account that they had better control and better information of what the sexual habits were in Holland, what sort of practices were performed, and therefore which group should be excluded first, before the whole group would be excluded.

Again, I think in answer to Mr Stanley, you said that the homosexual representatives explained to you that there were differences in behaviour between the homosexuals in the Netherlands and those in the United States?---Yes.

Was that a matter that you took into account?---Yes, and it was in fact - it is reflected in fact in the brochure, because the initial intention of the blood transfusion people was to exclude all male homosexuals.

Your Honour, I have no further questions. I would seek to have Professor Van Arken excused, your Honour.

HIS HONOUR: Any particular question the jury would desire to ask the doctor before he leaves?

FOREMAN: No, your Honour.

HIS HONOUR: Very well, no objection. Yes, you're excused, Doctor.

WITNESS WITHDREW

SHELBY LEE DIETRICH, sworn:

EXAMINED BY MR SHER

MR SHER: Doctor, your full name is Shelby Lee Dietrich?

---Yes, it is.

That is spelt D-i-e-t-r-i-c-h?---Correct.

You reside at GRO-C

California?---Correct.

And you're a medical practitioner?---Correct.

Doctor, I'm sure if you want to be seated during the course of your evidence today and tomorrow - I expect you'll be there tomorrow - if His Honour wouldn't mind?

HIS HONOUR: Stand or sit according to your preference?---I'd be delighted, thank you.

Doctor, would you look at this document please. Does that set out in summary form details of your career and the like in the curriculum vitae?---Yes, it does.

I'll tender that if your Honour pleases as a general exhibit.

EXHIBIT RX9 ... Curriculum vitae of Dr S.L. Dietrich.

MR SHER: Doctor, I want to ask you some questions about your experience and qualifications. I won't go through the whole of this document, but just some of the more pertinent matters. You qualified from the Michigan Medical School in 1949?---That's correct.

With an MD?---An MD.

Have you practised medicine effectively since your graduation in 1949?---Yes, I have.

What are the fields in which you have practised since 1949?---First I had three years of paediatric training. Following the training I practised in the fields of paediatrics. Paediatric orthopaedics and haematology.

Paediatrics is concerned with children is that right?---That is correct.

You also mentioned that you practised in the field of haematology?---Yes. I do.

Do you still practise in that field?---Yes I do.

For how many years have you practised in the area of haematology?---Since 1957 which is 33 years.

In that time can you give us some idea of the numbers of haemophiliacs that you have treated as patients?---I have treated or consulted on I would estimate 4000

to 5000 haemophiliacs in that 33 years.

Have you held any hospital appointments which hospitals dealt with haemophiliacs?---From 1962 until 1988 I was Director of the Haemophilia Centre at the Orthopaedic Hospital in Los Angeles. Beginning in 1989, my colleagues and I formed another haemophilia centre and another hospital serving the greater Los Angeles area.

Is that in Pasadena?---That's in Pasadena, California.

Is Pasadena in effect, a suburb of Los Angeles?---In effect it is.

Doctor, in the - your present hospital what's the name of it?---The name of my present hospital is the Huntington Hospital, Pasadena, California.

How many haemophiliacs are treated at that hospital?---At our hospital, at this time we have approximately 200 haemophiliacs under care.

That's a hospital you have been one of the directors of since early 89?---Yes.

You mentioned the previous hospital in Los Angeles?---The previous one, yes.

What was the name of that hospital?---The name of that hospital where I spent 26 years was Orthopaedic Hospital, Los Angeles.

That dealt with - notwithstanding its name it had haemophiliacs as patients?---Notwithstanding the name it was one of the largest haemophilia centres in the United States.

How many patients at any one time, haemophiliacs, would be patients on an in or out-patient basis at that hospital?---At that hospital we had a total registration of approximately 400 to 450 haemophiliacs.

Have you been treating haemophiliacs in one way or another for the past 33 years?---Yes. I would like to add that during that three decades I have also treated a number of adults.

Apart from your practical experience as a physician treating haemophiliacs - I just don't want to ask about all of them. Do you hold some professional positions on organisations or bodies associated with haemophilia?---Yes. Beginning of 1979 until 1986 I was Chairman of the Medical Board of the World Federation of Haemophilia. Additionally, I have been one of the medical secretaries of the World Federation of Haemophilia until the present time.

And have you been since 1983 a director of the World Haemophilia AIDS Centre in Los Angeles, California? ---Yes, I have.

I just want you a little bit about the - in world bodies that you tell us - I like the way you use the word "chairman" if I may say. I hate to think what you might be called in this country, but in any event you've been the person in charge - - - ?---Yes, sir.

Now, what companies and members are the World Federation of Haemophilia?---There is approximately 60 member countries of the Federation of Haemophilia.

Yes?---Representing local - National Societies of Haemophiliacs.

Is the Australian - is Australia represented?---Yes, it is.

And can you tell us the name of the Australian representative? ---The executive director of the Australia Society is Mrs Jennifer Ross, and I don't know the name of the designated president or representative.

Is Dr Riccard from Sydney one of the people on that particular body, or have I got it confused with one of the other world bodies?---You're correct. Dr Riccard holds - is one of the medical secretaries.

By and large amongst these 60 countries in the world that are represented on this body, can you just give us an idea of where these countries come from, are they just in Europe or elsewhere?---Well, by and large these countries do span the globe, but most are in the developed world, although there are member

countries from the Middle East, from Africa and less - less developed areas.

Yes?---Europe, UK, America, South America, Australia, New Zealand, etcetera are all represented.

Now, do you, apart from those particular bodies, are you or have you been involved in any other groups or organisations which have some interest in the AIDS problem, particularly in relation to haemophiliacs? ---Yes, beginning in 1983 I became an investigator for the National Institutes of Health of the United States, specifically the National Health Lung and Blood Institute - one of the institutes of the National Institutes of Health - who initiated a very large multi centre study called the Transfusion Safety Study. For five years I was the director of the LA - Los Angeles - clinical centre component, and I am still an investigator for the Huntington Hospital, I have retired from my previous involvement to some degree.

Are you a member of the board of directors of the AIDS project in Los Angeles?---I have - I was a member for some years until I resigned.

Were you a member of the AIDS Ann Hop Committee of the American Academy of Paediatrics for sometime?---Yes, I was.

Doctor, in your hospital, either the one in the Orthopaedic hospital in Los Angeles or Huntington where you now are, are any of the haemophiliac patients HIV

positive?---The answer is, the majority of severe haemophilia A and B patients are HIV positive in both institutions.

And has that now been the case for some years?---Well, it has been the case since we were able to test and recognise their positivity.

When was that first able to be done?---The casting in the United States, that is the HIV antibody test was first licensed in 1985. We began testing in orthopaedic hospitals in the fall of 1985.

The fall - - - ?---The fall for us means September or October.

And you've discovered that many of your haemophiliac patients are HIV positive?---Yes, we did.

Can you give us an idea of what percentage of them are HIV positive?---Yes, Factor 8 efficient patients - the percentage, I believe, is between 80 and 90 per cent positive. Factor 9, 50 to 60 per cent positive.

Has anyone instituted legal proceedings against you or your hospital?---No.

Now, I want to ask you some questions about haemophiliacs and the way in which they're treated. You're familiar, I take it, with the methods of treatment of haemophiliacs?---Yes, I am.

Can you tell us when you first became aware of the existence of Factor 8 concentrate for use for haemophiliacs? ---I became aware of the development of Factor 8 concentrate about 1965, following the development of its predecessor, cryo-precipitate, and from 1965 on, the research was progressing in the US very rapidly on a lyophilised - that is a freeze dry concentrate.

Were you involved in your hospital in any of that research work?---Yes, we were.

Were you personally involved?---Yes, I personally administered some of that first Factor 8 concentrate.

Did you test it out and see how it worked?---Well, one has to test for both safety and therapeutic effectiveness, and that's what we did.

When did you do that?---During 66 and 67 until - and 1966 until - and seven - until the product was licensed

for commercial use.

When was that?---I believe it was licensed about January of 67.

Did you commence to use it as a haematologist treating haemophiliacs, from about then on?---We used it both in research and then in the commercial phase just as fast and just as much as we could procure it.

Why was that?---Because it represented such a tremendous advance in therapeutic effectiveness.

Would you elaborate on that for us?---Well, prior to concentrate, patients with haemophilia were treated with dried whole plasma. Because of local circumstances pertaining to Los Angeles, we were unable to use cryo-precipitate. So the availability of this freeze drying concentrate which was approximately 10 to 20 times concentrated in volume over freeze dried plasma, which was virtually ineffectual, represented one of the great moments in haemophilia treatment history.

When you talk about freeze dried plasma, are you talking about cryo-precipitate?---No, I'm not. No, there was an old fashioned product called lyophilised plasma.

HIS HONOUR: Sorry, I didn't get it?---I said lyophilised plasma - literally freeze dried whole plasma.

MR SHER: Had you been using the cryo-precipitate?---No, we did not use cryo-precipitate.

What, in the whole of the 33 years?---I don't mean in the whole of 33 years we didn't use it, but as a

therapeutic tool, we went from whole dried plasma to concentrate.

What are the advantages of concentrate?---The advantages of the ability to raise the deficient Factor 8 level from zero or one per cent to a normal, or at least a level high enough to achieve blood clotting or haemostasis, without drowning the patient in fluid.

