HIS HONOUR: Yes, Mr Gillies?

MR GILLIES: May it please your Honour, I call Dr Leikola.

JUHANI LEIKOLA, sworn:

EXAMINED BY MR GILLIES

MR GILLIES: Is your name Juhani Leikola?---That's correct.

Do you spell your Christian name J-u-h-a-n-i?---That's correct.

And your surname L-e-i-k-o-l-a?---That is correct.

Are you a legally qualified medical practitioner?---That is correct.

Do you carry on practice at Kivihaantie -

K-i-v-i-h-a-a-n-t-i-e 7 - Kivihaantie 7, Helsinki, Finland?---That's correct.

Doctor, do you carry on the practice of medicine in the specialised field of blood transfusion?---Yes.

Did you obtain your basic medical qualification at the University of Helsinki?---That's correct.

Do you have any other medical qualifications?---None, except for that.

Did you obtain your Doctorate in medicine in 1968?---At the University of Helsinki, yes.

From 1975 to 1981 were you the Director of Laboratory Services of the Finnish Red Cross Blood Transfusion Service?---That's true.

Between 15 January 1982 and 1 August 1986, were you the head of the blood program of the League of Red Cross and

Red Crescent Societies in Geneva?---That is true.

In relation to that appointment in Geneva, to what extent did that require you to familiarise yourself with what was going on internationally in the blood transfusion community?---That was really the essence of the whole work, because it had nothing to do with Blood Transfusion Service - with any Blood Transfusion Service in Geneva. My main task was really to follow what was going on all around the world and then inform mostly the Red Cross Societies and the Red Cross Blood Transfusion Services, but also other Blood Transfusion Services around the world, what was going on.

So was the office in Geneva a sort of source of information for people with problems around the world?---That is correct.

Whilst you were at Geneva and subsequently, did you have close ties with the World Health Organisation?---We had very close ties, because we tried to work together in order not to waste too much effort for this purpose.

How important was it for you, in the proper performance of your job in Geneva, to know exactly what was going on around the world in relation to blood transfusion medicine?---Because that was my main duty to - to inform the Red Cross Societies and Red Cross Blood Transfusion Service of what was going on - that was really my main duty, to try to find out what was

going on in the world, and I may mention that I spent about one third of my time travelling around in different countries just in order to fulfil that task.

In relation to the balance of your appointments from February 1988, have you been the Director of the Finnish Red Cross Blood Transfusion Service?---That's correct.

As such is the Finnish Red Cross Blood Transfusion Service responsible for blood collection and fractionation in Finland?---That is true.

So, that in addition to collecting the blood, it manufactures the blood product?---Yes, that's true.

I want to ask you some questions relating to various positions held in Finland of a medical nature, where the resident internal medicine - I'm sorry, did you do your residency in internal medicine and surgery at the central hospital University of Helsinki, between 1968 and 1972?---That's true.

Were you the head of the blood group department of the State Serum Institute of Helsinki from 1972 to 1975?---Yes, until I came to the Red Cross.

You mention that you then became director of laboratory services of the Finnish Red Cross Blood Transfusion Service from 75 to 88?---That is true.

Then from 88 onwards, you have been a director as you have given the evidence, of the Finnish Red Cross Blood Transfusion Service?---Yes.

One of your overseas positions doctor, am I right in saying that from 1969 to 1970 you were the post-doctoral Fellow at the University of California, San Francisco?---That's correct.

What work were you performing as an incident of that

Fellowship?---I was doing research on immunology at the University of California Medical Centre in San Francisco.

Were you the visiting scientist of the Erwin Memorial Blood Bank of San Francisco in 1977 and 1978?---That is true.

Whilst you were in that position did you get to know and work with Dr Herb Perkins, who we have heard about in this case?---I got to know the work of Dr Herb Perkins, quite well, because I met him daily and I was working with him in this particular transfusion service.

We have heard how Dr Perkins was doing research work in respect of the hepatitis B core anti-body test. Is that something that is known to you, not so much from that contact but from subsequent contact with him?---That was done subsequently to my visit in that place but I met him quite often and it was quite natural that I was asking him what was going on at the blood bank. Then he was telling me about this research work.

Subsequently, as we have got in evidence already, became head of the blood program of the league of Red Cross and Red Crescent Societies in Geneva from 82 to 86. In relation to your memberships of varied learned associations concerning blood products, since this year have you been the president, sorry the vice-president of the European Plasma Fractionation

Association?---Since May of this year, yes.

What work does the European Plasma Fractionation Association do?---That is an association that was formed this year to unite the efforts of the "not for profit" fractionation centres in Europe that are using voluntary and unpaid donors, in order to provide a common forum, whether they came from the Red Cross or from the State run organisations.

Since 1980 have you been a member of the International Society of Blood Transfusion Council?---That is correct.

Since 1982, have you been on the Committee of Blood Transfusion Experts of the Council of Europe?---Yes, I believe that the committee is called, the Committee of Experts in Immuno Haematology and Blood Transfusion officially - that is otherwise correct.

What work has that committee performed since 1982?---That committee convenes once a year and it consists of prominent people in blood transfusion field from the member States of the Council of Europe which are now over - right now to discuss different problems that deem consideration and they share information what is going on in Europe.

And has the committee from time to time made recommendations to the European Committee - to the European community concerning such matters as the safety of the blood supply?---The safety of blood supply has been one of the prime interests for that committee, and the committee may give recommendations of its own but they are unofficial by nature. They may be also processed through the channels of the Council of Europe, and once it goes to the Committee of Ministers, then the Committee of Ministers may then give official recommendations to the member States.

Since 1982 have you been a member of the International Group of Red Cross Blood Transfusion Experts?---That is correct.

Would you indicate to Mr Foreman and members of the jury what work that group has engaged in since 1982, particularly with reference to the AIDS threat?

---The group was very much linked to my work in Geneva as the head of the blood program, or the league of Red Cross and Red Cross Societies. It convenes once a year and it discusses the programs such as the voluntary and unpaid nature of blood donations. The safety of blood, and also some technicalities used from the Red Cross point of view. Represented in that international group are 11 major Red Cross Blood Transfusion Services in the world, and it also devotes quite sometime to the problems of developing countries in order to give

advice, and expertise to those countries that are still developing.

What countries exemplify that category as a developing country?---Most of the African countries for instance are considered developing countries, South America, South East Asia, just to mention some regions of the world.

What are some European countries - are some European countries far behind others as far as learning in transfusion medicine is concerned?---Yes, they are certain differences between different regions of Europe, and the general trend is from our point of view that Northern Europe is more developing in this respect than Southern Europe, and it is certain that - that this activity is not quite as developed for instance in Portugal and Greece as compared to some Scandinavian countries.

In respect of publications to which you've contributed. Am I right in saying that you've either authored or co-authored in excess of 70 scientific publications relating to blood transfusion and immuno haematology?---That is an estimate. I don't know the exact number, but that is a correct estimate.

Your Honour, we tender the curriculum vitae of Dr Leikola.

EXHIBIT LX5 ... Curriculum vitae of Dr J. Leikola.

MR GILLIES: Doctor, in relation to the question of publications we have in evidence in a number of respects, or a number of issues, the newsletter

called Transfusion International. In 1983 were you the editor in chief of that specialist newsletter?

---That is correct. That was part of my - my duties in my office in Geneva to publish that paper and to be the editor in chief.

What was the purpose of that publication known as Transfusion International?---Because one of the main duties for my office was to give information to the Red Cross Societies and to the other interested parties, therefore the publication of that kind of newsletter was considered of being very important in disseminating that information and therefore it was an essential part of the job in Geneva.

What was the circulation of Transfusion International - did it go to all member countries of the Red Cross?---That is true. It is published in three different languages, in English, in French and in Spanish. It goes to all National Red Cross Societies which are about 150 right now, but in addition, it goes to transfusion services, whether they are connected with the ReEd Cross or not and I believe that the total distribution right now is close to 4000.

As an incident of your job as editor in chief, did you also contribute numerous articles to Transfusion International?---Both articles and editorials, yes.

In order to keep yourself informed for that task as well as other tasks which you had, did you make it your business to read and keep up to date with learned journals affecting blood transfusion medicine?---As much as I could, yes.

I want now to ask you some questions in relation to your personal acquisition of knowledge of the AIDS virus. When was it that you first believed that there was a

risk that the virus or infection, as it may have been then, that the infection was transmittable by blood or blood products?---I believe it was a first time some time in the beginning of 1983. However, it became clear to me that this was a potential risk, although maybe not risk perceived by me at the time, but potentially it could be a risk, in early May 1983 when we had a meeting of the international group of Red Cross blood countries and experts in Washington and when we had a chance to discuss this matter with our American colleagues.

When you left that Washington meeting in 1983, what was your personal appreciation of the risk?---How we understood the risk at that time was that it was connected with homosexuals mostly living in the United States who were being promiscuous. That means that they would have multiple partners and I must confess there that either we were naive or innocent or didn't really know about the sexual behaviours of these groups, but we thought that there two groups of homosexuals. There was one group, two men living together and going steady, and then there was one group, that free wheeling type of people who went to gay bars and to recreational drugs and so on, and we believed at that time that it was especially a risk factor from the later group.

From the promiscuous group?---From the promiscuous group.

When you say "we had the belief", what group are you talking about?---I was talking about the general idea that the group of Red Cross blood transfusion experts had then in Washington and later in that month also the European experts in the form of Council of Europe Expert Committee.

Where was that European Council meeting conducted?---I believe that it was in Lisbon but I'm not quite sure about the venue. I remember that it was at the end of May, 1983.

By that stage, by the time of the Committee of the Council of Europe meeting at Lisbon, what was your degree of understanding of the risk that the AIDS virus could be transmitted in blood products?---Well, it was about the same as in the beginning of May, when we understood that there was a potential risk for blood transfusion services in this respect, and therefore this Committee of Experts also produced a recommendation in order to disseminate this information to the field wider, so that everybody involved in the field would recognise that there might be a risk later on.

Was the recommendation of the Committee of Experts given publicity in Transfusion International?---That is correct.

Your Honour, might the witness be shown book 1. I'd ask that it be open for him at tab C10.

HIS HONOUR: Book 1. C10.

MR GILLIES: Doctor, you will see that that's a photocopy of the July 1983 Newsletter, Transfusion International. Would you turn to page 3 of that Newsletter?---Yes.

You will see that on pages 2 and 3 there is an editorial and that you appear as the author of the editorial is that so?---That's correct.

As an incident of that editorial, did you give publicity to the recommendation of the Council of Europe Committee of Experts recommendations on a number of matters?---Yes.

Are those recommendations set out in the last column of the editorial, that is the second column on page 3 with the paragraph commencing "Finally"?---Mmm.

I want to take you through that. In relation to the three recommendations contained in that article, were those the three recommendations or the three key recommendations of the Council of Europe Committee of Experts on Blood Transfusion and Immuno Haematology, consequential to the Lisbon conference that you have discussed with us?---That is correct.

I want to deal with the first recommendation. Namely to expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products. What was the reason for that first recommendation being made?---The reason for that was that because we didn't know any way of really preventing this transmission of a disease because it was not even known that it was a viral disease but this disease - we knew that there was some evidence that it could be transmitted via blood and because of this evidence then, it was thought that if there is a transmission that should be limited to a small number of recipients as possible, and therefore this

recommendation relates to that idea that as few people as possible would be then exposed to a putatively infectious unit of blood.

So it minimised the use of blood and blood products?---That is in a way the same thing, yes.

What of the second recommendation "To achieve national self sufficiency in the production of coagulation factor products from voluntary non-remunerated donors". What is the idea behind that. What was the idea behind that recommendation?---There are two components in that recommendation. The first one which I consider more important one, is to follow the principle of voluntary and unpaid donation, because I'm convinced that this is a safer source of blood for the recipient when the blood donor comes voluntarily and doesn't receive any compensation for it, his efforts, he is more likely to be open with his health history and because we have to rely on the information we are receiving from the donor, therefore it is important to follow this principle in order to, not to include those people that might be at risk of transmitting a disease. Secondly, national self sufficiency that relates to the idea that if this disease is spreading out of the United States as it looked like at that time, then it would be possible, maybe, to confine it in the United States and prevent its spreading to other countries by following the principle of national self

sufficiency, in those countries where it was possible.

As at mid 1983, to what extent did European countries have a voluntary donation system?---Most European countries had a voluntary and unpaid system already at that time. There were few exceptions to the question of using payment as a motivation of the donor, but most European countries - especially north of the Alps where truly volunteers aren't paid.

