AT 10.20 AM THE JURY ENTERED THE COURT

HIS HONOUR: Mr Foreman and members of the jury there is another overseas witness, a doctor, who is in Australia and has a fairly tight schedule to return to the United States. I've given leave with the consent of all counsel to that doctor being called now. Yes, Mr Sher.

MR SHER: Will you call Professor Paul Holland please.

PAUL VINCENT HOLLAND, sworn:

EXAMINED BY MR SHER

MR SHER: Professor Holland your full name is Paul Vincent Holland?---That's correct.

Where do you reside professor?---I live in GRO-C California. A suburb of GRO-C, California.

Where is GRO-C in relation to places that we might know a little better such as Los Angeles or San Francisco?---It is about 700 miles north of Los Angeles about 150 kilometres northeast of San Francisco.

You are a medical practitioner by occupation?---That's correct.

Would you look at this document please professor and tell us whether that is your curriculum vitae as at June of 1989. The first document in white?---Yes, it is sir.

The green document. Is that a list of the articles that have been published either solely or jointly with others by you - either published or in the course of

publication, numbering 150 separate articles?---That's correct. It is sir.

I tender those two documents as one combined exhibit if I may your Honour.

HIS HONOUR: Yes.

EXHIBIT RX21 ... Curriculum vitae and bibliography of Professor Holland.

MR SHER: If your Honour pleases.

I just want to ask you about some features of your career professor if I may. Did you graduate in medicine from the University of California in 1962?---That's correct. From Los Angeles.

Your present address and major occupation is at the Sacramento Medical Foundation Blood Centre in Stockton Boulevarde, Sacramento is it not?---That is correct sir.

In the course of your career in medicine did you, following your graduation, do a number of graduate courses in immunology. Immuno-chemistry. Genetics and virology at the Foundation for Advanced Education in the Sciences at the National Institute of Health at Bethesda in Maryland?---Yes, I did.

So the jury can understand where that is, is that close to Washington DC the capital?---Yes, it is about 12 miles from the capital.

Washington DC is actually surrounded by a number of - the district of Columbia is surrounded by a number of States, is it not?---Just two, Maryland on the north east side and Virginia on the south west side.

Is the City of Washington and its environs spread out into both Maryland and Virginia?---Yes, it is.

What exactly did you initially start doing when you moved to the National Institute of Health at Bethesda in Maryland?---When I started there in 1963, I was a staff associate in the blood bank and in the Haematology Department, and for three years I received training and education in blood banking and in haematology - that is both in diagnosing blood diseases as well as treating those diseases with blood and blood components.

What is that National Institute of Health at Bethesda, Maryland?---The National Institute of Health often referred to as the NIH is a one of a kind research hospital. It's world famous for its medical research. It has about a 550 bed hospital that takes patients from all over the world - although most come from America - that have a whole variety of diseases, and performs research on those individuals. So it's a place to go if you have a rare or an unusual disease - they treat a lot of patients with blood diseases, haemophilia, leukaemia, cancer, heart disease, and the whole purpose is to devise new treatments, new therapies

that will help them, and then to publish those studies in the medical literature so that other people in the country and in the world can use those treatments.

What was your career at this particular institution - you started off doing post graduate work and the like there, how did you progress through that institution - can you just briefly tell us what happened to you there?---Okay. To complete my training in internal medicine - because that's my primary specialty - I was sent to the University of California in San Francisco for additional internal medicine training, including training in haematology and blood diseases.

HIS HONOUR: Excuse me, Professor, would you lift the microphone up just a couple of inches?---Sure, okay. So the National Institute of Health sent me for two more years of training to complete my specialty, in San Francisco. But I stayed on their faculty and on their paid staff, and then I was asked to return and to become the Assistant Chief of the Blood Bank Department, and then gradually I became the associate chief, chief of a section, and for the last nine years that I was there I was chief of the Blood Bank Department for the hospital of the National Institute of Health until 1983.

MR SHER: When in 1983 did you actually leave there?---After I'd served more than 20 years in the service, you

can retire, and I retired and moved to my current position as the Medical Director and the Chief Executive Officer of the Sacramento Medical Foundation Blood Centre in Sacramento, California.

What was the date that you actually left the National Institute of Health?---I left in September of 1983.

In the course of your career there, did you also become involved in the academic world in universities in the Washington - that's the capital Washington, not the State of Washington - in the district of Columbia?---Yes, in addition to my duties at the National Institute of Health, I had three faculty positions - one as Associate Professor of Pathology at Georgetown University in Washington DC - I was Associate Professor of Medicine at the George Washington University School of Medicine, also in Washington DC, and I was Associate Professor of Pathology at the Uniforeign Services University at the Health Sciences, which is in Bethesda on the campus of the Betheseda Naval Hospital, and this is the (inaudible) Medical School for the whole country.

When you left the NIH in September 1983 and went to Sacramento, what experience had you had in blood banking and in the field of treating or dealing with haemophiliacs in Washington?---Okay, so in my primary position, which was the director of a blood bank department - we drew blood, we processed it, we

prepared it and in cooperation with a number of the haematologists there, we participated in studies to try out new treatments for patients with haemophilia as well as other kinds of blood diseases. So I was intimately involved that way. Further, we often did treatments on haemophilia patients in our department, and third now in my current position, we still do treatments on patients with haemophilia and other blood diseases, as part of an outpatient treatment - facility we have at the blood centre. And finally, I do go out to the hospitals - I might call on a regular basis to treat patients in hospitals in my region.

Tell us a little bit, would you, about the present position you have at the Sacramento Medical Foundation Blood Centre, what goes on there?---Our centre draws about 105,000 units of blood year. We're the sole blood provider for about 40 hospitals in North Central California, and we draw all the blood and prepare all the components for all those hospitals. In addition we are the transplantation service for two kidney transplant units, a heart transplant unit, and a pancreas transplant unit, so we do all the tissue typing and matching. And finally in a regular rotation we would often do therapy on patients with blood, and other types of disease in these regional hospitals, because except for the University Hospital no one else has the kind of machines that we have to go out, and do blood treatments.

Do you have some teaching appointments in California at the moment?---Yes, my major teaching appointment now is I'm a professor of medicine in the division of haematology and anthology, or cancer therapy, at the University of California, Davis, which is the medical school - that is based in Sacramento and in Davis, but a mild form of blood centre.

What sort of student population does that branch of the university in California have?---This branch of the University California has about 19,000 students. In the medical school there are about 500 medical

students.

Apart from your experience in blood banking and in treatment and in research, have you also been a member of the following organisation, the American Association of Blood Banks?---Yes, I have.

The American Society of Haematology?---Yes.

The International Society of Blood Transfusion?---Yes, sir.

The International AIDS Society?---Yes, sir.

I just feature to number them for purposes to identify your expertise in relation to this case. Have you been involved in doing work in relation to the AIDS, and the human immuno deficiency virus in the course of your career?---In a number of aspects, both beginning and early 1980 before this disease even had a number, we treated some of the first patients at the NIH. Since then I've been involved in studies on ways to identify people who may be carriers of what is now know in the virus of this disease. We do treatments on some patients with AIDS now as far as certain kinds of blood exchange treatments. I'm on a variety of committees, both within the blood banking community, and to the government - to the NIH - which overseas research being done to try to reduce the risk of AIDS being passed by blood transfusions.

Have you been involved in any special research projects in the last six to seven years that are related to AIDS, and HIV?---Yes, actually a number of them.

Primarily again, the idea of trying to make blood and the blood components that we transfuse safer. So, mostly we've been involved with ways of trying to develop better tests as well as better means to identify individuals who might be carriers of this virus. And finally, a sort of studies to look and talk to blood donors who are carriers of this virus, nonetheless donated blood anyway.

Have you been one of the joint authors in recent times in particular, a publication a month or so ago in the New England Journal of Medicine in relation to the prognosis of people who have been infected with HIV? ---I think my last publication in the New England Journal of Medicine was about a year ago, in October 1989.

That's right, it wasn't this year it was last year. October of last year?---Yes, sir.

There were two articles published in October in the New England Journal of Medicine concerning studies of large groups of haemophiliacs who'd become infected with HIV, and trying to determine their prognosis and the like?---Yes, I'm probably one of those.

We'll come back to that in due course, Professor. Now, amongst all the committees that you've been on in the course of your career, have you been on the medical board of the National Institute of Health? ---Yes, I have. That's a committee which deals with research on human subjects. All research on human

subjects has to be reviewed by medical boards to make sure that it's ethical and appropriate, and provides proper informed consent.

Have you been a member of the Scientific Council of the American Red Cross Blood Program?---Yes, I have. For about five years I was an adviser to them ruling on the research that is proposed and whether or not it was worthwhile research and should be funded.

Have you been a member from 1982 and still are of the Transfusion Transmitted Diseases Committee of the American Association of Blood Banks?---Yes, I have. I'm currently the chairman of that committee.

Have you been chairman and are you presently the vice-chairman - I'm sorry, are you the present chairman of the Standards Committee of the American Associations of Blood Banks?---No, I'm finished with that Committee. I was on that for about six years. That was finished in October of last year. I'm no longer on the Standards Committee which sets the rules for blood banking in America.

Have you been on the Transfusion Safety Study Committee of the NHLBI which I'll ask you to tell us what it stands for?---NHLBI stands for National Heart Lung and Blood Institute and it is one of the major institutes of the National Institutes of Health. A lot of the money for research that they spend is really devoted to research on patients at NIH but actually about 90 per cent of the money that's spent by NIH on research is to support medical research in the rest of the country and about 10 per cent actually goes outside of the country when they have

large research projects and this is an example of one. It is a $22 million dollar study which has been going on for five years to look at ways of making blood safer and to try to learn more about the transmission of AIDS and of the diseases to patients like those with haemophilia. They ask outside consultants, such as myself, to be advisory to the government. So several times a year I'm asked to fly to Bethesda, Maryland to look at the progress of the research and make sure that the government is getting its monies worth and that the studies are conducted effectively and that they are then published for the whole world to benefit from.

Are you the chairman of that body at the moment are you?---I have been the chairman for the last five years now.

Have you, in recent times, been involved in working for the World Health Organisation as recently as July of this year?---Yes, in July of this year I was invited as the sole American representative to come to Geneva in Switzerland for a week to try to develop a manual on quality control and blood banking for third world countries and our task was to try to help say in Central Africa for instance. Try to set up blood banking operations that would be optimal in terms of safety and quality and they invited, as I say 10 people from different countries to come and do this. It was an arduous week of very difficult work.

Have you, if I can leave some of the committees you have been on for a moment and talk about your publishing career. Are you presently a member of the Editorial Board of Transfusion?---Yes, I am.

Have you been an associate editor of that particular journal?---Yes, I have. I served a term as that.

What is transfusion. What's its task?---Transfusion is a medical journal. It is what is called a pure reviewed scientific journal that is, to publish studies in it, they must be evaluated by other scientists anonymously and then recommended for publication or not. It is the main journal for blood banking for America and to some extent for the world.

Have you been the course director of a Immuno Haematology and Blood Transfusion Graduate Program under the auspices of the National Institute of Health?---Yes. Under their graduate program there I was the director of the course for ten years which would teach blood banking and the updates on blood banking to graduate students, physicians and specialists in blood banking.

Professor, have you contributed a total of 150 articles to journals published both in America and elsewhere in relation to your specialty?---Yes, I have.

Of 150 that are either already published or are accepted for publication and almost all have to do with blood banking and primarily hepatitis and AIDS and blood

diseases that are transmissable by blood.

Have you published articles in the following magazines. The Journal of American Medical Association?---Yes, I would characterise them as medical journals and not magazines.

I'm sorry. I don't know why I said that. The Lancet, the English Publication?---Yes, sir.

New England Journal of Medicine?--Yes, sir.

Annals of Internal Medicine?---Yes, sir.

And others?---And others, yes.

You've heard of the MMWR, I take it?---Yes, I have. It stands for the Morbidity, Mortality Weekly Report.

What's that?---That is more of a newsletter, it's not a pure review, it's scientific journal, but it's basically a weekly newsletter that's put out by the Centres for Disease Control in America, which gives updates and early warnings of diseases or problems which they believe should be brought to the attention of physicians in America, and I've been a regular subscriber of that for many many years.

Is that a publication that is normally associated with blood banking and transfusion medicine?---Not at all, only a very small proportion of it has to do with blood banking and transfusion medicine. Most has to do with other infectious diseases. A lot is to do with other diseases in general.

Why was it that you were a subscriber to this publication?

---Well, we were primarily involved with Hepatitis research and inflammation of the liver, and a lot of information was published on that in the MMWR, and just in general, I wanted to keep up with what was going on in the world for any new clues of blood diseases. We were subscribers for many years.

Now, do you recall reading in the MMWR the early reports of cases involving opportunistic infections in

homosexuals?---Yes, the very first report was in June of 1981, and I recall seeing them.

And at the National Institute of Health in Maryland, did, very early in the days of what turned out to be AIDS, did the matter come to the attention of the hospital there, and you get some patients?---Yes, they actually had patients even beginning in 1980 because these are individuals with peculiar infections, infections that young men shouldn't haven, and often they were sent to the NIH for diagnosis and treatment and experimental therapies.

What sort of groups were these patients coming from?

---Initially, the major risk factor was men who were homosexual who were having very active sex lives, with literally hundreds, if not thousands, of other men, so they were very sexually active gay men who also often took drugs and then the second major category were individuals who were IV drug users, who also might have engaged to some extent, but who were shooting and using all kinds of drugs, primarily into their veins, using needles to inject themselves.

Well now, do you recall the occasion when there was a first report in America in the MMWR of any association between this new syndrome, which came to be called AIDS, and haemophiliacs?---Yes, in July of 1982 was the first report in the MMWR of three men out of approximately 20,000 haemophiliacs in America who

appeared to have this new syndrome, which we were calling AIDS, and that was the first report of it. Apparently, potentially being caused by any kind of a blood product because all the previous cases were in homosexual men with many partners who were IV drug users.

Now, was there a conference held in 1982 to discuss this new phenomenon, this new syndrome?---Yes, there was a special meeting held about two weeks after this publication in late July 1982, at which a number of experts from within and from without the government were asked to come to Washington for two purposes. One was to put some sense to what this new disease was - and it was called by a whole host of names at the time - and one of our purposes that day was to try to decide on a single name, and it was at that meeting that the name decided upon was Acquired Immune Deficiency Syndrome.

What was it called before that?---It was called GRID, or gay related infectious disease. It was called opportunist infectious disease. It had a whole host of terms that really looked at different aspects of it, but it was felt at that meeting that one of the purposes should be to give it a single name because it appeared to be a single entity.

What was the other purpose of the meeting?---The other purpose of the meeting was to look at the case histories of these three men with haemophilia to see if it was

possible that these men had gotten this disease from the blood components that they had received, and second, to see if in fact that one of the three theories - and there were at least three theories at the time as to what was causing this peculiar syndrome - whether they either fit in with any of those theories, or disproved any of those theories because up to that point in time, all the previous men that had this disease were either very sexually active gay men or IV drug users.

You were at this conference, I assume, from what you're telling us?---Yes, I was there all day.

What were the three theories that were being canvassed at that time amongst American medical profession about what was causing this new syndrome?---At that time - and you have to remember that time as 1982 - there were three equally plausible theories. One was that there was some new infectious disease which nobody could find that was somehow being transmitted sexually or by needles in these individuals. The second major theory was that individuals in the three categories, and that included these three men with haemophilia, were getting injected into them either by their veins or by the rectum, or one way or another, all kinds of foreign material in the bodies of these people were just being overwhelmed by all this foreign material, and their immune system was wearing out. And the third theory, which also - - -

Can I just interrupt you there?---Sure.

How did this concept of injecting foreign material into the body fit the three groups that you've mentioned, the two that were well recognised by now, the gay active homosexual, the IV drug user and the haemaphiliacs. Where were they getting their foreign material from? ---Okay. In each case they're getting foreign material from other human beings. Every human being is different, and if you get semen or blood or blood

materials injected into you from many different people your body tries to react to it, it sort of fights it off. So, in terms of homosexuals were getting it injected into their rectums. IV drug users were getting it injected into their veins, or haemophiliacs were getting injected - the material from literally thousands of other humans - all three individuals were having their immune system - their blood system - assaulted with literally thousands of different kinds of foreign proteins, and your body can only react to so many of these, your body is trying to protect you, and normally protects you against infections, and cancer and things of that nature, but it then comes overwhelmed by foreign proteins. It literally sort of gives us.

That was the second theory. The first one was the new infectious - what - - - ?---Some new agent which we couldn't culture - we wouldn't define in anyway, but it was partially - there must be some novel agent which was causing this.

The second one is the sort of - the overwhelming of the body's immune system by this foreign protein that's being - or foreign material that's been put into it?

---Correct.

What was the third theory?---The third theory which also fits for all three groups is that in each case all of these individuals were getting multiple infections of viruses and bacteria. And once again, your body

can only fight so many infections, and whether it's a gay man getting semen injected into his rectum, or IV drug users injecting things in their veins, or haemophiliacs getting pool products or the blood from many many individuals, all three groups were getting hepatitis, some of them were getting sexually transmitted diseases, many other infections. And again, your body can only react to so many infections, and then it becomes overwhelmed, so the third theory was also equally applicable to all three groups.

Now, you have by this time read in the MMWR of the three haemophiliacs who'd come down this syndrome, and it was being postulated that they in someway had got it. What was your view at that time as to whether or not the fact that three haemophiliacs from - I think three different parts from America got it, indicated it was a blood born infection at that time?---Well, it made it a possibility, albeit a very slim one, because first of all there were all young men, and they were all old enough to have sex, and they're old enough to use needles, and in fact a lot of them injected themselves with there own anti haemophiliac factor. So, all the other men having been in these two categories essentially, it was possible that these three men with haemophilia may have been either very sexually active gay men, but denied it, or were shooting drugs. More

importantly there was no connection between them and any other individuals who were getting this disease, and by that that I mean that each of those patients with haemophilia had gotten injections of material, but it'd been given to hundreds of other people, and nothing happened to anybody else. There were 20,000 other haemophiliacs in America who did not have this disease, including literally hundreds who got the same material. So, that made it less likely, although there's still a slight slight possibility that somehow they were different, and somehow they got infected, and nobody else did.

What was the next event reported to the profession that you became aware of that caused further speculation about the cause of AIDS and whether it was blood borne?---The next event that happened was of no - was in December of 1982 when a further report came out in this MMWR which described four more cases of haemophiliacs who appeared to have AIDS and in addition a baby, who had apparently died of this disease, who had received 19 transfusions at birth as part of an effort to safe the child's life. So, now we have not only seven haemophiliacs out of a total of 20,000 but you have the first possible case of a baby, who might have gotten this disease from blood. The baby couldn't have had sex or used IV drugs. However, all the other babies who had gotten this disease up to this point in time had mothers who were IV drug users. Mothers who were the sexual partners of gay men and/or sexual partners of IV drug users. So, even though you have this first baby who was transfused, once again you still wondered was it the transfusions or might it have been that this mother didn't want to admit that she was an IV drug user or didn't want to implicate her husband or sexual partner, that he was either a gay man or an IV drug user.

I gather from what you are telling that by this time there had been other babies who had come down with AIDS?---Yes, there had been a number of other babies

with AIDS who had not been transfused.

What was the consequence of this report in December of 82 upon your thinking. How did it effect your thinking?---You couldn't ignore it because it was a possibility. On the other hand millions of people had been transfused with blood products over the last ten years before that and nobody else had this. Nonetheless, on this very slim possibility of a single case the centres for disease control called a meeting in early January and the blood banking community called together a meeting in early January to see if this was a possibility to discuss it and if it were, to see what we could do to reduce this risk, even though this was only the first possible case. You have to really emphasise that - that in terms of millions of other people not having this, this was a very early case which we couldn't even prove for sure, but we felt we should do something about it.

Did you go to both those meetings?---No. I only went to the second meeting.

What was the second of the two meetings?---The second of the two meetings was held on January 6, 1983 in Washington DC. It was primarily a meeting of this Transfusion Transmitted Diseases Committee, this committee which is chaired with all these difficult tasks of trying to define if something is caused by the blood and if so, how to prevent it. It is made

up of experts in blood banking. In addition we have several additional experts in infectious diseases and immunology and for this particular meeting we invited people from the centres for disease control the specialists in epidemiology and AIDS. We invited the food and drug administration which regulates blood banking in America. We also invited three gay men. One, a gay physician and the other were heads of gay organisations, because clearly it was gay men who were very sexually active who were most at risk of this disease. Whatever our strategy was we wanted to talk to them and involve them in a way that would be beneficial to decrease the risk of the blood not increase it.

When you say "we", who are you talking of at this particular time, professor?---This committee is made up of approximately seven individuals from different parts of the United States. Such as myself. I was not the chairman at the time. These are specialists. The chairman was from Yale University. His name is Dr Bove.

That's B-o-v-e?---B-o-v-e.

Is that the same University where Professor John Dwyer was working at the time?---That it is sir.

So, you had Professor - was it professor or Doctor Bove?---It is Professor or Doctor Bove. Either one is fine.

From - - - ?---Yale University. In addition we had, myself and other experts from the Red Cross from

independent blood centres. From a plasma centre and as I said we always had some independent, sort of ad hoc experts assigned to this committee especially in terms of hepatitis and we had a paediatric immunologist on this ad hoc committee as well as we could invite other individuals that we wanted to have come and help us made deliberations. So at this particular one we invited a number of additional people included in that we invited members of the haemophilia committee also were there as I said members of the CVC epidemiologist, specialists on AIDS.

This meeting was held in Washington DC?---Yes, just outside Washington DC - Arlington, Virginia.

What was resolved at this meeting?---At this meeting - after a long day's worth of discussions of many different aspects of the problem and what we could do about it, was a joint statement was drafted. That joint statement was published one week later, remarkably fast time, by the American Red Cross, the American Association of Blood Banks and by the Council of Community Blood Centres, and was sent to all blood banks in America, and then to make sure that everybody got the word, it was subsequently published as an article in March of 1983 in the journal Transfusion.

I'd just like you to identify the original document of the publication Transfusion. If you'd look firstly - I think it's in book 2, A7 - the defendant's folder. Have a look at the plaintiff's folder for the moment, it's A17, book 1 - A17 in the plaintiff's book which is book 1. It's under the heading "The National Haemophilia Foundation". Is that the publication that you have in mind?---No, it is not.

Would you look at Transfusion Magazine, which is in the defendant's folder under tab A7. "Joint statement on Acquired Immune Deficiency Syndrome related to transfusion" and it refers at the bottom to the joint statement, "dated January 13, 1983, developed by the American Association of Blood Banks and a lot

of others there?---That's right, that's the joint statement I'm talking about.

If you go back to the plaintiff's book, you'll see immediately ahead of A17, the joint statement published in type form - a two page document?---Yes, that's the joint statement I was referring to as published for issue on January the 13th.

As a result of this meeting?---That's correct.

So the 13 January at A16 is the statement of this meeting which was published in Transfusion which appears under tab A7 in the defendant's folder?---That's correct.

The one at A17, the following day - the National Haemophilia Foundation - is not the one that you're talking about?---That's correct, that's a separate statement.

Were you aware of this other statement that was issued the following day?

HIS HONOUR: Sorry, which is the other statement?

MR SHER: There are two in the plaintiff's folder. One at A16, which is the product of this meeting which was then published in Transfusion in March, and the publication in Transfusion is in the defendant's folder.

HIS HONOUR: Yes.

MR SHER: Then A17 is the National Haemophilia Foundation publication the following day.

HIS HONOUR: Not the one?

MR SHER: Yes, that's not the one.

Have I got it right?---Yes, this one from the National Haemophilia Foundation is from their Medical and Scientific Advisory Council. We had no part in that one, but two of those members were present at our meeting.

Now, if I could just take you to the defendant's folder, under tab A7, it's there set out. If I can take you to the first column, to the paragraph commencing "The predominant mode of transmission seems to be from person to person, probably involving intimate contact. The possibility of blood borne transmission is still unproven and has been raised". See that?---Yes, sir.

How does that expression there reflect view that you held at the time?---Well, I am a co-drafter and co-writer of this, so it embodies my impressions as well as the consensus of the individuals that were there that day.

You then go on to talk about the eight cases and the newborn infant, and then end up with the sentence, "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." What do you say as to whether or not that reflected your opinion at the time?---Absolutely.

It then went on to say this: "The finding of cases of haemophiliacs, especially those who use anti-haemophilic factor concentrate, coupled with the long incubation period and the continued 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 realise there's no absolute evidence that AIDS is transmitted by blood or blood products, and we understand the difficulty of making recommendations based on insufficient data." What do you say as to whether that reflects your opinion at the time?

---Quite accurately.

And it then goes on to say - if we can just leave a little out - at the end of the next paragraph, about a third of the way down the second column. "Given the

possibility that AIDS may be spread by transfusion, we're 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. Additional caution in the use of blood and blood products, and reasonable attempts to limit blood donation from individuals or groups that may have an unacceptably high risk of AIDS." What do you say as to whether that reflected your opinion at the time?---Exactly.

It then goes on to say that "The specific suggestions are as follows" and you then list them. Firstly, you deal with educational campaigns, then you deal with autologous blood transfusions. That's sort of donating your own blood for subsequent use, is that right?---Yes, and it's really only practical for someone who knows they're going to have an operation in the next few weeks where they may need blood. It doesn't work if you've been hit by a truck, or if you've got cancer or haemophilia diseases like that.

It then says in three, "Blood banks should plan to deal with increased request for cryo-precipitate. Altered T lyophilised function, a component of AIDS, has been reported to be less frequent in haemophilia patients who are treated with cryo-precipitate rather than AHF concentrate." Was that what had been reported? ---Yes, it was reported about that same time.

And it says, "Although this does not necessarily imply the

cryo-precipitate is free of risk, this finding may lead to an increased demand for cryo-precipitate." What do you say as to whether that reflected the opinion you held at the time?---Very much so.

So, does that state the reason why you anticipated yourself that cryo-precipitate might be in increased demand? ---Yes, our general philosophy has always been to recommend products that come from the least number of individuals, so if you have a product that's made from thousands of individuals, and you have a product that's made from a few, the risk is clearly greater with the former, so in general, all other things being equal, you would recommend the latter.

Now, I just interrupt you at this point to ask you something about this. Were all things equal?---No, things were not equal because it depended upon the age of the patient with haemophilia - certainly small children could get by much more easily with a few units of cryo-precipitate. It had to do with the severity of the problem, whether it was just a minor bleed or major surgery. It had to do with the location of the bleed, leading into the eye, into the brain would be much more serious, so it depended upon, wherever bleeding was, the age of the patient, how much he had to give, how long and in addition, it had to do with what the patient had before. If the person's already had thousands of exposures, it really doesn't make any difference which one you

give them now because it's already too late. They probably have been exposed to everything they're going to be exposed to.

If you had a lot of cryo-precipitate, what do you say as to whether there was any point to switching from one - I'll withdraw that. If you had a lot of cryo-precipitate, what was the nature of the risk?---If you've already had exposure through many many units of cryo-precipitate, the odds are you've been exposed to Hepatitis and other diseases so much so that it doesn't make any difference now when you give them now a product made from thousands of people.

Then it goes on to say in four:

> Donor screenings 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 capitis sarcoma. All positive or suggestive answers should be evaluated before anyone donates.

Was that your view at the time?---Yes, because we found that there must be some initial signs or symptoms people actually got really sick with what this disease AIDS was called, and that it appeared in some cases that they had some of these symptoms. So, if donors admitted to these symptoms, then we thought it would be appropriate to ask them not to donate blood.

It then goes onto say, five:

> Persons with a responsibility for donor recruitments should not target their efforts towards groups, and may have a high incidence of AIDS.

What did you mean by that?---We meant by that that you should not go out to areas, and have mobile operations in areas such as certain parts of San Francisco, and New York where you knew there were a

lot of gay men who were having a lot of sexual activity, and not make a special mobile to that area, because he would probably be increasing the number of individuals who would be at risk who would be donating blood.