Is this capable of being used by the patient himself or herself?---Yes.

All haemophiliacs are male, aren't they?---All classic Factor 8 haemophiliacs basically are male, yes.

I'd be sexist if I keep referring to them as him?---No, you wouldn't be, as I am the chairman. The - - -

What about this concept of home use?---As soon as the concentrate was available, it was clear that in the small volume and the advantage of practically no side effects such as hives (inaudible), and severe allergic reaction, that this could be used at home - at least we thought so at our hospital. So beginning in 1968 we offered the opportunity to certain young patients - older teenagers and young adults - to learn how to inject intravenously. The response was overwhelming.

What happened in your hospital in relation to your patients using concentrate? What was their reaction?---Their reaction was overwhelming enthusiasm to accept and utilise this means of treatment at home or at work.

Did you have patients who didn't like injecting themselves?---Yes, we did. We had - - -

How did you cope with that?---We coped with that by first trying to educate them, and if that failed and the patient truly did not want to participate, we simply had to have that patient continue to come to the hospital for treatment.

Did that go on - - -?---That's gone on even to this day.

What difference did you yourself notice, as a practising haematologist, to the matters such as lifestyle and life expectancy of haemophiliacs in the last 10 to 20 years since concentrate's been available?---Well, if I can address the second part first - - -

Yes?---The question of life expectancy and mortality, I did a study on age at death of haemophiliacs in Los Angeles county and presented this data at a meeting of the World Federation Haemophilia in 1975. Before concentrate, the average age at death in Los Angeles county of haemophiliacs was 14 years of age. After concentrate was widely introduced, the average age at death was 30, and I felt this was a dramatic change, statistically. On the lifestyle question, the person and even the child with haemophilia who was on home treatment, was free from the umbilical cord of dependence on the hospital, of constantly being within reasonable range of a hospital - I believe you say casualty or emergency room - or the treatment centre for relief of pain

and treatment - I mean, and for administration of the product. So the change in lifestyle was as dramatic as the change in the life as at the age of death.

Now, I want to come back to ask you some detailed questions about this topic in relation to development of knowledge about AIDS and its concept of becoming a blood - knowledge of it becoming blood born and the like - but if we can put that to one side for a minute, I just want to ask you what has happened in your hospitals in the last 10 years - that is to say, from 1980 to 1990, in relation to the use of concentrate, notwithstanding the AIDS epidemic - what in fact has happened in your hospital in relation to the use of concentrate in that period?---Well, in that decade overall, our use of concentrate has gradually risen. There was a dip or a decrease in the curve of usage around 1984 and then, especially with the advent of heat treated and other viruscytal treated concentrates, the use has risen although I don't think it will continue to rise, but we are - we have continued over that decade to use concentrate and to employ it.

Did you continue to use concentrate during 1982/83 and 84 before the AIDS virus was discovered by Dr Gallow and announced in April 84?---Yes, we did.

Did you continue to use it after that up until the time when the HIV antibody test became available?---Yes, we

did.

Now, I want to take you now to some other questions about your experience. Apart from practising as a haematologist for that period of time in Los Angeles, have you visited or attended places around the world and consulted with or addressed or conferred with other haematologists?---Yes, I have.

Could you give us some idea of your experiences in that regard, including any in this country?---I've visited United Kingdom, Canada, Australia, New Zealand, as well as attending the regularly scheduled meetings.

Yes?---And Singapore.

When did you come to this country for the first time in relation to your medical practice?---In 1982.

For what purpose did you come here?---I was the invited guest speaker for the annual meeting of the Australian Haemophilia Society.

Did you attend that meeting?---Yes, I did.

Did you address - - - ?---Yes.

While you were in Australia did you take the opportunity to visit places within this country that treated haemophiliacs?---Yes, I did.

Where did you go?---I visited the Royal Prince Alfred Hospital in Sydney, and the Alfred Hospital in Melbourne, and the Children's Hospital in Melbourne.

Did you meet some of the haematologists who practised at those places?---Yes, I did.

And exchanged notes with them about practice and the like? ---Yes, we did.

And was that in 1982?---It was in October 1982.

And was that - prior to this journey back - was that the only time you've been to this country?---No, I was in Sydney in 1989.

And for what reason were you there?---I was asked there to be a witness in the trial - in the case of the - - -

It doesn't matter about the name, but you gave evidence - - - ?---I gave evidence in the H case.

You were once of the expert witnesses called?---That's correct.

Now, Doctor, I want to take you if I might now to your knowledge as a practising haematologist about AIDS, and its affect upon haemophiliacs. Were you in the habit of exchanging information with fellow practitioners in California, and elsewhere in the United States about matters of interest to you in

your field of haematology?---Yes (inaudible) band or network of physicians were treating haemophiliacs and, we both formally and informally at frequent intervals in the United States.

Did you have discussions from time to time with haematologist throughout the United States?---At least from major centres, yes.

Was that happening in 80, 81, 82, 83, 84?---Yes.

And were you also weeding the medical journals of the day?

---Yes, I was.

What medical journals in particular did you - as a matter of habit - read in those days?---In those days I read as a matter of routine, Pictorial of the America Medical Association, the New England Journal of Medicine, two paediatric journals and a similarly latter card - or medical newsletter which was condemned for material.

Did you as a matter of habit before some reason arose to do so, read the MMWR?---No, I did not.

Did you commence to read that on a regular basis at sometime?

---Yes, I commenced to read it and subscribe to it in either December or January 19 - either December 1982 or January 1983.

Was there a reason for that?---Yes, because of the announcement in MMWR of the cases of AIDS in haemophiliacs, and I knew then - that being - roughly December 1982 that MMWR would be an important source of information.

Prior to that had you read it on any sort of regular basis?

---I don't believe so.

And as far as you were aware did most haematologists read the MMWR prior to sometime in 82, 83?---Well, not prior to my knowledge. It was something in the library.

Had you in 1982 had drawn to your attention an addition of the MMWR which reported three cases in the July - I think - 16 July 82 edition, three cases of AIDS in haemophiliacs in New York?---Yes, that was drawn to my attention.

Do you recall when that was?---I would say within two weeks after the publication - - -

Yes?---It was drawn to my attention.

And then in the December edition of the MMWR there was a report of four additional cases, and of a case concerning a 20 month year old infant?---20 month old infant - - -

What did I say - did I say 20 month year? I mean a 20 month old infant - did you read those?---Yes, I did.

Did you read in the New England Journal of Medicine in the January 13 1983 edition the editorial written by Dr Jane De Forge?---Yes, I did.

Now, I want to ask you a bit about each of those particular articles. Rather than you guess at anything, so that we can all follow it. Could the Doctor be given the plaintiff's folder number 1, your Honour - - -

HIS HONOUR: Yes.

MR SHER: Book 1, and when you get it I'd ask you to look under the heading "tab A6" which is the extract from the MMWR, 16 July 1982. Doctor, this is of course only an extract from it, but looking at that document now do you recognise it as containing a report of three cases of pneumocystis carinii pneumonia amongst three haemophilia A patients? I think they were all from New York - no they are not - one is from New York, one is from Denver Colorado, and the last one is from - - - ?---Ohio.

I beg your pardon?---Ohio.

This was drawn to your attention you have told us?---Yes, it was.

Was this the first time you, as a practising haematologist had had drawn to your attention any report in America of any infection of what was either AIDS or a precursor to AIDS of haemophiliacs?---This was the first notice I had.

Can you recall approximately when it was that you read this material?---It was published in July and I'm sure I read it within one to two weeks afterwards. I just can't - - -

What did it convey to you?---Well, it conveyed to me that something strange and new was going on and I was concerned and interested but I guess that's what it conveyed, concern and interest.

Did it indicate to you at the time that there was any need for you to change any of the practices that you, as a practising haematologist, were following with your patients?---No.

As far as you were aware did it cause any change with any other haematologists that you were aware of in California in their treatment of their patients?---No. Not in July of 1982.

Would you look at, at that same booklet - I'd like to take you to tab number 10 and tab number 11 which are both from I think the same edition of the MMWR. One tab 10 relates to a report on three heterosexual

haemophilia A patients that had been reported in July 82 and four additional heterosexual haemophilia A patients who had developed one or more opportunistic infections accompanied by in vitro evidence of cellular immune deficiency. That's under tab 10. Do you see that there?---Yes, I see.

The next one is the report of the - of a possible transfusion associated AIDS case from California, a 20 month old infant from San Francisco?---Yes.

You've told us they came to your attention?---Yes, sometime during the latter part of December.

You read them?---I read it.

What did these documents convey to you as a practising haematologist?---I guess these reports you have referred to simply increased the depth and degree of my interest and concern that a new syndrome was present, certainly in haemophiliacs. The one case report of the AIDS in an infant, I did not ascribe such importance to one - an isolated case report.

As a result of reading that material, did you change any of the practises you used to treat your patients?---No.

Can you look at tab 13 which is the Jane De Forge editorial in the New England Journal of Medicine of 13 January 1983?---Yes, I have it here.

Do you have it there?---Mmm.

Did you read that in early 83?---Yes, I read it.

And did you know of Dr De Forge?---I knew of her, yes.

What did you know of the doctor?---I knew that her involvement in and professional experience in haemophilia was somewhat academic and removed from clinical bedside care.