What was the situation in the Southern European countries such as Greece for example, did they have a voluntary donation system?---In principle they have a voluntary system there, and voluntary unpaid system but to my knowledge but in - in Greece, in Italy, in Spain at that time and in - in Portugal there were different means of compensating the donor. It was not called the payment but just the compensation to the donor which is in a sense really didn't make very much a big difference.

What would they do? What's an alternate method of compensation?---Well, they were quite imaginative in - in this respect and - and - and maybe it was in terms of - of giving some money to the donor saying that this is compensation for your hours of the work, independent of the fact whether he was receiving his salary during the donation. It might be - it might have been in form of giving one or two days leave from the work, and so on. There were many different means of circumventing that principle that was much vigorously followed than north of

Alps.

That takes care of voluntary donations. What of self sufficiency. To what extent in mid 1983 did Europe have self sufficiency?---As far as the cellular products of blood are concerned, that means most of the red cells platelets, and then almost all countries in Europe where self sufficient, except for Greece that really had a program where Switerzland was sending red cells to Greece in order to help them in this respect. However, for plasma - different plasma products - especially for albumen and Factor 8, the situation was quite variable in different countries. Most European countries were not self sufficient for Factor 8 preparation in Europe at that time, and they were mostly importing Factor 8 preparation from the United States. The degree of self sufficiency where it for instance from France, that was almost totally self sufficient. The importation of Factor 8 was minimal as compared to the Federal Republic of Germany where most of the Factor 8 was imported.

In mid 1983 what was the perception of the risk of American concentrate being imported into Europe?---It was considered to be fairly high, because of two things. First of all, it was shown that - that especially in the United States and in those European countries that were using American derived preparations. There were cases of AIDS in haemophiliacs, but not in those countries that at that time were exclusively using their own preparations. Secondly, the plasma that is coming to the large American manufacturers, that is coming from paid plasma phoresis donors, and that is against the principle laid out here in - in number 2.

That takes us to the third recommendation contained in the editorial: "To avoid the importation of blood plasma and coagulation factor products from countries with high risk populations and from paid donors." What countries did the committee have in mind in making recommendation 3?---It is quite clear from this text that - that the United States was mainly - mostly intended in this respect. However, it could not be mentioned specifically that one particle are counted because there may have been other countries who also might have had high risk populations, and - and paid donors, and it didn't play any role where the country was the United States or anything else, when these two risk factors that are listed here were present.

How much of a risk did the committee perceive American commercial concentrate to be in Europe?---I cannot say how much risk it was estimated to have, it was recognised that it was a risk factor, but I couldn't be able to quantify the - the degree of risk that was perceived at that time.

To whom were the three recommendations communicated - you publicised them in your journal, but was there a more formal dissemination of those three recommendations?---These recommendations came out of the meeting of this expert group, and as I mentioned before, the recommendations of this expert group are unofficial, and this matter was considered so important that it was then processed through the Health Committee of the Council of Europe and then through the Committee of Ministers that included this recommendation, or they formulated this recommendation as an official recommendation from that organisation. That was then sent to the member States of the Council of Europe, to the attention of health authorities in those countries.

On page 3 at the footer, the first column there's the observation: "However, the donors should be provided with information on AIDS so that those in high risk groups will refrain from donating. As an example we reproduce below the information leaflet given to all American Red Cross blood donors." What was that leaflet?---The leaflet was handed to us at

the Red Cross expert meeting in the beginning of May in Washington, and that was included as an example, what kind of information one country's given to their blood donors.

HIS HONOUR: Mr Gillies, I missed the passage to which you referred then?

MR GILLIES: Your Honour, it's at the bottom of the first column on page 3 of the July 83 Transfusion International Newsletter, commencing "However" and concluding "blood donors".

HIS HONOUR: Yes, thank you.

MR GILLIES: Was there any Australian representation at the Council meeting at Lisbon?---I believe there was an observer, Dr Beale from Australia, who was attending that meeting.

Was the leaflet referred to in the editorial the one which related to, among other things, multiple partners self-exclusion?---I don't recall the text of the leaflet but I believe it was as you said.

If you turn over to page 4 of the newsletter, is that the reproduced leaflet on page 4 commencing "An Important Message to All Blood Donors" and concluding "American Red Cross"?---This is correct.

Now, did you conclude your editorial comment with the following observation: "That AIDS seems to be the newest member of a group of infectious diseases such as hepatitis, syphilis and malaria that can complicate haemotherapy. Transfusion International will follow the development closely and we will include new information on the disease in the coming issues of the newsletter"?---That is what I wrote, yes.

Was that policy followed?---That policy was at least partly followed because in several issues, not in every single issue that appeared thereafter, there were some news about AIDS and blood transfusion.

In particular, did Transfusion International follow the development of the problem closely?---Yes, sir.

I ask you to now turn to tab 16, C16 of book 1 - C16, that's

the October 1983 issue of the newsletter of Transfusion International, isn't it?---That's correct.

I'll ask you to turn to page 9 of that October 1983 issue and you'll see there an article on page 9, the second column, under the sub-heading of "AIDS" - do you have that page in front of you, Doctor?---Yes.

Does that describe the recommendation of the Council of Europe relating to a number of matters concerned with AIDS?---That is correct. This is formal confirmation of the recommendation that was made by the expert group earlier.

There's a mention of the Committee of Ministers. What is the Committee of Ministers and how does it stand in relation to the Committee of Experts?---The Committee of Experts consists of experts in the Blood Transfusion Service. These are medical doctors who have specialised in this field and who are really running Blood Transfusion Services. They make their expert recommendation and, if the organisation, Council of Europe, considers that this matter is of sufficient importance to health authorities, then it is further given to the Health Committee of the Council of Europe that is dealing with all health matters within that organisation, and further on, it is passed to the Committee of Ministers who can make then a formal recommendation which recommendation is then numbered and then this

is given through the official channels to each government of the member State of the Council of Europe.

Who are the Committee of Ministers, are they governmental people or are they scientists?---They are really governmental people. They are Ministers of - they are mostly foreign minsters but they represent the individual cabinets of each of the countries.

Yesterday Mr Stanley was cross-examining Dr Jones in respect of this in the context of what manufacturers should do. Is the - who is the recommendation to, who is the object of the recommendation mentioned in this article?---This goes to the government, to the attention of health authorities in each country.

So the recommendation is to governments?---That is correct.

There's been an objection in relation to reading. Would you read the recommendation - - -

HIS HONOUR: No, I heard what the objection was too. It wasn't to that. No need to waste time. Carry on.

MR GILLIES: Does it read "It recommends" - that is the committee "It recommends to governments of member States"?---That is true.

In dealing with the member States, who are they?---You mean who are the member States?

Yes, who are the member States referred to in that recommendation to government of member States. Who are the member States?---The member - member States - I cannot list all the member States of the Council of Europe, but I believe that a number of member States is right now 23 or 23 after Hungary joined Council of Europe very recently, and these are the member States, and the governments of these States are the governments that I'm referring to.

Do the member States include the so called south of the Alps European States?---Yes, sir, they do.

The first recommendation to the government of member States was to take all necessary steps, and measures with respect to the acquired immune deficiency syndrome, and in particular to avoid wherever possible the use of coagulation factor products prepared from large plasma pools. This is especially important for those countries where self sufficiency in the

production of such products has not yet been achieved. What was the idea behind that first recommendation to the governments of member States?

---The idea is the same as was - as appeared already in the previous issue of - of this newsletter with a little simpler language to say that - that as few as possible recipients would be subjected to this risk.

Now, the next recommendation is to inform attending physicians and selected recipients such as haemophiliacs of the potential health hazards of haemotherapy, and the possibilities of minimising these risks. Can you tell us what was behind that recommendation to the governments and member States?

---This - as you can see - AIDS was not specifically mentioned here, because it's part of - of the education of the specialists in this field towards the medical community, and also towards the patients such as haemophiliacs. In this case we were well aware of the disease, and - and we were very keenly following what is going on here. To remind them that - that transfusion of blood or blood products is never 100 per cent safe. It always carries a degree of risk that can be minimised, and therefore the intention was here not only to remind of the possible risks of AIDS in this respect, but also to remind these groups that are listed here that transfusion is never riskless, and therefore the indications for transfusion, and the indications for

use of this product should always be weighed against the degree of risk that is present there.

We've heard how in this country the care of haemophiliacs is entrusted to haematologists. Is that so in Finland? ---That is partly so in Finland. It is also done by paediatricians and specialists in internal medicine in consultation with haematologists who are specialists especially in - in this haemophilia care.

What of the lesser developed European countries, can it be assumed there that haemophiliacs will invariably be treated by haematologists?

HIS HONOUR: You'll introduce an international incident, won't you, if you describe other countries in that way?

MR GILLIES: I might well, your Honour. Perhaps I should extract a promise from everyone not to tell.

What is the situation, Doctor, can it be - could it be safely assumed then that in the European countries not as developed, that haemophiliacs would always be treated by haematologists?---I really couldn't answer directly to that question. All I can say that - that the health care system is more developed in the northern parts of Europe than it is in the southern parts, and therefore the consequences of - of that are evident. It's - in my belief it's very variable in different clinics, and in different hospitals in those countries, and therefore you cannot say that that is true for the whole country.

Now, in relation to the third recommendation to governments of member States, to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating, what was the idea behind that third recommendation?---The third recommendation, once again, was trying to get the message through to health authorities, that blood donors in one way or another, should be informed about this new disease so that those belonging to the risk groups that were believed at that time to be - the most important ones in this respect, so that the people who belonged to those risk groups, or having risk factors - they would refrain from donation.

The next lot of questions I desire to ask you, Doctor, is to draw on your experience in relation to the extent to which transfusionists and haematologists liaise and combine internationally. What can you tell us about that?---I think that in this field of blood transfusion, the international contacts are very important, because it represents a fairly narrow discipline in medicine, and it is very difficult to know what is going on if you meet only your colleagues from your home country, except for maybe the United States - that is so large. In Europe this collaboration has been going on for a long time which is exemplified by the presence of this group of experts in the haematology and blood transfusion

of the Council of Europe that has now been existent almost for 30 years time, and it has been considered the very useful forum of exchanging information. I would add to that, that in the scientific literature, it takes quite some time before the manuscript is - is processed through the journal, so when it is finally appearing, it reflects a situation maybe half a year, maybe one year, earlier, and also everything that you say in a scientific journal really has to be proven. On the other hand, when you meet people, then you are able to more freely talk about the trends and what is going on right now, and therefore I consider it most useful when you are changing the practices in your own country, in order to know what the - what the other people are planning to do.

As part of your international experience, did you consult by sitting on joint committees consisting of haematologists and blood transfusionists?---I was not sitting really in joint committees with haematologists and blood transfusionists. Many of the people in the blood transfusion field are also haematologists, and therefore they represent that field. But they were not formal joint committees or joint working groups that I would have attended.

Over the years have you visited Australia?---I have visited Australia two times before this time.

On any of the previous visits did you sit on as an invited guest at blood transfusion committee meetings?---I was - we were having the International Group of Red Cross Blood Transfusion Experts meeting in Melbourne in May 1986, prior to the International Congress of the International Society of Blood Transfusion that took place in Sydney. I was still then working for the League of Red Cross and Red Cross Societies in Geneva, and therefore, it was my ex officia duty to be present in that meeting, and we organised that together with the Australia Red Cross Society.

From your observations on your previous visits to Australia, what can you tell Mr Foreman and members of the jury about the extent to which you observed liaison between blood transfusionists and haematologists?---From my experience I would not be able really to comment on the extent of liaison between blood tranfusionists and haematologists in this country.

If the trend here is much the same as the overseas trend what would you expect the collaboration to be?---I would expect the collaboration be quite good as it is in other countries but I have no direct evidence of sitting in meetings where these two parties would be represented and therefore, this is what I would expect from Australia, based on my experience.

We have heard evidence how, with conferences, it is customary for one year for haematologists to run it, and the other year the blood transfusionists. Is that a trend that exists overseas as well in this field?---For the International Society of Blood Transfusion there have been two types of conferences. Most of the international congresses have been held in conjunction of the National Blood Transfusion Society and not with the Haematology Society, however, there have been joint congresses with the International Society of Haematology and International Society of Blood Transfusion, because these fields really go quite close to each other.