Then you go on to talk about the major area concerned is whether attempts to limit voluntary blood donation by individuals from groups with a high prevalence of AIDS are appropriate and pleasant. This question has medical, ethical and legal implications. What - would you just elaborate on that for us as to what was that you in particular had in mind in relation to that matter?---Well, what we were trying to accomplish was some way we could discourage or eliminate potential blood donors, and these are voluntary blood donors, who would be at greater risk of carrying whatever this disease might be, and finding a way to decrease their chance of being blood donors, but at the same time not putting some foreigns or some process in place that would have the opposite effect, and that was a possibility, you could do something which could make the blood supply safer, or you could do something which could make the blood supply less safe. And we were operating pretty much in the dark, we had to use our best estimates based upon all the expertise as to what was the most likely to do the most good, and the least harm.

I'll come back to ask you more about that later. You went on to say that - in sub paragraph A - that fewer than 10 cases of AIDS with possible linkage to transfusion have been seen, despite approximately 10,000,000 transfusion per year. Was that the state of the evidence at that stage?---Very much so. We knew how many units of blood were transfused in America each year, and we had heard of nine additional cases that were being investigate where it looked like a person had been transfused, and it looked like the person denied being either gay, or an IV drug user, and having in both cases a lot of sexual purpose. So, until those were better proven, that was the state of our knowledge at the time.

Then, you go on to say in sub paragraph B:

> There's currently considerable pressure on the blood banking community to restrict blood donation by gay males. Direct or indirect questions a donor's sexual preference were inappropriate.

Then you go on talk about that. Was that your view at the time?---Yes, it certainly was.

I just want to interrupt this now to just ask you to go forward a bit. Did you become involved in steps involving contact with the gay community with a view to seeing that whatever was done to voluntarily exclude high risk homosexuals was effective?---Yes, we did several things both beginning with this

meeting where we invited several gay individuals, and representatives of gay - gay community - on a national level, and further on a local level, beginning in the fall of 1983 when I first came to Sacramento, I met with a number of gay individuals, gay physicians spoke at gay groups, because we really wanted the co-operation of this group since clearly the very sexually active gay men with multiple partners were the highest risk for this disease, and they recognised that to, and so we wanted to work together to try to reduce the risk of such persons being blood donors.

What was the problem. Why did you have to work together?---Well, if you want to get the co-operation of a group you have to learn about that group you have to try to make sure that you explain to them what your goal is and you try to then talk to them and say how is the best way for us to discourage the high risk individuals, these gay men with many sexual partners, very sexually active individuals that you and I both know are getting this disease. How can we work together to do something to decrease their chance of coming in the blood bank in the first place and even if they do, seeing that they don't donate blood without in some way having the opposite thing happen, that is, having more of them come in for one reason or another and more people at risk donate and actually make the blood supply less safe.

I'd just like to ask you a few more questions about this. What did you see to be some of the dangers involved in seeking to get voluntary exclusion of the appropriate homosexuals from blood donations, if for example, you went out and banned or sort to exclude all homosexuals as distinct from just a group of homosexuals?---Well, it was a balance between having enough blood available and having the safest blood available. To give you an example of that. In America we have to import 100s of 1000s of units of blood into the United States. So we are not self

sufficient in blood. If we lost a lot of blood unnecessarily, it would mean that we would have to import even more blood from outside the country. So, that was one of our concerns. If you want to get rid of gay donors, most men who've had a gay sexual experience will never admit that. 90 per cent of them will not. So, basically you could say, well let's not let any more donate blood because we don't know whose had a gay sexual experience. But you'd lose more than half of your blood supply. So that was impractical also. So then you have a balance between trying to get at the highest risk individuals to get them not to donate blood and not put something into place which would make some individuals at risk, who were not blood donors now, deliberately donate blood because of what you have done. So, it was a very fine balance.

How could what you'd do, make people donate blood that wouldn't otherwise donate blood. What was the problem as you saw it?---Well, the problem as we saw it at the time - and we gathered evidence for this after when the test for the AIDS virus became available - was a good part, from input from the gay community. They said, if you say you are gay you can't donate blood. What is going to happen is 90 per cent of men will never admit to being gay and they are going to keep donating blood anyway. So, you may only get 10 per cent of them to stop

donating. More importantly, if that becomes an issue that to prove you are not gay you donate blood a lot of gay men, especially closest gay men who may be having a lot of sexual escapades to prove to their wife, to prove to their boss that they are not gay, are going to donate blood. That would make the system even worse. Finally, there were some very militant gay men who literally said that they would lie. They would go in there and they were not blood donors - they would go in and deny everything and donate blood, just to prove to the system that they could do this. If you have either or any number of the last two groups of individuals donating then your blood supply would be less safe by doing this than it was before that.

Why - I know I'm going ahead, but why was it that when screening was suggested and particular groups of gays were asked to exclude themselves that you didn't exclude all homosexuals?---Well, at the time all the evidence as that the only homosexual men that were at risk were these very sexually active partners. Individuals with sometimes a 1000 sexual partners in a year and these were individuals who were well known in the gay community as being fast lane gays. They were having all these sexual encounters. Taking drugs to be able to continue to do this. These are the ones getting AIDS. Whereas, most of the gay men in the community and there are

millions of gay men in America were not getting this disease, were not doing this, and in fact, made up a large proportion of the blood supply and were felt not to be at risk.

Well, then this recommendation went out, and as you say, as a result of this meeting that was held on 6 January, I think you told us?---That's correct.

What was the next step that you were involved in, Professor, that related to this particular issue?---Well, all blood banks received at the end of March 1983 - believe March 24th - a memorandum - a recommendation - from the Food and Drug Administration which regulates blood banking in America, which contained a series of recommendations, they are not laws, because they cannot make laws that fast in a democratic country - but they were recommendations that were asked to be put into place in blood banks and a separate set of recommendations were put out to be put into place in plasma centres, which primarily use paid donors, and it was then to be that those recommendations were supposed to be put into place by most blood banks and plasma centres as soon as feasible in the spring of 1983.

That was a couple of weeks after this joint statement was put out by this meeting that you've told us about? ---That's correct.

Would you look at the defendant's folder at book A6. It's headed "HHS News", do you see that?---Okay. Now, that's a news release, it's not the actual item that was sent to the blood centres.

Is that the - notwithstanding the fact it's a news release - is that the same as the recommendation that was sent

by the government to the blood collection centres?

---It essentially encapsulises them in a summary form.

Now, who were the persons at increased risk - if you look at page 2 of this document, you'll see that it says in the paragraph commencing "Persons at increased risk of AIDS are defined as those with symptoms suggestive of AIDS, sexually active homosexual or bisexual men with multiple partners, recent Haitian immigrants, present or past users of intravenous drugs and sexual partners of individuals at increased risk of AIDS" - was that the same as the recommendation that was put out by the government in the official document?---Yes, these were the defined risk groups, and until they were called then - because these were the groups that were developing this disease called AIDS.

From your observation of the material that was available, what do you say as to the accuracy of the high risk group in relation to homosexuals as being sexually active homosexual or bisexual with multiple partners?

---Well, this was the situation. Virtually all the gay men that were getting this disease were such very active homosexual bisexual men having sex with both men and women. We had many, many partners, these were the ones that were getting this disease.

This is the recommendation that was made by the government?

---Yes, it is.

What was your view as to whether or not it was an accurate description of the risk group at that time?---I think it was an accurate description of the risk groups.

What about the use of the expression "multiple partners"?

---Well, that caused a great deal of controversy, because it wasn't defined, it was meant to mean many, because all the studies up to that point showed that those gay men getting this diseases had literally many, many partners, and so they were not exactly counted or categorised by the CDC, but it was these individuals with many partners - so this was the simplest characterisation of that particular group.

You were telling us that the government followed the publication in Transfusion with this recommendation in March. What, from your personal viewpoint, was the next important event which affected your thinking about whether or not AIDS was in fact a blood borne disease?---Well, in January of 1984 there was a publication in the New England Journal of Medicine from the Centres for Disease Control which described about 20 cases now of apparent transfusion transmitted AIDS, or transfusion associated AIDS, and what was important is in most of those cases they were able to track the blood donors, and in most of the cases they found at least one donor was a very sexually active gay man, or who

was an IV drug user. So now it looked like - you couldn't just say there were 20 coincidences, especially this kind of coincidence, so in my mind this really made it much more likely that AIDS could be transmitted by blood products, even though we still didn't know the cause, we didn't know of any way of picking up the carriers.

When was it that you came to the view that AIDS was probably a blood borne disease?---I was pretty much convinced myself by the end of 1983. I had access to a lot of these cases, saw this article even before it was published, and I was pretty convinced in my own mind by the end of 1983 that it was very likely that AIDS could be transmitted by blood transfusions.

I think it's common ground that the recommendations that were made by the government in relation to the risk groups remained in the same terms until the latter part of 83, if not even early 1985. Can you help us in relation to that, when they changed the description of the risk groups?---The risk groups were barely changed over that next two year period time, because in fact the risk groups remained essentially the same, that is the very sexually active men, IV drug users, Haitians, and the intimate sexual partners of those individuals, and the numbers kept growing but the characterisations stayed almost the same with about 75 per cent being these very sexually active gay men, and about 15 or 20 per cent being IV drug users, and some being both, and then a small proportion being either the IV drug users, women, the Haitians.

When was the change made, can you recall, in the recommendation of the risk group in relation to homosexuals was broadened to include not just the multiple partner homosexual?---It really wasn't

until the fall of 1985 that this characterisation was significantly changed, and that was changed because after the discovery of the AIDS virus in May 1984, and the ability of blood banks to begin in March 1985 - to being to test people for the antibody to this virus. We then began to really talk to and interview men and women who were positive for this antibody to the virus, to try to find out more about why they donated blood if in fact they were at risk. And what we found is, this is now well into the middle of 1985, is that some of the individuals were blood donors who were positive for this antibody weren't just these very sexually active gay men, but some had not been very sexually active, and some had only used IV drugs once and a while, and some in fact of the gay men were married men who absolutely denied being either homosexual or bisexual, but may have had a sexual encounter. So, using the bases of that information the wording was changed in essence to say that any man who's had sex with another man since 1977, which is when we believed this disease came into our country, that those individuals shouldn't donate blood. But we couldn't know that until we had this test, and we couldn't interview in depth people who were infected with this virus, so it wasn't possible to make that recommendation until then.

I want to take you back to the time when you were involved in

blood banking in Bethesda before you went to Sacramento. What was done in 83 in that period between the early part of the year after this January meeting, and the recommendations were made, and September 83 if the blood bank that you were at in Maryland in relation to the screening of blood donors there?---Okay. The blood bank of the National Institute of Health which screened donors, it added several questions to each donor history form which we thought would get a more - really get those individuals who might be in the early symptoms of AIDS or high risk of AIDS, so that was our approach in 1983 to change our way of questioning donors who were about to donate blood.

What were the additional questions that were asked?

---Basically there were three. One had to do with intravenous drug use, one had to do with signs or symptoms of AIDS, fevers and chills and so on, and the other had to do with recent travel to Haiti.

What would a blood donor do when he came into the blood bank at Bethesda to donate blood in relation - what actually happened to the blood donor when he came in?---At that point in time - this is early in 1983 and through most of 1983 - they would have been given probably ahead of time, some information just about blood donation in general, by giving a pint of blood and things of that nature, and then they would have been asked a series of questions about their health history, including these three new questions, beginning in March of 1983. They then would have their temperature taken, their pulse taken, their blood pressure taken, and a sample of their haemoglobin to make sure they could spare a pint of blood. And if they looked in good health, and if upon examining both of their arms, we found no needle marks suggestive of IV drug use, then if they met all the criteria, they would be permitted to donate a pint of blood.

Who would be asking them the questions and having a look at them, and doing these simple medical checks that you've mentioned?---In general, it was nurses, but on occasions, it was physicians, and if there was

any question about a donor's history, then it was always referred to a physician for approval.

Did they have to sign any declaration, or anything like that, that they weren't in a high risk group?---No, all they had to do was sign that they had answered all the questions truthfully, and that they gave us permission to take a pint of their blood.

Were they given any sort of informational leaflet about AIDS? ---Not at that time.

What sort of screening was done after they'd donated the blood to ensure the blood was safe to use?---At that time, the main test would have been a test for the Hepatitis B surface antigen which would indicate individuals who were carriers of the type of Hepatitis called Hepatitis B. They would have the simplest test performed on their blood, and then at the time we were doing a number of experimental tests that we were trying to see if they would be of benefit in decreasing their risk of Hepatitis. But those are the main things.

In this questionnaire that they were asked, were any questions asked as to whether they had Malaria, or any - --? ---Yes, all the questions had to do with the history of Malaria, and travel to areas of the world where Malaria was prevalent.

What about Hepatitis?---There were a series of questions about Hepatitis, about liver inflammation, about yellow jaundice because we know that such individual could

become carriers of this virus.

When you moved to Sacramento in September 83, you took over the control there of the blood bank. You were director of it, I think you told us?---That's correct.

And so it was up to you to decide what was done in relation to the screening of donors there. What did you do about it?---I did two things. I wanted to make the information that we gave to donors much broader and much more than just an AIDS information sheet which is what a lot of blood banks were doing, and I wanted to have it about other diseases that could be transmitted by blood, diseases which were a lot more important than AIDS then, and still are today. And second, I wanted to make sure that it would be effective, and so on a regular basis, I met with a number of members of the gay community, gay physicians, gay groups, to try and figure out a way that we would discourage those individuals at high risk who were donating blood, and both in our recruitment efforts, and in our information sheet, try to teach these gay men who were at risk how to get out of their system, how to say "Well, maybe I had Hepatitis when I was a child, or I went to Africa, and I might have got Malaria", ways that we could teach them so that even if they were asked to donate blood, they would find ways to not donate blood without necessarily saying they were gay.

Were they given information leaflets?---Yes, we had a, what's called a "Donor information sheet", which had information about AIDS, about the signs and symptoms, the risk groups, but it also had information on viral Hepatitis, Malaria, Syphilis, other diseases that could be transmitted by blood.

Well, why did you have them all in the one document, and not give them a single document related solely to AIDS? ---We did it for two reasons. One is, as I said, that all these diseases could be transmitted by blood, and if you had any of them, we didn't want you to be a blood donor. And second, we wanted to do this in such a way so that you could say that "Something on that sheet applies to me", because our little signature card said that "I have read the information provided to donors, and none of them applies to me", so basically they could pick anything on there, and say "Something on there applies to me" without acknowledging that they were gay, or ever in the high risk groups. So we wanted to make it easier for those individuals not to donate blood.

Was that a problem in your view. Let's assume you'd given them a document saying you can't donate blood if you are a multiple partner homosexual. What problems would that have created?---Well, we didn't want people either to give the impression or to leave the impression, especially to their co-workers or their wife if she happened to be donating next to them, or their boss, that the only reason they weren't donating blood was because they were a homosexual having many sexual relations. We wanted to give them the opportunity to have other choices so that they wouldn't lie or be forced to go into the system and donate if they just - if that was the only risk factor.

What would happen to a blood donor in your blood bank from September 83 on until say the end of 84 when they came in to donate blood?---Well, if they donated blood they obviously had to pass all the criteria.

No. Just tell us what happened. In the same way as you have told us what happened in the National Institute of Health in Bethesda. What happened at Sacramento?---In Sacramento, when you came into the blood centre or to a mobile operation, the first thing that was done you were given this important information regarding blood donation. On that sheet were a number of things but especially was the description of what AIDS was. What the risk categories were. What the symptoms were. It also

described hepatitis. Malaria. Syphilis. How to get information - more about that. What doctors to call if you wanted to get some more information and so on.

Let me interrupt you there. What was the high risk group described in this document in relation to homosexuals?---The high risk groups that we used were exactly pretty much the same as was requested and recommended by the Food and Drug Administration. That is the homosexual, bi-sexual men, sexually active with multiple partners. We used pretty much the same wording at that time initially.

You come in you get shown this leaflet. What happens then?---Well, you are supposed to read it. You are given time to read it, then in a as confidential interview area as possible a donor interviewer, usually a nurse and sometimes a doctor would then, first of all say have you read this sheet and does any of it apply to you. If anything applies to you you shouldn't donate blood. If it did, they could get up and leave right then and there. If they said, no it is okay, then we would go through about 40 some odd questions, a lot of which related to the signs or symptoms of AIDS or about hepatitis and so on. We tried to as I said, teach people that if you couldn't admit to the sheet, you could at least say, remember or think you remember that maybe you had hepatitis or maybe you had malaria. That was another

way to get out of the system. As soon as you gave a positive answer to any of those things the thing stopped right there. If you got through all of those questions and you signed the piece of paper which said that you had read the information sheet, you had answered all the questions truthfully and none of this applied to you then you could proceed. Then we did your temperature your pulse, your blood pressure, checked the sample of your haemoglobin to make sure you could spare a pint of blood. We examined both arms to look for needle marks in case they might have been an IV drug users. Then if they look healthy and the nurse felt that they could donate a pint of blood then they proceeded and the nurse took a pint of blood.

Who did that. Who did these simple medical tests and the questionnaire and looked at their arms?---In general it was nurses. Because in California you have to use nurses or doctors. In addition you can use trained medical interviewers. But a nurse has to see you somewhere along the line and if there is any question of - about any of this, any ambiguity, any misunderstanding, then a physician is usually consulted and has to approve the donor.

Assuming there is no ambiguity or anything. Do you have to be seen by a doctor?---No. You do not.

What do you say as to whether doctors saw your blood donors. What percentage of your blood donors would have been

seen by a doctor?---Less than 5 per cent would have been seen by a doctor. 90 per cent would never have been seen by a doctor.

Do you have to sign a declaration saying that you weren't a member of a high risk group?---No. What you signed was - part of the donor history at the end of doing it, which said I have read the donor information sheet. None of this applies to me. I have answered all the questions truthfully and to the best of my ability and I gave you permission to take a pint of blood.

And how long did that system operate for - when did you change that system because of the AIDS problem?---We've only changed that system within the last year, and in the last year most of the blood banks in California have now gone, at this time, because a lot of time has passed and a lot of things have changed, to a much more direct series of questions which actually do ask people in some intimate detail about their sexual history.

Is that a convenient time, your Honour?

HIS HONOUR: Yes, Mr Sher. The jury may now go to the jury room for 15 minutes.

AT 11.34 AM THE JURY LEFT THE COURT

WITNESS STOOD DOWN

ADJOURNED AT 11.36 AM

RESUMED AT 11.50 AM

AT 11.50 AM THE JURY RETURNED TO COURT

PAUL VINCENT HOLLAND:

MR SHER: Professor, at the Sacramento blood bank, what tests were given to blood donated to see that it was safe for use from September 83 onwards?---From September 83 we were doing this Hepatitis B surface antigen test to pick up carriers of Hepatitis B virus, and we were doing a syphilis test. Subsequently we added additional tests. In February of 1986 we added another test, a test called antibody to the Hepatitis B core antigen - it was an antibody to a type of hepatitis called Hepatitis B. In October of 1986 we added another test, a test called the transaminase test, or it's called the L-amino transfer AIDS test, or abbreviated ALT, as another non specific test to pick up a type of hepatitis called non A, non B.

That's called Hepatitis C now, is it?---It's now called Hepatitis C. Then in April of 1985 we had added the antibody to the - to the human immune deficiency virus, the antibody to the AIDS virus, and then about a year after that we added another test - a test for a leukaemia virus that could be transmitted by blood, and then in May of this year we added another test yet, or antibody, to the Hepatitis C virus.

So that in 83 and 84 - the rest of 83 and the whole of 84 -

you were doing the surface antigen test for Hepatitis B, and a syphilis test?---That's correct, it was the main test to pick up infectious diseases in blood.

Now, what about a surrogate test for AIDS in that period before the HIV antibody test became available in 1985 when you started using it - why didn't you use a surrogate test in either - did you use any surrogate tests at all in either the National Institute of Health when you were there, or in Sacramento?---We did not use any surrogate test, meaning a test designed for one purpose and used for another purpose - to try to prevent AIDS, either while I was at the National Institute of Health, or ever in Sacramento.

When you got an HIV antibody test available in 1985, the question of a surrogate test for AIDS ceased to be relevant because you had a test for AIDS itself? ---Exactly.

Why didn't you use a surrogate test in that period - did you think about using one?---We thought very seriously about using a surrogate test - meaning again, a test which we hoped or thought might pick up some individuals who may be carriers of whatever was causing this disease, AIDS - and we thought about the number of them, and we thought about the benefits and the possible risks of those, and we encouraged - and I was aware of studies which were

trying to find out if any of them were valuable - but I didn't put them into place for two reasons primarily - one, there was no evidence that they were effective or even potentially effective, and two, if you put such a test into place and you call it a surrogate AIDS test, then you can make your blood supply less safe - you can attract people into the blood supply - will come in to get your AIDS test who wouldn't be blood donors, and we have evidence for that now, but it was mainly a concern at the time which I believe was very real and which actually happened.

Let me ask you specifically about two tests that have been mentioned in this court. Firstly, do you know Professor Engleman from Stanford?---Yes, I do, he's a neighbour about 100 miles away.

Did you know that at some time he was using a T-4/T-8 ratio assay test?---Yes, I was aware that beginning in July 1983 he was using this as part of an experimental study on some of the blood that was used at Stanford.

Now, why didn't you use that sort of test yourself?---We didn't for several reasons, although we looked into it. First of all it was such that it had not been completed to see if it was of any value. (2) It has to be researched because there were no licensed available agents that were tested to do this with. (3) It would have - unless it were clear that it was a research study it might have in fact attracted people in who weren't regular blood donors who just wanted to get an AIDS test. And I thought until the test was proved to be of value it would be inappropriate to use it.

What about the fact that you could have this T-4/T-8 abnormalities indicative of AIDS. What do you say as to whether it - in fact if you - assume you're got a test and it showed some abnormality in your T-4/T-8 cells, and the ratio one to another. Does that indicate that you're in the prodromal form of AIDS?---Well, it might but that's another reason why

I thought it was inappropriate to use that test. It's a very non specific test. 99 per cent of the time when they test as abnormal it does not mean you have AIDS. It can be abnormal for many many other reasons, including going out and lying in the sun, and putting the blood specimen in the refrigerator, or having had a recent cold or other non specific illness. So, it's a terrible test as far as being very specific, and I was very concerned unless it was proven that it was worthwhile that we would unnecessarily frighten and alarm many many people, because it was so non specific.

Now, another test mentioned in this court. Perhaps before I ask you that. How many surrogate tests were under the debate in American in 83, 84?---Well, there were at least 22 different surrogate tests which were suggested as possible tests which people should do research on to see if they might be of value, and I think that was part of the problem also. Which one did you pick if you were going to try one? How could you learn something from it? And if you did one and not the other were you doing the right? So, it was really very difficult, but there were at least 22 different ones suggested to be done.

Were any tests ever recommended as surrogate tests by the Federal Health Authorities?---No, surrogate tests for this purpose have ever been recommended then or now by the Federal Government.

What about the Association of Blood Banks and Blood Centres and that sort of thing. Did they ever recommend a surrogate test?---None of the blood making organisations ever recommended surrogate tests for AIDS screening.

Yes?--_They did subsequently later on recommended some surrogate tests after some scientific studies showed that they would be worthwhile, or what was called non A, non B Hepatitis, but never for AIDS.

What about another test that's been mentioned in this court, the core antibody test for Hepatitis B?---Okay. This is another test - was one of the tests which was suggested as a possible surrogate test for AIDS, because of the finding that many individuals with AIDS had also been exposed to the Hepatitis B virus, but it also had not been proven. It has a lot of non specific problems with it, and it's not a licensed or approved or recommended test for that purpose.

It's been suggested that it should have been used, because a lot of homosexuals got Hepatitis B, and it was therefore said "If you test people ;for the core antibody test, you're going to find people who may not admit to being homosexual, but who really are, and you can therefore exclude them". What do you say as to that sort of argument?---Well, there is no test for homosexuality first of all. Second of all this test which indicates infection with Hepatitis B

would much more likely in this - their studies to bear this out - would identify health care workers, doctors, nurses, dentists, technicians and so on. Would identify people from the Orient, of Japan, China, those areas where hepatitis is much more frequent. And other individuals who as far as you knew were not gay, so you would have lost a lot more individuals by this test than just potentially in proportion, and only in proportion of those gay men who you might want to rule out.

Well, what was your view as to whether there ought to be a surrogate test used in either of the blood banks you were at in 83 and 84?---Well, I recommended against it, and we never adopted them, even though in Sacramento there were four or five blood banks right next door to us - were using some surrogate tests for AIDS, but we felt there was no reason for (inaudible), there was no evidence to support them, and in fact more than likely to make the blood supply less safe, and that's why we didn't use them.

How would they make it less safe?---Well, you have a - a poor test which you don't know whether it's any good or not, and yet you tell people that it's an AIDS test, because that's why you're doing it, is to pick up AIDS carriers - and once again we found that this attracted people - this happened in the San Francisco area and happened to us after we had a true AIDS test - people donated blood, they were not blood donors, they came in purely because you had this test and the blood bank is a nice, safe, free, confidential place to get an AIDS test, if they say they have one - and nothing happens to you, you don't get reported to the State authorities or anything like that. So it attracts in - and if you have a terrible test - or test which you have no evidence that it works, once again, you're more than likely to bring in people who are at risk, and we know subsequently that a lot of people who were

carriers of this virus, were negative for this antibody.

Now, let's assume you'd adopted a surrogate test and you got lots of people in and you find you've got lots of people either with positive to the core antibody test or a T-4/T-8 ratio abnormality, or one other surrogate test, and you find lots of people positive and you get rid of their blood, you don't use it. What effect would that have had upon the blood supply, in your opinion?---Well, it has two very important aspects. First of all, depending upon your area of the country, you would lose from three to seven, or even 10 or 15 per cent of your blood supply you'd have to throw away, and none of us could afford to do that. We had barely enough to get by and to save the lives of many patients. Second, you can't just do this test and not tell people. You have to inform people and you have to try to explain to them that you're doing this AIDS test, and that you believe that most of them didn't have AIDS, and that's a tremendous problem, you end up with a lot of very frightened people, a lot of people who would then tell other people "Don't donate blood, they may give you this AIDS test and it's not a real AIDS test", and "Don't donate blood, it's going to cause problems", and we know that we caused a lot of people problems by this kind of approach - having to go to their doctors and get

checked out and get reassured that they might have AIDS because this was an AIDS test, but it isn't really proven, and we don't know what it means anyway, but your blood is no good, we're going to throw it away.

I want to ask you some questions about the use of cryo-precipitate and concentrate. Are there any advantages using one as opposed to the other, or disadvantages? How would you compare the two?

---Well, there are advantages and there are disadvantages to each one.

Let's talk about cryo-precipitate first?---Okay. Cryo-precipitate is a portion of the plasma from an individual donor which you prepare in a very special way, and then you must keep frozen in the deep freeze and is good for up to a year, and you must keep it very carefully, otherwise the anti haemophilic factor will deteriorate. It has a certain volume and also you don't know for sure - you can only take it from normal people, and you prepare it the same way - how much Factor 8's in there. So if you have a relatively small person or child and you don't need to get very much Factor 8, you can give a certain amount of this cryo-precipitate which you've kept in your blood bank refrigerator under careful storage, and in general you can get enough to treat that person.

Yes?---But if you want more convenience then you use this concentrate because it doesn't have to be kept frozen. It says right on the bottle how much is in there, so you know the exact dose to give and if you had to give a lot and you had to give a lot over a period of time, it is much more effective and much more predictable and you help the patient much more to give them these concentrated material which comes in this bottle already labelled with the amount on there. The downside is, for the latter it is made from 1000s of individuals and has a higher risk of hepatitis and other infections. But if you give enough cryo-precipitate - if you give 1000s of those, then you are going to get hepatitis too. But the point is the first is made from fewer individuals but you never give one bag of cryo-precipitate. You give 10 or 15 at a time. You can give too much so the concentrates, this pool of material is a more effective way to give more material with less trouble, more predicably, so it is a better therapy for a lot of patients.

Research work has been done in America in relation to the chance of getting infected with HIV if you get cryo-precipitate as opposed to concentrate. Have you actually been involved in any of that research work yourself?---I have not been directly involved and I am part of the overseer of one of the studies which involves six haemophilia centres in the United

States. Part of that Transfusion Safety study.