What did you think of the view that she expressed in that particular editorial?---My physician colleagues and I - we discussed this editorial - this is at orthopaedic hospital - because an editorial in the New England Journal of Medicine demands attention, and it was our - my opinion, shared by the others - that the recommendation that we use cryo-precipitate for treatment instead of concentrate was impractical and of no advantage and would in the - and would lead to greater morbidity in our patient group than continuing with our present practice.

Did you in substance agree with the views being expressed by Dr De Forge based on the material to which you referred in this editorial?---Well, no, we disagreed.

I'd like to take you to the editorial in Lancet that was published in April of 1983, and to get to that I think you might have to go to our documents. There was an editorial in Lancet written by Dr Peter Jones - it's tab 9 in the defendants documents.

HIS HONOUR: That's in book 2?

MR SHER: It's book 2, tab 9, and I don't think it appears in the actual document that it was written by Dr Jones,

but - - -?---It was my understanding that Dr Jones did write this, although he did not - - -

Doctor, that microphone is necessary because this is a court that is not famous for its acoustics, and you keep turning your head away - - -?---I'm sorry.

Now, looking at tab 9 of book 2 which has got an extract from this editorial from Lancet - did you read that? ---Yes, I - I neglected to add Lancet to my list of journals that I regularly read, I did read this.

So you read this at around about the time it was published? ---About two weeks later.

What was your belief as to who had written this particular editorial?---Well, it was my belief that it was Dr Peter Jones.

What do you say about whether or not you agreed with the views expressed in this editorial?---I agreed with the views expressed in this editorial.

Now, while you've got that book with you - can I ask you this. When you read in the MMWR about the four additional haemophilia AIDS cases and the one 20 month old infant transfusion case, did you discuss these matters amongst your colleagues?---Yes.

Did you learn from a colleague that the CCDC from Atlanta were having a conference in Atlanta in January of 1983? ---Yes, a colleague informed me that such a meeting was to be held, and further suggested that I should attend.

Did you?---And I did so.

Prior to going to that particular meeting, had you done anything else to try and find out what was going on about AIDS and haemophiliacs?---We - prior to the Atlanta meeting, which I believe was on January 5th 1983, we had a patient family meeting on the night of January 4th with a featured speaker being Dr Michael Gotlieb who is the physician who described pneumosystis - pneumonia is gay men - and we informed our patients that a new risk seemed to be present and we wished them to know of it, and that we were doing all we could to inform ourselves.

You mentioned Dr Gotlieb - he was known to you?---Yes.

Had you read some material he'd published in one of the medical journals?---Yes, he published the article in the December 81 New England Journal.

Now, this meeting that you had with your patients and this CDC meeting in January preceded the January 13th edition of the New England Journal of Medicine and Dr De Forge's editorial which came out on the 13th, apparently?---Yes, it preceded it.

You went to this meeting in Atlanta?---So, I went to the meeting in Atlanta.

Did you listen attentively to what was being said?---As attentively as one can listen who has been up all night. Yes, I listened very attentively. I was simply an observer. But there were representatives from numerous organisations present. The National Haemophilia Foundation which is the US haemophilia group. The - a Gay physicians group that I've forgotten the name of. Blood bankers. Epidemiologists. I guess that was in general.

Did you subsequently read in the Journal of the American Medical Association which I think is known as JAMA?---None as JAMA.

A report of that meeting in the edition of 4 February 1983, which I think you will find in the book you have in front of you under tab 2. Yes, I subsequently read that.

Have you read that article?---Yes, this is really a news report.

Is that a fair reflection of the sort of things that were said and the decisions or non-decisions made at that meeting?---Yes, it is a fair description.

How would you describe the concept of there being any consensus reached by the people present at that meeting as to what ought to be done?---I guess the best description I can give is that there was a consensus not to do anything radical at that time,

although the two major suggestions were put forth, one of donor screening and the other of so-called surrogate testing.

Did the meeting decide to introduce or recommend surrogate testing?---No. That meeting made no decisions at all and surrogate testing was not recommended.

What about donor screening?---Donor screening on a voluntary basis - may I just add a note of comment since Australia and the US are different. Voluntary donors come through the Red Cross and the local blood banks. Plasma donors generally come through a paid commercial system. The commercial paid plasma donor - fractionators decided they would begin to screen for high risk group membership. The voluntary blood sector, namely the Red Cross and all the associated community blood banks, did not institute such screening at that time.

Was any consensus reached by all those present at this meeting that donor screening should be introduced in relation to voluntary blood donations?---No. No consensus was reached. It was felt that direct questioning of voluntary donors regarding sexual preference was a violation of civil liberties.

You went back to California from this meeting in Atlanta?---Yes.

HIS HONOUR: Mr Sher, are you going to another subject?

MR SHER: I was just going to ask one more question.

HIS HONOUR: By all means.

MR SHER: As a result of that meeting was there any change in the practices that you followed at your hospital, by either you or any other of the haematologists in treating patients?---As a result of these developments we made two changes in our practise. The first was we deferred our suspended elective surgery in haemophiliacs. The second was that we put infants and small children up to the age of 4 whose parents would agree on cryo-precipitate and seldom treated patients and there was a third - there was a third change. We urged patients to treat haemorrhages at home, promptly but not to over use concentrate.

Just in relation to that there's one aspect of it I want to ask you tonight and that is this. Your decision to postpone elective surgery. For how long was that change in practise adhered to?---That was the adhered to that suspension for approximately three months.

What happened then?---In May of 1983 we resumed elective surgery on haemophiliacs.

And why was that?---We resumed it because the patients who wanted the surgery, wanted it very badly for orthopaedic reasons, quality of life and so forth. We had by that time been able to organise a small research study, so we could study these patients before and after surgery - study their immune systems. And thirdly, by May we had reached the conclusion that if any transmissible agent were present in concentrate, these heavily treated patients had already been exposed to it, so we might as well go ahead and operate on them.

If that's a convenient time?

HIS HONOUR: Yes, quarter past 10 tomorrow.

WITNESS STOOD DOWN

AT 4.16 PM THE MATTER WAS ADJOURNED
UNTIL THURSDAY, 4 OCTOBER 1990

SHELBY LEE DIETRICH:

MR SHER: Those documents that were put in yesterday - I think - Mr Wodak and I thought hadn't yet gone in absolutely, your Honour, I think they'd only gone in for identification, and it was intended clearly to put them in after Professor Van Aken - - -

HIS HONOUR: Yes.

MR SHER: They can be tendered absolutely.

HIS HONOUR: I will now admit them absolutely.

MR SHER: Dr Dietrich, yesterday evening when we adjourned I'd asked you some questions about what had happened at your hospital when you got back to California from the CDC meeting in Atlanta in early January, and you told us that there were three things that you implemented there, you put off elective surgery which you resumed in May. You cautioned patients against excessive use of concentrate, and you had put infants - small children - up to the age of four whose parents would agree, and seldom treated patients on cryo-precipitate?---Correct.

Now, what happened in relation to the group of patients, the infants and small children up to four whose parents had agreed - which you put on cryo-precipitate - did they stay on it?---No, they did not remain on cryo-precipitate. As soon as heat treated concentrate - Factor 8 concentrate - was available in sufficient

quantity we changed those children to heat treated concentrate.

Do you recall when it was that the heat treated concentrate became available - insufficient quantity?---In November and December 1984 it became available enough to treat that particular group.

Was there a problem in treating infants and small children with cryo-precipitate as opposed to the use of concentrate?---Yes, there is a problem - a difficulty. Cryo-precipitate can only be administered at the hospital number one, and some of those children were actually already on home treatment. Secondly, there is a waiting period while cryo-precipitate is stored for the infant. Thirdly, the volume is much greater than using the equivalent dose of concentrate, and keeping a needle in the vein of a small wiggly infant or chubby toddler is an extremely difficult proposition. We actually had one step of parents who walked out of the emergency room, they got so disgusted over the process.

But notwithstanding what you had learnt by January 83, and what you learnt thereafter you put children back onto - you keep them on cryo-precipitate up until late 84?---Correct.

And what about the seldom treated patients. What did you actually mean by seldom treated patients?---Well, there is a group of Factor 8 deficient patients

whose Factor 8 levels are in the borderline range and who require treatment only in cases of surgery or emergencies - major problems. So, they may have been treated one or two times in their lifetime, that's a seldom treated patient.

So they were put on the cryo-precipitate?---They were put on cryo-precipitate too.

Apart from the infants and the children that you have mentioned and these seldom treated patients, what did you do with all the rest of your patients, who up until January when you went to this meeting, had been on concentrate?---We remained on concentrate.

What percentage of the 400 to 450 patients at the hospital would therefore have remained on concentrate?---About two thirds. Two thirds of our group were severe Factor 8/9 deficient.

These questions arose as a consequence of me asking you about going to this meeting at Atlanta and what you heard at that meeting, these decisions that you have told us about that were implemented at the orthopaedic hospital, were they just yours or were they arrived at following discussion with colleagues at the hospital?---These decisions were arrived at in two ways. Discussion with my colleagues and information through the Medical and Scientific Advisory Council of the National Haemophilia Foundation who sent out frequent bulletins and these recommendations in general were their recommendations.

So, you were guided by the recommendations of the National Haemophilia Association?---To a great deal however not completely.