I want to ask you some questions about what your belief was as far as the safety of the Finnish blood supply in 1983 and 1984. What was your belief having regard to the fact that you have a voluntary donation system in Finland at that time?---We believed at that time, and I was really not physically in Finland, but I was working in Geneva, but from that point of view, I thought that Finland was one of the countries that really fulfilled the criteria that were established by the international experts, and therefore considering the circumstances, it was relatively safe. The Finnish blood supply.

What facts did you take into account in drawing that inference that the blood supply in Finland was comparatively safe?---Because Finland has always had only

voluntary and unpaid donors because Finland has been self sufficient for both cellular and plasma products and because it has a national organisation that closely liaises with the Haemophilia Association. Therefore, I think that considering the evidence that we had so far, the Finnish blood supply was relatively safe, as compared to other European countries.

Why were the other European countries, not as safe, or not perceived to be as safe as the Finnish blood supply?---I think there are two factors to that. First of all, I already mentioned the self sufficiency in other European countries was generally not achieved in contrast to Finland. Secondly, Finland is geographically fairly isolated from the rest of Europe. That means because it is sitting in the north east corner of Europe, it is not a place where people are going through and it is a relatively cold country and it is not very exciting country and therefore, I believe that it is not very tempting for those risk groups, that I was referring, to come to - there is not much going on in Finland.

(Inaudible) California anyhow?---No, it's very far from California.

We've heard evidence that throughout in Australia there's been a voluntary donation system, with a minor exception of New Zealand, essential self sufficiency. Was that something known to you in 1983?---That was known to me, yes.

How did the Australian situation compare with the Finnish situation as far as comparative theoretical safety of the blood supply was concerned?---For the first respect how this criteria were fulfilled, then I think that it was very comparable to - to Finland, and I had - and I still have great admiration to the system how it's run here in Australia. On the other hand I have been to Sydney, and I must say that - that it is in ambience it's closer to San Francisco than Helsinki.

Is that why when flying from the United States a stopover at Auckland and not at Sydney on route to Melbourne, Doctor?---Not directly for that purpose, but I try to avoid Sydney I must say that.

You mention that you had admiration at that time for the Australian system. What were the facts giving rise to your admiration for it?---First - when I was here for the first time then I attended the - and that I believe was in - late 1983 - in October, but I'm not quite sure of the date. You may check that. Then I attended the - the Executive of the Blood

Transfusion Committee in this country. Then I also got to learn the independence of the different Australian States, and I learnt to appreciate the fact that there are really different policies in different parts of this country. Nevertheless, the directors - the blood transfusion directors - were able to convene together - get together - and decide on common policies, and that I think - that was something that I learnt to appreciate.

I want to now ask you some questions relating to self exclusion screening. How the first self exclusion screening in the United States was put in place in March 1983, and that was a multiple partner homosexual self exclusion screen, that was known to you as a screen was put in place at about that time I assume?---Yes, sir.

When was it that in Finland the first self exclusion screen was put in place?---We had in Finland the first AIDS case, and I'm not referring to - to the case is through blood transfusion, but the very first case of AIDS in June or July in 1983. And in about October 1983 a message went through the Association of Sexual Minorities which is really representing the homosexual community in Finland. Also through the general press that male homosexuals that have multiple partners should refrain from giving blood.

When was that? Was that in October 1983 or a different date?---That was I believe in October 1983.

In February 1985 was a different screen put in place?---Then the police was some - somewhat changed, because it turned out that much of the language that we had been using that far, for instance a term with multiple sexual partners what - whatever that mean. Also what was it to be bisexual. Was it to have a wife and mistress or whatever that meant - - -

There's a Professor Hassig who grappled with the same problem. that adviser I hasten to add?---That's correct, and I believe that - that we were a bit naive in introducing medical terms that were not quite comprehensive to the targets, and therefore we made it simpler and broader in February 1985 saying that homosexual males should not give blood.

HIS HONOUR: What was that date you said, Doctor?---February 1985.

MR GILLIES: Then in October 1985, was the system adjusted in some way?---That is correct. In our country, 1985 was a very important year for the whole problem to be treated and it was not considered sufficient just to give the information to the donor but really include that in the health statement of the donor that he is signing, and therefore that was introduced to the health statement that each donor signs in October 1985.

So that was the signed declaration in October 85?---That is correct.

What was your belief in 1985 as to how the self-exclusion screen was working?---We believed it was working well because we had very good contacts with the homosexual community at that time and there were no cases so far found in Finland who would have had AIDS from either blood products or blood transfusion in Finland by summer 1985.

When was the date that Finland had its first AIDS case, not blood related but first AIDS case?---The first AIDS case was a homosexual man. That was either in June or July 1983.

When was the first blood related AIDS case in Finland?---The first AIDS related case of blood transfusion probably got his infection in 1983. We don't know exactly a date but that was diagnosed and we became

aware of that incident only after the viral test was available to us in May 1985.

I'll ask you some questions relating to surrogate tests and the first surrogate test I desire to ask you about is the Hepatitis B core antibody test. Is that a test that was known to you and known to you particularly through your association and friendship with Dr Perkins?---Well, the test was quite well known to me independent of my association with Dr Perkins because it's used in the diagnosis of Hepatitis B. On the other hand, it's used as a surrogate test to identify promiscuous homosexuals, as it was called at that day. That was - I discussed this with Dr Perkins in the early 80s but I don't recall the year.

We've heard from Dr Engleman that Dr Perkins was performing experimental work with the Hepatitis B core antibody test as a surrogate test. That was known to you that he was doing that experimental work, was it?---That - he told me about that, yes.

What steps did you yourself take through your contacts with Dr Perkins to inform yourself as to the effectiveness of that test as a surrogate test?---Well, I asked him about the results of introducing the hepatitis core antibody test and he said that he wouldn't know any of the results because he first had to do experiments in order to see whether it really would be effective in that

respect or not, and I believe the viral test then became available before those results were available, but my impression - and this is my personal impression from Dr Perkins - was that he himself did not quite believe it would be useful but he wanted to see whether it would be useful or not.

In what year was that, or was that throughout his belief up until the viral test became available?---That's correct, yes.

When did the viral test become available so as to supersede the surrogate test?---That became available in April 1985.

When we talk about the viral test, that's the HIV antibody test, is it?---That is the HIV antibody test, yes.

Did Dr Perkins ever recommend to you the Hepatitis B core antibody test as a useful surrogate test?---No, he - he wouldn't - he is a man that wouldn't recommend anything of which he wouldn't be sure, and he said that he first wanted to see whether it would be useful or not in his circumstances that he recognised were totally different from my circumstances.

In 1983 and 84 what was your opinion as to the Hepatitis B core antibody test as a surrogate test - was that seen by you to be a useful thing or not?---I didn't consider it useful.

Why did you not consider it to be a useful test as a surrogate test for high exposure people?---To my knowledge there really was no convincing evidence that it would be useful in limiting the number of AIDS transfusions to the recipient at that time, and that opinion was shared also by my European colleagues.

Was the test run as a surrogate test in Europe or not?---To my knowledge in no European country, for that purpose.

We've also heard of a second test which has been put forward as a surrogate test - the T-4/T-8 ratio assay. Is that a test that's known to you?---The test is known to me, although I have never performed it myself.

During 1983 and 1984 did you or the committees that you were a member of, turn their minds to the T-4/T-8 ratio assay as a surrogate test?---It was mentioned by passing, and it was a general consensus from the beginning that it was not a suitable test for any screening purposes.

That was your opinion too?---That was my opinion too.

Why was it their and your opinion that T-4/T-8 ratio assay test was not a good test as a surrogate test for a high exposure group to AIDS?---First of all, there are two reasons - one is the technical nature of - of that test. It has to be performed from fresh whole blood sample, that in all separation of the lymphocytes from the rest of blood, and then using two antibodies to identify the T-4 and T-8 cells, and that's a fairly lengthy procedure that cannot be automised. The second thing is that this is a highly non specific test that may turn positive in various different conditions, and therefore it lacks the specificity that is needed for screening of blood donors.

Now, I want to question you in relation to the development of the HIV antibody test. When was the HIV antibody test introduced in Western Europe?---It was mostly

introduced between May and June 1985, and the beginning of 1986.

As far as Finland was concerned, when did that country have the HIV antibody test in position as a routine test for all blood donations?---Well, for all blood donations as of beginning of 1986. We started its routine use in September - in the beginning of September 1985.

What was the reason for not having it in place at an earlier time than September 1985?---We made a pilot study on the usefulness of that test for Finnish circumstances, and we started 10,000 male donors from Helsinki area, because we figured that - that those donors would be especially at risk of transmitting disease, if any in Finland, and because in those 10,000 donors we found one positive, then the decision was made that as soon as the test was available to us in larger amounts, we would start that, and that took place in the beginning of September 1985.

Was it not until November 1985 that all of Europe was using the HIV anti-body test?---We were using - the whole country was using that from the beginning of January 1986.

In relation to heat treatment, as an inactivator of the HIV what comment do you have to make about when that was commenced in Finland?---That was commenced for our Factor 8 concentrate. The decision to try heat inactivation was made in the beginning of 1985. The first experiments were performed in the beginning of 1985. The method was ready for use in a larger scale in May of 1985. Then we needed clinical trials in order to see that it is really safe and it is performing the effect that it was supposed to perform on patients. These were carried out in July/August, 1985. We filed an application to our National Board of Health to change the procedure of manufacturing Factor 8 concentrate. Because we have a license from - or that is a licensed product by the National Board of Health. They approved that in two weeks time, which what I have been told, was the record time of processing an application through that Board.

So, when was it that all Finnish concentrate was heat treated?---That was October 1985.

During your period of membership on the Council of Europe, did it come to your note as to what was going on in Australia as far as heat treatment was

concerned?---I believe I heard about the heat treatment in 1985 the first time when we had a meeting of the Council of Europe group.

How was that regarded, if at all, by the European experts that Australia by that time, had a heat treatment procedure in place?---Because the Australians already had started the process and started that in their routine that helped us to convince also our health authorities that this was a necessity and we had to go on with that decision.

I next want to ask you some questions relating to warnings - warnings as between doctor and patient, warnings as between pharmaceutical product distributor and others and warnings as between manufacturer and others. Firstly, and in relation to manufacturers. In Europe were you aware of any concentrate that carried a warning in relation to the risk of AIDS being transmitted in the product. Whether the warning was in an insert on a label on the bottom or a notice on the package. Were you aware of any European manufacturer, having such a warning on its product?---To the best of my knowledge I was not aware of any of the manufacturers using that.

Were you aware of any distributor of pharmaceutical products having a warning to that effect on the product distributed by it?---I was really not following from my office in Geneva what was the content of different leaflets of different blood products that

were supplied by manufacturers, but nobody at least was pointing that out that here is a warning in contrast to all others, and therefore I was not aware that anybody would have been using that. It may have occurred but I was not aware of that.

that - this point exactly. I cou.
specific articles in that respect, no.
In relation to the duty to warn the pat
responsibility is that?---Well, th
responsibility is the treating doctor.
Your Honour, would this be a convenient moment t
going on to a different topic at this
keen to commence it but the preferenc
the break now.

HIS HONOUR: Yes, that would be quite convenie
may have their break.

AT 11.33 AM THE JURY LEFT THE COURT

HIS HONOUR: Doctor, you may leave the witness
stay in court or leave court, whichever

WITNESS STOOD DOWN

HIS HONOUR: Yes, Mr Rush?

MR RUSH: Your Honour, can I hopefully summar
putting to you yesterday succinctly?
Honour, there is no evidence that the
that his - in 1984 - that his HIV c
caused by the use of concentrate.
your Honour, that it's very importan
between concentrate and cryo-precipit
because this case in negligence a
Trade Practices is about concentr
nothing to do with cryo-precipitate.
We say, your Honour, that th
section under discussion - s

MR RUSH: Yes, it was your Honour.

HIS HONOUR: Yes, well, thank you. I'll defer further argument on this. The jury may now return.

AT 11.55 AM THE JURY RETURNED TO COURT

JUHANI LEIKOLA:

HIS HONOUR: Mr Gillies.

MR GILLIES: May it please, your Honour. Dr Leikola, I want to put some questions to you to enable you to contrast the Australian position with the Finnish position. Firstly, in relation to self exclusion screening. The evidence is that Australia had a multiple partner, homosexual, self exclusion screen in place by June of 1983. I think you mentioned the Finnish screen was February 85, was that so. You have also agreed that the American screen was put in place in March of 1983. What comment do you have to make about the speed of the Australian reaction to the problem that was confronting the blood supply?---That was certainly at least much faster than in Finland.