If you get a transfusion from cryo-precipitate and the donor has got HIV infection, what are your chances of getting HIV infection from the cryo-precipitate?

MR RUSH: Your Honour, I object to the question.

HIS HONOUR: Yes. On what basis Mr Rush?

MR RUSH: We are dealing with the United States not Australia your Honour. We haven't got a time factor in relation to the year or the period over which the so-called study has taken place. We haven't got a locality. It is well known, even on the evidence that's been given so far by this witness that areas of the United States were subject to greater infectivity than other areas of the United States. But particularly, your Honour in relation to its applicability in this country, any studies such as that, we would submit your Honour, it could not be shown to be applicable to the situation in relation to this country. We are dealing with a completely different type of blood supply. Completely, as I understand Mr Sher's argument, different circumstances.

HIS HONOUR: There are certain bases - certain differences between the two countries, but a great deal of evidence as between the two countries. I have permitted in evidence as between this country and the United States and other countries and subject to the jury being well aware that conditions are not

identical I regard this as admissible. I'll permit it.

MR RUSH: If your Honour pleases.

MR SHER: What's the chance of getting infected professor, if you get - getting HIV, if you get cryo-precipitate from somebody who has donated blood, which is made into cryo-precipitate?---I think that's what the important thing is, if that cryo-precipitate comes from a blood donor who is infected with this virus then the person who receives that has more than a 90 per cent chance of developing that infection. It is a very efficient and unfortunately, a very effective way to transmit this virus. If the cryo-precipitate, or the platelets or the blood has the virus and you transfuse it to someone more than 90 per cent in all studies, so far today, would develop the infection.

What about if you get an infected donor to a batch of AHF concentrate?---If one of the donors of the 1000s that go into the Factor 8 concentrate happens to be infected, the highest infectivity rate that anybody has found has been 50 per cent and it is probably that's unusual. So, it appears that that virus is so diluted out by all the other individuals in the pool that it is less likely to infect somebody.

Just while I'm asking you about. I want to ask you about what recent studies have revealed in relation to strains of HIV. What's been discovered in relation to HIV

as to whether it is all the same or whether there are different strains of it?---There are many different strains and there's strains you are to find by a chemical - very fancy research type studies, which will show minor differences. But there are also so-called epidemiologic studies where, if you look at the kind of infection, or the kind of disease that a donor or person has, and you look at what happens to the people who got their blood. There is a similarity. That is, if a donor stays healthy and yet is infected with this virus, then the people that receive the blood of that person which has his strain of virus in it, can also stay healthy a lot longer. On the other hand, if the donor gives blood, and then very soon after, gets AIDS or dies of this disease, then whichever way he gets the virus that he transmitted, they tend to get the disease much sooner, and have a higher chance of dying.

Let's assume that evidence was led in this case to show that a donor donated blood in August 1983, which was given to the plaintiff in this case, in about March/April 1984, and that donor is still alive and well and asymptomatic, there's no symptoms of AIDS at the moment. What does that indicate in relation to the strength of the strain of HIV involved in that donation in relation to this plaintiff?---Well, I would say it is a much better prognosis for the person that received the blood product than that person because from our studies, which we published last year, and others that I know about, when such individuals, blood was given to people and the individuals that received it, tended to go and be healthy a lot longer, for years longer, before they, a proportion of them tended to get sick with AIDS.

I was asking you about the difference between cryo-precipitate and concentrate. Can I ask you something else. The blood centres you've worked in in Maryland for many years, and then since 83, September, in Sacramento, what sort of blood products were made by those two centres, from the blood donations that you got?

---From the blood donations that, those blood centres that I worked in got, we could really physically make the cryo-precipitate ourselves, but for the factor 8 concentrate, we would have to send our plasma off to a company that would then fractionate it, and then would send us back, almost

never the same material we sent out, but they will send us back material made from many plasma donations, many other places. But in both blood banks that I worked in, we had both products, and we issued both products, and we advised people having used each of these products.

Apart from cryo and factor 8 concentrate, what else was the blood used for in these two blood centres?---Well, we made many other things. We made platelets, which are part of the blood that helps you clot when you don't have enough of these little factors in your blood. We also made packed red cells, we used whole blood. We used fresh frozen plasma for patients who had burns. We used cryo-precipitate for other patients that had trouble with bleeding, had a wound, we can make sort of a glue, an (inaudible) with cryo-precipitate. So we can use the different parts of the blood, and we did in each place, for a whole different variety of patients.

And did you have haemophiliacs in either or both of these places where you'd worked?---We treated haemophiliacs in both places in large numbers.

When you say "large numbers", can you give us some indication? ---Well, at any one time we were treating between one and 200 patients of haemophilia, our centre in Sacramento deals with a large haemophilia centre which has something in the order of a couple of hundred patients with haemophilia, they get regular

treatment.

Do you know Dr Shelby Dietrich and her work?---Yes, I do.

Do you know the size of the hospitals that she was at until very recently? Do you know the hospital that she was at?---Yes, they were treating even more than haemophiliacs. They have a large centre there in Los Angeles, like an orthopaedic hospital.

How does that rank in America for size?---That's one of the largest haemophiliac treatment centres in the country.

And are you aware of the other large haemophiliac centres in the US?---The largest one is in New York, but there's a large one in Seattle. There's a large on in Pennsylvania (inaudible) Pennsylvania. There are a number of these large centres scattered throughout the country.

And what's the name of the one in Seattle?---Called the (inaudible) Sound Blood Centre, it's affiliated with them.

Just going back to the activities of the blood centres you've been working at, you'd send out plasma to be made up into Factor 8 concentrate, and it would then be returned to you?---That wasn't exactly the term, we would buy or get other material which almost never was what we sent out.

Were they the commercial manufacturers that you're talking about, the people to whom you sent the plasma for Factor 8 concentrate?---That's correct.

And where would they get their plasma from, apart from people such as yourself?---Well, 80 per cent of the plasma in the United States comes from paid plasma donors who provide just plasma. Only about 20 per cent come through volunteer donors which come mostly from the excess plasma, or the part of the plasma which we take out the blood in volunteer blood banks.

What's your view about the relative safety of blood donated by paid donors, as opposed to blood donated by volunteers?---Well, from many studies that I've done in the past I'm on record as saying that when you pay people for their blood or plasma, then a much higher risk of transmitting disease, especially hepatitis, at least 10 times higher risk.

Can I ask you some questions about warning patients. You were treating people in both Bethesda and Sacramento with blood products?---That's correct.

Most of it made up by yourself, but including commercial Factor 8 concentrate?---That's correct.

Were you actually involved yourself in treatment?---Sometimes.

In 83 and 84 did you warn your patients about the risk of AIDS from the blood products that they were getting, whether it would be from the commercial people being sent back to you, or directly collected and processed by your own hospital?---No, we did not.

Why is that?---Well, first of all we didn't - we knew was a prudent risk. Second of all even when it was currently occurring it was an extremely rare remote risk in the order of one in a million, and third we thought that it was much more important that these individuals received these products to save their lives, and that even if we told them that such a risk existed they would have used it anyway.

Has there been a change in that practice?---Yes.

When was the practice changed?---In my blood centre we began in March 1987 to warn people about the risk of AIDS, and even though the risk was still very remote there was such a real and a proven risk and such a high chance of resulting in the fatal disease, we thought it was important to warn them, but not until March 1987.

I want to ask you something about heat treatment of Factor 8. Have you been involved yourself in supervising or having a look at the process of heat treating Factor 8 to protect people from anything at all?---We have not been directly involved, but I have been overseeing studies which looked at how effective heat treatment was in reducing the risk of both hepatitis and AIDS transmission.

When was attention first directed at the concept of heat treating Factor 8 for the purpose of protecting people from whatever was causing AIDS?---That began in the 1970s to try to develop means of heating

Factor 8 concentrate to reduce the risk of hepatitis, because we knew it was a very high risk. So studies began about 1975 or so to try to effectively heat treat Factor 8 without destroying it.

But I mean in relation to AIDS not in relation to hepatitis? ---Well, the studies to see whether it effectively killed the AIDS virus were really done later on, and were sort of accidental. They had already put into place a lot of the heat treatment methods, and then our point was to then see how effective they were, not only in stopping hepatitis, but seeing whether or not they also killed the AIDS virus.

When did the heat treated products become available for treating people with a view to protecting them from AIDS?---Probably the first heat treated materials were available in 84 and 85. So, up until - really until well into 85 we didn't have 100 per cent conversion to heat treated materials.

Well, developing heat treated Factor 8 is that a simple process?---No, it's a very difficult process. It took 10 to 15 years, and initially was not very effective and second also caused problems in destroying the Factor 8.

Now, I want to ask you some questions about your research work and experience in relation to the chances of a person with an HIV infection going on to develop full blown AIDS, and that sort of work. Were you

one of the co-authors of a study that was published in the New England Journal of Medicine on 26 October, 1989?---I think so, but could you show me to make sure?

Yes, would you just have a look - we've got the wrong on, pardon me a moment. Professor, have you studied the question of the likely prognosis of a person who is HIV positive that has not yet developed AIDS?---Yes, I have.

Have you been one of the co-authors of an article which actually researched a large body of haemophiliacs who were HIV positive?---Not haemophiliacs per se, but blood recipients.

Are you familiar with the other material that's been published in recent years relating to that topic, in which large groups of people who are HIV positive have been studied?---Yes, I am, I follow that very closely.

Are you familiar with material published - other than your own material - in the New England Journal of Medicine? ---Yes, I am.

Would you have a look at this document - is this the research paper published by a large number of doctors including yourself in the New England Journal of Medicine in September of last year?---Yes, I think it's October. Yes, John (inaudible) is the first author.

What was that study about?---That study was mostly to look at - if you had a blood donor who was infected with this virus, we wanted to know what happened to that blood donor in relation to what would happen to the people who received the blood from that person, and

what we found is that on average it took seven years to come down with AIDS after a transfusion from a blood donor who was infected with this virus. But that if a blood donor got AIDS sooner, then the patient was more likely to get AIDS sooner. Whereas if the blood donor did not develop AIDS, the blood donor stayed healthy - and many people stayed perfectly healthy with this virus, feel fine and no illness - that the same was more likely true of the recipients. So there was a correlation between the disease and the donor and what would happen to the patient.

Is that a copy of the article that you co-authored?---Yes, it's right here.

I seek to tender that, your Honour.

HIS HONOUR: Yes. Are you wishing to add it to a book?

MR SHER: Yes, your Honour. If we can put it under a tab in book 2 - I think there's tab 63. Does everyone have a tab 63?

HIS HONOUR: Apparently the jury does.

MR SHER: Have we got some 63s? You've got the tabs? Yes, that's what I was really trying to find out.

HIS HONOUR: This will go under tab 63 in book 2.

MR SHER: It states:

> We conclude that most recipients of HIV infected blood becomes sero positive, but AIDS develops in about half these recipients within seven years, and that the risk may be higher when AIDS develops in the blood donor sooner after donation.

Was that the conclusion you came to?---Yes, sir.

Well, that means that if half - about half develop it within seven years, that about half don't develop it within seven years?---Exactly, half of them were still quite well, they didn't have any evidence in AIDS in seven years.

In coming to a view about prognosis of people who were HIV positive, have you also had regard to other published material?---Yes, I have.

Did that include the article published on 26 October 1989 in the New England Journal of Medicine by a large group of doctors, the first author which was James Gotters?---Goedert.

Goedert?---Yes, sir.

Is that the article?

HIS HONOUR: How do you spell that name?

MR SHER: It's G-o-e-d-e-r-t, your Honour.

It also includes Dr Alledort - some well known names that we've had mentioned in the court. Gilbert White and others, Michael Lederman, that's the

article that - - - ?---Yes, sir. This is probably the largest study of long term follow ups of patients with haemophilia who've been infected with HIV, the virus of AIDS.

And in expressing an opinion about the prognosis of a haemophiliac infected with HIV, has this sort of material - part of the material upon which you base such an opinion?---Very much so.

I seek to tender it on that basis, your Honour, that is the material taken into account by the witness in forming an opinion about this document.

HIS HONOUR: Yes.

MR SHER: It's not objected to - - -

MR STANLEY: Your Honour, we would submit that it is not admissible, we don't object.

HIS HONOUR: You don't object?

MR STANLEY: No, your Honour.

MR SHER: I submit that it is admissible for what it's worth. Anyway, your Honour - - -

HIS HONOUR: Well, I won't express a view on that.

MR SHER: It doesn't seem to be necessary. Can that go under tab 68, your Honour? Have the jury got that tab? Have they been distributed, your Honour?

HIS HONOUR: They're just in the course of being added.

MR SHER: While that's been done could Professor Holland be shown book 4, your Honour, page 55?

HIS HONOUR: Yes.

MR SHER: It's the plaintiff's T-cell counts.

Professor, I'd like to ask you to look at the document which is at page 55 of book 4 which is the plaintiff's T-cell counts that have been taken since 5 September 1985 up until 24 July of this year. You've seen those previously I gather?---Yes, I have.

HIS HONOUR: We should have out before us at the moment book 4, page 55, and that article can still remain.

MR SHER: I just want the Professor just to identify the fact that he's seen them before, your Honour.

HIS HONOUR: Yes.

HIS HONOUR: Yes.

MR SHER: Professor, what we know about Mr PQ is, that he is in his late 40s. He is married with two children. He is in apparent good health although he is HIV positive. He is still in full-time regular employment. I ask you to assume that he was infected, initially by a blood donation from a donor obtained in August 83. That donor is still alive. That donor is asymptomatic and that that donation went into a batch of Factor 8 that was given and used by the plaintiff in about March/April 1984. The only other evidence we have about his current health or any tests is that at some stage he had a T24 antigen test and it was negative?---Okay.

They are the facts. In your opinion I should add to that also that he appears to have received a second contaminated batch obtained in about December, late December 83, given to him in August of 1984, but that donor has since died.

MR STANLEY: Your Honour, my learned friend says he appears to have done these things. That's not the case. It doesn't appear at all. There's no evidence about it and it should be specified that it is assumption.

HIS HONOUR: Mr Sher, has hypothetically put it that - asked the witness to lead - at this stage.

MR SHER: Yes, we were going to lead evidence on these questions.

HIS HONOUR: Yes, but Mr Stanley is quite correct.

MR SHER: Yes.

What's your opinion about the prognosis of that particular patient. He is not getting any medication at the moment. He is not on AZT or anything like that?---I think this patient, based upon these numbers and what you have told me has a favourable prognosis. That is, I think that he would fit in with the majority group that he could continue to go on for some years yet, without any signs or symptoms of AIDS. In fact, since his counts have been abnormal now for at least four years this would fit with that that he has a very benign infection or a benign form of the virus which does not appear to really be affecting him seriously in terms of the development of AIDS, which hasn't happened yet.

What - I mean, are we in the realm of guesswork here as to how long it may be before he does develop AIDS?---Well, it is in the realm of guesswork to some extent, but you base it upon the information you have and I would say that based upon these data and the article by Dr Gettard, that there is well over a 50 per cent chance that he could go for a number of years yet without ever getting AIDS and even once you get AIDS, 50 per cent of people will die within two years of getting AIDS, or what that means is, 50 per cent of people, after getting a clinical diagnosis of AIDS are still alive two years later and all of that is now changed and improved by the use of

therapies such as AZT.

I want to ask you about the experienced you had had in recent years, in relation to past events. It has been suggested here that medical examinations should have been conducted of donors and let's assume for a moment that the medical examination was a really comprehensive one. Based upon your experience what do you say as to whether or not, if you had examined - medically examined donors back in 83/84, you would have detected anything that would have shown that they were, at that stage themselves, positive to HIV?---Well, I don't believe we would have found anything and now we have good evidence to show that many people, infected with this virus are totally asymptomatic, have completely normal physical examinations and that's the rule. The vast majority are perfectly healthy and stay healthy for years without any physical finding - any sign that they are infected with this virus.

Did your blood banks turn their mind to giving people donating blood in 83/84 a more comprehensive medical examination than the fairly simple one you have described to us in your evidence?---Yes, we thought about it.

What did you decide?---That we had no evidence that would be effective. That it would, in all likelihood not reveal any finding that would lead us to believe that a person has AIDS and in fact it might identify

people who had other findings which were not consistent with AIDS and which really might unnecessarily rule them out.

So you asked them questions about symptoms and signs, and I suppose the nurse cast an eye over them?---Yes, the nurse cast a very careful eye over them, and we certainly looked for people in good health - and don't forget, we're dealing with volunteer blood donors, people who are trying to help other people, and we believe that their history is very important, they have no reason to lie to us, they're not being paid, and so we put a lot of faith in their history, and their reason for trying to be a volunteer blood donor, to help someone else.

I want to ask you a few more questions about your experiences with the homosexual community in California when you moved to Sacramento and you were conscious of the fact that a very large proportion of the high risk group were homosexuals. What were the problems that you saw at the time in dealing with the homosexual community and not, for example, just blanket banning all homosexuals?---Well, as I mentioned earlier, but I'll restate some of it - about 10 per cent of American men from studies done many years ago, have had a homosexual experience. So at the outset you can say that probably at least 10 per cent of American men have had a homosexual experience. But 90 per cent of those men would never admit to that, would never acknowledge that, especially in a blood donor setting. So we were faced with the fact that 90 per cent of those potentially having the sexual

activity, one, would not admit to it, and two, we believe the vast majority of them - not all of them - would have had minimal sexual numbers of partners, were probably not at risk for this disease. But more importantly, depending upon how we approach the gay individuals, who made up in many cities a large proportion of very good blood donors, that we wanted to make sure that we ruled out those who were at risk, or at high risk, that we believed to be at risk, and did not encourage those who were at risk who already were not blood donors - we didn't want them to come into the system and to donate blood - either to thwart the system or to prove they weren't gay - prove they weren't one of these kind of people. So it was a - a sort of a comprehensive approach to try to get those out at risk without bringing in those at risk who might've responded and tried to donate blood.

There have been a lot of questions asked in this court about homosexuals and a lot of assertions made from the bar table about what homosexuals are like. In your experience, are all homosexuals sexually active?

---No, that was another - another whole area, and that's why we had to talk to the homosexual community. There are gay men who'd never had sex with another man, they'd never had sex with a woman either. There are some gay men who are very faithful to their partners, there are some who have

relatively few partners. So there's a whole spectrum, just as there are in the heterosexual community, of people who don't have sex, are very monogamous, are very limited in their number of partners, or who are very active. And I think you have to keep that in mind, especially in the context of this disease.

We get the impression, because they're so overt and flamboyant and noisy and demonstrative about their homosexuality, that the vast majority of homosexuals are fast lane gays. What, from your enquiries, investigations and discussions with the gay community, would you say to such an assertion? ---Well, that's the marked exception. The vast majority of gays are not people you would ever recognise as being gay, that are both upfront about it and have this very active sexual life with multiple partners - that's the exception, and these are the ones who are getting AIDS.

Thank you, Professor.

HIS HONOUR: Mr Barnard?

CROSS-EXAMINED BY MR BARNARD

MR BARNARD: Professor, when was it that you first moved to Sacramento in 1983?---In September of 1983.

In Maryland, during the time up until September of 1983, you told us that you were doing some research in relation to haemophiliacs, is that correct?---Excuse me? We did research on?

On haemophilia?---Yes, sir.

What was the nature of that research?---Well, if you look at my bibliography you'll see that in the 1960s we were among the first people ever to use cryo-precipitate for patients with haemophilia.

That was in Maryland, was it?---That's correct, sir.

And was that research carried on up into 1983?---The main part of that research was completed in the 60s, but we did do some additional research especially with the material from haemophiliacs for many years in relation to - to infectious disease transmission.

In Maryland what did you have - was there a centre there for haemophiliacs, was there?---Yes, there was.

You were using both the cryo-precipitate and concentrate or supplying it to the haemophiliacs?---That's correct. We used both therapy.

And it was mostly concentrate that you used?---I couldn't exactly tell you the proportion. We used large quantities of each one.

HIS HONOUR: Did you say you used large quantities of both? ---Of both.

MR BARNARD: Had you at some stage engaged in home treatment? ---We recommended home treatment and issued material for home treatment, but it was almost always only with concentrate. You cannot effectively use cryo-precipitate for a home treatment.

You might tell the jury why that's so?---Well, as I mentioned earlier the cryo-precipitate must be kept at very cold temperatures, and a very controlled environment to make sure that it doesn't deteriorate. Second, before you give it to a patient it has to be carefully thawed out, and you have to make sure that everything that has precipitated this, whitish

material goes back in the solution otherwise it won't do the patient any good. So, it can only effectively be done in a hospital in a clinic. The concentrate on the other hand can be kept just in an ordinary refrigerator. It's very easy to mix up, and the haemophiliac himself, or his mother or brother can give this material very easily and effectively. So, they're quite different in their ability to reconstitute and get effectively into the person as well as the storage.

It is also a fact that you can have a reaction to cryo-precipitate, to protein, is it?---Well, you were more likely with large volumes of cryo-precipitate to have adverse reactions to have things happen to the person, then the most purified material which is called Factor 8 concentrate.

Can that reaction occur quickly after the taking of cryo-precipitate?---It can occur quickly or it can occur in hours or days.

Is there some advantage with using concentrate instead of cryo-precipitate in the sense that the reaction won't happen in the course of home therapy, and when you're away from the hospital?---Yes, it's - these kind of reactions are less likely to happen with this concentrate, and since it's been done by the person in their home, you certainly would like that not to happen at all, and it would be less risky - the less risky product compared to cryo-precipitate.

Can those reactions be life threatening?---They may be life threatening.

When was it that you started home treatment in Maryland, what year?---That probably would have been the early 1970s that we began to issue concentrate for home treatment.

Apart from the convenience of it, was there other advantages to home treatment?---Well, the advantages to home treatment are that the patient can get treated much faster, and more reliably and therefore minimise either the bleed or the complications of the bleed rather than waiting to get to the hospital, or wait to be see in the emergency room. Wait for the cryo-precipitate to thawed out. Wait for it to be administered, so you get much faster more predictable earlier treatment.

If you have a person on cryo-precipitate do you sometimes get to a stage where it's not effective in treating them in the sense that it's not controlling their pain, and their bleeding?---Well, this can happen with cryo-precipitate, and can occasionally happen with concentrate also, that you can't give enough - or you can't give enough without problems, but it's more likely to happen with cryo-precipitate, because of the volume that you may have to give in order to get effective treatment.

In what way can the changeover to concentrate recover that position?---Well, the advantage of concentrate

(inaudible) give a lot more anti coloured factor in a much smaller volume, and you can overcome this resistance much easier.

Yes?---It would be very difficult to do with cryo-precipitate.

Is it an advantage also to have the concentrate so that it can be used at home. Be given more readily. More quickly?---Absolutely.

When you moved to Sacramento, I haven't quite understood what was your association with haemophilia patients there?---In Sacramento?

Yes?---We are the main distribution centre besides the University for the (inaudible) factor concentrate and we are the sole supplier and the sole provider of cryo-precipitate for our whole region.

You yourself, were you actually - you were apparently seeing the haemophilia patients and so forth?---I did not see very many other than those that would come to our clinic and be treated or I would see at the University in the process of my teaching duties, or I would be treating them as part of an exchange therapy for other problems they had.

Do I understand your evidence that in Maryland the - you didn't change the treatment of the haemophiliacs during the time you were there. In other words they kept on the sort of therapy they had been on before?---We tried to individualise but if we thought it was appropriate to give cryo-precipitate we would give cryo-precipitate. If we thought it was appropriate to give concentrate we gave concentrate. In general for the kind of patients we saw in Maryland concentrate was much more appropriate because they were the difficult

patients. They were patients that needed surgery. Patients that had difficulty being managed on the outside, so were sent to this research centre for better therapy and for trying out new things.

There was no question of you changing a severe haemophiliac back from concentrate to cryo-precipitate?---It would be very unlikely to go - with a patient whose being treated regularly on concentrate to go back to using cryo-precipitate. It would be highly unlikely.

That wasn't done. Is that the situation?---Excuse me?

It wasn't done?---It was almost never done.

Again, in - when you moved to Sacramento, were the patients that you were involved with kept on with the sort of treatment that they'd had in the past?---In general yes.

You spoke of a - the - where there had been high donor exposure to - by a patient who had been involved in cryo-precipitate, there would be no reason not to change him over to concentrate if that was medically desirable. Is that correct?---That's correct.

I wonder if you could be shown what is exhibit PX6.

MR BARNARD: That's the blood products records of the Alfred Hospital. The cards relating to the plaintiff. There's cards there that extend over a period, I think from 1968 to 84, but if I could just draw your attention to the fact that you will see that extensive treatment over the years with cryo-

precipitate. There's a period on concentrate from 20 June 1980 through to July 1980. There's a period of again, on concentrate - one lot in April of 1981 and then you will see that - quantities and you will see the bags listed there - quantities of cryo-precipitate as given in the ensuing years until March of 1984 and I think we - to give you an example in the year - the calendar year 1983, the donors for cryo-precipitate would have added up in that one year to 739. Generally looking at that, would you regard that as a large donor exposure?---Very much so.

If it was medically desirable, would you see anything inappropriate in March of 1984 changing a person with that donor exposure over from cryo-precipitate to concentrate?---No, I would not, I think it's quite appropriate to do that.

What would you think of having cryo-precipitate in quantities of 739 bags in a year, is that a lot of therapy? ---That's a lot of therapy. For someone with severe haemophilia required a lot of treatment.

You told Mr Sher that you weren't warning patients in 1983 and 1984. Presumably the patients that you were concerned with gathered a lot of knowledge of their own, is that so?---Most of them had a lot of access to information from the National Haemophilia Society, from their own physicians that would be treating them as well as blood centre and myself.

But you didn't warn them because you thought the risk was sufficiently remote for that not to be necessary, is that so?---This is in regard to AIDS, and it was both not totally proven and very, very remote.

In the circumstances you thought it was more important that they get their proper treatment than be concerned about the risk of AIDS, is that so?---Absolutely, because without the treatment they would have severe complications and could even die, and then they didn't have to worry about the risk of AIDS.

Incidentally, did you yourself - were you involved in any research apart from the infectivity of cryo-

precipitate - have you been involved in any research as to the overall risk of getting AIDS or becoming HIV positive from cryo-precipitate as opposed to concentrate, or as compared to concentrate?---Not directly as compared to concentrate, but we certainly tried to follow up all possible blood components from our centre, which are from donors found to be HIV positive as well as other ways we had found them. We tried to track them all and determine how many might've been infected. So we did various kinds of look-backs, but we did not do a comparison of what the risk was versus getting commercial Factor 8.

You did find that haemophiliacs were becoming HIV positive merely from taking the cryo-precipitate, is that so? ---Yes, we did.

Now, you've also examined the question of window periods, is that so?---Yes, I have.

What's been the result of your research in that area?---I think I have to define that window means what I think it means?

Yes, you tell us what you mean by it?---Window phase is meant by a period of time from when a person gets infected with something - in this case we'll say the AIDS virus - to some point in time later on when you have some evidence of that infection, and the usual definition in this case is from the time they got infected to the time we have an antibody response,

which is our usual way of defining when you got infected, and that's the most usual test and the most usual definition. And what it means is that the majority - more than half of people who are infected with this virus, within three months will have an antibody response. About 90 to 95 per cent will have a response by six months - so for say 95 per cent of the people, that window period could be anywhere from weeks up to six months. Very rarely that window period - that is no antibody - even though they are carrying the virus, can be more than six months, but that's unusual.

Could I just have you clear that up. In other words, are you saying that 50 per cent of the persons who contract HIV will sero convert within a period of three months?---That's correct.

Then there's 45 per cent who contract the HIV virus will sero convert within the period of three to six months? ---That's correct.

This other five per cent, how long may it bo - what's the longest known period?---Well, the - depends upon the patient group, but some haemophiliacs have taken say, seven months or a little bit longer. In a few - a men - men who were infected with this virus by getting it through homosexual partners, there has been a window period in a very small percentage of them up to three years, that is they're carried this virus in them, and not made an antibody up to three years, and perhaps longer, but that's documented.