What was in this period - let's take 1983, what was the reaction of the haemophiliacs to the suggest that

they should change their treatment from concentrate onto something like cryo-precipitate?---Well, only a very small number of our patients on concentrate requested cryo-precipitate. I would say the number must be less than 10 per cent. It was a handful. If they requested, we exceeded. The remainder of the patients remained on concentrate although a significant number reduced their actual use of concentrate.

You told us how in January I think the day before you went to Atlanta you had had this meeting with patients and parents of patients?---Yes, sir.

You'd discussed with me I take it what you'd picked up through the literature and what you had learnt from speaking to colleagues about this problem with AIDS and haemophilia?---Yes.

Did you have other discussions of that nature from time to time with patients or parents of patients?---Approximately every three to four months we had a similar meeting of that group and we would bring them up to date on the most recent developments which we knew about.

Where were you getting the concentrate from in this period, 83/84?---All from manufacturers in the US. We bought from each supplier.

We you aware also that the Red Cross were making blood products in the US?---Well, I'd - let me explain, the Red Cross doesn't make blood products. The Red

Cross sends what's called recovered plasma or excess plasma to one of the fractionators who then makes it into Factor 8 concentrate.

What was your understanding as to the American Red Cross' donor base. Was it paid, un-paid, voluntary?---By Federal regulation the donor base is all voluntary.

What about the fractionators, the commercial producers?---The commercial producers pay their donors.

You continued to use then in 83/84 commercially produced Factor 8 concentrate obtained from paid donors?---Correct.

Were you aware in that period whether or not there was any warning given by the commercial producers as to any risk about AIDS in the - either in their packages or in package inserts?---The package insert is a set of you know, written warnings and information about concentrate and I don't believe during that time I read a package insert.

How did you regard the package inserts?---As a necessary piece of paper which the Federal Government demanded.

Did it have any affect upon you?---No.

Did you need to read it to know what the dangers were in relation to - - -?---No, I don't look to the package insert in concentrate for information.

Did you ever show the package inserts to any of your patients?---All patients who took concentrate home had the package insert and whether they read it or not, I don't know. We didn't show it to them.

What do you say as to whether or not you regarded it as necessary for the providers of the concentrate, whoever it was, themselves to give warnings to patients?---We would consider that to be an unwarranted intrusion into the physician/patient relationship.

Whose obligation do you think it was to give warnings, if any warnings were necessary, to patients?---I consider it the obligation of the medical staff, including physicians and nurses.

What did you do about that at your hospital?---That's exactly what we did. Our patients were counselled about the new problem by the nursing and physician staff and all questions were encouraged and answered.

As far as you were aware, did any manufacturer or distributor of concentrate in the US in 83/84 communicate warnings by word of mouth to patients?---By word of mouth, it's difficult to know. I don't believe that

any manufacturer's salesman representative would have been so bold, but I'm sure they answered questions.

What about any written warnings?---No written warnings - there were these bulletins sent to physicians from the National Haemophilia Foundation but not directly to patients.

As far as you were aware, was the American Red Cross - although they weren't actually producing concentrate, but they were producing the material that went in the concentrate - were they giving warnings to patients?---No, I'm quite definite about that. The Red Cross has no direct relationship to the consumer, that is, the haemophiliac or the blood recipient.

I want to take you back to the literature, without taking you right through it, in 83/84 to get - so you can tell the jury what you, as a practising haematologist with all these patients, gleaned from it and what you did about it. Did you keep up reading the literature in 83/84 concerning - - - ?---Yes, I did.

Concerning AIDS?---Yes.

Whatever was causing it?---Yes.

Whether it was blood borne and the like?---Of the speculations, I certainly was well aware of.

When did you come to the view that the evidence was sufficient to justify the conclusion that there was in fact a blood born transmissible agent which caused

AIDS?---About January or February 1984, I became aware and at least to myself believed that this was a blood born agent.

Did you know of Professor Montenier or Doctor Montenier from France?---I did not - I did know of him when I heard him speak in Paris in February 1984.

You went to a meeting that he addressed?---Yes, there was a meeting in Paris, France, and he was one of the speakers.

Did he speak about his discoveries in relation to the LAV?---Yes, he did.

What was your reaction to what he said at that meeting as to whether he had in fact discovered the agent which caused AIDS?---Well, my reaction was this was enormously interesting and full of possibilities but he, in the meeting where I heard him speak, he spoke about two patients, and I simply felt this was the beginning perhaps of unravelling this whole mystery but not by no means proven or the link made between what was called AIDS and this virus.

Are you familiar with Dr Gallow's work?---Yes, I'm familiar with it.

And I take it you heard about results of his work announced and published in about April or May of 1984?---Yes.

What was your view in relation to that work?---Well, my view in relation to that work was and is that he had established the link between the virus he called then HTLV3, now called HIV, and the syndrome called AIDS because of his biologic work and his epidemiologic antibody test.

Now, Doctor, during 1983 and 84 leading up to Dr Gallow's publications of his results, you've mentioned already that there were theories and speculation about the cause of AIDS?---Yes, there were.

Would you tell us what you regarded as the theories and the like during that period?

HIS HONOUR: Mr Sher, I missed the date that you mentioned.

MR SHER: 1983 up until 84 when Dr Gallow's work was published.

HIS HONOUR: Thank you.

WITNESS: In relation to haemophiliacs, the following theories were current. One was that the protein and concentrate and cryo had caused immune suppression and made the patient susceptible therefore to immune disfunction or weakening, and there is a lot of protein in those products. The second theory was that there was another virus - a common virus called cytomegalovirus, or CMV for short - which almost all of us have had, which is transmitted in blood, and that something was happening to activate this virus

and cause the immune system problem. The third theory was that there was some genetic susceptibility which haemophiliacs had. The fourth theory didn't quite apply to haemophiliacs, but it was that gay males had immune suppression from the proteins in semen that didn't really apply to the haemophilia group. I believe those were the current theories and combinations of those theories.

MR SHER: Did you regard the question of what was causing AIDS and how it was transmitted, as being settled in the medical debate during 1983?---Far from being settled, in the latter part of 1983 my colleagues and I wrote a big grant proposal to explore all kinds of variables about transmission. Now, it was - I would say, completely unsettled, at least in our minds.

During 1983 and 1984 in America there were people suggesting the adoption of some form of surrogate testing, in the light of the fact that nobody really knew what was causing AIDS and how it was transmitted?

---That's correct.

Were you aware of those suggestions?---Yes, I was aware of those suggestions.

What were the popular surrogate tests that were suggested during that time?---For donors?

Yes?---The popular surrogate tests suggested were a liver enzyme called ALT and Hepatitis B core antibody, and then a third one which really received very little

enthusiasm, was T-cell subsets.

Let's deal with each of those. Do you know who the proponents were of the first of those surrogate tests?---Well, ALT and Hepatitis B core antibody went together, and there were many proponents of that among epidemiologists.

Was any such surrogate test adopted, to your knowledge, in the USA?---In late - in sometime in 1984 - the date I'm not sure - the blood bank in San Francisco adopted ALT and Hepatitis B core testing.

Was there any official adoption of any surrogate testing in the USA?---No, there was no official adoption or regulation regarding surrogate testing until approximately three years later for hepatitis.

What about the people that were supplying your hospital with concentrate. As far as you were aware, were they using surrogate testing?---Those would be the blood bank fractionators, and at some point - the time which I don't know, but I believe it's 1986 - they began the use of ALT as a surrogate test for hepatitis non A non B.

Were they using any surrogate testing that you were aware of in 1983 and 1984?---No.

And you still use their product?---Yes.

Now, what about the T-4/T-8 cell ratio test. Do you know Professor Engleman of Stanford?---I know of Professor Engleman.

And do you know that he was a proponent of such a test?---Yes, I was aware of that.

What do you say about the ethicise of such a surrogate test?

---As a surrogate test for blood donors I believe that test to lack in both sensitivity and specificity, and those two qualities lacking lead to many false positives, and false negatives. So, my conclusion that test was useless and non standardised.

Would you just elaborate a little further on that. What in your view was wrong with it?---Well, first of all the technology was very very new, and subject to a great deal of laboratory variability from one day to the next. The four major problems at least were T-cell testing, and we're talking about mass testing here. One is variations in the individual being tested from stress, even sunburn, time of day the specimen's drawn, mild inner current infections like flu or a cold or something benign, so we have variations in the individual. Then there are variations in the laboratory, in the machine used in the technician skill, and so forth. Then there is

difficulty in establishing normal standards, and normal ranges, and there's enormous difficulty - in fact I consider it absolutely impossible to screen a donor on the basis of one determination.

In your view was that a useful test to be adopted?---As a surrogate test, no.

And were you aware of anyone apart from Professor Engleman in 1983 who used such a test?---I'm not aware of anyone else.

What about 84, do you know of anyone apart from Professor Engleman that used such a test?---Not to my knowledge.

And was it adopted as far as you knew officially by anyone? ---Not to my knowledge.

Was it a test that was being used as far as you were aware by the manufacturers of the concentrate that you used in your hospital?---No.

Now, in your opinion was there any efficacious surrogate test that could have been used to screen donors in 83 and 84 prior to the discovery of HIV?---In my opinion there was no effective surrogate test to the level that would be necessary for both sensitivity and specificity available until the antibody test for HIV.