How does it compare with other European countries?---As far as I know, compared to other European countries it really was a quick reaction.

In relation to the second leg of the screen, the total homosexual screen in Australia that was introduced between October and December 1984. I think you mentioned in Finland it was October 85. What comment do you have to make about Australia being

abreast of world developments in implementing a total homosexual screen by October/December, 84?---Finland introduced the total homosexual exclusion in February 1985, but certainly Australia was again ahead of us.

What do you say in relation to the Australian reaction compared to Europe in general as opposed to Finland in connection with the total homosexual screen?---To my understanding, it was about at the same time when European countries in general started that policy.

That's the Finnish?---Finland started that in February 1985 and that was after the Australian apparently instituted that. But we were also a little bit behind of some of the European countries as somewhat ahead of some other European countries.

Why was that. Why did you not have your total homosexual self exclusion screen in place, say by October/December 84, as in Australia?---As I said 1985 was a very important year for us as far as policy on AIDS and blood transfusion was concerned. We were late.

With the HIV anti-body screen, we have heard how that was available as a general laboratory test in Australia in October 84, and how by March 1985, it was universally used to screen all donations. I think you have mentioned that in Finland the screen was in place by September 85?---That is correct.

What do you have to say about the speed of the Australian reaction. Firstly, in having the laboratory screen

available in October 84, and secondly the universal HIV screen in place by March of 85?---I think in both respects Australia reacted quickly and especially instituting it into the routine and I must say that the Australian example was important for us when we made our decision to start general screening of blood donors.

Why was that Australian press important in influencing you to start your own screening?---Because otherwise the conditions concerning the system using all volunteers and non paid donors and by and large a national self sufficiency were about the same - then because Australia instituted this so quickly, then this helped us also to react to the situation and seeing that the situation really required a general screening for all blood donors as soon as possible.

Thirdly, in relation to heat treatment to inactivate the HIV, the evidence is that Australia routinely heat treated all of its product, and more specifically CSL heat treated all of its product from early November 1984. I think you've indicated that in Finland it was October 1985 before all the product was heat treated, is that so?---That is correct.

What do you have to say about the speed of the Australian reaction to routinely heat treat all concentrate by November 1984?---We thought that we reacted in a reasonable way of having it instituted in October 1985, and obviously Australia was 11 months ahead of us.

What general comment do you have to make about the general reaction of the Australian authorities - the CSL and the Red Cross, to the problem that had beset the world's blood supply?---Considering the circumstances at that time and considering my European experience, I would say that in this

respect, so Australia reacted in a reasonable way and reasonably quickly also.

I have no further questions to put to Dr Leikola, your Honour.

HIS HONOUR: Mr Sher.

CROSS-EXAMINED BY MR SHER

MR SHER: Could Dr Leikola be given book 1, please, your Honour, tab C10.

HIS HONOUR: Yes.

MR SHER: Doctor, Mr Gillies has already asked you some questions about the article you wrote which appears on pages 2 and 3 of this particular document. Are the facts stated in that document, so far as you were aware, true?---As far as I'm aware they were true.

Are the opinions expressed in that document opinions that you honestly held?---I beg your pardon?

Were the opinions that were expressed in the document about matters, your honest opinion?---Yes, sir.

One of the things that you say - if I can ask you to look at the paragraph at the bottom of page 3, the first column. There's a sentence there reading this: "Measures that could lead to inappropriate discrimination and to an emotive over reaction amongst recipients of blood and blood products must be avoided." Do you see that statement?---Yes.

Then it goes on to say at the very bottom of that page - the sentence in the last line commencing with the word "Most". "Most blood transfusion experts agree that

it's not appropriate to ask the donor's sexual preferences, even though it's known that male homosexuals represent the most important high risk group." What do you say as to whether or not Blood Transfusion Services around the world, to your knowledge, before the AIDS problem, ever had to consider asking the donors questions about their sexual preferences - had that ever happened before?
---Yes, sir, that has happened before. That happened in the late 40s in Germany when syphilis was quite prevalent in Europe, and then a number of questions were made at that time to the donors, but after that, in the general routine in the 60s and in the 70s, not to my knowledge.

The statement you make there was "No blood transfusion experts agree. It's not appropriate to ask a donor's sexual preferences". Why was that?---Well, we all agreed that - that if a donor comes voluntarily to give his blood, and all of sudden he's confronted with the questions that go into his privacy, and the relevance of which he really doesn't understand at that point. We were all unanimous in the respect that - that - then the donor should not be frightened by these questions, because we were relying on the voluntary will of the donors to come to the centre to give blood.

What do you say as to whether you had enough donors throughout Europe for the blood supply? What was the position? ---Would you repeat the question - - -

What was the position about whether you had enough blood for making the appropriate blood products. Did you have enough donors?---By and large there - there were enough donors for all cellular products. There were not quite enough donors to produce all the plasma products.

In that publication set out the American leaflet which appears at the next page - on page 4 - and the high risk group in relation to homosexuals there is set out at the top of the second column as sexually active homosexual or bisexual men with multiple partners. How long - as far as you were aware - in Europe was that the high risk group of homosexuals, that is to

say the homosexual with multiple partners defined in the material that was used to screen volunteer donors?---To my knowledge it started sometime - maybe September, October in 1983.

How long did that go on for before it was changed. Just to remind you, you said in Finland you changed it to all homosexuals I think in 1985 - or September 85? ---That is correct.

What was the general picture in Europe? When did other countries by and large throughout Europe change from homosexuals with multiple partners to all homosexuals?---By and large at the end of 1984 or beginning of 1985.

Just have a look if you wouldn't mind under tab 16, and at page 9. C16, page 9, Doctor. Now, towards the bottom of the page after you've set out the recommendations to governments and member States, in brackets after the third of them there are the words "An example of an information leaflet for donors is appended", do you see that?---Yes.

Can you tell us what the leaflet was that was appended to this edition of Transfusion International?---This refers to the same leaflet as - is reprinted in the previous issue of Transfusion International - produced by the America Red Cross.

Just a couple of more questions. Finland as I understand your evidence had a self contained, and had voluntary donors, but did you have to import any commercial

Factor 8 product at all in Finland?---For - - -

This is in 83 and 84?---For on - on treatment of uncomplicated haemophilia not - we imported about - maybe once a year a so called activated prothrombin complex to treat haemophiliacs who had inhibitors, and who were not - where a special was needed where the used of Factor 8 concentrate was not effective.

But essentially, apart from that you used your own product? ---Apart from that we used only the finished product.

And you're all volunteer donors in Finland?---That is correct.

Did you get any HIV positive cases from your voluntary blood donors in Finland?---Yes, sir. We had two haemophiliacs who contracted the infection.

What about transfusion cases. Did you get any HIV positive people from transfusions?---Five cases all together.

So, notwithstanding it was voluntary and self contained - - - ?---Yes, sir.

You got these cases?---Yes, sir.

Thank you.

CROSS-EXAMINED BY MR BARNARD

MR BARNARD: Doctor, you've been between 68 and 72 a resident in a hospital, is that so?---That is correct.

CROSS-EXAMINED BY MR BARNARD

MR BARNARD: Doctor, you have been between 68 and 72, a resident in a hospital is that so?---That is correct.

Were you treating haemophiliacs at that time, or was that just general work was it?---First of all, one year of that time I spent in the United States, so that means three years time, but I was not treating any haemophiliacs, no.

Does that mean you have never been responsible for the treatment of haemophiliacs?---Personally, not.

I see in your curriculum vitae that you are vice-president of the European Fractionation Association?---That is correct.

What is that association concerned with?---This association is concerned about the use of plasma products that are derived from voluntary and unpaid donors and extending the ethical principle, that in principle, "not for profit" institutions, should be preferably manufacturing the products that are derived from that kind of blood.

It is concerned with the fractionation of plasma to make Factor 8 concentrates, is that so?---Not only to make Factor 8 concentrate but to produce all plasma products.

In fact, that association promotes the proper manufacture of blood products, including Factor 8?---That is correct.

Doctor, I wonder if you would look at exhibit HX9. Doctor, that is the proceedings at a symposium of the Australian Society of Blood Transfusion held in Melbourne on 24 to 26 October, 1983. Were you - you have seen those proceedings before have you?---No. Sir.

You were present at that symposium weren't you?---Yes, I was present - I was not present at that symposium. I was present at the meeting of the executive of the Blood Transfusion Committee here, but not in this symposium.

Have a look at the contents of this, which is the fourth page. You will see, it records the participants on the left-hand column?---I'm sorry sir. It happens to be - - -

I beg your pardon?---I - you are correct sir. My name figures here.

If you look in the right-hand column, it records you as having given the paper on the "Procurement of Blood Components"?---It seems to be true sir. Yes.

Would you turn to page 38. You might see if that in fact, is the paper given by you?---I beg your pardon?

Do you recognise that as a paper given by you?---I have not seen this text printed, but I recognise this paper, yes.

You recognise it, do you. Just to refresh your memory further, if you could turn to page 46. Do you see there you recorded in the middle of the left-hand

column as having asked Dr Cash a question. You nodded. Is that correct. You see that do you?---Yes, I see it here.

Do you recollect having been at that symposium?---Yes, sir.

If I could take you back to your paper, and in particular to page 40 of the proceedings. Do you see that down the bottom of the left-hand column - you're talking about a voluntary plasma pheresis program?---Yes, sir.

You go on to say that "This is something that I think should be seriously considered if the need for Factor 8 preparations did grow so high that more plasma would be needed for fractionation purposes". What do you mean by that?---I mean two things. First of all, the need for Factor 8 preparations - the consumption of Factor 8 preparations was increasing at that time, and secondly, with the - proceeding from cryo-precipitate into concentrate, the yield of Factor 8 was lower and therefore more plasma was needed to - to fulfil that.

You went on to say "If the problem of the yield and the concentrate are not solved in the immediate future, then I think also here in Australia, as was mentioned by Professor Penington, plasma pheresis programs could be considered"?---Mmm.

You say yes to that - it's not recorded if you don't say yes, Doctor?---I say yes.

Well, in fact you were indicating here your approval for fractionation processes which produced Factor 8 concentrate, is that not so?---That is true.

In the course of that paper, you did not in any way suggest

that in Australia in October of 1983, cryo-precipitate should be used instead of Factor 8 concentrate?---Sir, I haven't read this through, but I don't believe that I was specifically suggesting that it should be used instead of concentrate.

You weren't suggesting to the persons present at this symposium that Factor 8 concentrate involved a greater risk to exposure to the HIV virus than cryo-precipitate?---No, I was not saying that, I was not saying the reverse either.

You told us that except for some special product that you got once per year, you were self sufficient with Factor 8 products in Finland?---That is correct.

The only product that you use is cryo-precipitate?---At that time that was the only product, yes.

When did the change take place?---In late 1984.

Was that a change totally to concentrate?---No, sir, still part of Factor 8 is used in form of cryo-precipitate in my country.

Is it correct that Finland was using solely cryo-precipitate for a much later time than other countries in Europe?---Finland and Norway, to be precise, yes.

What about Sweden?---Sweden started using concentrates earlier than Finland.

Why was the delay in Finland and Norway?---Both countries relied on domestic sources of plasma, and they didn't want to have importation of large pool products.

So the reason was to avoid importing concentrate, is that the situation?---That is correct, yes.

I wasn't that they regarded concentrate as superior to - sorry - cryo-precipitate as being superior to the concentrate?---There are two aspects to that. We recognised at the level of the yield that we were getting from the concentrate at that time, that Finland would not be able to cover all its need with voluntary finished plasma should there be an overall use of concentrate. Therefore partial use of cryo-precipitate was considered necessary also form that point of view.

With the present time, what's the percentage of concentrate used as compared to the cryo-precipitate?---From last year's statistics it was - it was almost exactly half in the form of concentrate, half in form of cryo-precipitate.

Doctor, were you aware of the recommendations put out by the National Haemophilia Foundation of the United States?---Concerning - - -

Concerning recommendations to prevent AIDS in patients with haemophilia?---I have seen a number of recommendations, but I don't recall here any specific recommendation by the National Haemophilia Foundation.

Perhaps I should ask that you look at book 1, tab 17 - or A17.

HIS HONOUR: 1, A17.

MR BARNARD: Were you aware of this type of recommendation that came out or was it something that didn't come

to your notice?---I think I saw this recommendation at the meeting we had early May 1983 in Washington.