For somebody who's received blood products, what's the longest known period there?---I'm not sure that we know, but certainly it's been shown up to seven months, but I couldn't point to you a paper which showed beyond seven months, but most people will after a blood will turn positive within six months.

Looking at possibilities, it means even though you are HIV negative on a certain date, and you're later HIV positive, you still could have been infected seven months prior to your - or something slightly shorter than seven months prior to your first test, is that

the situation?---Yes, sir.

And of course, when you're giving these figures, these figures relate to persons who in fact do - contract the HIV virus, is that not so?---Well, that's how we define against - - -

And of course somebody may be exposed to a contaminated batch, I think it follows from what you've said that a batch of concentrate, 50 per cent of the persons who are exposed may not become HIV positive, is that correct?---That's correct.

Whereas if it was infected concentrate it would be only perhaps up to 10 per cent who would not become HIV positive?---Well, infected cryo-precipitate.

Professor, answering some questions to Mr Sher in relation to prognosis, and you told him that after giving him estimates of years you said of those who do get AIDS, 50 per cent die, but all you suggested this was now - all of them don't within a period of two years, because of therapies that are available. In particular what were you speaking of?---Well, I was talking mostly about the studies on gay men, but they're probably not so different than other individuals, other adults, but before the advent of this new therapy AZT, 50 per cent of people who had a clinical diagnosis of AIDS, as in pneumonia, had the cancer, whatever was the manifestation. 50 per cent would be dead within two years. What that means is 50 per cent would be alive in two years. I

believe that that frequency has been remarkably changed with the use of AZT, that is a much higher proportion of people. Once they develop AIDS if they go on and go on with AZT a much higher proportion will be alive in two years and beyond.

You say once they develop AIDS are you suggesting that the AZT is being used after they have developed actual symptoms of AIDS, is that what you're saying?

---That's the best studies at the moment, but we are now starting people with this low T-4 counts before they get AIDS on AZT.

And you say you are now studying that, is that - - - ?

---Various groups are studying. I am not personally studying that.

HIS HONOUR: Is that a convenient time, Mr Barnard?

MR BARNARD: Yes, your Honour.

WITNESS STOOD DOWN

ADJOURNED AT 1.02 PM

RESUMED AT 2.15 PM

PAUL VINCENT HOLLAND:

HIS HONOUR: Yes, Mr Barnard.

MR BARNARD: Professor, operative procedures may subject severe haemophiliacs to greatly increased doses of Factor 8. Is that not so?---That's correct.

Would it be correct that both during 1983 and 1984, you would have been prepared to, or would have regarded it as appropriate to carry out operative procedures on a severe haemophiliac in circumstances where he had been subjected to a number of donors over many years. Even though the procedure was elective. Is that correct?---I'm not sure of your question?

In 1983/84, you would have regarded it as appropriate to carry out an operative procedure on a severe haemophiliac, even though that procedure was elective, although medically necessary in circumstances where that severe haemophilia had been subjected to large numbers of donors over a number of years?---Yes. My recommendation would be to use Factor 8 in that situation.

Before lunch and when you say Factor 8 do you mean concentrate is that it?---I mean concentrate, yes sir.

Before lunch I was asking you about the evidence you had given so far as prognosis was concerned. I don't think we have ever had an answer - is it known whether somebody who is HIV positive will necessarily come to getting full blown AIDS?---What we know so far is

that not 100 per cent do. That's true of all diseases. There's no disease where 100 per cent of people die or get the disease.

What's the state of knowledge at the present time so far as the HIV virus is concerned. What percentage is it known will go on to get full blown AIDS?---The best evidence we have is for gay men because they have been followed the longest time. The evidence at the moment is that if you have been infected with this virus for 10 years, one third of those individuals will have AIDS, about one third will have some lesser manifestation - some illness, called AIDS related complex which could be enlarged lymph nodes or some other problem. One third of those men will be totally asymptomatic after ten years of infection. That's the biggest series - the most number of people followed for the longest period of time.

Perhaps you might tell us, why do you select ten years, is that the period that's expired since it is believed the first one became HIV positive. Or why is the ten years selected?---The ten years is picked because we have been able to go back and identify gay men who were part of other studies for we have serums and we have samples and we can tell when they were infected. We can then follow them. They have been followed in regular studies. So, that's an actual number based upon following a certain number

of gay men, infected with this virus and known for ten years.

You are there speaking of gay men. Is it fair to use those figures in relation to persons who become HIV infected from blood products?---It appears to be as long as they are of the same age. That's why you have the study that we talked about earlier today from Dr Gettard which looked at haemophiliac patients who were over 35 as a group. They seem to be similar to other adults who were infected with this virus. In that study we talked about, after eight years of infection, if a haemophiliac had this virus for eight years, 43 per cent had developed AIDS. Or 57 per cent, more than half of them after eight years of the infection, were still well, did not have AIDS.

When you said the study we talked about, you're talking about the study which was written up in the paper of which you were the co-author that was produced this morning, is that correct?---No, I was referring to the study by Dr James Goedert - G-o-e-d-e-r-t - from the New England Journal of Medicine, also from October of last year, and which they initially studied over 12,000 haemophiliacs, it followed about 350 of them for a long period of time. So, it's based mainly on that 350 in that study, patients with haemophilia.

HIS HONOUR: Tab 64, I think, Mr Barnard.

MR BARNARD: Yes, if your Honour pleases.

You said 42 - sorry - that's 43 per cent, is it?---43 per cent haemophiliacs over 35 had come down with AIDS when followed for eight years after the onset of their infection.

The other 57 per cent, can one put any prospect on known figures on their future?---Well, you can make an - a educated guess, and there are so called computer models of this, and you would have to say at the outset that it should take at least another eight years before all of them theoretically would become infected, but we don't know that for sure. All you can say is that the curb is going up, and it should continue to go up, but it is highly unlikely that it will ever reach 100 per cent. It's not true of any disease, including this one.

When you say it's highly unlikely to reach 100 per cent, that is that it's likely that there are some who will not go on to getting full blown AIDS?---That's correct.

At what percentage does one fix that number - or estimate that number?---Unfortunately we haven't followed enough people long enough. I told you from another study following people for 10 years a third of them - 33 per cent - were still perfectly healthy, had nothing wrong with them, and what we don't know is how much longer they will go, they're been followed, but they probably will increase but we don't know.

Would it be fair to say that they'd be more than a third or may be less than a third?---It would be fair to say that as time goes on that the proportion who don't come down the disease will get smaller and smaller. That is after 12, 15 years it may be 30 per cent, 20 per cent. If you check, keep going up, the curb is going up, but it probably never reaches 100 per cent.

When you say 30 per cent, 20 per cent, it's 30 per cent and 20 per cent of the total number, is that right?---Of the total number who will go for even more years, and be perfectly healthy, except they're carrying the infection.

You've told us of the way patients have been treated in the institutions with which you've been associated, and you've told us of the practices in which you've been involved in treatment, and in the collection of

blood. Do you now regard the practices and treatment as being appropriate and prudent having regard to the state of knowledge at the time, that's back in 83 and 84?---In this particular case, yes.

Your practices and your treatment you say they were prudent having regard to the state of knowledge at that time?---That's correct. They would be very similar and I think appropriate in both cases.

Incidentally, I don't know if you've got folder - book 1 there, the plaintiff's documents. You were giving some evidence about a July 1982 MMWR - and I just wanted to ask you if you would look at the - if you would look under that heading, at document A6 - the plaintiff's book - - - ?---This is July 16, 1982 MMWR.

When you were referring this morning in answer to questions from Mr Sher to the July MMWR - is that the article to which you were referring?---Yes, this was the first notation that three patients with haemophilia also had AIDS.

Thank you.

HIS HONOUR: Mr Gillies.

CROSS-EXAMINED BY MR GILLIES

MR GILLIES: If it please your Honour.

Doctor, in March of 1983 when the American self exclusion screen was first put in place, how many known AIDS victims were there in the United States?---I would have to check and see, but it was certainly in the hundreds if not in the few thousands.

In the United States there was not a voluntary system of blood donation, was there?---No, sir, the vast majority of blood in America - whole blood is collected from voluntary donors - 98 plus per cent.

In relation to the plasma that was used in the production of concentrate, was that mainly produced from paid donations?---Yes, approximately 80 per cent of the plasma that goes into the Factor 8 concentrate comes from paid donors.

In Australia at that time, in March of 1983, we've heard that there have been no reported AIDS victims, and we've also heard at that time, as now, that there was an exclusively voluntary donation system. I want you to compare the theoretical advantages that Australia

had at that time with the situation that prevailed in the United States, particularly in relation to the voluntary blood collection system, and also the fact of there not being a reported AIDS case at the time?---Okay. Well, I think the system here is superior, because you have both an entirely voluntary blood supply, an entirely voluntary plasma supply, and being volunteers, they say it is much safer, carries much less risk, so I think you had a better system in both counts. Second, we had a much earlier onset of the disease AIDS occurring in the United States, and therefore a much higher risk much sooner of that disease in retrospect, as we find out, being transmitted by blood and plasma. So I think on that count also you were luckier - more fortunate - than we were in that apparently the disease was introduced into your country later than ours.

I want to put to you three areas of Australian reaction - again compared to the United States reaction - for your comments and I want to put it under three headings. First of all, self exclusion screening, secondly, implementation of HIV antibody test and thirdly, implementation of routine heat treatment. Firstly, as far as self exclusion screening, the first leg - that is the multiple partner leg - was implemented in Australia in June of 1983. What do you say as to the speed of the Australian reaction

in relation to its implementation of part one of self exclusion screening?---I think it was excellent, I think it was remarkable that you put it in place so early.

In relation to the second self exclusion screen - that is the all homosexual screen - that was implemented in Australia by December of 84 and in some parts by October of 1984. What do you have to observe in relation to the expedition of the second self exclusion screen in Australia?---Again I think it was remarkable you were ahead of us.

We've heard that not only was there a total homosexual screen implemented by the dates that I've mentioned - by December 1984, but that in addition, legislative backup was given to the screen in that it became a criminal offence to make a false declaration in the form. What observation do you have to make about that?---Well, I think again it was something done here before it was done even in parts of the United States which don't have that to this day.

Am I right in saying that the United States total homosexual ban was not put in place until, I think you mentioned the fall of 1985, is that so?---That is correct.

What months did you have in mind there?---I believe it was September of 1985.

The second area of comparison that I want to put to you. It relates to implementation of the HIV antibody test. We have heard that in Australia the test was being conducted in October 1984 and that it was fully implemented as a screen, as opposed to a mere test, by March of 1985. What observation do you have to make about that on this question of speed of reaction to the problem that presented itself?---Again, I think it was remarkable that in America the test was not licensed until March 2, 1985. It was not available at many blood banks such as my own and could not be put into routine use until April and in some of our banks we were not able to use it and get it as a routine, until July of 1985. So, if you were doing it in March, I think that was fantastic.

In relation to the third head of comparison, namely implementation of heat treatment, to inactivate the AIDS virus, the evidence is that in November 1984, and from November 1984, concentrate was routinely heat treated to inactivate the AIDS virus. What observation do you have to make about the speed of

the implementation of the heat treatment procedure?---I think again it was very good. I'm not sure whether that meant that 100 per cent of all Factor 8 concentrate in your country was heat treated at that time because in my country even though it was being issue, there was not sufficient to replace the unheated material, so unheated material kept being issued into early 1985 in America.

The evidence will be that all concentrate was heat treated from November 1984, in Australia?---I think that's remarkable and commendable.

In relation to this question of heat treatment, Mr Sher has asked you some questions already about that, how it commenced in relation to heat treatment for inactivation of the hepatitis - of the hepatitis virus. I want you to specify if you would, when it was first utilised, or when tests were first conducted to facilitate its utilisation in respect of inactivation of the AIDS virus?---Well, tests could not be really used to see how good it would inactivate the AIDS virus until the AIDS virus was discovered and that wasn't until May of 1984. So, it wasn't until some time after that that you could evaluate whether or not the virus was in there and really not until 1985 to see whether it actually worked, because then you had a test to apply to patients with haemophilia to see if they got

infected or not.

What practical difficulties are attendant to heat treatment of concentrate. What are the problems that must confront the scientist?---I'd like to give you an example to explain that because it was a very difficult task. People worked on trying to heat treat Factor 8 for more than 10 years and the best way to make it seem simple to you is, it is like cooking an egg. If you are going to boil an egg and I'm sure all of you can do that, you can boil it for about three minutes, and the white will be hard and the yoke will be soft. If you want to hard boil the egg. Cook it for about 10 minutes. That means the yolk is hard and the white is hard. But nobody, not you, nor I, nor a rocket scientist, can cook an egg in such a way that the white is not cooked but the yoke is. The yoke is hard. That was their problem. The yoke is like the virus of AIDS. The white is like the Factor 8. It is much easier to cook the white of the egg, the Factor 8 and you have them all mixed in together. So, it took them years and years to work out a system functionally, to cook the yoke - cook the virus, without cooking the white. That was the problem and it took a long time to work that out and it is still not perfect in the sense that you do cook a little bit of the white, the Factor 8 in the process of killing all the yokes or all the Factor - all the virus that's in there, of AIDS.

And would you elaborate on the problem referable to the reduction in potency of the concentrate - the reduction of the clotting factor in the concentrate as a spin off of heating the product?---Yes, I just said - in the process of trying to protect the white - the egg, like the Factor 8 - you in fact don't totally protect it. So you lose some, you destroy some. So you get some Factor 8 out at the end, but you've lost a lot in the process. So the heat treatment destroys some of the Factor 8 in the process of destroying all the virus.

Well, what do you say of the Australian conduct in implementing a routine heat treatment procedure in November 1984 - was it humanly possible to do it earlier than that time?---I really don't think so, knowing that all heat treatment isn't the same - in fact the first heat treatments were pretty effective, but they were not perfect, some virus still got through, and it's only as you follow patients and with the most recent heat treatments that appear to be completely effective. So the fact that you put it into practice anyway, that you recognised the loss of the Factor 8 you'd have, and that you made it a universal approach - I think is fantastic.

You've been asked some questions by Mr Sher in relation to warnings and I want to ask you some questions now about warnings, insofar as they affect the

manufacturer. What do you say as to whether or not the manufacturers ought to have been giving a warning during 1983 and 1984 that the concentrate carried with it a risk of transmission of HIV?

---Well, first of all I'd say of course the manufacturer can never warn the patient - the manufacturer never sees the patient, the doctor sees the patient. So there's no way for the manufacturer to tell a patient with haemophilia "Here is a risk". What the best a manufacturer can do is inform the doctors - in this case the haematologists - and I think it was so well known already that these products - whether cryo-precipitate or Factor 8 concentrate - carry risks, and the more you gave the more was the risk, that it was really kind of self evident, so it was not really necessary. So we knew there were risks, but they saved lives, and we knew that sooner or later you're going to get most of the risks, and finally, at that time we still didn't know how much the risk was, we thought it was very low, because the vast majority of haemophiliacs were not getting this disease, they were doing very well.

We've heard from Dr Shelby Dietrich who gave evidence that had she looked at an insert that did happen to carry such a warning, she would've simply said "So what? I already know it". Would you say that to be representative of the views of expert haematologists

at that time?---Yes, and I would go even further, because basically it's the question of either bleeding to death or dying or having a severe deformity, and if you said there's one chance in a million or one chance in a hundred thousand, or whatever the chance is of getting something versus having a lot of pain or being blind or dying, most people would've said "I would rather take this product and live and get through this".

The plaintiff in the present case is a severe haemophiliac and was a severe haemophiliac, needless to say, during 1983 and 84. What do you say as to concentrate being the optimum form of treatment for him and his survival?---I think the Factor 8 concentrate was a better approach for this kind of a patient with such severe haemophilia, all the problems he had, and especially after having so many products in the past. So in my view, that was the best therapy.

How important is it that a severe haemophiliac have the best available product for his condition?---Would you repeat the question?

How important is it that a severe haemophiliac had the best available product as a coagulant for his condition? ---Well, it's - it's very important because haemophilia - you want to minimise the complications, minimise the difficulties and so you want to optimise, you want to get the best therapy to reduce their bleeding and their complications and

their problems, and the best way to do that, in my view, is to use concentrate, Factor 8.

Is that a life or death situation?---It can be very much a life or death situation depending upon where the bleeding is. If it's into your brain or into your eye, different areas like that, and it can be life-threatening. If you don't get it fixed, you don't get it stopped you can die.

Why is it so important that the preparation be administered as quickly as possible once an attack of bleeding is commenced?---Well, the sooner you can treat it, the less bleeding you're likely to have and the sooner you will begin to resolve it, and the less likely the complications, the deformities or any other problems. So you want to get it as soon as possible to cut down the bleeding, and begin to resolve the bleeding as quickly as possible.

You've dealt with joint bleeding, you're dealt with intra-cranial bleeding, what about intra abdominal bleeding, is that a serious consequence of severe haemophilia?---It certainly may be, you can die from it.

We understand how you can die from an intra-cranial bleed, how does the intra-abdominal bleed present itself as a life-threatening situation if not controlled by optimum therapy?---Well, in this particular situation you can bleed so much it would shock, and if you're in shock - - -

HIS HONOUR: Would you say that again, I didn't hear it?

Yes, in - in this particular situation when you

bleed into your abdomen, if you loose enough blood you go into shock, your blood pressure drops way down and unless that blood volume is replaced very quickly you can die just from having insufficient blood in your vessels, and being - flow into your brain and your heart and your kidneys. So, you can die by actually bleeding into your abdomen in this particular situation.

How is it that concentrate with the possibility of home, and therefore immediate treatment is an advantageous regime of treatment to cryo-precipitate with the delays consequential to the latter preparation?

---Well, it - it - the concentrate, because Factor 8 concentrate has two advantages. (1) you can kept it at home in your own refrigerator, and at the first sign of bleeding you can start it, rather than waiting to get to the hospital. Second, it's a more concentrated - - -

HIS HONOUR: Excuse me a minute. Mr Gillies, are you seeking to get anything further from what Mr Sher got this morning as between cryo and concentrate?

MR GILLIES: I have been, your Honour, yes.

HIS HONOUR: So you're desiring to - you're not merely taking the Professor over what Mr Sher took him over this morning?

MR GILLIES: No, I'm anxious to make this particular point clear, your Honour. There has been some overlap but not completely co-incidental, your Honour.

HIS HONOUR: Yes, very well.

MR GILLIES: I was asking you to compare the advantages of the concentrate over cryo-precipitate having regard to this question of more expeditious commencement of treatment?---Okay. And I started out by saying that Factor 8 concentrate you can have at home in your refrigerator, and he could start it right away. The second thing is it's a more pure, more concentrated form, so you can get higher levels and more predictable levels. You have be more sure of what you're getting and what the effect will be. And finally, the concentrated material is less likely to have a bad effect in terms of a reaction for other problems with your blood, so it has that advantage also.

Yes, thank you, Doctor. I have no further cross-examination, your Honour.

HIS HONOUR: Mr Stanley - Mr Rush, is it?

MR STANLEY: Mr Rush can take this witness, your Honour.

HIS HONOUR: Mr Rush?

CROSS-EXAMINED BY MR RUSH

MR RUSH: Professor Holland, when you gave evidence, Professor, in the H case in Sydney last year, who did you gave that evidence for?---I'd like to think I was a medical expert for the court, but in fact I was asked by the Australian Government to come down and give testimony especially on behalf of the Commonwealth Serum Laboratories.

So you're aware who Mr Gillies represents is this court, are you?---Yes, sir.

Who does he represent?---I believe it's the Commonwealth Serum Laboratories.

And that's the body that you gave evidence for in Sydney last year?---Well, I was - they said - I like to think I was giving testimony for the court, and I was - happened to be asked by them to come down and testify.

Professor, the people that paid your bill to come out to Australia last year were - it was paid on behalf of the Commonwealth Serum Laboratories?---I presume so, or the Australia Government and I - - -

The people that are paying your bill to come to Australia to give evidence in this court this year is the Australian Red Cross?---I hope so.

So you gave evidence for the Australian Red Cross this year and the Commonwealth Serum Laboratories last year? ---Yes, sir.

What you say, Professor, is that you believe it's very important for an expert witness to be divorced from the court, is that what you say?---Yes, sir.

Not to enter into the arena of litigation, but to give an impartial and objective statement to the court? ---Exactly.

You have given evidence on behalf of defendants in the United States from one corner of it to the other, haven't you, Professor?---I'm not sure what you mean, sir.

You don't understand that question?---No.

Well, what I'm putting to you, Professor, is that in the United States over recent years you've been taken away from the Sacramento Medical Foundation fairly often to give evidence on behalf of a number of blood banks?---Yes, let me clarify that.

Could you just answer the question, Professor? You've given evidence in the United States in recent years on behalf of a number of blood banks?---Yes.

You've given evidence on behalf of Cutter Laboratories?---Yes, sir.

You've given evidence on behalf of medical hospitals?---Yes, sir.

And all the evidence that you've given has been in relation to people - on behalf of defendants - is in relation to people that have AIDS or have contracted the HIV

virus?---Yes, but I'd - - -

That's what the cases have been involved about?---Yes, but I'd like to qualify my answer.

You can qualify it to Mr Sher or qualify it later. I just want to take you to a few things first, Professor. You have never given a deposition and never testified on behalf of a plaintiff, have you?---I have tried, but they didn't like my opinion, sir.

You have never given a deposition and you have never testified on behalf of a plaintiff, have you?---Yes, I have.

You've deposed on behalf of a plaintiff?---Yes, I have.

It's been taken down in evidence?---Yes, sir.

When was that?---Twice.

When was it?---Within the last five years.

Did you give evidence this year in the United States on behalf of a defendant?---No, I did not.

Did you give evidence in a case of raid against Cutter Laboratories?---I gave a deposition.

In that deposition, on your oath did you say that you had not deposed and not given testimony on behalf of a defendant?---Depends what you mean by defendant, sir. I have given - if you've qualified that - - -

I'll ask the question again. Not deposed and not given testimony on behalf of a plaintiff?

HIS HONOUR: Mr Rush, your earlier question, I think, was defective in the same way. I think you should ask again.

MR RUSH: What I'm putting to you, Professor, is that you have

not deposed, you have not testified in any case in the United States concerning transmission of HIV on behalf of a plaintiff?---That is correct.

When I say that you've given evidence from one corner of the United States to the other, you've given evidence on behalf of the Southeastern Wisconsin Blood Bank? ---That's correct.

You've given evidence on behalf of the Bonfields Blood Centre in Denver?---Correct.

You've given evidence on behalf of the United Services Blood Centre in Denver?---Correct.

You've given evidence on behalf of the Ventura Blood Centre? ---That case never went to trial.

Where is Ventura?---It's in California.

You've given evidence on behalf of the Los Angeles Red Cross? ---That's correct.

You've given evidence four or five times for the Irwin Memorial Blood Centre?---I've been deposed at many times, yes. This is all over the last five years, by the way.

Whereabouts is the Irwin Memorial Blood Centre?---San Francisco.

You've testified on behalf of Cutter?---Yes, I have.

Cutter being a large fractionator of blood in the United States?---Correct.

And a distributor of commercial concentrate?---Yes.

And in Sydney last year you testified on behalf of the Commonwealth Serum Laboratories?---Correct.

You say to the court that it's very important that you're seen as an expert witness?---That's exactly right.

You say that it's very important that when this court assesses the evidence that you give, that they see you as an injective and an impartial witness?---Yes, sir.

And that's what you've come to Australia this month to be, is it?---Absolutely.

When you were asked to give evidence in this case, when was it, Professor?---It was some months back.

When you were asked to give evidence in this case as an expert, you saw yourself as giving expert testimony in an impartial and an objective way?---Absolutely, sir.

Have you acted in that way totally professor, in relation to your conduct in this case?---In every way.

Because it is important that you don't descend into the court - or the litigation - become a lawyer. Is that right?---Absolutely. I wouldn't want to be.

You are not an investigator on behalf of anyone in this court are you?---I wouldn't say that, no.

Your employer in America is the Sacramento Medical Foundation?---Yes sir.

Just have a look at this document professor. Just read it or have a look at it and then hand it back to me?---Okay.

Give it back to me. It is a document professor, that bears the Sacramento Medical Foundation imprint at the top of it?---That's correct.

Do you observe that?---Yes, sir.

It has been faxed hasn't it, from your centre?---Yes, it has.

Where was it faxed to - the date that it was faxed is 20 August, 1990?---Yes, sir.

Where was it faxed. Did you have any part in the faxing of it professor?---Yes sir, I had my secretary fax it.

Where was it faxed to?---It was faxed to the law offices here.

It was a document used and handed at the bar table by Mr Sher, in an attempt to attack the credit, or attack Professor Englemen.

MR SHER: It was handled by me. Stop making pejorative statements. I object to the question. It is just a comment. It may or may not have been. It is

certainly not established as a fact.

HIS HONOUR: It is open to Mr Rush to say the way it was relied on but there shouldn't be further comment.

MR RUSH: As a document relied on by Mr Sher and put to Professor Engleman and a document provided by you. Is that right?---That's correct.

A document provided by you in an attempt to discredit Professor Engleman?---No sir.

To discredit his T-4, T-8 testing?---It was a document to provide the truth.

So, as part of your area of expertise, you saw it has being part of your - as your job in this case to provide this sort of material for cross-examination of Professor Engleman?---I thought it was part of my job to make sure that the truth came out about this and everything else.

The truth - without going into the document, it was - it is a document dated May of 1989, isn't it?---That's correct. It shows something very important.

Important or not, as part of your expertise - as part of you being the impartial and objective witness in this case you have done research and investigation in an attempt to provide ammunition if you like, for the other end of the bar table. The Australian Red Cross?---That's not correct.

So, the provision of this had - it wasn't the sort of investigation over and above the call of expert evidence was it?---It related to expert evidence.

You still say to the court, you have come here, come to Australia as you volunteered professor to give impartial, objective evidence, not to be called on behalf of any part, but to be seen by the court as an expert?---That's exactly right. Not only that I'm doing it on my vacation time.

Professor, have you treated haemophiliac patients?---Yes, I have.

When did you start treating them?---In 1962.

What about in the 80s. How many did you treat at the National Institute of Health?---In the 80s - there would probably have been a handful in the 1980s.

What do you mean by a handful. Five, six or what?---A couple of dozen - in that order. 12. 15. 20.

So in proffering the opinions as an expert in the treatment of haemophilia we are now to understand are we, that you have treated 10 or 12 patients in the 1980s?---You said while I was at the NIH in the 1980s. That would be 1980 to 1983.

From 1980 to 1983 at the NIH you treated 10 or 12 patients.

MR SHER: You keep changing the figures you know.

MR RUSH: (Inaudible) answer?---I said, I thought that in that period of time at that place, I treated in the order of 12 to 24. I couldn't give you an exact number.

Did you treat any other haemophiliac patients apart from those at the NIH?---Not directly, but in consultation I did, yes.

So you had direct responsibility totally for the medical care of those patients at the NIH?---No sir.

When you say you treated them what do you mean if you didn't have direct care - conduct and direct care?---I meant that I issued the material, some cases actually infused it. In some cases they were within my blood centre undergoing therapies where I actually gave them.

So they were people that came into your hospital for treatment, and then left to go back to their clinicians, is that what you're saying?---Not exactly. They would be there for research studies, and as part of that they were allowed to get treated.

And you would treat them for the period of time that they were in the hospital?---As part of their treatment, I wasn't the only one.

So, for a little time at least while they were in the hospital you had something to do with the haemophiliac patients?---That's correct.

What about since 1983?---Since 1983 I've probably seen more, because many of them came to our outpatient facility, and that we are part of studies to do different kinds of treatments on those - especially those with AIDS.

Do you have the full-time care of haemophiliac patients?---No, I don't.

So they're people that come into get their blood product, or that sort of thing are they? They're not there for treatment of their haemophilia?---Some are there for

treatment of the haemophilia, but only temporarily while they're in my centre, or I'm in the hospital next to them are they under my care.

You're not like a person that treats haemophilia at a haemophilia centre?---Not exactly - - -

Like Dr Dietrich?---No.

Doctor, you have offered the opinion to this court that you didn't think it was appropriate to warn those patients that you did have contact with, to warn them about the risks of AIDS until 1987?---That's correct.