When the antibody was actually - when the virus was actually discovered to peoples satisfaction in 1984 by Dr Gallow, was it immediately accepted in American that that was the cause of AIDS, or was there still

some debate?---There has been debate which continues even to the present, but the - - -

HIS HONOUR: Did you say until the present?---Until the present. I would say the scientific community accepted his work however in a proportion of over 90 per cent to a small minority.

MR SHER: Once the virus had been identified - I think it's common ground - that work commenced a pace to develop tests to detect it?---That's correct, yes.

And to your recollection when was that test licensed and available in American?---The test was licensed in the latter part of March 1985.

Before March 85 in the US were tests available on an unofficial basis to try and find the antibody to HIV in donors?---They were available through certain researchers on a somewhat informal basis.

When was it adopted by the organisations collecting blood for use in concentrate, or any other blood product in the US?---It was phased in - the Red Cross - the voluntary blood sector began in Los Angeles - I can only address that really accurately - they began the end of March testing all donors.

Which year?---End of March 1985, and the fractionators also began at the same time, but again there is a phasing period.

You happen to mention in passing in one of your answers just a few moments ago the concept of the voluntary donor. In the US you've told us the fractionators who made

the concentrate used paid donors, that the Red Cross who also collected blood, and some of which went on to be used in fractionation, is voluntary donors?---Yes.

What's your view about the desirability of having firstly voluntary donors to provide a basis for making blood products?---That is a question that's difficult to be black and white about.

In an ideal world all donors should be voluntary but the US is not ideal and is very large and the availability of paid donors gave us, the treaters, and the patients a very adequate and affordable supply of concentrate. So, I accepted that as a product of capitalism.

What about the concept of being self-sufficient in your own country as distinct from having to rely upon imported blood products what do you say as to that as to a desirable objective?---I think again ideally that is desirable but I have also seen in countries where haemophiliacs have a shortage of therapeutic products of concentrate, because there isn't enough plasma, and not enough donors and when I see an individual who needs surgery and can't have it, then I have to wonder if I think that system is ideal.

Are you aware of the fact - perhaps I should withdraw that because I'll be accused of leading you if I put it the way I was going to - what is your understanding of the Australian scene?---My understanding of the Australian situation was based on my visit here in 1982. I knew the voluntary system and the concentrate production system in general terms and in - perhaps I should stop there.

What do you say as to whether it would - as to the safety of a blood donation system like Australia had in 83/84, compared with the one in your own country?---Specifically I thought the Australian blood system was safe in 1983 and early 84. In fact, so safe because of the voluntary donor that the organisation of the Transfusion Safety Study which I referred to yesterday, had selected Australia as well as Finland and Portugal to be control study countries for the study we intended to do in the United States. I had in fact had arranged for our contacts with Dr Riccard in Sydney about that study.

What was that study going to do?---Well the study did study the natural history of AIDS in recipients of blood and blood components and concentrate.

What period of time are you talking about when this study was proposed and you were considering using Australia and Finland and Portugal?---The first organising meetings for the study began in April and May 1983. In the summer - that is I should say July of 1983, I made the contact with Dr Riccard and on through the successive months we were in contact with Australia, Portugal and Finland about the organisation of the study.

I want to go back about asking you a few questions about concentrate and the need of the haemophiliac. How serious to a person is having haemophilia?---I

didn't understand you - - -

How serious a disease or condition is it?---To have severe haemophilia?

Yes?---Well, it is life threatening without treatment. Prior to concentrate we had a very high mortality rate.

How important is it to a haemophiliac to get treatment quickly?---It is very important to get treatment very promptly.

What are the consequences of delaying treatment?---The consequences of delaying treatment can be grouped under the crippling problems of bleeding into joints with more and more destruction to the joint and of course pain and, in the case of internal bleeding, delay in treatment can lead to death.

How important is concentrate to cope with these sort of problems?---The concentrate was vital to cope with these problems.

As compared with cryo-precipitate, are there advantages?---The advantages are the fact that most severe patients of our group, when they had these problems, could treat themselves at home and then come to the hospital, or even be treated at the scene of a car accident, as contrasted with cryo which took time to thaw, to mix, so forth.

How important was it to have an adequate supply of concentrate?---Well, I consider it extremely important. I've been through concentrate shortages and they are very difficult to deal with and they do lead to increased morbidity and maybe mortality.

Is that a sort of a constant worry for a haematologist, the adequacy of the supply?---Yes, we had a shortage in 1988 and early 89. At the moment, we have - that is not a concern in the United States, but any haematologist, I think it'd be a constant worry. It's like not enough money in the bank account.

You can't die from not enough money though, can you?---No, but

you - I agree.

Now, Doctor, did you have some incidents that took place in your hospital during the AIDS scare, before it was known what caused AIDS and heat treated concentrate became available, so you were forced to use the concentrate that may have been infected, with patients concerned about those risks and not using concentrate?---The first of these incidents was memorable. After the January 1983 meeting and a subsequent meeting, when we had informed patients of what we knew and how little we really knew, a young boy age 18, whom I had cared for from many, many years struck his - - -

MR RUSH: Your Honour, if I may object at this stage? I recall when I was leading Dr Gatenby through his evidence and attempted to elicit patient histories from Dr Gatenby and my learned friend, Mr Sher, objected on the basis that the patient histories were at best hearsay and not permissible.

MR SHER: This is not hearsay.

MR RUSH: It appears to me that, at this stage, Mr Sher is attempting to elicit in the same manner a patient history from this doctor.

HIS HONOUR: Yes, Mr Sher, it will be necessary for you to make clear the sources of information to which you are directing the attention of the witness.

MR SHER: I want you to speak of your own knowledge?---This is my own knowledge, this was my patient - - -

HIS HONOUR: And making it clear, in order to meet the objection, that the doctor is speaking not of histories given to her.

MR SHER: Doctor, I want you just to tell us and only tell us what you know yourself from your own knowledge what happened with this patient and not what you were told by anyone about this patient?---This is my - - -

HIS HONOUR: Including not what she was told by the patient - the patient's views - - -

MR SHER: Well, your Honour, you'll find out when the story is told that - - -

HIS HONOUR: Beg your pardon?

MR SHER: There's no chance of that - - -

HIS HONOUR: Yes.

MR SHER: Would you just tell us what you know, solely of your own knowledge, of what happened to this particular patient?---Yes, the mother of the patient called me that he was unconscious and I immediately directed her to have him transported to the nearest hospital. They lived about 100 miles - or more than 100 kilometres from Los Angeles. On arrival at the hospital, he lived only a few hours and died of a severe head bleed.

Had he been taking concentrate or had he switched to cryo-precipitate - that patient?---He had been on concentrate because of the great distance and I questioned the mother after - - -

Just a moment - - -?---Sorry.

This is the part that I don't think you are allowed to tell us. As far as you were aware, had he been using concentrate prior to this particular incident?---No.

HIS HONOUR: He had not been using - - - ?---He had not been - yes, sir.

MR SHER: What effect did this have upon the way in which you conducted your practice in the hospital - this particular incident?---This particular incident caused us to reinform and re-educate patients and emphasise the importance of early treatment.

I'll just take you - if I might - to the recommendations of the haemophilia - National Haemophilia Association, which is in one of these booklets - if you'll just pardon me a moment and I'll find it. Could Dr Dietrich be shown, your Honour, 2B of the defendant's publication book under tab B1, the Haemophilia News Bulletin of 11 May 1983?

HIS HONOUR: Yes, book 2B, B1.

MR SHER: Doctor, if you look at that document which is a haemophilia newsnote from the National Haemophilia Foundation from New York, urging people to maintain the use of clotting factor - it says in the first paragraph: "The NHF has recently recognised and is concerned about the fact that public media coverage of AIDS is causing some patients to abandon appropriate use of blood products because they fear contracting AIDS. The NHF AIDS Taskforce considers this to be an inappropriate response and urges haemophiliacs to maintain the use of clotting factor in their treatment of haemorrhagic" - - -?

---(Inaudible).

"Episodes." Were you familiar with that particular recommendation?---Yes.

Was that the medicine you practised at your hospital?---Yes.

Was that the advice that you gave to your patients?---That was.

Did you regard that as appropriate advice?---Yes, I did.

Notwithstanding what was then known about AIDS and the possibility that it was transmissible through blood and might be in the Factor 8 concentrate?---Notwithstanding, the benefits of treatment outweighed the risks.

Doctor, I want to ask you something about what was done in America in relation to the screening of donors. In March of 1983 the Red Cross and the blood banks and

the like introduced the voluntary screening of donors, including homosexuals with multiple partners, and the document setting that out - if you could be handed the plaintiff's folder, and it's set out in the Transfusion magazine in book 1 under tab A28. Do you have before you an extract from Transfusion, March/April 1983?---Yes, I do.

That's an American publication, is it not?---Yes, it is.

Is that one of the publications you read?---No.

Did you have access to it?---I had access to it.

It refers to a joint statement that was made by the American Association of Blood Banks, the American Red Cross, the Council of Community Blood Centres, with assistance from the American Blood Commission, the National Gay Taskforce, the National Haemophilia Foundation and representatives from the American Blood Resources Association, the Centres for Disease Control and the Food and Drug Administration. So it's a pretty big team of advisers there. Were you familiar with this series of suggestions that apparently emanated in January of 1983?---Yes, these are the formal - this is the formal report and recommendations that really emanated from the January 1983 meeting.