You told us that in book 1, C10, that you put out recommendations in the Transfusion International. Do you recollect that, the recommendations of the Council of the Europe Committee of Experts on blood transfusion?---Yes, sir.

Was that in anyway intended to conflict with or vary the recommendations set out by the National Haemophilia Foundation?---Not - not really, no, it had nothing to do personally with this recommendation.

In other words, so far as the physicians treating haemophiliacs are concerned you would expert them to have regard to the National Haemophilia Foundation recommendations, rather than to a recommendation put out by your organisation?---Well, sir, I think we were all concerned about the safety of haemophiliacs, and there were different approaches to this problem.

If I could ask you to look in the book which you're looking at, at tab C16 which was your newsletter of October 1983, and in particular at page 9. You've told us that the recommendation of the Committee of Experts was to governments of member States. Now, that was communicated to - what sort of person that attended, a minister, was it?---That was communicated to the Committee of Ministers who are the ministers attending.

That Committee of Ministers would be politicians, is that so?---Yes, sir.

The likelihood is that those politicians would not have medical qualifications?---That is very likely.

The recommendation that's sent forth is just in the terms that appear between inverted commas on that page, is that correct?---I don't have the full text of the recommendation with me here so I cannot comment. That - these were the salient points of the recommendations.

In respect of the second recommendation, it speaks of the potential health hazards of haemotherapy. Now, it gave no indication what those potential hazards might be?---In this context, it doesn't give any indications what those hazards may be.

How is the Committee of Ministers to know what those potential hazards might be - could you tell us how you expected them to know?---I don't think it was up to the Committee of Ministers to know all the health hazards, different specific hazards, as far as blood transfusion was concerned. I think it was more important for them and to emphasise the risks of blood transfusion in general and to have the National Health Authorities to become aware and remind them about these possibilities.

Are you saying that the hazards spoken of are the hazards which the local health authorities or local transfusion service perceive to be the

hazards?---Well, this recommendation goes to the National Health Authorities. It usually goes via the Ministry of Health and then it is sent in each country to the parties concerned, as are - as is deemed by the Health Authorities.

So they have to decide, the parties concerned or the health authorities, had to decide what they thought the possible hazards were?---That is correct.

Again, it would be the health authorities or the parties concerned would have to themselves decide what the possibilities of minimising the risks were?---That is right.

Really, the central part of this recommendation was to persuade health authorities and transfusion services to pass on their knowledge to physicians and selected recipients?---That is correct.

Now, you spoke of a collaboration between or you were asked questions about collaboration between blood transfusionists and haematologists. Have you yourself been involved in any position where you were required to collaborate with the haematologists or people treating, for example, haemophiliacs?---I don't think I have been involved in those cases where I would have been required to collaborate with them, but because the transfusion service was the main supplier of the product, it was very natural that contacts were kept with the haematologists who were treating the patients.

Those responsible for a transfusion service have knowledge about how the transfusion service is operated, is that so?---In general, that is so.

They would know what sort of donors are being admitted to the transfusion service?---There at least they give instructions and guidelines what kind of donors should come.

By doing that, they should know what the risks are of infection or contamination of the blood arises out of the running of the transfusion service?---Yes, by and large, yes.

It is information with regard to those risks that you see the transfusion service as being responsible to pass on to the medical profession. Or people using the transfusion service's products. Is that the situation?---The awareness of the risks that should lead into two directions. First of all, trying to preclude the kind of donors that are considered to be high risk donors in this respect, and also to try to have educational approaches to clinical doctors, who are treating these patients, but it is really not the responsibility as such of the transfusion service director.

To educate the persons using. What would the director be seeking to educate the users of blood products about. What would he pass on to them?---It is his moral duty to inform about the new developments that are, the information is in his possession to inform his clinical colleagues, but I don't think he can interfere with the individual decision or the how the physician is treating his patient.

What about telling the physician about the risks associated with the blood products?---That goes in the form of education and information.

Incidentally, after you knew that, in 1984, that the blood supply could carry the AIDS virus, after you were aware that in fact cases had occurred, did you still continue to use cryo-precipitate?---We still continued in Finland using cryo-precipitate.

Did you, at some stage, treat cryo-precipitate to kill the HIV virus?---That is correct, in 1987.

Between 1984 and 1987, what did you do to prevent recipients of the cryo-precipitate from getting the HIV virus?---Applying these principles that were listed here. I mean, using volunteer donors and using the self exclusion of the donors.

So, even after you had the knowledge that blood could carry the HIV virus, you used cryo-precipitate and the only precaution - or the precaution you took - the only precautions you took were to exclude homosexuals?---That is true.

Use a volunteer service?---True.

Not to import any blood product?---That is correct.

I'm sorry could you refresh my mind as to the date when you excluded homosexuals completely?---That was in February 1985.

Just the other matter. Of course, whether a particular patient should be treated with cryo-precipitate or concentrate, is not a matter in which you have expertise is it?---No sir. That is correct.

HIS HONOUR: Mr Rush.

CROSS-EXAMINED BY MR RUSH

MR RUSH: Dr Leikola, there are two haemophiliacs in Finland that are HIV positive. Is that the position?---That is correct.

I think you said there were five transfusion cases?---That is true.

You have a voluntary system?---Yes.

It is a system of blood that comes from within your country?---That is right.

Do you know how many haemophiliacs are HIV positive in Australia?---I don't have the precise figure.

It is in the realm of 200 to 300 is it not. Is that right?---I can't comment that, because I don't know that. But I believe you are right.

There are 117 known transfusion cases in New South Wales alone. Are you aware of that figure?---I was not aware of that figure.

There is a very big difference between the Australian volunteer system as far as the incidence of AIDS is concerned and the Finnish system, isn't there?---It seems to be difference between these countries, yes.

Not just a little difference, but an enormous difference. Wouldn't you agree?---Yes, in that respect, yes.

So, when we talk about the precautions that are taken in Finland and the precautions that are taken in Australia, we are talking firstly, about two very separate blood transfusion systems, aren't we. Two very separate countries?---We are talking of two different countries, that is correct.

Did you have, you said before that you came via Auckland, and avoided going to Sydney. Did you have a Sydney in a town, or a city that compared with Sydney in Finland in 1983 or 1984?---No sir.

Did you have as what's known here as the Gay Mardi Gras?---I beg your pardon?

A procession up the streets with - for the gay community with their floats and exhibiting their floats and themselves up the main streets in any of the streets of Finland in 1983 or 84?---I was living in Geneva,

but I don't think that I would have encountered them in Helsinki, no.

Were you aware that homosexuals were as a source or as a group a significant donor group for the Finnish blood system, in 1983 or 84?---We had no reasons to suspect that there would not be homosexuals within our transfusion service, within the donor core.

But what I put to you Dr Leikola, did you suspect that they were a significant group?---It depends what you mean with significant.

A large group. A big percentage?---We didn't have any idea of the percentage as I mentioned here before, I didn't know how many homosexuals we had in Finland at that time, but we did not have any reason to believe that there would not be homosexuals within the donor core.

Dr Leikola, one of the reasons for these two haemophiliacs - two haemophiliacs being HIV positive in Finland, is that you used small pool product. Cryo-precipitate?---I believe that it is partly related to the fact that we have only 2, yes.

The haemophiliacs in Finland that were treated with cryo-precipitate, they have a life expectancy that is equivalent to a person that doesn't suffer from haemophilia at all, do they not?---That is true.

Those people that were treated with cryo-precipitate in Finland were treated well for their haemophilia?---I believe so.

It is shown by the figures and the studies that have been done in Finland to show that the haemophiliacs life expectancy is the same as the average man in the street?---That is true.

Doctor, in a voluntary system, a voluntary blood system, those that run the blood system are expected to make reasonable enquiries of their donors to see where they come from and what their health is?---I beg your pardon?

The Red Cross in Australia for instance, you would expect to make some enquiries of a donor as to check the donor's health, their status as far as health is concerned?---Yes, that is done also in Finland.

We have heard from Dr Hassieg last week in relation to what was done in Switzerland - and the Red Cross system in Switzerland would be something that you were familiar with?---Yes, sir.

They had physical examinations of their donors, did they not?---I don't know whether they are including physical examination of their donors.

Professor Hassig gave evidence that in 1983 and indeed I think he said through the 60s and the 50s, a physical examination was part and parcel of the system every time a donor came in to give blood. Was that something that you weren't aware of?---If he said so, I believe it was true but then it depends how you define this physical examination.

What about in Germany - do you know what the Red Cross was doing in Germany as far as physical examination is concerned?---I didn't have any details about what was going on as far as physical examination of donors in Germany was concerned.

Would a record of a donors weight, what the donor weighed, would that be something that would be part and parcel of what you'd expect when you've got a donor coming in that you'd ask him about his weight?---Yes, sir.

That the blood system or the Red Cross in whatever country it is keep a record of the donor's weight?---Yes, sir.

So that if a donor comes in and he's given blood, let's say, last May and he comes in in November, that the Red Cross, the people taking the blood, can say "You've lost a stone in weight" and that would be significant, wouldn't it?---Well, the weight of the donor was asked for in order to fulfil the minimum

requirements for giving blood so that he would be big enough to give one pint of blood and I believe there that many transfusion services in Europe, they did not ask the weight of the donors but they asked "Are you above this weight limit?" and therefore that kind of systematical follow up would not have been possible, at least in my country.

But in 1983, Doctor, asking that question put a person on guard as to the specific symptoms for AIDS, didn't it?---Would you repeat your question?

Weight loss, severe weight loss or sudden weight loss, was known as an early sign for AIDS?---Yes.

So asking the question about weight and keeping a record of weight was something that put both the people receiving the blood and the donor on guard as to an early warning sign for AIDS?---I don't think it's an early warning sign of AIDS. It's not of the very early symptoms of AIDS but that was one of the symptoms of AIDS. The weight really was applied for in order to meet this minimum requirement.

It's the same with night sweats, is it not - that's a sign, if you like, that - or an early warning sign in relation to AIDS?---I'm really not an expert in the clinical signs of AIDS but I believe what you say is true.

But they were - both the weight loss and the night sweats - that was material appearing on the early leaflets that were handed out to donors, wasn't it,

Dr Leikola, in 1983, in Europe, in Australia, the United States?---In the United States at least that was included. I don't know about the detailed text in Europe.

Doctor, you've given evidence of what went on in relation to leaflets and self-exclusion in Europe and you've offered opinion of what happened in Australia. Do you know what went on in Switzerland - you were in Switzerland - in relation to the leaflet that was handed to donors there in 1983 or 84?---I - I couldn't read the text of all these leaflets that were used in Europe and I don't think I was commenting out of my memory the content of the leaflet that was given here in Australia. I can comment my own country.

Doctor, certainly the evidence that you've given to this court is that by May 1983, you held a belief that AIDS was capable of being transmitted in blood?---At least that there was a definite possibility for that.

And as a consequence of that possibility, the various steps which you have spoken about - the meeting of the Experts of Transfusion in Europe, those meetings took place as a consequence of that possibility?

---Yes, sir.

Doctor, that group of Experts on Transfusion in Europe was a prestigious group of transfusion experts?---It's difficult to comment on that, because I was myself member of the group, but I think it was considered as a prestigious group.

We've heard from Dr Hassig that he put various recommendations of that group into effect in Switzerland, without a recommendation from the government. That was something that was open to the various transfusion services, wasn't it?---Sir, Switzerland is a very particular country, where they have 26 cantons, and each of the canton has their own health minister, whereas there is no federal Minister of Health, and I think that he acted very reasonably without waiting something to come from the Federal Government.

As you said in Australia, when you went to the meeting in October, we had directors from all around the States talking about the steps that they would take?

---That's right.

Doctor, to Mr Sher you said that what you expressed in C10 of the plaintiff's folder, book 1 - the facts that you outlined in that document were true, and that the

opinions you expressed were honestly held, is that correct?---Yes, sir.

Can I just take you, Dr Leikola, to page 2 of the editorial that you wrote - to the third paragraph in the left-hand column where you say "By the end of April 1983, close to 1400 cases of AIDS had been reported to the authorities in the USA. In Canada the number of patients was 24, and a recent survey made by the Council of Europe revealed that the disease occurs in at least most, if not all of the 21 member countries. In Japan there are a few cases suspected of being AIDS, and some patients have been seen in Australia. There is no doubt that this is a worldwide problem and the World Health Organisation has responded to this challenge by arranging an international conference on AIDS in November of 1983" - - -?---Yes.