So, in 1987 you decided that you should warn patients that they faced the prospective risk of contamination of HIV by using such things as concentrate?---That's correct.

Doctor, Mr Gillies asked you about 1983 and 84 - and warning labels - do you remember that question?---Yes, sir.

And you didn't answer him directly, did you, because you said "Look, the warnings never get to a patient", is that your view?---That was probably my answer.

Doctor, it's your belief, is it not, and your opinion that the manufacturers of concentrate should have been putting warning on their product in late 1983?---For what?

A warning about what we're talking about in relation to the risks of transmission of AIDS as a consequence of use of Factor 8 concentrate?---No, I don't agree with that.

When do you say, Doctor, that there should have been a warning on Factor 8 concentrate?---Well, I think I told you a moment ago that I didn't think there should be a specific warning until at least 1987.

What about Factor 8 concentrate?---It couldn't have been before 1985 because we didn't really known for sure, so it would have to be in that period of 85 to 87.

You don't know for sure?---No, sir. I can't fix a point in time.

Not only Doctor have you come to Australia to be an expert witness I take it, did you come to Australia to tell the truth?---Absolutely.

Doctor, I have before me some evidence that you gave on deposition in the case of Ray against Cutter Laboratories, and I suggest to you Professor, that you gave that depose, not in 1989 which you said before, but on May 22, 1990, do you remember that? ---You'd have to show me. I'd like to see it.

Just have a look firstly at the first page of it. Perhaps if you turn to the back of the page and you'll see the header. Do you remember that?---Yes, sir. May 22, 1990.

If you give it back to me now. You do recall, now do you, deposing on behalf of a defendant in 1990?---I didn't say I didn't.

But you recall now giving your evidence in this case, do you, in Ray - - - ?---I recall giving a deposition on May 22 as you've just shown me, yes.

This time you were down in Miami, Florida, is that right?---No, sir.

Whereabouts were you?---Sacramento - look on the front.

You're giving it in Sacramento - - - ?---I believe - - -

You were giving your evidence in Sacramento - - -

MR SHER: He gave a deposition, don't confuse depositions with evidence. That's constantly been done and I object to it. The jury may not understand it, and it's about time they did. I object to it being constantly suggested that the witness gave evidence when what he gave was a deposition. There's a different, Mr Rush knows it, the jury perhaps don't.

HIS HONOUR: Mr Rush asked him did he give a deposition.

MR SHER: He keeps changing from evidence to deposition - - -

HIS HONOUR: Mr Sher, your addresses come later.

MR SHER: I object to the form of cross-examination, your Honour.

HIS HONOUR: I will not permit these constant interruptions.

MR SHER: Your Honour, if I have a matter that I believe is appropriate to take an objection I'm duty bound to take them, and with respect I will. I don't believe - - -

HIS HONOUR: Your present objection's overruled.

MR SHER: Very well, your Honour.

MR STANLEY: Professor, when you give a deposition you give it

on oath, don't you?---Yes, sir.

And it's transcribed, is it not?---Yes, sir.

And you get an opportunity for the deposition to come back to you and you can correct it?---That's correct.

Now, in May 1990, a couple of months ago, Professor, I suggest to you that you were asked these questions. Just to put it in its full context, by the lawyers who were acting for the Rays, the Plaintiffs in this case, and you were asked about when a warning should have gone on concentrate and you said "It would not have been appropriate to do that on or before December 1982". Then you were asked "Would it have been appropriate to do it in January 1983?" You said "I don't think so". Then the question was asked "Have you really looked at the question to tell me when you think it would have been appropriate?" You answered "Yes, I have". And then was asked "When was it appropriate?" Your answer was Professor "I would say probably sometime later on in 1983, certainly before January 1984". Not only that Professor you were asked "Where should the warning have gone?" You said "It was" - the question was asked "Would it have been appropriate to start - place - are you talking about placing warning on package inserts?" And you said "That would be one place, yes". "What other places would you think it would be appropriate later on in 1983, or certainly before January 1984 to start warning about the risk

of AIDS?" Your answer "Other places would have been information to physicians". And the question said "And how would that be communicated to?" And your answer was "Could be a variety of ways. Could've been through the MMWR. Could've been through the FDA bulletin. It could be through mailings to experts in the field, that kind of thing". Now, Professor, four minutes ago or five minutes ago - - -

MR SHER: Are you going ask him if he (inaudible). It's all just assertions from the bar table. Your Honour may be right, but Mr Rush can't give evidence.

MR STANLEY: Professor, four or five minutes ago you said you gave evidence in the case of Ray against Cutter Laboratories, is that correct?---That's correct. You have the deposition.

Is what I've read to you and the questions and the answers, is that part of the deposition that you gave on oath? ---I don't know, I'd have to see it. You'd have to show me - - -

Have a look at it - - - ?---You're just paraphrasing it. Okay. I've read it now, what's your question?

Is that the evidence that you gave on oath in that case in the deposition in May 1990?---This appears to be the deposition I gave. I don't see the correction, so I don't know whether it was correct or not.

Can you hand it back to me, Professor?---Sure.

Professor, when did you say to this court, five or six minutes ago, that it would have been proper to have placed a warning on concentrate, relating to HIV?---I thought I said that it could have been in 85, or thereafter. Isn't that what I said?

I think you might have also said 87?---What I said about 87, was that's when I thought it was appropriate to put it on blood products, like cryo-precipitate in transfusions.

So, what you are saying is it professor - is that it is all right for the manufacturers of the concentrate, they should warn by 1983, late 1983 - but as far as my patients are concerned I'm not going to tell them and it is not appropriate for me to tell them until 1987?---No. What I'm trying to tell you is that the evidence was that there was a better reason and higher risk - potential higher risk for concentrate than for other blood products and therefore it would have been appropriate to potentially earlier put a warning, if you are going to do that for that product, as compared to a blood product.

Professor, this is a pretty big issue, isn't it in America and in this court. Warnings that go on concentrate?---Yes, although I don't think it should be.

Maybe you don't, but in America - in the United States of America when you gave evidence in May of this year, it is appropriate to have a warning on concentrate

in late 1983?---I said it may have been. I don't think I said it should have been.

You said - the question was "When would it have been appropriate?" Your answer: "I would probably, sometime later on in 1983, certainly before January 1984". That's not maybe is it?---That would be the earliest that it would have been even possible to make such a suggestion.

But you know professor, from your great experience in litigation, this type of litigation, in giving evidence for Cutter Laboratories, that this is a pretty important issue don't you?---Well, some of the lawyers have made it out to be very important yes.

Some of the lawyers have seen it as very important and asked your opinion on it?---That's correct.

No doubt that's why you think you have been asked it in this case?---I presume so.

How do you then justify telling a court in the United States professor, that late 1983, certainly before January 1984 as appropriate, when you give evidence in May and it is sometime in 1985 when you give evidence in Melbourne?---I don't think there is really a difference first of all. Second of all, we have much better data, much better evidence with the discovery of the test and with the antibody to really know what the risk is. Until that test was available we really couldn't know what the risk was

and that test wasn't available until after May of 1984.

Professor it is because people didn't know about the risk that it was being put on these products, wasn't it?---I don't understand your question?

HIS HONOUR: Rephrase that question. It wasn't clear.

MR RUSH: I'll ask you something else professor. Professor, what I want is an answer to my question. You know in litigation that this is an important issue. You have given on your oath in May of this year in the United States that a warning should have been on a product late 1983 or early January 1984, and in this court you are putting it back at least a year later to sometime in 1985. Knowing it is an important issue, how do you justify those two answers?---I think quite easily. I think once again there they were trying to say what should have been done and I didn't say it should have been done. I said that that was the earliest that they could have potentially put it on there. I don't think it was well enough known until 85 to really document what the risk was. We didn't really know.

When did you think Mr PQ, the plaintiff in this case, when do you think he sero-converted?---In my view, anywhere from six months to a year before the first positive test, which was in October of 1984.

So you would put it probably in 1984?---Potentially there's a good chance that it was in 84.

So, in this case it is important isn't it professor to have the warning on product after he has sero-converted from your point of view?---I didn't say that. I don't think the warning has any bearing on this anyway.

It has a bit of warning I suggest to you professor, on the evidence that we have got here, when you go on oath a couple of months ago as to January 84 or late 1983 and in this case you say 1985, why it is important I suggest to you is that you know - you know, don't you, that it is an important issue as to when the plaintiff, Mr PQ, sero-converted in this case?---That has nothing to do with it.

You see I suggest to you professor, that - - - ?---I know what you suggest but I disagree with you.

What I put to you professor and suggest to you is that you have tailored your evidence in this case to fit in with the facts?---That is absolutely not true sir.

You see, you say to us, Professor, that that's the very earliest the warning should've gone on. That's what you said just a minute ago, isn't it?---What I said was that was the very earliest that anybody could've even thought about a warning, yes. It would've been inappropriate before that.

HIS HONOUR: Mr Rush, I see it's 10 past three, is that a convenient time?

MR RUSH: Yes, it is, your Honour.

HIS HONOUR: The jury may go to the jury room for 15 minutes.

AT 3.12 PM THE JURY LEFT THE COURT

WITNESS STOOD DOWN

ADJOURNED AT 3.12 PM

RESUMED AT 3.25 PM

AT 3.25 PM THE JURY RETURNED TO COURT

PAUL VINCENT HOLLAND:

MR RUSH: Professor, I still don't think you've answered the question I put to you before the break. If you can just tell us in simple terms why is it that a warning's proper in 1983 - late 1983 when you give evidence in the United States, and why not until 1985 when you give evidence in Australia?---Well, I tried to explain to you that I didn't think it was really appropriate then either. I said that was the earliest possible time that it might've been appropriate to give a warning. I really don't think it was appropriate till after that.

So that's the explanation that you offer to the court, is it?---That's the major one. The second one is that the warning really is nothing to do with the therapy, in that most patients - given the choice of dying from bleeding - would have disregarded the warning anyway.

Professor, I'm more concerned with the dates. I want to know why 1983 is proper in the United States and 1985 is proper here?---I didn't say that.

Perhaps if I just read from your evidence. "Have you really looked at the question to tell me when you think it would've been appropriate?" - talking about the warning - answer, "Yes, I have." "And when would it have been appropriate?" "I say probably sometime

later on in 1983, certainly before January 1984." Now, you haven't offered any explanation there when you've given that opinion, have you?---No, what I said there - and I thought you just said it again - is I said probably and that would've been the earliest that warnings might've been appropriate.

So "I would say probably sometime later in 1983" - that deals with 83. But then you go on "Certainly before January 1984" - there's no doubt about what you're saying there, is there?---I think there is.

What's the doubt about "certainly"?---Well, again, it's a question of whether we're talking about blood in general, cryo-precipitate, Factor 8 or whatever, and also what - the amount of evidence we had at the time, and I think we had not that much evidence at that time to make it quite so certain as you're implying.

Well, can you direct us to any new evidence between May of 1990 and October of 1990?---Between May of 1990?

Something that would explain why you can say 1983 in May and 1985 in October?---Well, until the test was available, as I told you, after May of 1984, we couldn't even know what the risk was for sure. So in fact we couldn't quantitate that risk until we could test people, and we couldn't do that until 1985.

But you knew that when you gave this evidence?---I don't understand your question.

You knew there was no test available when you testified in May of 1990, when you said 1983?---I didn't say what you're implying. What I said was that would be the earliest that you could potentially have a warning. I'm not in favour of the warning, I think the warning is immaterial.

Well, you say you're not in favour of the warning?---That's correct.

Yet in this case, in May of 1990, you went on to say where it should be put?---No, I said if you wanted to have a warning, these are places you could put a warning.

Would it have been appropriate to start - this is the question -"Are you talking about placing warnings on package inserts?" and your answer "That would be one place, yes." There's no qualification about that, is there?---No, I don't see why not.

You didn't qualify it when you gave evidence in May, did you? ---I was answering the question which said "That is one place where you could have put a warning" - that's my answer.

Then the questioner said "What about other places would you think it'd be appropriate in 1983 or certainly before January 1984 to start warning about the risk of AIDS?" and you answered "Other information would've been to physicians." There's no equivocation about the warning there, was there? You volunteered that, didn't you?---They wanted some other examples where you might put warnings, yes.

Those are other suggestions.

And you gave it to them, didn't you? You told them "Other places would've been information to physicians." - That's what you said in that case?---I was giving them other suggestions, yes, sir.

You didn't say to them "Look, there's no test for HIV", or you didn't offer any excuse why there shouldn't be a warning when you gave evidence in May, did you? ---What I did not say is that you must or you should even give warnings.

Then they went on "How would that be communicated to them?" and you answer "In a variety of ways. It would have been through the MMWR. It could be through the FDA bulletin. It could be through mailings, to experts in the field, that kind of thing"?---Exactly, if you wanted to give warnings those were ways to do it.

And yet to Mr Gillies, after once this afternoon you said there was no need to give warnings to experts in the field?---I don't think I quite said that. I said I thought that I don't think it was necessary. I don't think it was material. I don't think it made any difference.

But here when you gave evidence in the United States about other ways, one of the ways you - you volunteered I suggest Professor was - "Could be through mailings to experts in the field, that kind of thing", that's what you said, wasn't it?---I gave that suggestion, yes, sir.

That's be a very good way, wouldn't it, for a manufacturer of a pool product to warn about the dangers that are associated with the pool product?---That would be one way, but of course they already knew what the risk was anyway.

The next question "Would another way be for individual manufacturers to instruct their sales forces to make sure they told hospitals, pharmacists, doctors, that they sold a particular product to about the problem?" Your answer to that Professor I suggest was "It might be. I believe it's a very good one". Do you still believe it's a very good one?---I think it's another way to give warnings if you want to give warnings.

Do you believe that one of telling the individual manufacturers to instruct their sales forces to make sure they told hospitals, pharmacists, doctors about the problem, do you still think it's a - in your words "a very good one"?---It's one of them, yes, if you want to give a warning.

There's no suggestion in that case that they don't need a warning, is there - - - ?---That wasn't the question - - -

And I suggest - sorry?---That wasn't the question.

No, but I mean - I'll read it again for your, Professor. "Would another way for individual manufacturers to instruct their sales forces to make sure that they told hospitals, pharmacists, doctors that they sold a particular product to about the problem?" And you answered "It might be. I believe it's a very good one". Do you still believe it's a very good one?---I think it's one of the ways you could have done it if you wanted to give a warning, yes.

Then there was still more. "Are there any other ways that you could think of that it would have been appropriate in addition to package inserts, and the ones you've just talked about?" You answered "Yes". "What others?", and the answer was "Publishing scientific studies, documenting the degree of risk, and that it existed". Did you give that evidence in May, Professor?---I believe so, you just read it from there.

Do you know when the infection was - the alleged infection was as far as it concerned the plaintiff in that case? ---I have no idea.

No idea?---That's correct.

Weren't you asked an opinion in that case about when that plaintiff suffered his infliction?---I gave - probably if I were and I think you'd have to show me, would be a statistical probability of when he was most likely infected.

Do you remember giving evidence in a case of Gallagher, Professor. Gallagher against Cutter Laboratories on August 19, 1986?---I believe so, that was more than four years ago, but I believe I did.

I want to read to you some evidence about warning. The evidence - or the deposition - I'll get it strictly correct. The deposition that you gave on oath in this case. The question put to your Professor "I'm asking you when you think the manufacturer of Factor 8 should have included a warning on their product,

that the use of Factor 8 product could lead to the transmission of AIDS?" I suggest to you Professor your answer was "My estimate would be 1983, and probably the latter part of 1983. There was sufficient evidence that haemophiliacs were definitely at risk of AIDS". Did you give that evidence in 1986, Professor?---I may have, but if I could see it I could verify it.

Do you want the whole lot or just the page?---I'll take the whole lot.

It's marked with a yellow tab - - -?---Okay, I could note my whole answer there.

Would you like to read out anything that you think I've left out?---Sure. You read the first part but not the second part. Answer was "My estimate would be 1983 and probably the latter part of 1983. There was sufficient evidence that haemophiliacs were definitely at risk of AIDS, and with the presumption that they might have received the AIDS from blood products, than in fact that it was a potential risk, and the magnitude of the risk and what kind of the warning could be, I couldn't specify because the risk was very small at our best understanding of it".

Professor, the part that I want to draw your attention to is that you gave the date there in 1986 as appropriate for a warning, as late 1983, did you not?---In the answer to this question, yes, that's what I said.

So in 1986 when you're testifying in the United States, it's late 1983. In May of 1990 when you're testifying in the United States, it's late May 1983. But when you come to Melbourne in October of 1990 - is there something funny about the question, Professor?

---Yes, but go ahead.

I'll put the question to you despite the humour. In October of 1990 when you come to Melbourne, it's 1985. Do

you want to explain that to us, Professor?---Sure. These were estimates based upon a minimal evidence and without anything we knew about this virus, we didn't know it was caused by a virus - we had no test for it. It wasn't until 85 that we have a test that we can really quantify in any way what the risk is. Up to that point it was a very minimal risk at best, the best we could understand it - and in the light of the idea that you should potentially warn people about potentially the minimal risk - that's what I was talking about. What I'm talking about today is until you have that test, until you apply that test, you don't really know what the risk is, and it wasn't until 85 that we really had an idea of the magnitude of that risk, because now we could test people.

Well, Professor, I don't claim to have your qualifications, but my question is directed as to your evidence about dates. The question is directed as to why, when you were asked about warnings in the United States, it's late 1983, and when you're asked in Australia in October of 1990, it's 1985. Now, my question's not about any of the other things, it's about why there is a difference in those dates?
---Well, I tried to tell you. In 1985 we now know what the risk is, we can quantify it, we can be specific about it. In 1983 we could not.

So that's your answer, is it?---Yes, sir.

Could I have the transcript. I want to put to you, Professor, that despite your volunteered protestations about being not called on behalf of any party, but an expert and impartial - that you've come to Australia to tailor your evidence for this case?---I respectfully disagree, sir.

I suggest to you not only that - that you've gone right into the litigation field and provided information for cross-examining of other witnesses for the Red Cross?---And I disagree again, sir. I wanted to set the record straight.

But you agree that you were provided with that document I showed you, don't you?---Absolutely.

Professor, you'd agree with this, would you not, that the risk of HIV infection or AIDS, increases with the number of donors that you're exposed to?---In general, yes.

The greater the number of exposures to donors, the greater the risk of infection with HIV?---In general, yes.

I suggest to you professor, that in previous testimony in the United States, you have given evidence that all things being equal - all things being equal that you would avoid giving a product from a large donor pool, where you can give a product from a single donor?---I'm sure I said that.

That as a general theory is correct, isn't it?---As a general theory. As you pointed out. Yes sir.

Professor, it is right to say isn't it, that a severe haemophiliac, all things being equal can be managed equally as well on cryo-precipitate as he can on concentrate?---No. I disagree with that.

How do you disagree with that?---I said I disagree with that. It is not appropriate.

Why not?---Well, if you look at one of my papers there as published in 1968 I believe you can see when you give a lot of cryo-precipitate to a patient you can get additional problems. Not only reactions. You can destroy their blood. There are problems you cannot give as much Factor 8, through cryo-precipitate as effectively as you can with a concentrate of Factor 8. It has much more risks in terms of additional problems.

So, is that the only reason?---No. It is also in terms of the dose. You can give a much more specific dose with the Factor 8 concentrate in a more convenient form -

higher levels for a longer period of time. So, it is better therapy.

Professor, so in summary you would say that a severe haemophiliac can't be managed equally as well on cryo-precipitate?---I would make that statement yes. Depending upon the situation, that in general, if you want to make a generalisation, that you are better of managing an adult severe haemophiliac for surgery and a lot of other things with Factor 8 concentrate, compared to cryo-precipitate.

Let's go back to that case of Gallagher in 1986 Professor Holland?---Okay.

August 19, 1986. I suggest these questions were asked of you and these were your answers. "Do you have any opinion on the issue of whether a severe haemophiliac can be managed equally on cryo as on commercially manufactured Factor 8?" You answered: "Give you my opinion? I would say that in many cases they probably could, but we really depend upon a lot of other circumstances. That is, if they got hit by a truck I would say no. But on day to day operation, probably many, if not most could be managed with cryo-precipitate." Did you give that evidence in 1986?---I believe I did if you read it from there.

How does it compare with the evidence that you have just given to the court?---It doesn't contradict it.

Doesn't it?---No.

So, do you say the evidence that you have just given to the court is to the effect that, that on day to day operations, probably many if not most could be managed with cryo-precipitate?---Yes. I still stand by that. They are not inconsistent.

If that is the case at the time we are talking about 83/84, you would agree that certainly by mid-83, it was recognised that haemophiliacs were in trouble when they were being administered the concentrate. There was a risk?---I'm not sure what you mean?

There was a risk to haemophiliacs who were using the commercial concentrate from large donor pools?---Yes, but there was also a risk from cryo-precipitate.

But the risk from the large donor pool was a lot greater than the risk from single donor cryo-precipitate wasn't it?---For hepatitis it was.

So, you say do you, that the risk wasn't as great for AIDS?---We didn't really know the exact risk at that time sir. In any case, I tried to tell you that if you got equivalent amounts that the risk was probably about the same for AIDS.

So, you are saying you didn't know the risk at that time?---We were making an educated guess about the risk.

You knew that pooled products with large donor pools - you knew they were a risk didn't you?---For hepatitis yes, for sure.

For any virus?---Not for any virus. For some viruses they are less risky.

By the middle of 1983, Professor, the reports were coming in from all over the place about haemophiliacs with problems - with AIDS as a consequence of the use of the concentrate?---There was some. There was also some haemophiliacs who got AIDS from cryo-precipitate.

Does the fact that you're using volunteer blood in relation to the pool, does that influence you as to the risk? ---Not really. If you have 10,000 volunteer donors, or 10,000 commercial donors in a pool, the risk is going to be not significantly different, just because you have so many.

Because where you've got lots of donors in a pool, thousands of donors in a pool, any benefit that you conceivably might have from the volunteer blood supply is lost, isn't it?---Largely, yes.

Because you can't say where you're putting 2000, a thou or more donations into one pool, you're going to get people no matter how hard you try that are going to be positive for Hepatitis B. In 83, 84 potentially AIDS, and it's going to confuse the whole volunteer blood supply in that pool?---To some extent I'd still rather start with volunteer plasma, but give the choice, and with the numbers it wouldn't make to much difference.

So when you're pooling blood whether it's volunteer blood, or paid blood, once you put them in the pool any benefit that might be claimed for the volunteer

blood is lost, isn't it?---It would be largely lost, yes.

So as far as a volunteer blood supply in the manufacture of pooled concentrate is concerned, once you put it all in the pool it's lost any benefit that it might have had from being volunteer blood?---No, I didn't say that.

Isn't that right?---No - - -

Most of any benefit it had?---Okay, the losers will get part of the benefit. It doesn't loose at all.

But where you've got a single blood product from a volunteer blood supply that's probably - that's where the benefit of the volunteer blood supply is?---In a single case, but nobody gets a single transfusion, less of all a haemophilia.

As a general proposition, Professor, let's start with the general proposition. Where you've got a single unit of blood from one donor that's where the volunteer system's at its best?---Yes, sir.

But what you say is that it looses much of its overall benefit when it's put into a pool?---Yes, much of the benefit's lost.

Mr Barnard gave you the evidence that in the year before he went onto concentrate, Mr PQ, the plaintiff in this case, I think he said was exposed to 730 donors, do you remember him asking you that question?---Yes, sir, in one year.

Do you know how many donors he was exposed to when he had his

first infusion of concentrate?---Not exactly, it could be anywhere from 1000 to 10,000.

So what had happened in one year in 1982 was gone in the 10 minutes that it took him to have his first infusion of concentrate?---Well, you could say he got seven or 800 volunteer materials that year plus hundreds in the years before, so in fact his risk was already there.

But he wasn't get them, Professor, from Los Angeles, was he? ---Excuse me?

He wasn't getting his blood from Los Angeles?---No, I hope not.

Or San Franciso?---Not that I know of.

And he wasn't getting it from Sydney, do you know that?---Not that I'm aware of.

Do you know anything about where the blood comes from that he was using - the plaintiff was using - that made up his cryo-precipitate prior to March 1983?---For the cryo-precipitate itself?

Yes, do you know where the blood came from?---My understanding is that for the cryo-precipitate most of it would have come locally, that's not true of the concentrate.

So, you're understanding is that the concentrate is Australia wide, and the cryo-precipitate is locally?---That's my understanding since there's only one manufacturer.

And do you know anything, Professor, can you gave us any

evidence about what the risks in the various cities were of AIDS in Australia?---No, not off hand, no.

Do you know if Sydney was a higher risk than Melbourne?---Not off hand, no, sir.

But you do know that the single donor blood, the cryo-precipitate, that came from his local area and the pooled product came from all around Australia?---That's my understanding. That most of it would have come locally.

Of those patients, professor, that you have treated - the severe haemophiliacs, what percentage of them have died of AIDS, have AIDS, or are HIV positive?---I have to go backwards. In America about 75 per cent of haemophiliacs are infected with HIV virus. As far as what percentage that I've personally seen that have died, I couldn't tell you what percentage of them are alive or dead. I have been seeing them since 1962 and I don't keep up with them all.

What about your patients since 1982?---I don't even know that sir. All I know is how many are infected. I don't know how many have died.

How many are infected?---75 per cent are infected. 25 per cent are not infected. Despite getting Factor 8 concentrate.

75 per cent of your patients either have the virus or did, is that right?---They are antibody positive.

Are antibody positive?---Correct.

Any died?---Some have died, yes.

Are you able to tell us professor, what percentage, or proportion of those patients are dead?---No. I don't know.

Of the patients that you've treated since 1982?---No. My

impression is the vast majority are still alive, but I don't know what percentage are dead.

Are you able to say what percentage have got AIDS?---No. I can't even tell you that. I can tell you what per cent are infected with the virus. Most of those do not have AIDS.

So, you can't tell us - of your patients you can't tell us what percentage have died, or what percentage have got AIDS?---That's correct. I have not made a compilation.

Professor, in giving your evidence this morning, you refer to the July 16, MMWR. Giving your evidence about that you indicated to the court well, there was some question about whether they may have been IV drug users, I think you said?---That's correct.

There was some question about whether they were homosexual?---That's correct.

Did you read the MMWR report?---Yes, I did.

What did that say about their sexuality?---As I recall, it said that they didn't admit to it. But you can check me exactly.

What you are saying is that the doubt is, about those three patients, is that they might have been IV drug users or they might have been homosexual?---Or both.

Or both?---Yes. Because if you look in the MMWR they used to stratify and say which haemophiliacs were gay, which haemophiliacs were IV drug users. You used to have to separate them and it is known that that happens,

sir.

Was there any doubt about their sexual status or their drug use in the report of the MMWR?---In my view, yes. Just because they did not admit to it, it doesn't mean it wasn't so.

I'm reading your Honour from tab 6 of the plaintiff's folder. Folder 1.

HIS HONOUR: A6 is it?

MR RUSH: Are you - is this book 1?

HIS HONOUR: Is this book 1?

MR RUSH: Folder 1 - book 1, I'm sorry your Honour. Tab 6.

HIS HONOUR: A6?

MR RUSH: A6 I'm sorry your Honour.

That's the MMWR report of July 16 professor. Is that right?---Correct.

Concerning three persons with haemophilia with pneumocytis. Is that right?---Correct.

The first paragraph reads does it not "CDC recently received reports of three cases of pnemocystiscarinii pneumonia amongst patients with haemophilia A, without underlying disease. Two have died. One remains critically ill. All three were heterosexual males. None had a history of IV drug abuse. All had lymphopenia. Two patients who were specifically tested have had in vitro laboratory evidence of cellular immune deficiency". Nothing about homosexuality there is there?---It doesn't make it not so. We have known people who have gone to their

death denying it and only after their death have we discovered that they were homosexual or IV drug users.

You have three men and the report is that all three were heterosexual?---That's what it says.

And none had a history of IV drug use?---That's what it says.

And you know, don't you, Professor, that those cases would've been referred to the CDC by their treating doctors? ---Yes.