Did you conduct your practice in your hospital in Los Angeles in the knowledge that these recommendations had been made by this body?---Yes.

Then in March 1983 the blood banks and the like announced publicly that there were screening the voluntary donors to their organisations, and the screening is on a voluntary basis and directed towards amongst the homosexual population, those with multiple partners. Were you aware of that?---I was aware of that.

Now, firstly, what was your understanding in 1983 at about that time of what the homosexual population constituted as a risk group?---Well, I think I had rather limited understanding of that whole risk group. I was aware after the January 1983 meeting of factors in the gay community leading to sexual promiscuity, and my impression was that multiple partners lead to increased risk of infections.

What was your view as to whether April and March 83 in American was appropriate to ban homosexuals with multiple partners - not ban but voluntary screen then?---Screen - my idea was that this seemed appropriate though - from a realistic point of view - I thought it was probably going to be ineffectual.

What about all homosexuals at that particular time, was it your view that they ought to have been screened out?---I didn't have that view. I - I - information

I had - and I have to repeat it, was culturally very limited - was that - was homosexuals with multiple partners who represented the risk.

Did you think the screening was going to work?---No, I didn't.

Why is that?---Because I practised medicine a long time, and people don't tell the truth either for reasons of voluntary or involuntary motivation.

What else did you think could be done other than to screen people out, and try and get them to disqualify themselves?---I didn't think anything could be done more than that until a blood test - a serologic test - the HIV antibody test became available.

Now, I want to take you Doctor to another topic. Doctor, you've told us that a large number, I think you put it as high as 80 to 90 per cent of your severe haemophiliac patients are HIV positive?---That's correct.

Have patients of yours at either the hospital you're at until the end of 88, the beginning of 89 and the present hospital developed AIDS?---Yes, they have.

And have you been responsible for treating them?---I've been responsible for supervising the medical and nursing staff that treated them.

Have you followed the development of the medical science in recent years in relation to the treatment of people who develop AIDS?---Yes, I have.

And haemophiliacs?---Yes.

And the drugs and that, that is available?---Yes.

You no doubt heard and used the drug AZT?---Yes.

Are there other drugs that you're using at your hospital?---AZT is the licensed drug for use. We are in - we are using a chemical relative of AZT called DDI only on a limited protocol basis, and then we use other drugs to prevent the infections.

You've told us that some of your patients have gone from HIV positive to AIDS?---That's correct.

I assume some of them have died?---Correct.

Have you been provided with a copy of the T-cell count of Mr PQ?---Yes, I have.

Just to make sure we are talking about the same document just refresh your memory on this document if you wouldn't mind. Page 55 in the plaintiff's folder book 4, your Honour.

HIS HONOUR: Book 4, page 55.

MR SHER: That T-cell count analysis we are told is the T-cell count of Mr PQ?---I understand.

You've had that sent to you in America?---I have had that sent to me.

You have looked at it?---I've looked at it.

You have actually chartered it yourself and - to see what picture it shows?---Yes, I did that.

What comment do you make about those T-cells counts?---I think the first comment I would make is the extreme variability of the - of both the T-4 and the T-8 counts. They go up and they go down. There is a gradual downward drift but any one individual determination seems to be somewhat erratic.

That's your first comment. Is there any other comment you would make about them at the moment?---I noticed when I graph this out which is more easily apparent than I a sheet of paper like this that is T-suppressors, which are the T-8 cells showed quite a

rise at one point and that is a biologic response to HIV infection and the T-4 cells showed extreme variability perhaps due to the factors I have already mentioned.

How accurate are these T-cell counts in your experience?---Any one determination, that is at one point in time, if one is going to make a therapeutic decision you have to repeat it. Sometimes we even repeat it twice before making a therapeutic decision. On accuracy I would assume these to be accurate counts for this laboratory because I am not - acquainted with the laboratory but I am assuming it is a standard, high quality laboratory. So that's - one just has to view these results over time.

Assuming these were T-cells counts of a patient of yours. I want you to assume that this is a patient of yours a 45 year old male in your hospital and you have got this material before you, what would you be doing with him?---On that assumption, directing attention to the T-cell results of August 1989, when the T-4s, CD4 they are marked here, were 230 we would have repeated that. If that result was still the same at that point we would have started this patient on AZT.

People have talked in this court about the side effects of AZT. What do you say about - in your experience, about the side effects of AZT?---At the high dose which was 200 milligrams, six times daily or 1200

milligrams, side effects were quite frequent. Consisting usually of anaemia. At the lower dose we are now using, the lower dose is 100 milligrams, five times daily or less than half of that higher dose, we have encountered minimal side effects and have had to switch patients from AZT to DDI I believe only two patients so far, out of a total of nearly 50.

You would have then started this patient, assuming the test in August 89 was where his CD4 count was 230 was confirmed onto AZT at that stage?---Yes, because in August 89, or perhaps September, we got the information from the AZT study that was done in the USA, that low dose AZT was effective in - what's the words I want - not preventing but delaying, the onset of AIDS very effective and that AZT should be instituted when the T-cells drop below 500. We began that policy about August or September 89.

So that's why you picked that date rather than because of the CD4?---That's right, I picked that date.

I assume it follows from that that you'd have him on AZT now? ---That's correct.

What would you expect to happen if you put him onto it now? ---I would expect that if he had been on AZT from August or September 89 - - -

Well, he hasn't?---He hasn't - you mean now? Sorry.

I asked you to make the assumption that he gets put onto it now?---I'm sorry, I misunderstood. On that assumption, I would expect that he would - pardon me. I can't answer that question accurately unless I know his general physical condition.

Let's just leave that for a moment. If you're trying to work out the prognosis of a haemophiliac who's got HIV positive tests, apart from T-cell counts, are there other tests you can give?---Yes. We do a battery of tests for treatment and prognostic purposes - the general physical exam I refer to - a complete blood count, including the platelets, and the P24 antigen test which is a test of HIV activity in the blood, it's different from antibody. P24 - which is one of the viral products - antigen is present early in the disease and then very late, as the disease progresses.

With all that battery of tests, you'd have much better information and a better idea of what the prognosis of the patient would be?---That's correct.

I want you to assume for the purpose of my next question that the only P24 antigen test that's been conducted was negative - - -?---All right.

His general health is reasonable, and that he has these T-cell counts - the most recent of which in July of this year was on that document - and you were to put him now onto AZT?---All right.

MR STANLEY: When was the test done, P24?

MR SHER: I don't know. The only evidence is that at some stage he had a P24 antigen test and it was negative. That's the only evidence we have, all right?---All right.

Now, let's take those factors - you've got a 45 year old male, reasonable general health, living at home and working full time with wife and two children, he's got T-cell counts as set out in that document - the only P24 antigen test that he's ever had - and I can't tell you when it was - was negative, but if he's your patient now, you're going to put him onto AZT. What do you think his prognosis would be?---I think his prognosis, given all those circumstances, is for at least two to four years more of reasonable health. The reason I say that is based on our patient experience and the other factors and all the assumptions that I'm giving the answer on - that he's now in reasonable health and his blood count and platelets are reasonable too - in other words, he is showing decline on this - T-4s, but his immune system is functioning.

Well, if he stays in reasonable health for another two to four years, are you aware that there is massive work going on at the moment trying to find drugs to treat AIDS or vaccines or cures, or whatever?---Yes, I am well aware.

Is that going on in your country?---That's going on in our country.

Are multi millions being spent on it?---Yes, it is.

What's your objective with your patients?---Our objective of treatment with our patients, all summed up, is to - is twofold. To buy time and to improve or maintain present quality of life.

I suppose the hope, if it's no more than that, that within the time that you buy, something will develop as a result of all the research?---Yes, a better anti viral drug, better drugs or vaccines, whatever.

When you say that the prognosis here is two to four years, are you assuming AZT therapy?---Yes, I'm assuming AZT therapy.

What would happen after that period?---To prognosticate on one patient is really very difficult, but after that period I would expect minor infections to appear, such as shingles or herpes (inaudible), candidiasis, other minor opportunistic problems, and those can be treated, but after four years - which would be 10 years after sero conversion - I would then be prepared for more serious infections such as pneumocystis.

Are there drugs available to treat that?---Pneumocystis?

Yes?---Pentamedene and a combination drug called Bactrim in the USA.

That's all I wanted to ask about that subject. Would your Honour just pardon me a moment?

HIS HONOUR: Yes.

MR SHER: Now, I just want to ask you some questions, Dr Dietrich, about hepatitis and haemophiliacs. What's been your experience in relation to the use of the concentrates causing haemophiliacs to develop hepatitis?---Well, our experiences reflects everyone else's experience that approximately 80 to 90 per cent of haemophiliacs treated with concentrates show evidence of Hepatitis B infection, evidence from blood tests. A significant number, not quite as high, but perhaps half of haemophiliacs show evidence of infection with what is now called Hepatitis C, previously called non A non B.

Notwithstanding those discoveries, did people stop using the concentrate?---No, people did not stop using concentrate but the awareness of these problems led to the development of heat treated concentrate.

When was that - when was heat treated concentrate for the hepatitis problem developed and available?---It was developed and - - -

If you don't - - -?---I'm sorry.