So as far as you were concerned in writing this editorial, you were talking about AIDS as a worldwide problem? ---That is correct.

A problem that affected not only the United States of America, but it affected the countries in Europe, it affected Australia and Japan - all around the world?---This was written in order to show that - that the disease is spreading all over the world.

The next paragraph, Doctor - you say: "How does this concern Blood Transfusion Services, blood bank directors, blood donor recruiters? There is relatively strong

evidence indicating that the disease may be transmitted by blood. In United States it's reported 11 haemophiliacs have contracted AIDS, and additional haemophiliacs with AIDS have been observed in Europe. There is a suspicion that commercial Factor 8 concentrate prepared from large pools of US plasma has been the source of infection." So what you're saying there is that as far as you were concerned, the evidence of transmission of AIDS by blood was quite strong?

---The possibility for that was quite strong, but it was not proven.

But being strong, steps had to be put into force to counter the possibility?---That's correct.

At that stage, Doctor, the main spread of AIDS had occurred in homosexual communities, had it not?---And drug abusers, yes.

But by comparison, if you like, homosexuals as a group were a far bigger group than the drug abusers?

---Homosexuals at large were a bigger group, but it was believed at that time that the homosexuals with multiple partners - the promiscuous homosexuals were the group at risk, and I cannot comment on the size of these groups as compared to each other.

Your first case of AIDS in Finland - it is reported, is it not, was as a consequence of a visit by a US homosexual?---I don't have any particulars of the source of infection of the first case in Finland. I know that that was a homosexual man.

You don't know or are unable to comment that it's reported in the literature I suggest that that US homosexual was responsible for the - or a US homosexual was responsible for the first case of AIDS in Finland?
---I have no evidence for that, that I could specifically quote, but I think that - that's a likely explanation for that.

You knew at least by May 1983, did you not, Doctor, that there was considered to be - and this was reported I suggest in the Washington leaflet you're spoken about of Red Cross blood transfusion experts - there was reported to be a link between the Sydney homosexual community, and the homosexual communities of San Francisco and Los Angeles?---I must say that - that I don't recall that particular aspect from - from the meeting we had, but I think that is very likely.

You see, Dr Beale, I suggest to you reported that to the meeting that you were at. Although you agree it's likely, you have no recollection of the report?
---I believe what you say is true.

You know Dr Beale quite well, do you not?---That's correct.

Have you taken over his position in Geneva?---Vice versa, sir.

I'm sorry?---Vice versa. He has taken my position in Geneva.

So, if that be the position, Dr Leikola, that there is that link between Sydney and San Francisco, and it was known about in 1983, that is something that you as a blood transfusion expert would see as being very

important as far as important knowledge for the people running the Blood Transfusion Service in Sydney?---From my point of view it would be important information, yes.

Because you were aware at that time that the risk of transmission of AIDS between homosexuals and as a blood born disease was something where you say the evidence was quite strong?---Yes, sir.

And so steps to go about in some way accounting for that problem had to be taken?---Mmm, that's true.

That problem of direct communication between a major city in Finland and San Franciso or Los Angeles, it's not a problem you had, is it?---Not to my knowledge even though I am not aware of the travel schedules of the Finnish homosexual.

It was something I suggest to you as far as Sydney and San Francisco is concerned, it was well known in 1983?

---I believe it was at least much better known than any Finnish connection with those cities.

If you, Dr Leikola, in 1983 were running the Red Cross Blood Transfusion Service in Sydney knowing of that problem, it's something that you would have addressed and addressed thoroughly, is it not?

---That is very difficult for me to comment, because I don't know the exact conditions in the Sydney population.

Were you aware, Dr Leikola, that the director of the Blood Transfusion Service in New South Wales in May 1983

expressed the view publicly that no homosexual should donate blood?---I know that he expressed that view, but I was not aware of the date.

It's a view that was expressed in your presence in October of 1983 by Dr Penington wasn't it?---That is probably true.

Because you attended the meeting or the executive sub-committee meeting of the National Blood Transfusion Service in Melbourne?---In October, yes.

At that meeting, Dr Leikola, Professor Penington was the chairman?---That is correct.

You had the directors of all the blood transfusion services right around Australia in attendance at that meeting?---They were all represented there, yes.

There were no treaters of haemophilia at that meeting were there?---I don't recall that.

Exhibit RX15 your Honour. Page 8.

HIS HONOUR: Do you want that shown to the witness?

MR RUSH: Yes, your Honour.

Do you see at page 8 Dr Leikola under the heading "Acquired Immune Deficiency Syndrome"?---Yes.

It starts of "The chairman briefly commented on some salient points relating to AIDS, which he had asked to be Minuted separated"?---Yes.

If you go to the third paragraph there and I'd ask you to - I'll read it to you, if you see about half way down the paragraph, the Minutes say "The disturbing fact was the increase in the USA of the syndrome amongst health care workers. Although it was acknowledged that some of these might be homosexuals this had not yet been ascertained with certainty. Despite the

fact that the Australian situation differed from that in the United States, it seemed wise to discourage all homosexuals from giving blood". You were at that meeting, weren't you Dr Leikola?

MR SHER: Your Honour, I'd ask that the witness be given an opportunity to read the whole of that paragraph, not just that part of it. There is other material on this very topic in that paragraph your Honour.

HIS HONOUR: What do you say Mr Rush?

MR RUSH: Your Honour, I'm cross-examining the witness and the specific point I want to take him to, in my submission, I put fairly to him, and it is the only point I wish to address with this witness.

HIS HONOUR: Yes, I'll permit the cross-examination.

MR RUSH: You see Dr Leikola, you were at that meeting weren't you?---Yes, sir.

That's what Professor Penington said to the meeting, isn't it?---This is what, according to this record, Professor Penington said to the meeting.

Do you recall him saying that?---I have no specific memories about this part of the statement he said seven years ago.

When it says that it was wise to discourage homosexuals from giving blood, all homosexuals from giving blood, that is wisdom that you would agree with, isn't it Dr Leikola?---I think he says here that it might be wise to discourage homosexuals from giving blood and it wasn't specifically stated, if I'm not mistaken

that all homosexuals - was it?

I think if you read it doctor, it says to "discourage all homosexuals from giving blood"?---I beg your pardon.

MR SHER: Your Honour, this is the very point I raised, and I raise the objection again. There is other material in this very paragraph and the witness is being mislead in my submission, if he is only being taken to a selected part of it, and I object to it happening in this fashion.

HIS HONOUR: Mr Sher, this is an exhibit which can be looked at by the jury and it - - -

MR SHER: It is not before the jury at the moment, your Honour.

HIS HONOUR: It can be referred to in addresses.

MR SHER: With respect your Honour, it is not answer to - that a witness is being mislead into a suggestion that this is all there is in this Minute about this topic. You don't have to look much further to see that there is something more. The suggestion is that this is all that was said, and it is misleading and it shouldn't be permitted. I object to it.

HIS HONOUR: You show me the paragraph. Take the copy from the witness, yes. I see what the time is. I'll have a look at it over lunch.

WITNESS STOOD DOWN

ADJOURNED AT 1.01 PM

situation was in Australia at the time, as distinct from Finland - that this was a proper step, and in my submission, to talk about my behaviour as though I've done something wrong, is a build up by my learned friend in an effort to create some sort of atmosphere that normal cross-examination and proper cross-examination is in some way to be regarded as not fair, as it affects this witness.

HIS HONOUR: Yes. I don't take the view that there's been any impropriety committed before me. I propose to take the course which seemed to me at lunch time to be the appropriate course - to ask the witness to return to the witness box and read the whole of the paragraph and then to permit cross-examination to continue. Bring in the jury and the witness may return to the witness box.

AT 2.28 PM THE JURY RETURNED TO COURT

JUHANI LEIKOLA:

HIS HONOUR: Doctor, on the page that is open in the folder to be handed to you - that's the page that was before you earlier when you were giving evidence - would you read in full the paragraph which starts with the words "To date" and ends with the words "Low risk group"? Do you see the paragraph I mean?---The third paragraph?

What are the first words in it?---"To date there has".

What does it end with?---"Low risk group."

Yes, just read that to yourself - - -?---Okay.

MR RUSH: Doctor, just so I can clarify one thing with you. You see where the sentence that I was directing you to commences in the middle of the paragraph - "Despite the fact that the Australian situation differs from that in the United States, it seemed wise to discourage all" - do you have the word "all" there?---Yes, sir, I do.

So if I can just read that to you. "Despite the fact that the Australian situation differed from that in the United States, it seemed wise to discourage all homosexuals from giving blood." The first thing I want to ask you is, was that said at the meeting, do you recall?---Would you repeat your question?

Was that said at the meeting, to your recollection, or words to that effect said?---I really cannot recall whether the word "all" was included or not.

Having regard, Doctor, to the Australian situation, that would've been a wise step, wouldn't it?---Regarding the situation, I think that what is said in this sentence was reflecting the mood of Professor Penington at that time.

It was a wise step, wasn't it, to exclude all homosexual donors, in the context of AIDS?---When it says that it seemed wise to discourage all homosexuals from giving blood, I think it seemed wise.

Wise in October of 1983 and wise back in May of 1983?---I beg your pardon, I don't understand?

I won't go on with that. Doctor, that wisdom of excluding all

homosexual donors is even strengthened when you consider that you are pooling plasma from the blood received into a pool containing thousands of donors, isn't it?---Mmm.

It's more important to have that exclusion when the plasma from that blood is being used to make pooled concentrate?---As far as the consequences are concerned, yes. But as far as the principle of exclusion, I don't think it makes any difference whether you are preparing large pool preparations or small pool preparations.

Because once you pool blood, the benefits of a volunteer supply, for instance, can be lost?---That is quite true.

Once you put - in the Australian context - once you put thousands of blood donations together, you're putting the good with the bad?---Evidently if you have bad in - to be included in that pool.

Doctor, you said in your evidence that you've had an association for a time in the late 1970s, in San Francisco, with the Irwin memorial Hospital?---That is correct.

And Dr Perkins at the Irwin Memorial Hospital?---That is correct.

And that, I take it, is an association that has continued throughout the decade of the 80s?---On and off, yes.

In your position with the Red Cross that you had in Geneva, I think you told Mr Gillies that you had an

opportunity to make observations of the methods of blood collection right around the world?---That is correct.

Included in that during that time, you made observations of what was going on in the United States?---In some parts of the United States, yes.

Does your expert knowledge, Doctor, in relation to blood collection procedures, go to what was being done in 1983 at the Irwin Memorial Hospital?---Not specifically there. I - I was mostly concerned about the American Red Cross and their blood services. Whatever I heard from Irwin Memorial - because that was an independent blood bank - that was much more casual.

Sorry, Doctor?---It was casual by meaning that if I happened to hear something from that, I had a special interest of knowing what was going on. Especially, I must say, in the field of literature.

What about in the field of the manner in which the Irwin Memorial Hospital went about screening their donors?---I had very little to do with any screening of donors, and these aspects were not particularly interesting to me, considering the background what I was doing there.

Were you aware doctor, of the American Association of Blood Banks?---I know that association.

Did you keep informed and in touch with what that association was recommending to its blood banks in relation to the exclusion of donors in 1983?---Not systematically, because I'm not a member of that association, but I saw some of their information.

That association is - its members are volunteer blood banks, are they not?---They are volunteer blood banks and individuals.

Are you aware of any recommendations as to that association, to its blood banks, as to whether donors should sign forms when they come in to donate blood?---They have made so many different recommendations that association, to all of its members, that I don't recall any specifics.

Doctor, you have spoken about cryo-precipitate and spoken about it in Finland, are you aware of - during 1983 and 1984, you were situated and lived in Switzerland?---That is correct.

Are you aware doctor, of the recommendations of the Haemophilia Advisory Board in Switzerland, in relation to the recommended use of small pool cryo-precipitate as opposed to concentrate?---I don't think I was aware of the details of that kind of recommendation, because I happened to be in Geneva, but just being in Geneva didn't mean that I had a particular interest in Switzerland.

So, you are unable to tell us what their recommendation was?---I'm not able to tell that, no.

Certainly, as far as your - the body, the International European Blood Transfusion Experts are concerned you are able to tell us that their recommendation as of 1983 - May of 1983 as I understand it, was that people or persons should - recommendation is to - "1. Expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factors products"?---That is true.

The reason for that is that the smaller the number of donations a recipient of blood is exposed to, the less chance he has of getting AIDS?---That is true.