The first one's a 62 year old man, probably the person that's treated him all his life?---Sir, husbands and wives don't know what their husbands and wives do, and at the same time - as I pointed out to you - 20,000 haemophiliacs are out there without this disease. There were thousands of people with this disease who were gay men and IV drug users. And so you have to make the presumption that that's a possibility, and just because someone says "No", or their doctor doesn't know it or the wife doesn't know it, doesn't make it so.

If anyone was going to infer anything from those case histories, it would be the opposite - - -?---No, sir.

Just let me put the question. Opposite to the inference that you've drawn, isn't it?---No, that was part of the discussion - that whole day was "How do you know they are not IV drug users, at least on one occasion, how do you know they're not gay men just because they say they weren't?".

So you say to the court, "There's a question about this report because although the report says they were

heterosexual and none had a history of IV drug use, there's still a doubt about it and they might've"? ---Absolutely, I've had to inform husbands and wives that their husband or wife was gay or homosexual when I found that they were infected with this virus.

Then you referred to the baby that was diagnosed with AIDS in December of 1982?---Yes, sir.

This was the subject of another MMWR report, was it not? ---Correct, December 10th, 1982.

Perhaps if I can take you to that - it's tab number A12 in the folder in front of you - - -?---It doesn't seem to be.

A11, I'm sorry. Doctor - - -?---Yes, sir?

Professor, about that report, you say that possibly the mother abused drugs, is that an explanation for that? ---Yes, all the other babies mothers had such a risk factor with something like that.

Don't you think the fact that CDC publish a report where the mother is not such a person or there's no report of the mother being such a person, distinguishes it from the others that you refer to?---No, sir.

You were responsible, you've told us this morning, Professor, for drafting the January 13th joint statement from the blood banks?---That's correct.

That's at tab 16 in the same folder. So we're talking about a December report and then something that you put together in January of 1983?---Correct, about three

weeks later.

If you go to the second paragraph - you, as a co-author, state "The predominant mode of transmission seems to be from person to person, probably involving intimate contact. The possibility of blood borne spread, still unproven, has been raised. This latter impression is reinforced by eight confirmed cases in haemophiliacs treated with anti haemophiliac factor, AHF concentrate". Nothing there about anyone being homosexual or an IV drug user, is there?---No, we didn't put it in.

They're confirmed cases in your view, three weeks after the baby in December?---No, the term "confirmed" there was used in terms of the CDC saying they were.

So the CDC had said they were?---It was the CDC's impression that they were probably transfusion transmitted, yes. It doesn't make it so, but that was their impression.

Then you go on "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". Nothing there about a mother being an IV drug user or some other way of being infected, is there?---No, it wasn't their purpose.

What I suggest to you Professor is that you're saying there, that they're cases that we should take notice of?

---What we said is yes, exactly that, that this is the possibility, and therefore we're going to act in that possibility.

Not as you're come to this court, not throw doubt upon them by saying "The mother might be an IV drug user, or the three in July they might be homosexual". What you said on January 13, shows no doubt - throws no doubt upon this status of their diagnosis, doesn't it?

---No, the doubt was there. We just didn't put it in this document.

And then you go on "One baby with 19 units of blood components, one of which was from a donor who died later of AIDS, and by fewer than 10 unconfirmed case reports in other transfusion recipients". So, what you're saying "Look, we've got some certain ones here, and we've got 10 unconfirmed transfusion cases", that's what that document says, isn't it?

---No, sir.

What's it say?---What it says is there are seven cases of haemophilia, and one transfusion that was said to be this, that is it was said to be not to have the other factors. The unconfirmed cases hadn't been investigated yet, and so we didn't know anything about them. But we took the possibility that this was so, and we acted on it. I think we acted on very minimal evidence.

Professor, I'll take you to the next paragraph. It says "The finding of cases in haemophiliacs, especially those who used AHF concentrate" - - -

MR SHER: You've left out of the last paragraph seeming you're busy reading this - construing it from the bar table. I object to this form of cross-examination.

MR RUSH: I object to Mr Sher, your Honour.

MR SHER: Your Honour, I am making an objection and I anticipate your Honour will hear me on it.

HIS HONOUR: Yes.

MR SHER: My objection is this. There are three passages in this document which my learned friend has not taken the witness to, and obviously doesn't intend to, because he's passed off the two of them already. The first is the statement ahead of the bit he read. The second is immediately after the bit he read, and the third bit is at the top of - at the bottom of that column and the top of the next page. All that's been ignored by the questioner, and a suggestion's been made that there is just an assertion in this document as though these matters are all uncontestable confirmed cases.

In our submission it's an untendable proposition.

HIS HONOUR: Mr Sher, you have your opportunity of re-examining the witness at the end of the evidence. It's open to counsel to cross-examine about passages

in documents. It's not - the jury are aware of what is being done, and if counsel cross-examines in a way to give a wrong impression the jury are very aware of that, but it's for Mr Rush to conduct his cross-examination in his way.

MR SHER: In my submission, your Honour, he's not entitled to misconstrue a document, and to make suggestions about what's in a document when it's clear from reading, and that the suggestion's unfounded. It's misleading and it's - in our submissions it's not permissible cross-examination, that's my objection, your Honour.

HIS HONOUR: I regard the cross-examination as admissible.

MR RUSH: Your Honour, Mr Rush has said certain things about the way I'm cross-examining - - -

HIS HONOUR: I don't want an argument, and I have overruled the objection, and I asked you to proceed with your cross-examination.

MR RUSH: Professor, the part I didn't read - the part I've jsut read to you wasn't read by Mr Sher this morning, was it?---I'm not sure that either of you have read the whole thing.

He didn't read anything about eight confirmed cases of haemophiliacs treated with - - -

HIS HONOUR: Mr Rush, this litigation is between the plaintiff and the defendants. It is not between you and Mr Sher.

MR RUSH: Yes, your Honour.

If you go to the next paragraph, Professor. The finding in haemophiliacs, especially those who use AHF concentrate coupled with a long incubation period, and the continuing increase in reported cases is of sufficient concern to warrant the following suggestions for action on the part on blood banks, and transfusion services?", do you see that?---Yes, sir, and it says "Given the possibility that AIDS may be spread by transfusions" - - -

Yes?---"We're obliged to respond with measures that seem reasonable at present".

So, you agree at that time there was the possibility of a long incubation period?---Yes, we said that. We said "Given the possibility".

And there were continuing reported cases of AIDS?---That appeared to be due to transfusions, yes.

Because in 1982, 83 they just kept on - the numbers kept on increasing, didn't they?---Later on, yes.

But by the beginning - or January - the end of January 1983 you say, do you, that the recommendations here were in place in blood banks in the United States?---They were recommended to be put in place, yes.

Are you able to say whether they were or weren't?---I can't speak for our blood banks. I can tell you which ones - some of which did and some of which didn't.

Were they in place at the blood bank at - that you were dealing with at the NIH?---I told you which parts we implemented in in AIDS.

Were you - did you implement a questionnaire?---We added three questions to our history, yes, sir.

What about the - when did the questionnaire with 40 questions that you've spoken about, when did that come into operation?---That was in Sacramento in the fall of 1983.

So we're talking about September 1983?---September, October - October's better.

Tell me, did you bring that questionnaire to court?---No, I did not, sir.

Did you bring any document that you handed out to blood donors to court?---No, I wasn't asked to.

You weren't asked to bring the questionnaire with the 40 questions on it for donors to - - -?---No one asked me to.

Well, Professor - - -

MR SHER: He is suggesting - Mr Rush is suggesting that this witness has been doctored in some way. Your Honour, I object to this form of behaviour. It's a grossly offensive cross-examination and nobody is free of criticism from that end of the bar table. This case ought to be confined to the facts.

HIS HONOUR: Mr Sher, let's get on with the litigation.

MR SHER: Well, your Honour, I object to this type of vile suggestion of improper behaviour and the suggestion - if my learned friend wants to assert it, let him assert it - have the courage to say it and then we can call some evidence to rebut it.

HIS HONOUR: Continue with the cross-examination.

MR RUSH: If it please your Honour.

You didn't bring the questionnaire to court, Professor, is that right?---No, I didn't bring anything to court.

But when a donor came into the blood bank in Sacramento, he was taken through 40 questions, was he?---Yes, on a whole host of things.

Some of those questions relating to AIDS?---Early signs or

symptoms of what we believed to be due to AIDS, yes.

Specifically asked questions about the prodromal form of AIDS? ---What we thought it was, yes.

The night sweats, the fevers, the weight loss?---Correct, I believe so.

So the nurse, when a donor came in, in October 1983, to your blood bank, took that donor aside and took that donor through the questions, ticking boxes or filling in the form as appropriate?---That's essentially correct, yes.

Then the donor was asked to sign his registration form, as having been taken through it?---Correct.

And having truthfully answered?---Correct.

And that again is October of 1983?---Yes, sir.

Every time the donor came into your blood bank, he was taken through the same procedure?---Pretty much. We changed the questions periodically and changed the information sheet, but yes.

Taken through the questions and signing his donor registration card?---Correct.

Professor, paragraph 5 over the page - just for the sake of completeness, I don't want to leave anything out - if you go to number 4 at the bottom of that page it talks about "Donor screening should include specific questions to detect possible AIDS or exposure to patients with AIDS", that's what your questions were aimed at, is it?---They were related to that.

Then over the page, paragraph number 5 - "Persons with

responsibility for donor recruitment should not target their efforts towards groups that may have a high incidence of AIDS" - what does that mean?

---Well, as I told you before, we specifically would not schedule mobiles in areas of town or gay groups that would identify it as such, that might have individuals at risk - that is very sexually active gay men.

And finally, to go to item 1 - three quarters of the page - it reads: "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." Now, the American Red Cross is one of the signatories to this document, was it not?---Yes, it was.

What that is saying is that blood banks and transfusion services should be going out and telling the physicians that are treating these people, about the problems of balancing, for instance, cryo-precipitate against concentrate?---It might include that, and we've been doing that for years.

You are a co-author, and the recommendation is to extend educational campaign to physicians to balance the decision to use each blood component against the risks of transfusion?---Yes be they established or under investigation.

Sensible advice for blood banks and transfusion centres?---I like to think so.

You'd like to think it was done, wouldn't you?---Yes. I certainly made an effort to do it and I believe most of my colleagues did to.

Professor, the screening procedures that you have spoken about, you've spoken about sexually active homosexuals with multiple partners. Is that correct?---In essence, yes.

That is one source that you did not want?---Yes.

As far as a volunteer blood supply is concerned, or a paid blood supply, each is going to attract homosexual donors, isn't it?---I'm not sure what you mean, why would it attract them?

You are not going to get homosexuals confined to being paid donors are you?---I doubt it but it is not an attraction there, the way you put it.

In this court there has been talk about the IV drug users being particularly perhaps, attracted to the paid blood donation - the plasma centres. But as far as the homosexual is concerned, that falls across a different class doesn't it?---I don't know what your question is?

What I'm trying to put to you professor is that it has been put that the IV drug user is more likely to go and give blood for payment. Is that something you agree with?---Largely, yes.

The distinction I'm trying to get from you is that you are not going - homosexuals aren't necessarily going to go to - just to a paid blood centre are they. They are going to go to both volunteer and the paid blood section?---Depending upon the time and if they wanted to be a donor, yes that's possible.

HIS HONOUR: Is that a convenient time, Mr Rush?

MR RUSH: Yes, your Honour if I can just put - - -

I haven't got a - they are not particularly going to go to a paid centre as opposed to a voluntary blood centre are they?---I'm not sure of your question. But I think what you are trying to say is that - I understand your attraction, that doesn't bother me.

HIS HONOUR: Quarter past ten.

WITNESS STOOD DOWN

AT 4.12 PM THE MATTER WAS ADJOURNED
UNTIL TUESDAY, 16 OCTOBER 1990

HIS HONOUR: Mr Sher, I have concluded on reflection that I was discourteous and unfair to you yesterday, not dealing expressly with your objections, and I apologise for that.

MR SHER: It's unnecessary, your Honour, I'm grateful for that indication.

HIS HONOUR: I propose to mention that to the jury.

MR SHER: I don't think that's necessary.

HIS HONOUR: The other thing is this. This morning I'm dealing with some absentee jurors, but this afternoon I would like to proceed with that argument about the resources of the defendants, if that's convenient to counsel.

MR SHER: Can I tell your Honour what we've sort of programmed for the next few days so your Honour knows where we're headed. We anticipate that Professor Holland's evidence will probably conclude during the morning sometime. We were then going to try and finish off our three unfinished witnesses - Miss Minogue, then Sister Duffy and then Dr Archer. There's a Dr Perrot from Canada, who we'd like to call today as well, your Honour. So hopefully Friday afternoon will not be affected. The jury's plans for Friday afternoon - - -

HIS HONOUR: Yes.

MR SHER: And I hope that by the end of this week - early next

week, we will have concluded our three incomplete witnesses.

HIS HONOUR: That doesn't impinge at all on my suggestion of arguing that question?

MR SHER: No. Dr Archer obviously comes down from New South Wales, but I would imagine that we'd need him tomorrow in any event, even if we don't need him immediately. But we'll know that better tonight, your Honour.

HIS HONOUR: Yes, very well.

MR STANLEY: Your Honour, can I say something about your Honour's indication that your Honour is going to speak to the jury about the matter in relation to Mr Sher?

HIS HONOUR: Yes, Mr Stanley.

MR STANLEY: It's obviously entirely your Honour's business what your Honour says to the jury about your Honour's conduct of the trial, but we would submit that to say anything to the jury is unnecessary in the circumstances, and that it may well have effects that it shouldn't have. The jury weren't caught, they observed what happened and it was for them to make an assessment of the situation, and we would submit that for your Honour to make comments along the lines of those you made to Mr Sher would be not only unnecessary, but could be dangerous and we would urge your Honour to reconsider.

HIS HONOUR: Mr Stanley, I may not have been specifically

detailed in what I said. There were two occasions when objections were taken and I didn't expressly deal with them. I instead addressed Mr Rush and told him to proceed, and that was a discourtesy and an unfairness, it's only that. Mr Stanley, I'm not unconscious that on the front bar table there has been a great deal of play before the jury, but it did seem to me that I was discourteous and unfair, and if one takes that view, it's better to take it in front of the jury.

MR STANLEY: Your Honour, I don't profess that we have been entirely blameless in this regard, but I do maintain that the byplay at the table in front of the jury has not essentially come from this end, and your Honour made the statements - following on objections that were not properly taken by my learned friend, they simply started off in the way of comment, of interruption, and then when he had perceived that was not going to get your Honour's attention, it then became an objection, and that was when your Honour answered him.

In my submission, for your Honour to - as it were - indicate that Mr Sher's conduct in those situations was appropriate by express comment to the jury. In my submission it would be placing an unfair and an incorrect version on what in fact happened.

HIS HONOUR: Yes.

MR STANLEY: In my submission, it should be left at that.

HIS HONOUR: Mr Stanley I'm not unconscious that there has been a substantial barrage of comment audible to the jury from the other end of the bar table but - and that I think, is a matter on which I should comment if it continues. But I appear - I think on reflection that I appeared to treat counsel in a way that counsel is not entitled to be treated and it is my conduct that I think ought to be corrected.

MR STANLEY: If your Honour pleases.

HIS HONOUR: Bring in the jury.

AT 10.25 AM THE JURY ENTERED THE COURT

HIS HONOUR: Mr Foreman members of the jury yesterday there were a couple of occasions when objections were taken by Mr Sher. I didn't expressly rule on them but indicated to Mr Rush to proceed. I have concluded on reflection that that was discourteous and an unfair course of conduct by me and I have apologised for Mr Sher for it. The matter may now continued and Professor Holland may return to the witness box.

PAUL VINCENT HOLLAND:

MR RUSH: Professor Holland, when you gave evidence for Cutter Laboratories in the case of Gallagher, I suggest to you that you put before the court that you were aware of data to show that volunteer donors were at high risk of getting AIDS - or the AIDS virus, than

paid donors?---I'm not sure what you are saying. Is that a statement or a question?

I'm putting to you that when you deposed in the case of Gallagher on behalf of Cutter Laboratories, you deposed that you were aware of data to the effect that volunteer donors were at a higher risk of the AIDS virus than paid donors?---I don't recall that and unless you are talking about western blood confirmation, I'm not sure it is true.

I put to you yesterday that you deposed in the case of Gallagher on August 19, 1986. Do you recall that?---No I don't. I'd like to see it so you can show me.

I'll show it to you in a minute but do you recall yesterday I showed you the deposition in Gallagher?---Yes sir.

You looked at it and agreed that that was your deposition?---Yes sir.

It was given on August 19, 1986?---That's correct.

And on that occasion you were deposing, giving sworn evidence for Cutter Laboratories?---Yes, but I'm sure I based it on data at the time.

I suggest to you in the context of the risk of the AIDS virus as paid donor against voluntary donor, that you said this:

> The commercial manufacturers would argue the opposite. They had data to show the opposite.
>
> Q: To show what? A: The paid donors have lower risk of carrying the retro AIDS virus than volunteer donors. They have data to show that.
>
> Q: Do you think that data is reliable? A: I have to believe it. I mean it's published. It's presented at meetings. I've no reason to doubt it.

Were those questions asked and did you give those answers in 1986, Professor Holland?---Yes, I did.

And do you still stand by the proposition that the commercial donor or the paid donor is a lesser risk of AIDS than volunteer donors?---No, sir, because in retrospect those data were not properly collected, and they're not properly interpreted, and further data would discount them.

So, you've changed your view, you accepted that material then, but you don't accept it now?---I said I would have to accept it then based upon what they told me. I

now know from subsequent data that the way they calculated it, and with confirmatory testing it was probably not correct.

Professor, on that occasion you were giving evidence for the collector of the paid blood, Cutter, is that right?---I was being asked my expert opinion, sir.

On that occasion you were being paid by Cutter Laboratories?---They paid my fee for my consultation, correct.

For your expert opinion?---Yes, sir.

And they are the collectors of the paid blood, Cutter Laboratories, are they not?---Largely, yes.

And you were giving evidence for the volunteer blood collector, the Australian Red Cross?---Yes, sir.

The fact that you no longer stand by that comment's got nothing to do with who's paying your fee?---It has nothing, and I said that further data would invalidate those data, and I didn't get to see them, and they have been subsequently shown by Western Blood not to be true.

You say you didn't get to see them, but in answer to that question you said "I have to believe it. I mean it's published. It's presented at meetings. I have no reason to doubt it"?---Okay.

You obviously saw it?---No, I didn't say I saw it. I said I have to believe it. They presented it.

"It's published"?---I didn't say I saw it.

"It's presented at meetings". Were you at the meetings?---Sometimes, yes. Sometimes, no.

"I have no reason to doubt it"?---Because I had no reason to doubt the voracity.

You gave evidence yesterday, Professor, that the change in treatment for Mr PQ, the plaintiff in this action in March 1984 from cryo-precipitate to concentrate was appropriate?---Yes, sir.

Have you ever examined the hospital records in this case? ---Yes, I have.

The totality of the hospital records?---All of them.

Have you - do you know what age Mr PQ is?---He's in his 40s now.

Whereabouts?---I don't recall exactly.

Do you know what he's employed as?---I believe he works for a firm as a salesman, but I'd have to refresh my memory, sir.

Do you know what his convenience was with cryo-precipitate, whether he found it a bother, or whether he - - - ? ---I'm not sure that he was asked that. I'm not sure that's in the record.

When you say you're not sure whether he was asked that, what do you mean?---There's no - from my recollection of the record which is about this high and I didn't memorise. It didn't say "Is this a convenient to you? Did you like this?" I don't believe it's in there, sir. Unless you could show me, I would be happy to see it.

What record have you been shown, Professor?---The hospital records.

You don't know whether he's found it a bother to use cryo-precipitate or not, do you?---Not for a fact, no.

You don't know whether it was easy for him, difficult, what the position was?---Well, I can come to a supposition that since he had to go to the hospital for it, it must have been some bother.

But as far as his view of it was concerned and whether it bothered him, you don't know that?---It's not in the hospital record. I didn't see it.

Professor, you gave evidence yesterday that you're on some committee in the United States in relation to informed consent?---That's correct.

A committee dealing with blood - with human tissues and transplants, is that correct?---That's correct.

The idea or the committee - the function of the committee, is it, is to ensure that people know what's happening when these medical steps are being taken?---In experimental situations, sir, when using experimental tests, like an unlicensed test or a new product or a new drug or a new therapy.

When you change a patient's therapy, when you change that situation, it's important that the patient - the patient - is aware of the change and what the consequences of the change is, is it not?---In general, I would agree with that, yes, sir.

It's important that the patient is informed of any risks that might be associated with the change of treatment?---As well as any benefits and drawbacks of each and of not receiving that therapy.

As well as any drawbacks, any benefits, any risks - all those

things should be explained to the patient?---Absolutely.

That's a vital tenet of the medical profession to inform the patients so that they also can be in on the decision?---Very definitely.

Professor, you gave evidence yesterday that more than half the people infected with the HIV virus, within three months have the antibody, if tested?---That's correct.

Your evidence is that - is it not - that the majority of people will zero convert or show that antibody in a period between two weeks and three months after they receive the infected blood or blood product?---I didn't say that, sir, you misquoted me. I said 50 per cent would be positive by approximately three months. I said 95 per cent would be positive by six months.

Professor Holland, we've been provided with a statement or a summary of your evidence in this case prior to you coming to court?---Excuse me - my evidence in this case prior to my (inaudible) court?

Your evidence - you've been - we've been provided with a document that sets out a summary of material - what you're going to say?---Okay.

Now, Professor, in relation to - if I can just clarify this - in relation to material or in relation to the zero conversion, is it your opinion that people will zero convert between two weeks - the majority of people

will zero convert in a period between two weeks and three months after receiving infected blood?---If by majority you mean more than 50 per cent - that is, 51 per cent - it's pretty close to the border line depending upon which study you want to pick, which series you want to pick. It's on that order of about 50 per cent or so.

Will zero convert between two weeks and three months after receiving blood?---On that order, yes, sir.

Professor, you gave evidence yesterday - at page 5907 of the transcript you were asked about surrogate tests. Mr Sher said to you "Well, what was your view as to whether there ought to be a surrogate test used in either of the blood banks you went - were at in 83 or 84?" and you answered "Well, I recommend against it. We never adopted them, even though in Sacramento there were four or five blood banks right next door to us were using some surrogate test for AIDS but we felt there was no reason for there was no evidence to support them and in fact it was more likely to make the blood supply less safe and that's why we didn't use them". Do you recall giving that evidence?---I sure do, sir.

So there were three of four blood banks in Sacramento using the surrogate test?---No sir around San Francisco at the San Francisco Bay.

When you talk about four or five blood banks right next door to us. What's that mean San Francisco?---Yes sir.

It is about 100 miles away and their territory abuts against the territory we serve.

It is the same as when you talk about Professor Engleman being a neighbour of yours?---That's correct.

He's about 100 miles away as well?---That's correct.

Are you aware of a study by Dr Perkins of the United States in relation to surrogate tests?---I know Dr Perkins very well. I'm familiar with much of his work. I don't know what you are referring to exactly.

A study in relation to what the possibility of hepatitis B core antibody test and the effect that may have had if used as a surrogate test?---Could you give me the time frame sir.

Are you aware of a study by Dr Perkins?---I'm aware of 100s of studies of Dr Perkins.

Particularly in relation to that - in relation to that material?---I'm aware of some studies on this issue yes. You have to tell me the time frame the one that you are referring to.

When you talk about a time frame what do you mean?---I'd like to know the date of the study that you are talking about. When it was conducted and when it was published.

If I can ask you this, have you given evidence professor, in relation to work done by Dr Perkins as to the effect the hepatitis B core antibody test as a surrogate test could have had if used in the American blood banking situation in 1983. Have you previously given evidence on the testing done by Dr Perkins in that contest?---I have previous discussed and studies have been conducted in February of 1983 on the use of the antibody to the hepatitis B core test as a possible surrogate test, to which he concluded it would have been worthless, in fact, might have been counter-productive.

I suggest professor you gave evidence in a case of Wilson against the Erwin Memorial Blood Bank on August 21 1987. Just to get it straight. You gave sworn evidence in a deposition on that date?---I'm sure I gave a deposition in that case, yes.

What I put to you professor is that this question was asked of you and this was your answer. Let's go back to your statement there is no proof now that anticore would be an effective method of surrogate testing for transfusion associated AIDS. You made that statement "There is no proof". "Do you have an opinion personally as to whether it is an effective method of surrogate testing for AIDS?" Your answer was I suggest "That Dr Perkins own data that about a third of individuals with anti HIV now test (inaudible) have anticore and with the presumption

that 90 per cent of individuals who get transfused with blood - that is HIV positive will come down with the HIV infection - that's extenuating circumstance, but we will say there would be some potential value in what we know now as a possible surrogate test. That's the closest to any kind of potential proof I think we now have." Is that question asked and was that your answer professor?---Yes, but now we are talking about two and a half years later when we had a test for AIDS and we could now apply it in retrospect. So, I still stand with my previous comment that at the time in 83 and 84 there was no data to support that that would have been any good and even that suggestion does not prove it would have been of value because they never followed the patients that received that blood to find out what happened to them.

What you say do you not, is that there was the potential that the surrogate test was used to save about a third of people infected now with HIV?---As we analyse those samples, two and a half years later, there was that potential yes. Possibility. But we had no idea whether or not on the other side we may have caused more than twice as many cases of AIDS by that test. That's what's missing from that sir.

Sure, it's a look back now and looking back to what might have happened. What you're saying is that if the surrogate test had been used, potentially a third of people who now have HIV could have been saved from that contamination?---At the same time that twice as many might have got infected in which case you would have had twice as many cases.

But the use of the surrogate test might have saved a third of people?---But if I save 33 and I kill 100 that's not a very good ratio, sir.

Do you really think by using the surrogate test that that would have happened, Professor?---Yes, sir - - -

You do?---Absolutely.

Professor, in evidence yesterday to Mr Gillies - you gave evidence at page 5955 of the transcript - when you were asked about a ban of homosexuals giving blood in Australia. Mr Gillies put this question to you:

> In relation to the second self exclusion screen, that is all homosexuals screen, that was implemented in Australia by December 1984, and in some parts by October 1984, what do you have to observe in relation to the expedition of the second self exclusion screen in Australia?
>
> A: Again, I think it was remarkable. You were ahead of us.

Do you recall giving that evidence yesterday?---I sure do.

And you say it was remarkable and we were ahead of you, because you thought it was an idea?---Yes, from data we learned afterwards, not at the time.

From data you learned afterwards. You wanted proof, did you? ---Absolutely, I think you should always have proof. You don't just do these things out of thin air.

But that was a remarkable thing and a very good thing, was it? ---In retrospect it was.

What was the data that changed your mind that was so important?---After the tests for AIDS virus became available in March 1985 we would then test blood donors who were positive for this antibody, and then we could ask them "Why did you donate blood if you thought you might have been at risk?" And in careful questioning in great depth and detail of talking to them, and their sexual partners, we found out that some of them had had homosexual experiences, but they didn't want to admit to it. They didn't declare themselves as homosexuals, that they had gay sexual experiences. So, we said "Now, we learned something about you. We will now change our history, our information sheet because clearly a few of you who should not have been donating blood continued to", and we wanted to make sure - we wanted to diminish that risk. So, we used information gathered in 1985 to validate what you did here in 1984.

But in October 1984 there was no universal screen for blood

donors, was there?---What's the question?

In October 1984 there was no universal screen for blood donors?---What's a universal screen for blood donors?

Every blood donor that came in to give blood in October 1984 in Australia didn't have his blood tested for AIDS, did he?---No, it should not have been - - -

Well, the fact that you can test blood in 1985 would have nothing to do with this screening of homosexuals in October 1984, would it?---It has everything to do with it, as I've tried to explain to you, sir.

But he would have got a ban in Australia in October 1984, not 1985?---And what I said was that you were ahead of the game, because by information we found out in 1985 that you were correct, that you should have done that, and that you did it, and we couldn't do it and we didn't do it, because we didn't have the evidence.