I don't blame you but it's hard to stay still in one spot, but every time you move away from the microphone, it

sort of - you go off the air?---Sorry - on the air. The heat treatment was developed in Europe. In 82, I believe, it was available. There was a great deal of pressure from the European physicians treating haemophilia to do something about hepatitis, so it was developed - I mean heat treated concentrate - and then it was licensed in the United States in the spring of 1983 and available, but in very limited amount.

That's about May 83, is it - April/May?---I'm sorry - May 83, yes.

It became available in limited amounts?---Very limited.

What was that heat treatment directed towards?---Directed toward hepatitis.

Yes, was - - -?---Hepatitis B and hopefully non A non B.

When did it become freely available?---Actually it did not become freely available until January/February 1985.

What about heat treated concentrate directed towards the AIDS virus?---Well, after Dr Gallow's discoveries of April 1984, the CDC in Atlanta, during this period of June/July/August 1984, did some experiments and they actually used the LAV virus but it's the same, I think, and they spiked concentrate with the LAV virus and then heated it and they found that heat treatment destroyed the virus. So in September 1984, the CDC, at an invitational meeting, announced these results which led to a recommendation in October 1984 that heat treated concentrate was preferable.

Did it start to become available after that date?---It - it started to become available, but the manufacturers had to shift over their manufacturing, the FDA had to approve it, so some months ensued before it was widely available.

Was the heat treated concentrate directed towards the AIDS virus heat treated the same way as the concentrate that had been heat treated directed towards hepatitis?---Initially, yes.

Initially, what happened subsequently?---Well, the initial heat treatment varied from - from among the four manufacturers. There was wet heat treatment called pasteurisation, and there was dry heat treatment. The CDC's experiments were on dry heat treatment, and appeared to be very effective. Subsequently dry heat treatment at the temperature and time initially used proved not to be completely adequate, again HIV, and that development however did not occur until 1987.

Initially when heat treatment was used in relation to concentrate, did it have effect upon the potency of the concentrate, and on the Factor 8?---It had effect on the amount of Factor 8 that could be recovered from the plasma. The heat treatment broke down the protein to such a degree that one could recover from the plasma, the raw material, only 50 per cent or less of the Factor 8 that was in there.

When did your hospital start to use heat concentrate as a

matter of course for your patients?---After I attended the CDC meeting in September my next move was for us to attempt to buy all the heat treated concentrate we could.

That's September 84?---That was really November 84.

Now, I just want to take you back to just a few other matters that arose out your chairmanship of the medical board of the World Federation of Haemophilia. Did that body have a conference in Stockholm, Sweden in July 1983?---Yes, it did.

Were you involved in organisation of that conference?---I organised the running of the medical board for that conference.

What was the conference directed towards?---Well, the conference overall had many topics, but the medical board focused on this problem then called AIDS.

Yes?---And in preparation I corresponded with physicians in many parts of the world asking - asking those physicians if they'd had cases called AIDS, and informing them we would discuss the problem at the Stockholm meeting.

Did in fact a discussion take place at that meeting?---Yes, a very interesting discussion did take place, and at that point in July 83 we actually tabulated about 20 cases of so called AIDS from other countries, and

- - -

This is haemophiliacs?---This is all in haemophiliacs.

Yes?---Yes, and discussed the matter.

Can you recall at that stage how many cases they'd been in the USA?---In July 1983, I think they'd been 20 or 30.

And were medical practitioners from around the world at this conference?---Yes, haematologists.

Haematologists?---Right.

And when you went back to your country and your hospital in July, August 83, you had the knowledge that you'd gained at this particular conference in July 83 in Stockholm?---Yes.

And were other colleagues of yours from your hospital at that conference, or were you the only representative there?---I was the only - I was the only representative there.

I want you to assume that the steps taken in the USA in March of 83 to introduce a voluntary screening of donors, in so far as homosexuals are concerned - homosexuals with multiple partners - was introduced in Australia in like form in about June, that is to say about three months later. What is your view as to the reasonableness of that conduct bearing in mind that Australia had, to your knowledge a self-contained voluntary system?---Your reasonableness seems reasonable. I don't know that I had any reaction to that one way or the other. I felt that if the US was doing it, it was appropriate for other countries to do it.

You had this somewhat cynical view about whether it would work at all?---I had that same cynical view about wherever it was introduced.

Could you think of anything else that could have been done at that time?---I can not think of anything else.

HIS HONOUR: Mr Barnard?

CROSS EXAMINATION BY MR BARNARD:

MR BARNARD: Doctor, you were asked a moment ago about the Stockholm conference in July of 1983. Do you recollect that Dr Sawers from the Alfred Hospital was present at that conference?---No. I don't.

There were no doubt a lot of people present there?---I didn't understand you.

There were a lot of people attended that conference?---There were something like 700 or 800.

You have met Dr Sawers at conferences over the years, have you not?---Yes, I have.

You just don't remember whether he was at that one or not?---Correct.

You spoke in answering questions about the De Forge editorial that the need for bed side experience. May I ask you to expand on that. Why is it necessary to have experience when one is dealing with haemophiliacs?---It enables one to put problems in perspective. I think that's the most important asset of bed side experience. Judgment is enhanced. Text books can give answers to things but only bed side experience gives wisdom and judgment.

Is it correct that the condition of haemophilia is very variable in the way it effects people?---Would you repeat that. I am having trouble understanding you.

Is it correct that the way in which haemophilia effects people is very variable?---No. It is not true exactly. Severe haemophiliacs with less than 1 per cent Factor 8 in general tend to have similar problems and similar bleeds.

You spoke of telling Mr Sher of the importance of getting treatment quickly. You spoke delay could cause bleeding problems in the joints?---Yes.

How severe can those problems become?---They can become severely severe as measured by pain and crippling. They are not life threatening.

When you say crippling what in fact happens?---The joint is

destroyed by the blood in the joint and the cartilage and the bone actually erode away.

Of course, what does that mean for the person suffering from such a condition?---I brings greatly increased morbidity, decreased function and decreased ability to perform daily activities of living.

Now, do all severe haemophiliacs have a risk in relation to a bleed that occurs inside their cranium?---Yes.

What's that risk?---Well, that risk is death, primarily, and secondly, severe brain damage.

If a haemophiliac suffers, for example, pain behind an eye when there's no explanation for it, is that something that causes great concern?---Great concern. That's called a retro-orbital bleed.

What could be happening?---Well, that could be - that can endanger the vision in the eye and it also might indicate a bleed within the head itself, within the cranium.

What about in the abdomen, can bleeds occur there?---In the abdomen, did you say?

Yes?---Yes, bleeds occur there, either within the abdominal cavity, which is called retroperotineal, or even within the gastro intestinal tract.

How serious can those bleeds be?---Those can range from death mortality to extreme blood loss. They can be very severe - there is a range problem there.

Can you predict with any particular patient that they're not going to have these serious bleeds in the head or in the abdomen?---You cannot predict with any patient whose laboratory value you know is severe - less than one per cent.

Doctor, I want to just tell you something about the plaintiff in this case. He was born in June of 1945 and the diagnosis of haemophilia was made at the Melbourne

Children's Hospital in February of 1946, following abnormal bleeding after circumcision. He was first seen by a Dr Sawers during the course research in 1953. At the age of 16 months he'd had severe nose bleeding, and at the age of five he had bleeding into his right knee joints and into the muscles of his right thigh. Before seeing Dr Sawers in the course of research in 1953, he experienced multiple episodes of bleeding into many of the (inaudible) joints, into his soft tissues, muscles and skin, and from his gums. Now, is there significance of somebody having bleeding at that early age in a haemophiliac?---It sounds characteristic to me of severe haemophilia.

When Dr Sawers saw him in 1953 he carried out blood tests in glass tubes, when he found that the plasma clotting time was extremely prolonged as compared with normal, but it could be corrected by the normal human plasma when treated with Barium Sulphate, but could not be corrected by plasma stored at room temperature over 14 days. Is that consistent with severe haemophilia?---Yes, that's also the technology of 1953.

It's changed now?---Yes.

If I could tell you also that he then came under Dr Sawers care in 1953 at the Alfred Hospital where he was treated for decaying teeth - - -?---For what?

Decaying teeth, he had tooth problems - - -?---Mmm.

He had bleeding into his ankle joints at that stage, and in fact at that time his problems with his ankles were such that he had to be put in callipers. He thereafter attended at the Alfred Hospital from when he commenced there in 1954 until 1984, between 350 and 400 times. The majority of these attendances were for bleeding into the joints - I think it was 260 attendances - bleeding into the muscle soft tissue and of course he had tooth extractions, and as is typical of a severe haemophiliac, his episodes of bleeding usually caused swelling of the joints, stiffness, great disability, pain and often pain of great severity. All of these attendances involved treatment with blood or blood products. That's the sort of history that relates to a severe haemophiliac?---Yes, it is.

In fact he did at one stage have one episode of severe paralysis of his right leg which lasted for two years as a result of bleeding into a muscle at the rear of his abdomen in the right (inaudible) muscle?---That's retroperitoneal.

That's - is that something that severe haemophiliacs tend to get?---Yes, it is.

He did have of course permanent damages to his joints, and I think for example, one of the more severe joints was the right knee which - as early as 1972 - was reported - 1973 was reported (inaudible) and logically to suffer gross destruction of the joint surface with locking. The recurrent bleeding into his joints became more frequent, and it affected cartilages and tissues and they became - I think is described - as target joints?---Target joints.