As a general principle in medicine doctor, in 1983, exposing any recipient of blood products to as fewer donors as possible, was a proper and sound principle was it not?---That was a proper and sound principle and I think it still is.

Doctor, if I can just ask you one more question about homosexuals. Are you aware of a study that has been done, strangely enough you might think, comparing Australian homosexuals with Finnish homosexuals?---No. I must say that my knowledge about Finnish homosexuals as such is very limited.

Are you aware of a study which made a direct comparison between - in 1983 - it's made a direct comparison of homosexuals in Finland, and homosexuals in Australia that was published in the British Journal of Venereal Disease. It made a direct comparison as to education, social class, sexual partners per month? ---That may be true.

Did you read it do you think?---No, I don't think because I was not following the venereal literature of a scientific nature.

Just from your general knowledge of medical issues, Doctor. You'd be aware that as far as homosexuality is concerned, it doesn't occur in one class of people as opposed to any other class of people, does it? ---I don't think it bears any relevance to the class of people.

So when you talk about the down and outs, or when one talks about the down and outs that might be attracted to donate plasma to commercial plasma collectors, you can't be so direct or certain in relation to the type of person being homosexual that might donate blood to a Blood Transfusion Service?---I didn't quite understand your question.

There is on the one hand with the commercial collectors of plasma?---Yes.

Who are paid for their plasma, you might say on the one hand that they tend to attract people who are down and out, down on their circumstances. But on the other

hand where you're dealing with homosexuals you can't - you just don't confine them to a certain strata in society, do you?---I don't think that the paid or voluntary system makes any difference as far as the homosexual practices of the donors are concerned. However, I think that it does make a difference as far as drug addicts are concerned.

It's not different as far as the occurrence of AIDS caused by homosexuals is concerned though?---I beg your pardon?

There's no difference - if I can put it to you - there's no difference - I'll withdraw that. If I can put it to you this way. You're going to get people from all classes who are homosexual donating - - - ?---Yes.

Blood, aren't you?---Yes.

And whether it's commercial or not is irrelevant to the homosexuals donation of blood?---For the homosexual behaviour per se yes.

Doctor, you were asked about warnings and you were taken to the transfusion international in book 1, C16, and I'd just ask you if you could go back to that briefly, Doctor.

HIS HONOUR: Book 1, C16.

MR RUSH: Doctor, just - - - ?---I beg your pardon, which page?

Page 9?---Thank you.

These are recommendations of 23 June 1983?---That is correct.

Again, in the recommendation 2 if you like, and the first

one's taking necessary steps and measures with respect to AIDS, and in particular - and then the first recommendation repeats the - in essence what we're referred to about - to avoid coagulation factor products prepared from large plasma pools?

---That is correct.

Then the second, Doctor, is to inform the tending physicians and selective recipients such as haemophiliacs of the potential health hazards of haemotherapy, and the possibility of minimising these risks?---Yes.

So that is a recommendation, firstly, directed to physicians?---Yes.

Then recommended to the recipients of blood products?

MR GILLIES: Your Honour, I object to this line of questioning. It misstates the document completely, in our submission. It's not the first time it's happened. Could I take your Honour to - - -

HIS HONOUR: Mr Gillies, I had occasion a few minutes ago in the absence of the jury to reprimand counsel for making comments about fellow counsel and I make the same comment to you in the presence of the jury.

MR GILLIES: Yes, I should have remembered, your Honour, and I regret having done it. Your Honour, my learned friend has put to the witness that what the committee was doing was recommendations to physicians and selected recipients. The fact of the matter is the committee was making recommendations, not to physicians, but to governments of member States and we object to the questioning being along the lines of recommendation going directly to the information of attending physicians. It recommends to the governments of member States that they take all necessary steps, and in particular, the three specified steps.

HIS HONOUR: Yes. Well, on the background of what has just been said, I ask you to rephrase your question, Mr Rush.

MR RUSH: Doctor, Transfusion International, who gets it?---A

variety of Red Cross Societies, institutions, and individuals working in this field.

So every Red Cross Society or League in the world, is that - - -?---Every Red Cross Society in the world gets this publication, yes.

To physicians?---This goes to a number of physicians, yes.

What sort of physicians?---They are mostly involved in Blood Transfusion Services in the collection of blood and processing of blood.

What other people, apart from physicians?---They are, to my knowledge, mostly technologist and administrators who are working in blood banks but I don't have a complete profile of the readership of this little newsletter.

Why, Doctor, did you put recommendations that are directed to European governments in this magazine that was going to Red Cross Societies and physicians and technicians?---I think I had a very good reason of putting it here because I'd learnt through experience that many of these international recommendations that go to governments, they just go to their shelf of government official who thinks that when he has received this recommendation, he has done his duty and therefore, in two consecutive newsletters, we were trying to spread this information that it would be received by those ones who were really involved in this process and we did not rely completely in every country's information

system from the Ministry of Health down to the people concerned. Therefore, we made different approaches in order to try to keep this education going on.

By sending these recommendations to those people, Doctor, did you hope that they'd be acted upon?---We had a good hope that they would at least become aware of these recommendations that were being done in Europe and we were hoping that this would be a model for their further action.

When the Committee of Experts on - the European Committee of Experts on blood transfusion makes recommendations, are they solely for the purposes of government or are they for the type of people that you've just spoken about as well?---When the Committee of Experts make their recommendations, then that is intended mostly for professional people working in the field. However, when an official weight is placed upon this particular recommendation through the acceptance of the recommendation by the Council of Ministers, then we hope that we have another channel for this information to go to the right hands.

And so, Doctor, when the committee of experts made a recommendation - as I've read to you - there were four attending physicians and selected recipients such as haemophiliacs as potential health hazards of haemotherapy and the possibilities of minimising these risks, what were you intending to do? What was you aim?---This - the publication of this recommendation in this newsletter was aiming exactly at this, so that they would become aware of these facts.

What was the importance of informing physicians?---I think it was very important to inform the physicians that were treating haemophiliacs about different new aspects of blood products, and the risks involved in using blood products, and to - to get this message through to the people who were treating patients, both with coagulation factors and with cellular products.

Is that sort of recommendation distributed to the Red Cross in the various countries, something that you would look to the Red Cross in an individual country?---This recommendation was of course not a Red Cross recommendation, but it was a Council of Europe recommendation. It was made public in this newsletter in order to give this information, because it had news values.

But when you published the recommendation and put it in a magazine produced by the League of Red Cross

Societies, and the recommendation is to inform - under the heading AIDS - to inform attending physicians of possibilities of minimising the risks of AIDS. When the distribution involves International Red Cross Societies, as the editor was it your hope that they would act on the recommendations?

MR SHER: Your Honour, I object to that question. (Inaudible) can hardly bind any recipient, they're not to know what's in his mind.

HIS HONOUR: What do you say to that, Mr Rush?

MR RUSH: I put it strongly, your Honour. I put it that he was intending to - - -

MR SHER: That wouldn't make any difference. I'd object to that on the same basis.

HIS HONOUR: I uphold the objection.

MR RUSH: What was the purpose, Doctor, of sending this recommendation to the Australian Red Cross Society?

MR SHER: I object to that too, your Honour. It's just another way of trying to get an opinion from this witness as to what he would have liked to have happened, and unless that was communicated to the recipient it would have had no bearing on the matter whatsoever. I object to it, your Honour, as irrelevant.

HIS HONOUR: What do you say, Mr Rush?

MR RUSH: Your Honour, this is a document discovered by the Australian Red Cross. It's been put forward as a

document of the League of Red Cross Societies, and this man at the time holds a distinctly high position in the Red Cross. And in my submission having regard to his position in the Red Cross, and the fact that the Doctor firstly publishes it as the editor, and then directs it to International Societies, his purpose in doing that in my submission is material evidence.

HIS HONOUR: No, I regard that as to remote and peripheral, I uphold the objection.

MR RUSH: If your Honour pleases.

Doctor, in your evidence this morning you spoke about the - in the context of this document as being part of the education of specialists in this field, and haemophiliacs. You gave that answer to Mr Gillies in examination-in-chief. Could you explain what you mean by that?---Could you repeat the question?

Sir, you were taken to this document - - - ?---Yes.

By Mr Gillies in your evidence-in-chief, and Mr Gillies you might recall got you to read out that paragraph that I've just read out, and part of your - your answer in part you referred to - that you saw this as part of the education of specialists in this field, and with haemophiliacs, that's the note that I have of your evidence when you were asked about this recommendation?---That is true, sir.

Could you explain to us just what you mean by that - what you mean by the part of the education of specialists in this field and of haemophiliacs?---Well, specialists in this field get their information from different sources, and one of the sources are scientific journals. The handicap with scientific journals is that the information appears so late that they are reflecting time that may go six months up to one year before it is being published. Therefore these informal newsletters - they reflect what is going on in the field right now, because the delay in - in publishing these little pieces of news is so short, that - that we were hoping to give some impression to the readership what was going on, and as an example, this recommendation was then published.

When you say "we", Doctor, who are you talking about?---I was the editor of a chief, and I refer to the whole staff publishing this little newspaper.

Doctor, just putting that aside for the moment. As a general medical principle, do you accept that the doctor has a duty in relation to his patient to warn the patient of any potential risks in relation to treatment that the doctor may be giving the patient? ---That is true as a general principle.

Because the patient should be in a position to make an informed decision in relation to the treatment that's being offered to him?---That is correct.

Doctor, in relation to warnings, you said that you were not

aware of any warning in concentrate that was distributed in Europe during the period 1983 or 1984?---As far as the product labels or packages or the insert leaflets are concerned, yes, that is true.

Did you treat haemophiliacs?---No, sir.

Were you regularly in touch to look at the product, to look at the box, to look at the label, to look at the package insert?---Personally not, no, except for our own products.

The Finnish product?---That is correct.

But you weren't making concentrate in 83 or for most of 84, were you?---Not at that time, no.

Did you have any warnings on your cryo-precipitate?---No, sir, no.

Were there any warnings, to your knowledge, that were - let's start with the commercial concentrate that was distributed in Europe. Were there any warnings on the labels or the package inserts?---I cannot really answer that question, because I haven't seen all the packages and insert leaflets of all products in this field.

So there could've been a warning for hepatitis, but you're not really - because you haven't looked at it or looked for it - you're not really in a position to say?---I'm not really in the position of say, concerning all the products that are available in the world.

Your Honour, I'd ask that the witness be shown book 4, the

plaintiff's folder, at page 57.

HIS HONOUR: Yes.

MR RUSH: Doctor, that's a package insert which accompanied Factor 8 concentrate produced by the Commonwealth Serum Laboratories in February of 1984?---Yes.

Doctor, that's a package insert which accompanied Factor 8 concentrate, produced by the Commonwealth Serum Laboratories in February of 1984?---Yes.

If you go to the second column from the left, you see there, it says "Warning". I would ask you just to - perhaps, if you read from "Warning" over into the next (inaudible) and "Down for reports on use". Do you see that?---Yes.

Doctor, you see there at the top of the page in the right-hand column, it talks about the risk of transmitting hepatitis being still present, in the - - - ?---Yes.

Factor 8 concentrate. In the next paragraph it refers to the possibility of intravascular haemolysis?---Yes.

Were they, in your opinion, appropriate warnings in February of 1984?---I think they were appropriate and they are almost exactly the same ones that we gave to our concentrate when it became available in Finland.

You have told the court doctor, that it was your opinion by May of 1984, that there was a real possibility of this AIDS being blood transmitted?---That was a real - - -

83, I'm sorry?---That was a real possibility, yes.

It would have been proper, would it not, to have included in this document that you have before you, a warning in relation to AIDS?---Transmission of hepatitis was a very well established fact from the experience from many years behind that and the transmission of AIDS was a distinct possibility. I think that there is a

clear difference between these two risks as far as establishment of the real risk is concerned.

Doctor, one was established and one was new, wasn't it?---That was new and that was a possibility, yes.

As a warning, I suggest to you it would have been proper and having regard to the knowledge which you have spoken about, as it was proper to put intravascular haemolysis as a warning, it would have been proper to have warned of AIDS?---The intravascular haemolysis is also an established fact that had been put in these warnings already, long before.

Knowing about it, all the more reason to give a warning, but with AIDS, you have got something that is known about, known to be blood born. It should carry a warning shouldn't it doctor, this sort of document?---I think sir, that the means of getting the information to the treating doctors, who are really specialised, not only in haematology but in haemophilia care in general, that doesn't in general go through the leaflets or inserts of pharmaceutical products, but that goes through the scientific community and through the educational efforts that we are doing otherwise. So, I don't think that inclusion of a warning here, or leaving the warning out here, would eventually make very big difference for those specialists or are specialised in the treatment of haemophilia.