It would have been even more laudatory and praiseworthy if it had been done in May 1983?---No, I think in May 1983 the best evidence we had at the time was that you would have encouraged a lot of homosexuals to donate blood who would not have donated blood. You would have increased the risk of the blood supply, that was the best evidence we had at the time. You cannot disregard that. If you're going to talk to gay people and get that information you cannot throw it out the window, because that is very very

important, and that's what they said. We had no reason believe they were lying to us. We had to pay attention to this.

Tell me Doctor, you were asked yesterday about the July 1982 MMWR and the December 82 MMWR, remember that?---I do.

And you said that you had to look at that very carefully, because potentially the haemophiliacs referred to there, and the child - the mother may have been infected or the haemophiliacs may have been homosexual?---That's exactly correct.

Doctor, have you given evidence in the United States when talking about those very reports in the MMWR to the effect that haemophiliacs are known to be more homosexually inclined than the rest of the community?---Yes, sir.

That they're more likely to be IV drug users than the rest of the community?---Yes, sir.

Do you have one paper that you can point us to, to support that?---Not at the moment, sir, but I talked to hundreds of haemophiliacs, I treated them and I talked with them personally, and I found this out - and further, if you look in the MMWR, you will notice that there are categorisations. It says "Haemophiliacs who were also homosexual, haemophiliacs who were also IV drug users, haemophiliacs who were homosexual and IV drug users" - they were separated by those groups, and if you want to look, you can find it.

You were asked that question in May of 1990, weren't you - whether you knew of an author, a paper, a journal, a publication that would support this contention of yours that haemophiliacs are more likely to be homosexual or IV drug users. You were asked that

just months ago, weren't you?---That's correct.

And you didn't have one then, did you?---I didn't have one at my hand, no.

And you haven't gone out, prior to giving evidence in this case, to look it up?---No, I haven't, have you?

It's an extreme view, isn't it?---Not at all, talked to a lot of other - - -

It's a view that suits the purpose of trying to discredit the material that's in the MMWR?---No, sir. Let's go back to those seven cases. When you have seven haemophiliacs who had AIDS, 20,000 do not - those 20,000 got some of the same product, some of the same "potentially infectious material" - you have to wonder, how did they get infected and the other thousands did not? And with all the cases at the time, the homosexual men, the IV drug users, cannot just throw that out the window.

You knew about the incubation period though, didn't you? ---When?

Well, in July of 1982?---We had no idea of the incubation period of AIDS in July of 1982 because we had no way of documenting it.

Were you aware of a study organised by CDC from July 82 to the end of 82, directed to haemophilia centres in relation to prodromal form of AIDS?---Yes, but that still doesn't tell you the incubation period.

Were you aware of how many reports there'd been to the CDC of people with pneumocystic or capitis sarcoma, since

1980?---Yes, but that in no way tells us the incubation period. Until the test is available, till the virus was discovered, we had no idea what the incubation period was.

It's an incubation period, is it not, Professor, that extends up to two years?---Incubation period is two different definitions. I think you should clarify them for us, sir, but I will clarify for the jury. One incubation period means from the time of infection to the time of some evidence of disease - that could be a test such as a test for the virus. Another definition is the time of infection to the time of disease, and the disease is AIDS, and those are vastly different, and until we have the test, we cannot know the former or the latter.

When did you become aware of the incubation period?---We couldn't really know it for sure until we did studies with the tests available after March of 1985, for sure.

I'm not talking about for sure, but when did you sort of appreciate that the incubation period was a real risk in relation to the problem of blood donation and the development of AIDS?---We had some only early clues that it would be based upon transfusion recipients only. We couldn't know it for haemophiliacs, IV drug users or gay men.

I'm reading from the Journal of the American Medical Association, Professor, of 4 February 1983. I'm

reading from page 2 and it says "In addition, the disease has a latent period as long as one year or more. The infant described earlier received" - this is December - "received blood transfusions at birth, but did not show clear signs of AIDS until after one year of age. That's the few cases seen so far associated with blood transfusion, and Factor 8 concentrate administration may indicate that many cases are incubating". Didn't you accept that?

---Well, I don't recall specifically reading it, but it says "Many cases are incubated" - that doesn't tell us the incubation period.

Did you accept it, or not, Professor?---I'd like to see it. This is a news article, sir. You represented it as an article of a medical journal. It's not so. I think you should make that clear and where are you talking - where are you quoting from - this medical journal which isn't here? Can you show me?

Doctor, I represented it as a publication of the journal, The American Medical Association. I'm talking about page 2, in column 1?---Okay, but it - - -

Three quarters of the way down the page?---Okay.

I suggest to you it's a report of the CDC meeting of January 1983?---Okay, so it's a news article. It's like reading the newspaper, sir. Keep that in mind. Now, what are you referring to?

I read it out to you, Professor. It's - - -?---Okay, so the newspaper reporter who wrote this article said that "In addition, the disease has a latent period as long as one year or more" because it's based upon that single case of the baby and we had no idea in most cases what the incubation period was.

What about the baby?---In that baby, presuming that baby was infected by the transfusion - and that's a big presumption since this was the first case - then the incubation period in this particular baby appeared to be about one year from the time the baby apparently got infected to the time that the baby had what we've classed to be signs of symptoms of AIDS.

So that's February 1983 and you don't accept it because it's a newspaper report, in your words, and you just don't accept it?---Well, it's not a medical journal, it's not a medical article and all it is is a newspaper man's description of what he heard at the meeting.

May I cite to you something, Professor, that you

wrote?---Sure.

That might help us?---Please do.

I put the date on it - 13 January 1983?---Okay.

"The finding of cases of haemophiliacs, especially those using AHF concentrate, coupled with the long incubation period and continuing increase in reported cases, is of sufficient concern to warrant the following suggestions" etcetera. Now, I suggest you wrote that, as you told us yesterday, on 13 January 1983 as part of the document prepared by the Association of American Blood Banks?---That's exactly correct.

What you've said to us in this court, the way you've explained the document that's before you now, bears no resemblance with the aim of your own words that you wrote a month before, doesn't it?---No, if you look at my own words, it said "We believe there was a long incubation period, we didn't know what it was and we could not know what it was".

So that explains it, Professor, does it?---Absolutely.

That's the explanation you offer to the jury in this case in disassociating yourself, in the words that you have, from that article - that's the explanation that you offer is that this - this just - coupled with a long incubation period, you say that that wasn't something that you were sure of?---That was our best guess at the time because - as I said - because we had no idea. We could not know for sure what the incubation period was.

Tell me, Professor, is there any equivocation in these words? "The finding of cases in haemophiliacs, especially those who use AHF concentrate, coupled with the long incubation period and continuing increase in reported cases, is of sufficient concern to warrant the following suggestions." Is there any equivocation there, Professor, about "coupled with the long incubation period"?---No, it was our best guess at the time. It was like the word "confirm" you used yesterday. We used that word because the CDC did. We could not confirm it. No one could confirm it at that time.

But until your own words were put to you, Professor, it's a best guess that you weren't prepared to acknowledge in this court two minutes ago?

MR SHER: Your Honour, I object to the question (inaudible).

HIS HONOUR: I regard it as permissible cross-examination. I permit it.

MR RUSH: So it's a best guess, Professor, that you weren't prepared to acknowledge until your own words were put in front of you - isn't that correct?---I don't understand your question.

What I'm - the question is - - -?---What are you suggesting?

I'm suggesting and putting to you, Professor, is that what you've said to the court prior to this document being put in front of you doesn't truly represent your views as of 1983 in relation to the incubation period?---No, sir.

What I'm putting to your, Professor, is that you're not telling the truth?---Hardly, sir. I tell you the truth.

If you can just finish off on that document, Professor, the joint statement. The paragraph I didn't take you to yesterday is paragraph 3 which says:

> Blood banks should plan the view with increased requests for cryo-precipitate -

and I'll you through the whole paragraph in a minute. Why was it that blood banks should prepare, and plan the view with increased requests for cryo-precipitate?---Because where it's possible, whether that was appropriate therapy for small children or for (inaudible) that would be better therapy, because it would give less exposure, less numbers of donors for those patients.

It goes on:

> Ultra T lyophilised function that a component of AIDS has been reported to be less frequent in haemophilia patients who are treated with cryo, rather than AHF concentrate?---Yes, less frequent but not absent. That is was the point there, that both those that got cryo-precipitate as well as those who got Factor 8 had these T-4 T abnormalities.

I'll read the whole paragraph to you - - - ?---Okay.

"And although this does not necessarily imply that cryo-precipitate is free of risk this finding may lead to an increase demand for cryo-precipitate". Now, what I want to ask you - nothing about cryo-

precipitate - what I want to ask you is that the altered T lymphocyte function a component of AIDS. You recognised that on January 13, 1983, the altered T lymphocyte function was a component of AIDS?---It was said to be, and it was said to be part of the process, yes.

You put that out as your joint statement to all blood banks - all volunteer blood banks - that the altered T lymphocyte function was a component of AIDS?---Yes, as well a component of about 99 other things.

Well, there's nothing about the 99 other things, is there? ---No, but that was well known as the time, and still is.

Again, no equivocation that it was anything but a component of AIDS in that document, was it?---Through that whole document as an equivocation it was based upon our best guess at the time saying based upon minimal evidence that we thought we ought to do something, based upon very very slim evidence.

Professor, there's no equivocation in your statement that the altered T lymphocyte function is a component of AIDS. No equivocation in that statement, was there? ---That's a description to try to relate the two, sir.

You read the MMWR, didn't you, Professor?---Yes, I said I did.

I'm reading from the July - I'm sorry - 4 March MMWR 1983, page 2:

> Although the significance of these

immunological alterations is not yet clear they're occurrent in at least two groups at high risk for AIDS suggests that the pool of persons potentially capable of transmitting an AIDS agent maybe considerably larger than the presently known number of AIDS cases. Furthermore, the California cluster investigation and other epidemologic findings suggest a latent period of several months to two years between exposure and recognisable clinical illness.

You yourself didn't accept that there was a latent period for AIDS?---I never said that. I said that there was probably a latent period for AIDS. I said we had no idea for sure, although it was but I could not know how long it was until we had tests for the virus or the antibody for the virus.

In just finding the MMWR, your own statement, the JAMA that you have in front of you, there was plenty of material which was leading the epidemiologist, the CDC, the National Haemophilia Foundation to that very point that there was an incubation period for AIDS up to two years?---I think so. All diseases have an incubation period. This one would have one too.

So all we were seeing and all you were seeing in this period of time in early 1983 was the tip of the iceberg,

that's the affect of the incubation period, isn't it?---We had no idea of that, but in retrospect we know that, yes.

But you just said that you know all diseases have an incubation period?---That's correct.

Therefore there had to be the submerged iceberg, isn't that?---To some extent, but you have no idea of the extent of it or how to identify it.

Professor, what does symptomatic HIV infection mean?---Symptomatic HIV infection means individuals who have signs or symptoms, complaints, diseases, physical findings which fit with the infection HIV stands for - human immune deficiency virus. In the infection of the virus which we believe causes AIDS.

So, on physical examination on observing you notice that - you can detect the physical signs of prodromal AIDS, is that what it means?---We believe we could in some cases, yes.

It - you can have people who are HIV infected and show no signs whatsoever?---That's the majority, yes sir.

You can have people who are symptomatic with the HIV infection?---Absolutely. Then we usually call them that they have AIDS.

So, you would certainly distinguish between the two?---Yes sir.

Yesterday you gave evidence to Mr Sher and your paper was tendered on the natural history transfusion associated infection with the HIV virus. Remember that?---Which one. Can you tell me?

The one in the New England Journal of Medicine?---Whose the person - I think I'd like to make sure.

Ward?---Okay. Thank you.

You were one of about, it looks like twenty contributors to the article is that correct?---That's right it was a large study.

It was a study of homosexual men?---It was partly.

In conclusion of that article professor, it was stated in summary, almost half the recipients of blood transfusions who have been infected with HIV for seven years or more now have AIDS?---That's correct. In total that was their finding.

So, half the people that have been given the transfused infected blood after seven years had AIDS?---In this study that's correct.

In that study. Then you went on to say "And most have symptomatic HIV infection"?---Yes. If that's what it says I have to agree with you.

I thought you said you were a contributor to the study?---I haven't got it in front of me and you are reading from it and I can't see it.

So, what you are saying is that half within seven years - half of this study within seven years had AIDS?---Correct.

Most after seven years had symptomatic HIV infection?---That's the same group.

I'm sorry?---Can I see it please. I'm not sure what you are reading. Yes. It is the same group of people. They have AIDS and they have evidence of it. They have symptoms of it.

We are not to conclude from what's written there that as far as the group is concerned, seven - after seven years 50 per cent have AIDS and most of the group have symptomatic HIV infection?---No. You are to conclude that the other 50 per cent were fine. Were

healthy. Didn't have symptoms.

Is that what that says?---That's what it says.

Can you just read it to us?---It says "That half the recipients of blood transfusions have been infected with HIV for seven years or more now have AIDS and most have symptomatic HIV infection. It is the same group. You would have to read the whole sentence sir."

Just for the sake of argument professor. If you took Mr - I'll withdraw that. Professor I want to take you back to - finally take you back to what we were talking about yesterday?---Do you want to give this one up?

Give it up?---Yes.

If you say that's what it says professor. I'll accept it?---That's what it says. I wrote it. That's what it says. Okay. Thank you.

If you say that's what the written article says I'll accept it. Professor remember yesterday we were asking about this case of GRO-A against Cutter Laboratories?---Yes sir.

The one that you now recall you gave evidence in May of 1990 in?---Yes I remember.

You didn't remember initially but once it was put to you you remembered?---I don't recall the dates that well until you told me the exact date.

That concerned three young boys. Three brothers that were infected with the HIV virus?---That's correct.

And as we've established, Professor, yesterday, in that case you were asked about when warnings should've gone on the AHF concentrate?---We talked about that, yes.

You said that a warning should be on the concentrate in late 83 or early 84?---I'm not sure exactly, but that's what you imply though.

That's in effect what was read out to you. Do you accept that or not?---They asked me that question and I responded to it.

With 83, 84?---I said it might've been appropriate at that time, yes.

You said, Professor, yesterday, that you didn't recall whether you gave an opinion as to when those three boys were infected?---I don't recall, no, sir. I don't memorise all those things.

The fact is that you did give an opinion in that case as to when those three boys were infected with the HIV virus?---I probably gave my best estimate of when they did, and if you want to read it, you can tell me what I said.

You don't recall it?---No, sir, I have not a photographic memory, and I don't memorise everything, like I'm sure you must, in that material in front of you.

You see, I put to you the question and answer, Professor. "Now, what opinion do you have with reference to causations that effects each of the three GRO-A boys in this case?", and you answered "Okay. My overall opinion is that these boys - all three of them -

were likely infected before December of 1982 and they were probably infected by one or more of the Factor 8 concentrates - various manufacturers that they received. I think that's the most likely way that they were infected." Does that jog your memory a bit, Professor?---Sure, but I'd like to see it for sure to make sure you're quoting it properly. Okay, that's what he said and I agree with what I said.

So I have quoted it properly?---I think in this case you have, yes, sir.

Now, in that case, Professor, if I can just read to you what your evidence was, again, in relation to a warning. I want you to remember that your evidence in relation to the date of infection in this case was December 1982. A question was put to you "It would not have been appropriate" - you answered - "to do that on or before December of 1982" and that's to put a warning on concentrate. "Would it have been appropriate to do it in January of 1983?" "I don't think so." "Have you really looked at the question to tell me when you think it would've been appropriate?" "Yes, I have." "And when would it have been appropriate?" "I would probably - sometime later on in 1983, certainly before January of 1984." Then you went on to talk about the appropriateness of putting it on inserts. Do you want to check that?---No, we went over all this yesterday.

What we didn't go over yesterday was, Professor, that in that case you were giving evidence about an infection in December of 1982?---That doesn't say that, sir, read it again.

"My overall opinion is that these boys - all three of them - were likely infected before December of 1982."?

---Yes. What I said was that they were infected before December of 1982. What I meant was that by December of 1982 they were already infected.

So, already infected by 1982. What we didn't have - - - ?---By December of 1982.

By December of 1982. What we didn't have when I asked you these questions yesterday was that date. That's correct isn't it?---I'm not sure we covered - - -

MR SHER: I object to the question. We did have it. Mr Rush had it all the time. The question is offensive and in my submission, it is inappropriate.

HIS HONOUR: I'll permit the question.

MR RUSH: What we didn't have professor yesterday when I was cross-examining you on this issue as part of the cross-examination, was that dated December of 1982?---I don't recall that we talked about the fact that they were infected before, in my opinion, December of 82.

See, you gave your evidence there as it being appropriate to have a warning on the concentrate, some time later on in 1983 before January of 1984. That's right isn't it?---If that's what you read.

That fitted in pretty nicely with the fact situation in that case, didn't it?---I know what you are implying.

You know what I'm implying, don't you?---Yes I sure do.

You are not telling the whole truth when you come to Melbourne, that's what I'm implying?---That's absolutely not true sir.

That you tailor your evidence to fit in with the fact situation?---No. I gave my evidence on the case as I know it at the time and in relation to the facts

of the case sir.

I'll just read to you professor what you said in this court yesterday at page 5976 of the transcript. 5976. "When do you say doctor, that there should have been a warning on Factor 8 concentrate?" "Well, I think I told you a moment ago that I didn't think there should be a specific warning until at least 1987." I said "What about Factor 8 concentrate?" You answered "It couldn't have been before 1985 because we didn't really know for sure so it would have been in that period 85-87"?---Okay. The first had to do with blood transfusions and the latter was that we couldn't be sure and specific about the risk because we couldn't know that risk for sure until 1985. I'll stand by that.

It fits in pretty well with this case to give 87 or 85/87 as the date for a warning, doesn't it professor?---It fits with the data and it fits with the facts.

It fits in because you have managed to move your date - move your date to 1985/87 to fit in with when Mr PQ was contaminated?---No sir.

I put to you, do you recall this, that in another case, the case of GRO-A you gave the date as again late 83 early 84 in relation to the appropriate time to have a warning on the concentrate?---Is that a statement or a question.

That's correct isn't it?---What's the question?

The latter part of 83, in the case of GRO-A against Cutter

when you were deposing for Cutter, you said it would be appropriate to have a warning - - -

HIS HONOUR: Would you start that question again. It is ambiguous.

MR RUSH: In the case of GRO-A professor, that's GRO-A GRO-A against Cutter Laboratories, you gave evidence to the effect that they should have had a warning - I'll just find the page - on the concentrate in late 1983. Is that right?---I don't think so.

You don't think so?---No. Please show me where it says I said in the record "They should have had a warning".

This question was asked of you in 1986 in the case of GRO-A I suggest professor. Question page 60 of the deposition. I'm asking you when you think the manufacturer of Factor 8 should have included a warning on their product that the use of Factor 8 product could lead to the transmission of AIDS. Answer: "My estimate would be 1983 and probably the latter part of 1983. There was sufficient evidence that haemophiliacs were definitely at risk of AIDS and with the presumption that they might have received AIDS from blood products, that in fact was a potential - a potential risk - although the magnitude of the risk and what kind of warning I couldn't specify"?---Exactly. So, I didn't say that you should put a warning. I didn't say anybody should put a warning. It doesn't say that.

So, when you were asked "I'm asking you when you think the manufacturer of Factor 8 should have included a warning on their product that the use of Factor 8 could lead to the transmission of AIDS and you say my estimate would be 1983 and probably the latter part of 1983, there was sufficient evidence that haemophiliacs were definitely at risk of AIDS, you are saying that that doesn't mean there should have been a warning on Factor 8 concentrate?---I didn't say that. Read again what it says.

I suggest that's just what you said professor. That you said - in summing up that evidence you said what I'm saying is there doesn't need to be a warning on the concentrate?---I'll stand by what I said sir.

So in two cases in the United States you refer to 1983 as appropriate for a warning, late 1983 early 84 in one, and late 1983 in GRO-A. Do you accept that?---What's the question?

They were dates that you'd previously given as appropriate for a warning?---No, I said it may've been appropriate, I didn't say that it should be done.

But as far as - it might be appropriate in Australia between 1985 and 1987, that's what you said yesterday?---I said until 1985 you could not put a specific warning regarding the risk because you couldn't know what it was for sure until 1985. And without that test you could never be sure.

Just for the record, Professor, the date that you gave that you deposed in GRO-A for Cutter Laboratories was 19 August 1986?---Okay.

Professor, I want to read two pieces and that's going to be the end of my cross-examination of you. In this same case of GRO-A, was this question asked of you and is this your answer, at page 77: "Doctor, do you have an opinion as to whether the degree of contamination of a blood product with AIDS virus makes any difference in the likelihood of infection by recipients of contaminated blood?" - answer: "I wish you wouldn't use the term contaminated because it has an entirely different connotation medically than scientifically. You can say infected or virus." Then question: "Of infected blood?" -

answer "Yes, we've talked for years and I've been teaching for many years - emphasise that the greater the number of donors to a pool, the greater the risk of transmitting an infectious agent, and the main model we used for years and years was hepatitis, and we also recommend, given the choice - all other things being equal - that you would avoid giving a product that came from multiple donors as opposed to giving a product from a single donor." Were those questions asked of you and did you give that evidence in the case of GRO-A against Cutter Laboratories?---Presuming you read it correctly, and I would emphasise "all other things being equal", that's a very important qualifying statement.

One other matter, Professor, at page 44, in the case of GRO-A again. Question: "Do you have any opinion on the issue of whether a severe haemophiliac can be managed equally on cryo as on commercially manufactured Factor 8?" Answer: "Give you my opinion, I would say that in many cases they probably could, but we really depend upon a lot of other circumstances - that is, if they got hit by a truck I would say no. But on day to day operation, probably many, if not most, could be managed on cryo-precipitate." Was that question asked and did you give that answer in the case of GRO-A ?

---Yes, and you asked me yesterday and I answered it yesterday, and I agree with it, and I stand by it.

It's very important to point out the elements of it.

Professor, I asked you questions yesterday also about haemophiliacs that you've treated in the 80s that have AIDS or have been infected with the HIV virus, and you could tell us only that you knew 75 per cent had been infected with the HIV virus?---Yes, and therefore I knew that 25 per cent were not, therefore the 25 per cent did not have AIDS either.

That's good, but what I'm asking you, Professor - as far as your severe haemophiliacs are concerned, those that you've treated in the 80s - what percentage of them have HIV virus?---About 75 per cent, the same per cent.

So it's 75 per cent of your severe haemophiliacs?---That's correct.

Seventy-five per cent of your moderate haemophiliacs?---I believe so, yes.

Seventy-five per cent of your mild haemophiliacs?---I'm not sure of that number, sir, but I think it's probably close to that also. I'm not sure of that number.

So your mild might be close to 75 per cent?---It's possible. I'd have to check the data.

Your moderate you think are 75 per cent?---Yes, sir.

As far as the severe are concerned, they're 75 per cent?---Yes, isn't that remarkable that only 75 per cent of severe haemophiliacs given thousands of concentrates - 25 per cent are not infected.

So you think having 75 per cent that are infected with the HIV virus is a good result?---I think it's interesting that all the products they got, many of them never got this disease, despite Factor 8 concentrate, cryo-precipitate, in large numbers.

HIS HONOUR: Mr Sher?

RE-EXAMINED BY MR SHER

MR SHER: Just to take you to the evidence about which you've just been asked - when you were asked in the case of GRO-A about whether a severe haemophiliac could be managed equally on cryo as on commercially manufactured Factor 8, you said "It depends on the elements". What are the elements you had in mind, Professor?---The elements have to do with the age

and size of the patient. It has to do with the severity of the bleed, where the bleed is, how long you're going to have to give the therapy and, really, what you're purpose in giving the therapy is. So all of those things come into play, whether you give a few doses of cryo-precipitate or many or switch to Factor 8 concentrate.

Now, I want to take you back to the repeated cross-examination about the evidence you gave earlier this year in the case of GRO-A about a warning, and this is a passage that you haven't had read to you from the transcript at any stage by Mr Rush, notwithstanding his lengthy cross-examination - I'm reading from page 41, Mr Rush, you might like to follow it. Question, "I thought you said that warnings would have been appropriate in late 83?" Answer, "Right, because of the possibility, because of the epidemiologic associations, to be absolutely certain and be on the firmest ground for warning, you really need the aetiologic agent and you need proof that it's the aetiologic agent". Question, "That's the absolute?" Answer, "Correct". Question, "Guarantee - correct?" Answer, "No, I'm not sure about that absolute guarantee. That's the proof. Up to that point, you're guessing". Question, "But you would agree that it's - whether you call it a guess or not - it would still have been appropriate in late 83 to start warning people about it?" Answer, "That would

have been the earliest time that it would begun to have been appropriate to raise the possibility of the risk and therefore in your words 'some kind of warning'". Is that the evidence you gave in the Ray deposition?---I believe so since you're reading from it.

Just look at it - see I've marked?---Yes, sir. That's what I said. "That would be the earliest time that it would begun to have been appropriate to raise the possibility of the risk and therefore in your words" - the lawyer's words - "'some kind of warning'".

That's the evidence you gave earlier this year in the same case of GRO-A that Mr Rush has been questioning you about?---Yes. That's another part of the same.

It's in the same deposition?---That's correct.

When you said "to be absolutely certain and be on the firmest ground for a warning, you really need the aetiologic agent and you need proof that it is the aetiological agent and up to that point, you're guessing", what did you mean by that?---I mean by that, just because you think you have the virus of AIDS, which was described in March - or May 84 - and then you have a test available the following spring, in early 85, we still didn't have the connection which you always have to have that this virus in this person put into this person results in the same disease and it's the same virus. That evidence we didn't have until 1986 as a matter of fact.

So, when you told the jury yesterday when Mr Rush was cross-examining you, and you told the jury that your evidence in this case was about the earliest time that it would have been appropriate to give a warning, and you weren't referred to page 41 of your deposition in which you said that. What do you say as to whether your evidence earlier this year in GRO-A was consistent with your evidence to this jury in this case?

MR RUSH: I object. I put a passage of evidence and it was clear and unequivocal in what was said, and Mr Sher's referring to another passage of evidence which is different, and to be asking this witness whether his evidence is consistent or not, having regard to Mr Sher reading a passage, I have read a passage, it's not a matter for this witness to say whether it's a consistent version, it's a matter for the jury.

HIS HONOUR: The position is it is a matter for the jury, but in re-examination it is open to counsel to ask the witness what the witness said he meant by the statement, and the form which has been adopted by Mr Sher is a form which is (inaudible) you're objection's overruled.

MR SHER: What do you say Professor as to whether what you said in the case of GRO-A earlier this year was consistent with what you told this jury in this case?---Yes, I think so, and it shows if you really

have to look at the whole thing - I just pick out a sentence here and there - when you try to quote people, and try to make what you think they mean to say.

I want to ask you something about the American procedure so the jury will understand exactly what we're talking about when we talk about a deposition. In America is it part of the procedure in civil proceedings that the other party can ask a witness from - that the other side has said they intend to call - to attend an office and be asked questions?

---Absolutely, that's how those depositions are taken.

And then - what actually happens with a deposition. Is there a judge there or anyone to adjudicate it on the questions, and anything about them?---No, there is absolutely none.

What actually happens at a deposition?---You have an attorney asking a number of questions. You do not have your own attorney there to in anyway advise you, talk to you. You are just there to answer questions under oath with no judge, no third party there who looks after your witness.

Is the solicitor for the party that's going to call you the witness there?---Yes, they can listen in.

Do they get a chance to ask you questions as well at the deposition?---They may, yes.

And on this occasion in the case of GRO-A, were you asked any

questions by the lawyer for the party that was going to call you as a witness?---I don't recall, but it was at the end of that.

When you were given an opportunity to make corrections, what's involved in making a correct to a deposition?---You give in your deposition usually within the - a month or so. You are given the opportunity to read it. You cannot touch it, you cannot mark it at all. You must on a separate sheet put your corrections or things that you think were written down improperly, or misunderstood and you submit them, and usually they put others in addendum, and supposed to be attached when this becomes official.

Do you know - did you get the depositions in the Ray case sometime after you gave your testimony on 22 May? ---I believe so.

Did you make any addendum on that occasion?---I probably did.

