons refrain from donating plasma and/or blood is especially important for donors whose plasma is recovered from plasmapheresis centers or other sources and pooled to make products that are not inactivated and may transmit infections, such as hepatitis B. The clear intent of this recommendation is to eliminate plasma and blood potentially containing the putative AIDS agent from the supply. Since no specific test is known to detect AIDS at an early stage in a potential donor, the recommendation to discourage donation must encompass all members of groups at increased risk for AIDS, even though it includes many individuals who may be at little risk of transmitting AIDS.

As long as the cause remains unknown, the ability to understand the natural history of AIDS and to undertake preventive measures is somewhat compromised. However, the above recommendations are prudent measures that should reduce the risk of acquiring and transmitting AIDS.

Reported by the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health.

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**AMERICAN ASSOCIATION OF BLOOD BANKS**

National Office Suite 600, 1117 North 19th Street, Arlington, Virginia 22209 (703) 528-8200

January 13, 1983

TO: AABB Institutional and Associate Institutional Members

FROM: Edward O. Carr, MT(ASCP)SBB, President

RE: JOINT STATEMENT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME
(AIDS) RELATED TO TRANSFUSION

The American Association of Blood Banks, the American Red Cross and the Council of Community Blood Centers have developed the attached Joint Statement on Acquired Immune Deficiency Syndrome (AIDS) as it relates to transfusion.

This statement is the result of deliberations at a meeting of the AABB Committee on Transfusion Transmitted Diseases chaired by Joseph R. Bove, MD, held on January 6. Present at this meeting were representatives from the American Red Cross, the Council of Community Blood Centers, the American Blood Commission, the American Blood Resources Association, the Centers for Disease Control, the Food and Drug Administration, the National Hemophilia Foundation, and the National Gay Task Force.

It is felt that the recommendations contained herein constitute an appropriate response to the current situation.

As stated in the document, new developments will be monitored carefully and a revision in the recommendations issued if warranted by additional scientific evidence.

**JOINT STATEMENT ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)
RELATED TO TRANSFUSION**

American Association of Blood Banks, American Red Cross, and Council of Community Blood Centers

Recent reports of abnormal immune function, Kaposi's sarcoma, and opportunistic infections in some gay males, Haitian entrants, and intravenous drug users and in others suggests that a new disease of unknown etiology has appeared in the United States. The disease has been called Acquired Immune Deficiency Syndrome (AIDS). Over 800 cases of AIDS have been reported with a very high mortality rate. While the major foci seem to be New York, San Francisco and Los Angeles, cases have been reported from other areas of the United States.

The predominant mode of transmission seems to be from person to person, probably involving intimate contact. The possibility of blood borne transmission, still unproven, has been raised. This latter impression is reinforced by eight confirmed cases in hemophiliacs treated with antihemophilic factor (AHF) concentrate, by a case in a newborn infant who received 19 units of blood components, one of which was from a donor who later died of AIDS, and by fewer than 10 unconfirmed case reports in other transfusion recipients. No agent has been isolated and there is no test for the disease or for potential carriers. Evidence of transmission by blood transfusion is inconclusive.

The finding of cases in hemophiliacs, especially those who use antihemophilic factor concentrate, coupled with the long incubation period and the continuing increase in reported cases is of sufficient concern to warrant the following suggestions for action on the part of blood banks and transfusion services. We realize that there is no absolute evidence that AIDS is transmitted by blood or blood products, and we understand the difficulty in making recommendations based on insufficient data. There is a need for additional information about this disease. Public health authorities should allocate resources to study the etiology of AIDS, its mode of transmission, and appropriate preventative measures and therapy. Blood centers and transfusion services should continue to assist public health agencies investigating AIDS. Given the possibility that AIDS may be spread by transfusion, we are obliged to respond with measures that seem reasonable at present. The lack of a specific test means that our major effort must revolve around two areas: 1) additional caution in the use of blood and blood products and 2) reasonable attempts to limit blood donation from individuals or groups that may have an unacceptably high risk of AIDS. Our specific suggestions follow:

1. Blood banks and transfusion services should further extend educational campaigns to physicians to balance the decision to use each blood component against the risks of transfusion, be they well-established (e.g. hepatitis, cytomegalovirus, malaria) or under investigation (e.g. AIDS).
2. Autologous blood transfusions, as an alternative to allogeneic transfusion, should be considered more frequently, especially in elective surgery.
3. Blood banks should plan to deal with increased requests for cryoprecipitate. Altered T lymphocyte function, a component of AIDS, has been reported to be less frequent in hemophilia patients

who are treated with cryoprecipitate rather than AHF concentrate. Although this does not necessarily imply that cryoprecipitate is free of risk, this finding may lead to an increased demand for cryoprecipitate.