Doctor, you say that, but what about the patients where there

is a warning. Many of the medications and pharmaceuticals that were used in day-to-day life have warnings on them, don't they?---That is correct, but none of them warn about all the risks.

The pharmaceuticals we use in day-to-day life have warnings on the labels and on the packets?---That is correct concerning some risk factors, yes.

The warnings are there, not for the benefit of the doctors, but for the benefits also of those that are using it aren't they?---Yes, about some of the pharmaceuticals, yes.

Don't you think doctor, that the haemophiliacs that were using Factor 8 concentrate, at this time in 1984, had a right to be informed on the label or the packet of the concentrate as to the potential risk that was associated with AIDS?---The Haemophilia Society the Societies of patients themselves, were very clearly informed and that is a very special group of patients, that know each other and get their information through the societies. I don't think it would have made any big difference in the use of these concentrates that this warning would have been printed here or not.

But, Doctor, a manufacturer of a substance that a person is injecting into his body can't rely on what the person might have been told by the Haemophilia Society, can it?---No, but as I said before, all the risks are not mentioned in these inserts.

But, Doctor, if you look at warnings in the tiers, if you like, and you've got a tier perhaps with the doctor/patient relationship and you'd have a tier, a second tier and a second level of warning here, between the manufacturer and the patient if the warning's on the package label or the package box?---I would maintain that - that from the attending physician's point of view, these warnings that are printed in these leaflets, they play a minor role as compared to the scientific, technical and medical information that they are supposed to have received and keep on following.

But here, Doctor, we're dealing with a disease which is fatal, are we not?---I know.

That's all the more reason and all the more onus on a manufacturer and distributor to put a warning in relation to AIDS on his product, let's say, in March 1984?---This is something that I cannot comment.

Doctor, just in - a couple of questions on heat treatment - in 1984, I put to you that from your expert knowledge in Geneva, you would have known that every donor of plasma in West Germany that was - the plasma was

going to concentrate products was given the Hepatitis B core antibody test?---That is true.

The reason they were given that test was specific, wasn't it?---Yes, in Germany, yes.

The reason they were given that test is that their blood, if they were positive to the antibody, would not be accepted in the pool of blood for concentrate?---As far as hepatitis is concerned, yes.

Part of the reasoning in relation to every plasma donor for the concentrate pool in West Germany that was positive to hepatitis B being excluded is that it was seen as going to excluding donors that were high risk of AIDS?---That may be true.

Indeed, Dr Leikola, there's been a study in Finland, has there not, in relation to the effectiveness of the Hepatitis B core antibody test in relation to picking out the people at high risk for AIDS?---There have been some studies, yes.

One of the studies - do you know a Dr - you might have to help me - Suka Leesabale?---Yes, I know her.

How did the pronunciation go?---Close enough.

Are you aware of studies that she's done in relation to Hepatitis B core antibody as a surrogate test for AIDS?---I know some of her studies but certainly not all.

I want to read something to you, Doctor, to see if it concurs with your own view. "The present results emphasise the silent nature of Hepatitis B virus infection in

homosexual men as only 29.3 per cent of the infected men had clinical hepatitis. The history of Hepatitis B virus infection showed a weak association to HIV sero positivity whereas the overall prevalence of Hepatitis B core antibodies at the end of the study associated highly significantly with the HIV infection." Is that - or what I read to you concur with what you understand of the studies that have been done in Finland in relation to the Hepatitis B core antibody test being associated with - highly significantly - with HIV infection?---Your Honour, could I read the text?

Yes.

HIS HONOUR: Yes?---It is the part that has been emphasised by yellow - - -

MR RUSH: Feel happy to go to whatever part you like doctor, but I've underlined or marked the part that I read to you?---Thank you.

HIS HONOUR: Doctor you might read that over the break. The jury have a break of 15 minutes now. The jury can go to the jury room.

AT 3.12 PM THE JURY LEFT THE COURT

WITNESS STOOD DOWN

HIS HONOUR: Gentlemen, I enquire once again, I will each afternoon, is there any reason to revise the estimate that this case will finish by the end of the - the evidence will finish by November. Mr Stanley?

MR STANLEY: We've got nothing to add, your Honour.

HIS HONOUR: Mr Sher. Mr Barnard.

MR BARNARD: No your Honour, we still have only the one witness.

HIS HONOUR: Mr Sher, did you wish to put something?

MR SHER: Yes, your Honour, I'm a bit concerned about the line of questioning that was now just being pursued, it is not as though this witness is being asked his opinion. What my learned friend is trying to get in evidence is evidence of a study in Finland. That's not permissible. It is objectionable on a number of accounts, but your Honour, to merely ask a witness as this witness was, do you agree that that was the

HIS HONOUR: That would be a masterly saving of time. Bring back the jury I won't - is there something else you wanted to say.

MR RUSH: I'm not sure, your Honour. Would your Honour allow me - I'll adopt that course if it is acceptable, your Honour, otherwise I can - what I intended to do your Honour - - -

HIS HONOUR: I don't care - put it in your memoirs and I'll read them. Mr Sher?

MR SHER: That's an objectionable course. It can't possibly have any bearing on this witness' views as to what was appropriate in 83 and 84, that he read something published in 1986, apparently for the first time in 1990. It is just not relevant. It can only be a view expressed with the benefit of hindsight, and his evidence has been as to what his view was in 83 and 84. It can't possibly be influenced by something published two or three years later.

HIS HONOUR: I'll permit the question to be put. Bring back the jury.

AT 3.32 PM THE JURY RETURNED TO COURT

JUHANI LEIKOLA:

HIS HONOUR: Yes Mr Rush.

MR RUSH: Doctor, can I have the article back please. Doctor having read that article does it - you expressed a view to the court this morning that in 1983/84 you didn't think the hepatitis B core anti-body test was a valid test for AIDS. Having read that article, do

you change your view, or do you retain your view?---That is a very interesting piece of research what's been done there.

HIS HONOUR: Doctor, you don't need to go into any detail. Merely you answer as to whether you have changed your view or not as to what you said about the view you held in 1983/84?---Yes, your Honour. No, I haven't changed by view.

MR RUSH: Doctor, certainly in 1983/84, people held different views to you about the validity of the hepatitis B core anti-body test as a surrogate test for AIDS?---I'm sure there were different views, yes.

As we have referred to, there was that test adopted in West Germany for every one that was donating plasma to concentrate in West Germany. The hepatitis B core anti-body test was adopted?---I believe you are correct.

Doctor, the hepatitis B core anti-body test was also adopted in 1983 and 84 in some countries as a surrogate test for non-A, non-B hepatitis?---Yes, that is a different issue.

Was it adopted in Europe for that purpose?---For non-A, non-B hepatitis?

HIS HONOUR: Are you saying it was or was not?---If you are referring to 1983, I don't think it was introduced.

MR RUSH: What about 84?---I'm not quite sure about the years, but I do know it was instituted later on in some European countries.

It wasn't a specific test for non-A, non-B hepatitis, was it?---That is true.

But it was adopted because if you were positive for the hepatitis B core anti-body test, it was adopted as a - that was adopted and seen where it was used, as also a possible good surrogate test to see if you had the non-A, non-B?---As a surrogate test, yes.

Doctor, in relation to heat treatment - heat treatment's nothing new, is it, it's been used in albumen since 1948?---That is correct.

What about pasteurisation, Doctor - how long has that been known as a technique for eliminating virus, including retrovirus from blood?---Pasteurisation as a procedure has existed for a very long time for treatment of dairy products. It has been used for albumen preparation for a long time, but as such, what we call pasteurisation as far as I understand, has not been used as such for other blood products.

HIS HONOUR: Not used - you dropped your voice - for?---For treatment of blood products, other than albumen.

MR RUSH: Are you aware, Doctor, of the Bering Pharmaceutical Company?---I'm aware of that company, yes.

Did they make a product which was known as Haemate P - H-a-e-m-a-t-e P?---I'm not familiar with the product, but I know that they are producing Factor 8 concentrate.

Doctor, do you know when they produced a pasteurised Factor 8 product?---I don't know when.

I put to you, Doctor, that there was such a Factor 8 concentrate product in 1979 available in Europe - pasteurised Factor 8 concentrate product. Are you aware of that or do you know that?---Depends on the definition of pasteurisation. I believe that the heat treated product was available.

So there was a heat treated product available in 1979?---If

you say so - I was not aware of the year.

When do you think it was first available - heat treated product?---I don't know.

Doctor, you in 1975 until 1981 were employed as a Director of the Laboratory of Finnish Red Cross?---That is correct.

Then from 82 to 86 you were employed by the Red Cross in Geneva?---I had a leave of absence from my job in Finland, yes.

But you were with the Red Cross in Geneva?---I was there with the League of Red Cross and Red Crescent Societies in Geneva.

In Australia in 1983 you were visiting here as a guest of the Red Cross?---You may call me that way, yes.

And you were called here by the Commonwealth Serum Laboratories?---I did not visit Commonwealth Serum Laboratories at that time, no.

But Mr Gillies - you were here again in 1986, is that right? ---That is correct.

Why were you here then?---I was for the Red Cross group - group of Experts meeting in May 1986, followed by the Congress of the International Society of Blood Transfusion.

Did you come into contact with the Commonwealth Serum Laboratories then?---With Dr Shiff, yes.

How is it, Dr Leikola, that in geographically remote Finland - when were you approached to give evidence in this case?---Would you repeat your question?

When were you approached to give evidence in this case?---I believe I was approached in May this year.

Did someone see you, or what?---Later on in the following months I received one visit from Australia.

Who visited you?---There were four representatives, I believe, of the CSL in this case. That can be verified by people present here.

MR GILLIES: Your Honour, I want my learned friend to justify the relevance of that enquiry. It's something that escapes us - whether a witness can be taken through who's asked him to come. If my learned friend wants to develop and say "Someone got at you" or "Influenced your evidence" or "Have you come along to tell lies because of the approach?" - that would be a relevant line of enquiry. But in our submission, a simple enquiry about "Who invited you along?" and being left there, can be of no probative value at all.

HIS HONOUR: Well, I won't pursue this because I can see a number of ways in which if particular answers were given, it would be relevant. If other answers are given, it turns out not to be relevant. The evidence was given without objection and any further questions would need to be justified. I don't take the matter further.

MR RUSH: I have no further questions, your Honour.

MR GILLIES: That underlines the point, your Honour. That precisely underlines the point.

HIS HONOUR: Mr Gillies, counsel has to object before answers are given, not afterwards.

MR GILLIES: Well, your Honour, an objection to counsel cross-examining is only very sparingly made, in my submission, and one sits there assuming that a line of questioning is going to be made relevant rather than objecting to the question as it comes, and in our submission - and that's part of the licence allowed to the cross-examiner. Other examples exist, your Honour, questions, for example, of some witnesses in relation to whether their organisation has been sued falls into exactly the same category. In our submission, it's a matter of complete propriety on our part to assume that a line of questions is leading somewhere, and just as the question's asked of certain witnesses as to whether they've been sued left us in the air, likewise that last line of questions could only be regarded - - -

HIS HONOUR: Mr Gillies, this is taking time for no purpose at all. Often in cross-examination, questions are asked which produce nothing useful at all. Those latter questions fell in that category but one never knows until one knows the answer.

MR GILLIES: Yes, exactly right, but that's the point that we'd make. That's why - - -

HIS HONOUR: Mr Gillies, I don't wish to hear you further.

MR GILLIES: May it please your Honour.

HIS HONOUR: Yes, you may now re-examine - - -

MR GILLIES: I have no re-examination of the Doctor. If no one has any further questions of him, may he be excused, your Honour?

HIS HONOUR: Do the jury have any questions of Dr Leikola?

FOREMAN: No, your Honour.

HIS HONOUR: There's no objection to that application for excuse? You're excused, Doctor.

WITNESS WITHDREW

HIS HONOUR: Yes, Mr Gillies?

MR GILLIES: Your Honour, I am in a position to call in another witness but it's our preference that a legal ruling precede that. As your Honour will be aware, there is a debate going on before your Honour at this stage - - -

HIS HONOUR: And you'd be embarrassed in the presentation of your case if I didn't give the ruling before the next witness is called?

MR GILLIES: We wouldn't be sorely embarrassed but it is a