When you make a correction are you allowed to change testimony that you've given?---No, only you can do this on a separate sheet of piece what you think the correction should be.

Just to go back to the testimony you gave in this case when you were asked about the question of warnings by Mr Gillies - at page 5975 and 6 - was this the answer you gave:

> I think I told you a moment ago that I didn't think there should be a specific warning until at least 1987.

What did you mean then by a specific warning?

---Well, he's - apparently he's referring to transfusions such as cryo-precipitate and blood, and that one way or another through the whole consent process that the patient should be told that there was a potential risk albeit small in this case of AIDS.

You were also asked about a document that Mr Rush sort of waved around and I think he even showed you but didn't tender it in evidence, that he suggested that you had dug up and sent to the lawyers in Australia as a means of discrediting Professor Engleman. Do you recall that questioning?---I sure do.

Would you look at this document please and tell us if that's the document Mr Rush showed you?---Yes, it is document from our laboratory because we do this test.

You also - you weren't asked by Mr Rush why you sent it and what the purpose was to be achieved by sending it. Could you tell us now?---Yes, the question was raised as to whether or not the T-4, T-8 testing is a licensed test and the point I wanted to make was that it was not in 1983 or 1984. It is until this day. There is not a licensed approved test and therefore you cannot legally do it, or ethically do it on blood donors. That's part of a study which is part of informed consent. This follows the Nazi experiments in Germany and that's why we have such rules in America.

At whose request was that document sent - I'm sorry I withdraw that - how did you come to send that document to people in Australia?---I wanted to clarify the situation in America about the use of this particular so-called surrogate test and to show that it was a purely researched test which had to be done

with informed consent. Donors permission and that it should have been done appropriately and properly and ruled upon by science and not charged for by the way, because you can't charge people to do research on it.

Does that document indicate that it is such a test?---It also shows that this is not, in any way described as a surrogate test for AIDS and it says specifically "Not for research use. Not for use in diagnostic of therapeutic procedures".

I tender that document if your Honour pleases. If it is not in evidence I will tender it your Honour.

MR RUSH: May I have a look at it before it is tender your Honour.

HIS HONOUR: Yes, Mr Rush.

MR SHER: I'm not sure whether - is it or is it not for research purposes that material?---It says most emphatically and I drew an arrow on it - it says "For research use only. Not for use in diagnostic" that is in testing "Or for therapeutic purposes". That is an (inaudible) treatment.

I tender that your Honour. Your Honour, I don't think my re-examination will take more than about another five to ten minutes then we could let the professor go.

HIS HONOUR: Yes. That course can be followed. I'll put this first.

MR SHER: Actually on reflection it might take a little longer because I have to take him to some documents. It

might take about twenty minutes or so.

HIS HONOUR: How is this document described Mr Sher?

MR SHER: Would you tell us what a proper description of it is?---This is a so-called package insert. It goes with the re-agents, the T-4, T-8 testing re-agents. It describes what the testing material is for. How to use it and how not to use it if you are going to do a T-4, T-8 test.

HIS HONOUR: Mr Sher. All I want is a description from you to go into the - to designate the exhibit.

MR SHER: Package insert for reagent T-4, T-8 test.

EXHIBIT RX22 ... Package insert for re-agent T-4, T-8 test.

HIS HONOUR: The jury may now go to the jury room for fifteen minutes.

AT 11.37 AM THE JURY LEFT THE COURT

HIS HONOUR: Professor you may leave the witness box and either stay in court or leave the court.

WITNESS STOOD DOWN

MR STANLEY: Your Honour, before counsel leave, could I just ask your Honour - would your Honour be good enough to indicate was it the answers your Honour gave at page 6015 of the transcript that your Honour was referring to at 10.15 this morning with Mr Sher and then to the jury?

HIS HONOUR: I haven't looked at the transcript, I was going on recollection, Mr Stanley.

MR STANLEY: Your Honour, if it was those two matters, we - - -

HIS HONOUR: Mr Stanley, my recollection was that on two occasions objections had been taken by Mr Sher and I didn't rule on them, I merely said to Mr Rush to continue.

MR STANLEY: Well, your Honour on one occasion said "Mr Sher, let's get on with the litigation" and then on the next occasion, "Continue with cross-examination", but both of the statements that were made by my Mr Sher to provoke those, we submit, were totally unwarranted. He was making a speech to the jury to try to protect the shattered credibility of the witness, and indeed, what he said was - the first statement from Mr Sher at page 6015 - and this was after Mr Rush had put these questions to him. "Tell me, did you bring the questionnaire to court?" "No, I did not, sir." "Did you bring any document that you handed out to blood donors, to court?" "No, I wasn't asked to." "You weren't asked to bring a

questionnaire with 40 questions on it for donors?" "No one asked me to." "Well, Professor" - then Mr Sher interrupted. "He is suggesting - Mr Rush is suggesting that this witness has been doctored in some way. Your Honour, I object to this form of behaviour, it is grossly offensive cross-examination and nobody's free of criticism from that end of the bar table - that includes me as well. This case ought to be confined to the facts." Your Honour then said "Mr Sher, let's get on with the litigation." "Well, your Honour, I object to this type of vile suggestion of improper behaviour and the suggestion - if my learned friend wants to assert, let him assert and have the courage to say it, and then we'll call some evidence to rebut it." Your Honour then said "Continue with the cross-examination".

Now, your Honour, what happened there was, we say, quite improperly Mr Sher raised a matter which was not properly based upon the cross-examination, and he made allegations against not only Mr Rush, but against me, and they were allegations that were let pass at the time because of your Honour's response. Your Honour in effect poured oil over the troubled waters that were at the bar table at that moment and we were happy with things left on that basis.

But if those matters are the matters that your

Honour referred to earlier, we would submit that we should've been given the opportunity at the time - as indeed we would've, had it been a proper objection and we'd been asked to reply. We would've indeed indicated our position. Those questions do not suggest anything improper on the part of any of my learned friends, they're asking a witness "Have you brought the documents with you?"

HIS HONOUR: Mr Stanley, counsel are entitled to have a ruling on an objection taken, however little substance it has.

MR STANLEY: If your Honour pleases.

PAGES 6077 TO 6084 HAVE BEEN REMOVED BY ORDER OF THE TRIAL JUDGE

AT 11.58 AM THE JURY RETURNED TO COURT

PAUL VINCENT HOLLAND:

MR SHER: Professor, when Mr Rush commenced to cross-examine you and right at the outset he asked you some questions about the fact that you've given evidence in other cases. Firstly I'd like to ask you how many actual cases have you testified in court as distinct from giving a deposition? How many cases have actually gone to court?---About 10 of these cases have gone to court in the last five years, so about two per year.

HIS HONOUR: What did you say? How many?---About 10 have actually gone to court, so it's an average of about two cases per gone have gone to court in the last five years.

MR SHER: I'm asking about you. Have you testified in those cases?---I've testified in court 10 times in these kind of cases.

It was put to you that - at page 5967 and 8 - that - it was asserted "All the evidence you've given as being in relation to people on behalf of defendants?" and then you said "Yes, but I" - that wasn't the whole question. I'll read it all:

> And all the evidence that you've given has been in relation to people on behalf of defendants is in relation to people that have had AIDS or contracted the HIV virus?
>
> A: Yes, but I'd - - -

then Mr Rush cut you off and said:

That's not the cases of being involved about?

A: Yes, but I'd like to qualify my answer.

What the qualification that you wanted to make then that you weren't asked to give, because Mr Rush then said you can qualify it to Mr Sher, or qualify it later?---Yes, I wanted to point out that I had been approached by the attorneys for patients, that many times they have asked my opinion having giving me material to review, and then I'd given my opinion to them, and one of two things has happened. Either my opinion was not very helpful to them, and not very favourable, and therefore they said they're not going to use me, and I said I thought that was unfortunate, because my opinion is my opinion. Or I had discovered in my views some flaws, some error or some negligence in these cases, and they have never gone to court, because in fact they went ahead and settled the case, because the thought they were likely to loose it.

The suggestion implicit in this cross-examination is that you're just a defendant's man, and you'll say anything that's necessary on behalf of the defendant, what do you say to that?---I think that's absolutely not true, but that was the impression that was trying to be created.

It was put to you by Mr Rush - this is at page 5999, your

Honour:

By the middle of 1983, Professor, the reports were coming in from all other the place about haemophiliacs with problems - with AIDS - as a consequence of the use of the concentrate?

A: There was some. There are also some haemophiliacs who got AIDS from cryo-precipitate.

What do you say as to whether in the middle of 83 there were as was asserted by Mr Rush, reports coming in from all over the place about haemophiliacs with AIDS as a consequence of the use of the concentrate?---Well, the point is there were, sir, cases coming in - a handful - one here, one there, and so on, that the - vast majority of haemophiliacs in America, 20,000, as well as thousands of others in the rest of the world were not developing this disease, and especially important was that they were getting the same materials. Some of the same bottles that were given to those who apparently got AIDS were given to hundreds of others, and they did not develop AIDS.

I want to take you to an actual contemporaneous document, just to see how many cases there were coming in from all over the place as Mr Rush suggested in 1983. Would you look at the defendant's folder of documents at tab number 21. At the MMWR for December of 1983.

HIS HONOUR: Two?

MR SHER: It is book 2 your Honour. It is tab A31 and it should lead us to MMWR of 2 December 1983 and I'd like to take the Professor firstly to the first page, the first paragraph and then to the chart on the back of it just to see how many cases there really were. Does your Honour have that?

HIS HONOUR: Yes.

MR SHER: It says this. This is on 2 December 1983. "In 1982 six haemophilia A patients who had developed pneumocystitiscarinii pneumonia and other opportunistic infections" - he meant the CDC case definition of AIDS were reported by CDC. "As of November 30 1983 physicians and health departments in the United States have reported a total of 21 AIDS cases amongst haemophilia patients, 19 among patients with haemophilia A, and 2 amongst patients with haemophilia B. In addition seven cases from outside the United States, meeting the CDC definition of AIDS in association with haemophilia A have been brought to the CDC's attention. Of the haemophilia cases in the United States, one was diagnosed in 1982. Eight in 1982 and twelve to date

in 1983 figure one. Two patients are known to have other risk factors requiring AIDS." If we look at figure one over the page, you will see a chart for 1981/82 and 83 and I think, and I'd ask for your view on this, that the last four columns are meant to be 83 or am I wrong about that. Yes, I think I am right because if you look at the asterisk on the end of the top column it says "As of December 30 1983"?---That's correct. So it covers the first eleven months of 1983.

It is in four quarters. You can see there are three cases in the first quarter. Four in the second. One in the third and to November 30 there were four in the fourth quarter. Okay?---Yes.

That means that in 1983 in America, there had been reported to the CDC a total by the middle of the year of seven more cases. Is that - - - ?---That's correct.

Yes?---Seven.

Seven. So that for it to be asserted via the questioner that reports were coming in from all over the place about haemophiliacs with AIDS as a consequence of the use of concentrate by the middle of 83, how many cases do you say were reported in 83 to the CDC by the middle of the year?---Only seven by that first six months of the year.

Then if we go back to the description of the cases and it doesn't say which of these are - two of the patients are known to have other risk factors for acquiring

AIDS - I assume that means other than blood products?---Yes, it means that either they were gay men having sex with other men, or were IV drug users.

In relation to the rest of the world so far as reported to the States was concerned there had been seven cases from outside the United States?---Yes, out of thousands and thousands of patients with haemophilia in the rest of the world.

So, professor just in relation to this allegation, reports were coming in from all over the place about haemophiliacs by the middle of 1983. In your view, about how many cases were there altogether, accumulatively by the middle of 83 in the United States?---We have a total of 21 in the United States, out of 20,000 haemophiliacs.

Take it to the middle of 83. Don't count the four - the five in the second half of the year - it gets us down to 16 doesn't it?---So, it is only 16 by the middle of 1983.

And that's over a period of 81, 82 and half of 83?---Correct.

And seven from the rest of the world?---Correct.

Do you regard it as a fair description of the reports that were coming in, and were being published to describe them as reports coming in from all over the place about haemophiliacs with AIDS as the consequence of the use of the concentrate?---Yes, I think this really shows you how few cases even met the definition which was an arbitratory definition.

How many haemophiliacs all together are there approximately in the United States, or were there back in 83?---We knew that there were approximately 20,000 haemophiliacs in the United States receiving therapy.

Let me while I've got that book there. I think perhaps I've got to take you to the plaintiff's book. I want to take you now to the - back to the MMWR at December which reported this incidence case to one aspect of that report that Mr Rush didn't take you to. Would you look at that, please, that's under tab 11 of the plaintiff's folder. Just keep that one there in case I need it again.

HIS HONOUR: One tab 11.

MR SHER: Tab 11, your Honour, under day 11 in book 1.

Now, do you have tab 11 that shows the possible transfusion associated AIDS case from California, the 20 month old infant?---Yes, sir.

I want you to look if you wouldn't mind at the second page -

the column on the first page - at the paragraph commencing "Several features of the infant illness". Do you have the same one as I'm looking at? Are you under tab 11?---This is the second page - this is page 6.

I want you to look there. Just look over here, Professor. Tab 11, it's set out in that fashion. I want to draw your attention to that paragraph there?---Okay.

Okay?---Yes, I see it.

Do you see that? That paragraph commences:

> Several features of the infant's illness resembled those seen amongst adults with AIDS.

All right?---Yes.

And then the last sentence of that same paragraph says:

> Nonetheless since there's no definitive laboratory tests for AIDS any interpretation of this infant's illness must be made with caution.

Do you see that?---Yes, sir - - -

Did you read that at the time?---Yes, I did.

What was your view about whether or not this being the first report of a transfusion case in America, and would it fair to say in the world?---In the world.

Was evidence of the fact that AIDS was at that stage proved to be blood borne?---I think it made it very tenuous. It was very very unsure that this really was transfusion transmitted AIDS.

Nonetheless there was a meeting held in early January of all those people, including all the blood banking people at which you went which issued this January 13 statement?---That's correct. Sir, we responded very quickly on very minimal potential possibility of something.

I want to take you that statement, because you were asked some questions about that by Mr Rush this morning, and that's in the same folder and it's under tab 16. Do you have it there?---Yes, sir.

Now, you recall Mr Rush questioning you about it, and making allegations to you from the bar table that there was no equivocation in the words used in selecting parts of that article that he read to you. Remember that questioning?---Yes, I sure - - -

I want to draw your attention to some other parts of it, and see whether - what your view is about whether there was equivocation. He read from the third paragraph - see that?---Yes, sir.

I want to take you to the paragraph immediately proceeding the bit Mr Rush read, which reads:

> The predominant mode of transmission seems to be from person to person probably involving intimate contact. The possibility of blood borne spread still unproven has been raised. This latter impressions reinforced by eight confirmed cases in haemophiliacs treated with anti-

haemophilic factor concentrate. By a case in a new born 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 the potential carriers. Evidence for transmission by blood transfusion is inconclusive at this time.

What do you say as to whether that was in anyway a qualification of what was being said in this document?---I think it greatly qualified what we were saying, that there was really not very much evidence, and certainly no way of proving any of this.

Well, then Mr Rush read you the first sentence of the next paragraph, but there he stopped and I want you to read on, or follow me while I read on. The commencement of the fifth line: "We realised that there's no absolute evidence that AIDS is transmitted by blood or blood products, and we understand the difficulty of making recommendations based on insufficient data. There's need for additional information about this disease, public health authorities should allocate resources to study the aetiology of AIDS, its mode of transmission, appropriate preventative measures and therapy." What do you say about the reasons for putting that in the document?---Because we really wanted to emphasise that a lot more needed to be learned - a great deal of study needed to be put into place, especially by the Public Health Service, to try to learn more about this disease and how it could be transmitted.

Let me take you over the page to the second last paragraph. "These recommendations are made with full realisation that the cause of AIDS is unknown and the 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's warranted." What was the purpose of putting that in the document?---We wanted to really point out how little we knew and how we were making recommendations based upon such a minimal possibility, but we still thought it was something which we shouldn't ignore, we should do something about, even though we knew so little at the time.

Professor, to get the American blood banking industry to change its practices and to take preventative steps and the like, how difficult is it for that to be done in a country as vast as America?---Well, it's difficult because of size, it's difficult because we all like to operate on information that we can be sure of - scientific data published in journals that have been peer reviewed, and so we were operating on known facts, known information, and without that it's very difficult to do things based upon suppositions and minimal information which is not substantiated.

What are the consequences of some dramatic change in the way in which blood is collected and the amount of blood collected in America?---The consequences could be very severe. America, as I mentioned before, is not self sufficient in blood, we did not collect enough blood to save a lot of patients lives. In order to

get enough blood we had to bring it in from other countries, and so the potential was if you disrupt a system, that many patients would die for a lack of blood or blood components, and this possibility that some patients might be saved, so we thought it was very important to say these things - not to compromise the blood supply in general.

Would your Honour just pardon me a moment?

HIS HONOUR: Yes.

MR SHER: You were cross-examined by Mr Rush about - this is at 6005 - about the MMWR report of 16 July where they reported about three patients with haemophilia who had pneumocystitiscarinii and he asked you whether there was anything in the article about these patients being homosexual - the possibility of them being homosexual and you responded to that by saying "It doesn't make it not so. We have known people who have gone to their death denying it and only after their death have we discovered they were homosexual or IV drug users". Firstly, I ask you this. When this document - that's the report in July of 82 - was discussed at this meeting held on 6 January, were you the only person at that meeting that raised questions about whether or not these three haemophiliacs might possibly have some other explanation for getting pneumocystitiscarinii?---No. A number of individuals at this meeting both within and without the government raised the same questions and concerns.

What to you and the others present, were the possibilities with these three particular cases?---I think with the fact that all other individuals up to these three had these other well-known risk factors, they were mostly men, they were old enough to have had sex and to use IV drugs. That it remained a distinct possibility that these three haemophiliacs might have engaged in those activities since the

other 20,000 didn't have this disease.

Professor, you told us in answer to this question that you had known people who had gone to their deaths in effect, denying that they were gay or IV drug users. Was that evidence based upon personal experiences of yours?---Yes, as well as publication in the literature regarding that very first case of transfusion AIDS.

What, in your experience, did you find happen when you had somebody who appeared to be HIV positive and the question arose as to whether or not they were homosexual. What sort of responses did you get when you interviewed such people?---Very often they didn't want to admit it or didn't think it applied to them, but upon a lot of discussion and interview many of them would recall homosexual experiences in the past which they weren't proud of and didn't want their wife to know about that kind of thing. So, they really didn't come up front and didn't tell us initially when they donated the blood that they should not have donated because of that fact.

Just to go back to this infants case again. Could you have a look for me at - again at the defendant's book 2 at tab A12. It is a publication in Lancet on 30 April, 1983. I think you told me when I asked you some questions about peer review journals in which you had published that Lancet was one of them. Were you in the habit of reading Lancet?---Yes, sir

regularly.

This is an extract from Lancet of 30 April 1983 about this particular infant's case. Do you see that?---That's correct.

Do you recall whether or not you read that around about the time it was published. I suppose you would have got it in America in some time in May of 83?---That's correct, I did.

I want to take you to the discussion on page 957 to the third paragraph. See the heading "Discussion"?---Yes, sir.

The paragraph is probably marked "We believe that AIDS developed in this patient as a result of an infectious agent being transmitted by blood product administration. It is possible however that he was born with a primary immuno deficiency disorder, which did not show clinical signs until six months of age". You wouldn't have been aware of that view being expressed in January but with hindsight and now having had your memory refreshed by looking at it. What do you say as to whether, in relation to this infant, that particular explanation was a matter that needed to be evaluated and considered?---Absolutely as the author has pointed out, they weren't sure that this was AIDS in this child - it could be a congenital, that is the child was born with some kind of immune deficiency which took until six months of age to become evident.

Now, I want to ask you this. What do you say as to the speed with which and the extent to which the people responsible in America for guiding blood banks acted in relation to the risk that AIDS might be a blood born disease?---Well, I think it was absolutely remarkable that they responded so quickly and in such a widespread fashion based upon one possible case which had so many doubts about it and yet, because of that slim possibility, they decided to do something.

Just to go back to that article again, two of the authors of that particular article, Herbert Perkins - I think you've said his known to you?---Yes, I know him very well.

What about Selma Dritz - did you know her?---I know her less well, but I know her.

Were they people whose views you respected?---Yes, including the main author, Dr Allman, an expert in the field of paediatric immunology.

I'll just take you - this is the final matter - to another exercise that Mr Rush indulged in when he took you to a transcript, but to not all of it, in the case of Gallagher - - -

HIS HONOUR: Mr Sher, that's a - - -

MR SHER: We've already done that in relation to - - -

HIS HONOUR: Mr Sher, that's a clear comment you're making in the course of your re-examination which you're not entitled to.

MR SHER: Well, your Honour, it's - well, I agree with respect, your Honour, that it is a comment but it's permissible, I submit, to draw attention to the fact that I'm going to now direct the witness's attention to some passage in the transcript that he wasn't taken to.

HIS HONOUR: Well, you may ask him that, but to make the comment you did is impermissible in re-examination.

MR SHER: If your Honour pleases.

I wanted to take you, Professor, to the Gallagher transcript and to page 42, you having been asked some questions about the - whether paid donors were at higher or lower risk than volunteer donors - remember those questions of Mr Rush?---Yes, I do.

I want you to listen to this. Question: - I'm reading now, your Honour, from page 42 of this transcript - "Is there any data as to whether volunteer blood donors are representative of the public at large?" Answer: "They are and they aren't. They're different people. They're not totally representative of the public at large, no, volunteer donors are not". Question: "Let's compare paid donors and volunteer donors?" Answer: "That's a better comparison". Question: "You would agree with the proposition that paid donors, by virtue of their lifestyle, SOE status, are at higher risk for carrying AIDS than volunteer donors?" and you said "I'm not sure there's evidence for that. That might be my

opinion. I'm not sure there's proof. Certainly, they have a higher risk of hepatitis. We know that from studies. I know it's documented that if you are paid for sure, that you're at higher risk for AIDS". Did you - were those questions asked of you and did you give those answers?

MR RUSH: Your Honour, it hasn't been read correctly. (Inaudible) know, and it reads "I don't know it's documented".

MR SHER: Well, your Honour, I'll read it again. I thought I've read it correctly and it does read "I don't know" and I'm sure I have - - -

HIS HONOUR: I don't have the transcript before me so would you read it again?

MR SHER: I'd just like you to look at this document, at page 42 where I've marked it, to page 43 where I marked it, and tell us whether that's an accurate transcript of the evidence you gave?---Yes, that's what I recall saying.

Just to go back to it, the question that you were asked - at the bottom of the page - was this:

> You would agree with the proposition that paid donors by virtue of their lifestyle SOE -

which stands of socio-economic I assume -

> status are at higher risk for carrying AIDS than volunteer donors.
>
> A: I'm not sure. There's evidence for that, that might be my opinion I'm sure there's proof.

Did you give that answer?---Yes, I did.

"Certainly they have a higher risk of hepatitis, we know that from studies. I don't know it's documented, but if you were paid for sure that you are at higher risk for AIDS"?---That's what I said.

And then later on you were asked the questions that Mr Rush took you to about the fact that you said that there were some data that had been published which the commercial people had, that you said you had to believe because it was published?---I said I had to believe because they presented it at meetings and published, yes. They presented it.

Before you were asked those questions that Mr Rush read out, you'd expressed that it might be your opinion that paid donors were at a high risk for carrying AIDS than volunteer donors?---Yes, and now we have the data to back that up.

MR RUSH: Your Honour (inaudible) in the light of your Honour's rulings, but I'd ask your Honour to read the two pages of the transcript that Mr Sher has taken this witness to, the bottom of page 42 and then page 43. In my submission, your Honour, to suggest that later on I took the witness to those questions misrepresents the manner in which I cross-examined the witnessed.

I did not take him later on. The questions that I took the witness to are intertwined with the very matters that Mr Sher has raised with the witness. In my submission he's misrepresented the manner in which I cross-examined this witness.

MR SHER: Your Honour, that's not an objection in my submission. What's happened is that my learned friend having taken the witness to part of the transcript, I'm now taking him to the rest, and Mr Rush apparently objects to that. The only question, your Honour, is whether I have taken the witness to other parts of the transcript, and the witness agrees that they're accurately read.

Mr Rush could have taken this witness to the passages I've now read, he chose not to do so.

HIS HONOUR: Mr She, much of the problem arises from the inclusion of comment from the questions.

MR SHER: Your Honour, in my submission in re-examination it is appropriate for me to take the witness to parts of the transcript - - -

HIS HONOUR: Mr Sher, I've been asked to read these pages. I'll read these and then you may address me - - -

MR SHER: Your Honour, with respect, it's not appropriate. I'm entitled to elicit from this witness that there was other testimony given by him directly on this topic immediately before the passage that Mr Rush read out. Now, it's not a matter, with respect, for your Honour to interpret the transcript.

HIS HONOUR: Mr Sher, I've been asked to read these two passages, and I propose to read them.

MR SHER: If your Honour pleases. I thought, your Honour, that's all I'd done. But subject to your Honour's telling me I made a comment - - -

I just want to ask you something about your evidence there.

HIS HONOUR: Before you leave that - Mr Rush, I do not see any objection in the way in which this evidence is being brought out, as long as it's brought out without comment.

MR RUSH: Thank you, your Honour.

MR SHER: I think what I'll do, your Honour, is I'll just read the whole lot and ask the witness if we can borrow - just listen closely to what I now read out to you and I'll read the whole passage on this topic that's been referred to. Question: "Is there any data as to whether volunteer blood donors are representative of the public at large?" Answer: "They - they are and they aren't. They are different people, they are not totally representative of the public at large, no. Volunteer donors are not." Question: "Let's compare paid donors and volunteer donors?" Answer: "That's a better comparison." Question: "You would agree with the proposition that paid donors, by virtue of their lifestyle - SOE status - are at higher risk for carrying AIDS than volunteer donors?" Answer: "I'm not sure there's evidence for that, that might be my opinion. I'm not sure there's proof. Certainly they have a higher risk of hepatitis - we know that from studies, I don't know

it's documented that if you're paid for sure that you're at higher risk for AIDS." Question: "I don't understand you, Doctor?" Answer: "The commercial manufacturers would argue the opposite and they have data to show the opposite." "To show what?" Answer: "That paid donors have lower risk of carrying the retro AIDS virus than volunteer donors. They have data to show that." Question: "Do you think that data's reliable?" Answer: "I have to believe it, I mean, it's published - its presented at meetings, I have no reason to doubt it." Are they the questions and answers?---Yes, sir.

So you expressed - before referring to this data that the commercial manufacturers had - that it might be your opinion that paid donors were at a higher risk for carrying AIDS than volunteers?---That's correct, and I thought that's what I said.

Now, that was given in 1986?---Correct.

What's your view now as to whether or not paid donors were higher or lower risk than volunteers for transmitting AIDS?---My opinion now, based upon current data, is that when you properly collect the studies, that paid donors are much more likely to be carrying the AIDS virus - from actual studies done in the past couple of years.

I just want to ask you a few more questions - go back to the commencement of the cross-examination. Have you

tailored your evidence in this case?---Excuse me?

Have you tailored your evidence in this case to suit what you believe to be the interests of the Red Cross?---I certainly don't think so.

Has anyone suggested that you should?---Mr Rush did.

Anyone apart from Mr Rush?---No, sir.

What do you say as to whether you've told the jury the truth about the facts in relation to what you did at the NIH and at Sacramento?---I've tried to tell you exactly what I knew at the time, how I operated and to the full truth to the best of my ability.

Insofar as you've expressed opinions, what do you say as to whether they are your honest opinions?---They're my honest opinions, which means those are my impressions or thoughts.

Thank you, I have no further questions, your Honour. Professor Holland would like to be excused.

HIS HONOUR: Do the jury have any questions that they would like to ask of the professor before he leaves?

FOREMAN: We have no questions, your Honour.

HIS HONOUR: Thank you, Mr Foreman. I take it there's no objection from counsel?

MR BARNARD: No, your Honour.

HIS HONOUR: You're excused, Professor Holland - - -?---Thank you, sir.

WITNESS WITHDREW