4. Donor screening should include specific questions to detect possible AIDS or exposure to patients with AIDS. In particular, all donors should be asked questions designed to elicit a history of night sweats, unexplained fevers, unexpected weight loss, lymphadenopathy or Kaposi's sarcoma. All positive or suggestive answers should be evaluated before anyone donates.
5. Persons with responsibility for donor recruitment should not target their efforts toward groups that may have a high incidence of AIDS.
6. A major area of concern is whether attempts to limit voluntary blood donation by individuals from groups with a high prevalence of AIDS are appropriate at present. This question has medical, ethical and legal implications.
 - a. The presently available medical and scientific evidence that AIDS can be spread by blood components remains incomplete. Fewer than 10 cases of AIDS with possible linkage to transfusion have been seen despite approximately 10 million transfusions per year. Ongoing epidemiologic studies of all cases of AIDS are being conducted at this time. Should evidence of a clearly implicated donor population become apparent, specific recommendations to the blood banking community will be made promptly.
 - b. There is currently considerable pressure on the blood banking community to restrict blood donation by gay males. Direct or indirect questions about a donor's sexual preference are inappropriate. Such an invasion of privacy can be justified only if it demonstrates clear-cut benefit. In fact, there is reason to believe that such questions, no matter how well-intentioned, are ineffective in eliminating those donors who may carry AIDS. Blood banks should work with the leadership of groups which include some individuals at high risk of AIDS.
7. While there is no specific test for AIDS, there are laboratory and clinical findings that are present in nearly all AIDS patients. The use of these non-specific markers, for example, lymphopenia, immune complexes, and anti-HBc, are being evaluated in those areas of the country where AIDS is prevalent. We do not advise routine implementation of any laboratory screening program for AIDS by blood banks at this time.

These recommendations are made with full realization that the cause of AIDS is unknown and that evidence for its transmission by blood is inconclusive. We believe, however, that we must respond to the possibility that a new and infectious illness has surfaced. Until more information is available, we believe that the measures outlined above are prudent and appropriate.

We will continue to monitor new developments and revise our position promptly should medical or scientific findings indicate that a different course of action is warranted.

This joint statement was developed by the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers, with assistance from the American Blood Commission, National Gay Task Force, and the National Hemophilia Foundation. Also in attendance were representatives from the American Blood Resources Association, the Centers for Disease Control and the Food and Drug Administration.

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AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS
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August 2, 1983

Statement of Dr. Neil Schram, President, American Association
 of Physicians for Human Rights, submitted to the sub-committee
 on Intergovernmental Relations and Human Resources.

Mr. Chairman and Members of the Committee:

I appreciate the opportunity to express my concern over Federal Funding for AIDS. The American Association of Physicians for Human Rights is the national organization of gay and lesbian physicians. We have members in over 35 states and Washington, D.C. Our organization has produced guidelines to reduce the risk of AIDS by blood transfusion and to decrease the transmission of AIDS sexually between gay men.

It is clear to us that AIDS is a unique occurrence involving cancer, infectious disease and immunology. Epidemiologic studies continue to be critical in our understanding of the disease. There is also concern about the spread of AIDS via blood or blood products. Thus, several medical agencies are involved with the study of AIDS -- Centers for Disease Control, FDA, National Cancer Institute, National Institute of Allergy and Infectious Disease, and National Heart, Lung and Blood Institute.

The number of cases of AIDS continues to grow at an alarming rate. It is therefore essential, that research be coordinated at all levels as efficiently as possible.

We are, however, very concerned about the apparent lack of a coordinating group to oversee AIDS research. With no effective treatment available, it is obvious that vast amounts of research will be necessary.

We therefore strongly urge the creation of an independent group of medical experts to oversee research in AIDS to prevent needless duplication of effort and to ensure that no important areas are overlooked. Further, decisions about the spending of available funds and need for additional sums should be determined by such a group. Input from the affected risk groups to such a panel of experts is very important to assist in obtaining necessary background information for the planning of research projects.

We have written to Health and Human Service Secretary Heckler and Assistant Secretary Brandt requesting assistance with three goals. The first, is to see decisions about AIDS research returned to the medical community rather than remain a political issue. Secondly, we must see the panic about AIDS calmed.

Perhaps most importantly we want to see gay males made aware of the findings of the Centers for Disease Control regarding factors apparently increasing the risk of acquiring AIDS. Our guidelines, published in February 1983 and similar ones produced by other gay and lesbian physician groups have already produced a documented decrease in sexually transmitted diseases among gay males in New York, Los Angeles and Denver.

Further dissemination of our risk reduction guidelines would result in still fewer STD's and, hopefully, of AIDS. Prevention by risk reduction is our only hope at present.

I would like to share with the Committee my deepest concern about the total lack of response to our request for assistance to this date.

I thank the Committee for the opportunity to submit this testimony.

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