Do you know that term?---Yes, I do.

What do you understand that to mean, Doctor?---It's a term used to mean that an individual bleeds into particular joints more than other joints, and that's the worst joint or joints for that individual. That joint's the target of the bleeding.

On a number of occasions he had to be given intravenous Fortral on visits to the casualty?---Intravenous what?

Fortral, you don't know it - - - ?---No.

It probably has another name - to kill pain?---To kill pain.

An analgesic. His visits in 1983 were 53 visits to the

hospital. In other words the rate of visits - the frequency of attendance during 1953 increased - sorry - 1983 increased. The history factor following that was so far as specific areas were concerned, that he had a manipulation of the right knee and elbow joints in September 1984. He went on to have a synovectomy of the right elbow in 1985, the knee joint was eventually replaced in November 1988, and when that was replaced his ankles flared up again. Doctor, in 1984 - perhaps I should first ask you - does all that history seem to you to be consistent with a severe haemophiliac?---Yes.

In 1974 he was first offered home therapy on concentrate?---I understand.

What would you say as to the appropriateness of that at that time?---I'd call that highly appropriate for a patient with that kind of history.

Incidentally, you commenced your home therapy in the 70s, did you?---We commenced in 1968.

When was it that you first produced concentrate?---1967.

You didn't have the concentrate - O1 concentrate in the 19 - earlier than that?---No.

And when was it that you first started using cryo-precipitate? ---We never did use cryo-precipitate to any degree, except for von Willebrand's patients, and for very mild haemophiliacs.

Perhaps I should ask you in relation to the cryo-precipitate. When - so the jury might understand the difficulty

of using it - the plasma is in the bag, is that so?

---There is a frozen sludge in a plastic bag.

And that's frozen - - - ?---That's kept frozen.

At temperatures what, below minus 20?---Below minus 20, yes.

So that when you come to use it, if the patient were to use it at home, he has to take that out of the freezer?---And thaw it.

And thaw it?---Thaw it, yes.

He doesn't take that straight from that bag, it has to go into a transfusion bag, does it not?---Well, usually we pool the several bags. An adult would require 10 to 20 of those bags so we thaw it and we put it all in one bag for transfusion.

But to put it in one bag, there are problems with sterility, is that not so?---Yes, there are - there can be.

So that you can control that problem of sterility in a hospital but with greater difficulty with that if you have a patient doing it in their own home, is that so?---Well, we believe that.

Of course, the thawing is a process that has to be carried out carefully?---Yes, very carefully. If you thaw too fast, you destroy the Factor 8.

Is it a procedure that takes a long time?---It can take at least an hour to - or more - to thaw and prepare 10 to 20 bags.

Do you agree that because of the risks involved in it, that it's not appropriate for home therapy to use the cryo-precipitate?---Yes, there's one other risk and that's severe allergic reactions, and all that put together, we never consider cryo-precipitate for home use.

How quickly does the allergic reaction occur?---It can occur

almost instantly. I mean, within a few minutes of the administration.

Is it so that a patient can be on cryo-precipitate for a long time and then, despite the fact that they've never had an allergic reaction before from one batch of - or one bag of blood, they may get that allergic reaction?---It's unpredictable and that can occur.

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

MR BARNARD: Yes, your Honour.

HIS HONOUR: Jury, go to the jury room for 15 minutes.

AT 11.37 AM THE JURY LEFT THE COURT

HIS HONOUR: You may leave the witness box, Doctor, and either remain in court or leave the court if you choose?---Thank you.

WITNESS STOOD DOWN

HIS HONOUR: Mr Barnard, is it convenient for you to resume your submission?

MR BARNARD: Yes, if your Honour pleases. If your Honour pleases, I could inform your Honour and my learned friends that my learned friends may learn from an article that has been published in the New South Wales Bar News, "Managing the Long Civil Trial" by Young J. Perhaps your Honour will have the opportunity of writing a sequel to it?

HIS HONOUR: Is that the one that was delivered in Darwin in July?

MR BARNARD: 10 July, your Honour.

HIS HONOUR: Yes, I heard that paper.

MR BARNARD: Yes. Hand a copy to Mr Wodak so that he - - -

HIS HONOUR: Yes.

MR BARNARD: If your Honour pleases, I was raising with your Honour the authorities in relation to this matter and we submit that looking at these authorities do indicate the problems that are associated with documents being put - themselves being put before the jury, and we submit that the fact that these problems, although found in other areas, do also occur when documents are put in to indicate the state of knowledge. The difficulty here, your Honour, being that the articles that have been selected have been selected by the plaintiff's or the party's legal advisers and, even beyond that, your Honour, the plaintiff here has tendered articles which have been highlighted which is really the legal advisers view of the relevant part of that article and is not, in our submission, what it ought to be - the expert view of the meaning of that article. The - - -

HIS HONOUR: Both the plaintiff's and the defendants documents have been highlighted.

MR BARNARD: I think they have your Honour but not necessarily by all defendants, your Honour. The difficulty about it is your Honour that as has been demonstrated, that the experts don't always accept that highlighting as indicating the true meaning of the, what the article says.

I was about to refer your Honour to H and another, the Schering Chemicals and another. That's S-c-h-e-r-i-n-g. Reported in 1983. 1 All England Reports 849 at 853. Where in the particular passage there is, your Honour, a considerable discussion about the admissibility of the documents under legislation and under Supreme Court rules. It was an action brought against the defendants who are a pharmaceutical company for personal injuries alleging negligence in the manufacture of a drug. The plaintiffs applied for an order allowing them to adduce as evidence in the action, copies of documents consisting of summaries of the results of research into the drug and articles and letters about the drug published in medical journals. After dealing with the Civil Evidence Act 1968 and the rules of the Supreme Court the judge, Bingham J, when on at page 853 to discuss any other basis for admission. He said at the bottom of that page:

> Accordingly I feel unable in
>
> . . . . . (reads) . . . . .
>
> shown to be proper.

That goes on to be a later authority supporting the views expressed by Professor Baker in his book. There is also your Honour a later reference to the same principle. In the Federal Commissioner of Taxation and Hamersley Iron [1980] 33 ALR at page 251. Particularly at page 273 where the discussion takes place.

This is the judgment of Gobbo J, where he says:

There were a number of other

. . . . . (reads) . . . . .

by the company and others.

It's perhaps unfortunate that His Honour didn't consider the question of usage - that's perhaps more comparable to what's involved in this case here, but he left that open. He did have regard to the text books, he followed the principles which were accepted and laid down by Professor Bacon.

Now, your Honour, what we say in relation to this matter - and I don't want to labour it - is simply this, that what the state of medical knowledge was at a particular time is a matter of expert evidence, and we say in that expert evidence the expert can rely upon and get support - and even quote from learned medical journals - and in doing so, indicate what they are and even read them - incorporate them in his evidence. But in our submission, your Honour, not only should they not be tendered, but most certainly they can't have any evidentiary value of their own.

Your Honour, perhaps another example I should tell your Honour about is the case, your Honour, of Haughian, I think it is. H-a-u-g-h-i-a-n and Paine - P-a-i-n-e. It's reported in 1986 volume 46 of the Suscatuan Reports at page 186. It's a useful example, your Honour, because here they were seeking

to rely on what's set out - we would describe here as inserts, your Honour.

HIS HONOUR: Yes.

MR BARNARD: Which one would be tendering as evidence of notice being given. At page 193, under the heading "Oxicell and Surgical Package Information as Evidence".

HIS HONOUR: This was a case in which proceedings were being taken in respect of a drug, the drug having - - -

MR BARNARD: A product your Honour, yes.

HIS HONOUR: Caused deleterious results, yes.

MR BARNARD: There Walker J says:

> There are in evidence with
>
> . . . . . (reads) . . . . .
>
> reasons for writing. In Wigmore - - -

He quotes Wigmore's discussion of the scope and policy of the exception your Honour, and I think that's been quoted elsewhere. He goes on to say "What are the reasons". He then appears still to be quoting from Wigmore when he studies the reasons. Then he goes on to say:

> This seems as close as
>
> . . . . . (reads) . . . . .
>
> new light on the exception - - -

He refers to Owries, another Canadian case - - -

> Has cast a new light
>
> . . . . . (reads) . . . . .
>
> exaggerate assuming the legal - - -

HIS HONOUR: What was that last sentence "I am not satisfied"?

MR BARNARD: Yes your Honour.

I am not satisfied that there

. . . . . (reads) . . . . .

evidence in themselves.

Your Honour, that is an entirely different sort of example, but what one may say your Honour, taking a medical article, and we can take the De Forge editorial, the value of that could not be determined by a judge or a jury. It has to be looked at just like the present witnesses looked at it and said, well it is an academic with no bedside experience. Of course, looking at the article on one's own the jury or the judge is just quite incapable of bringing that expert knowledge and experience to bear in interpreting the value of that article.

Your Honour, when one has a mass of conflicting articles, and confused articles where one has to decide whether that provides any - what basis of knowledge for a profession. In our submission, in the absence of some expertise it would be wrong to conclude that a jury is entitled to make up there own mind in relation to that matter.

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

MR BARNARD: Your Honour, I was only going to add a further sentence - - -

HIS HONOUR: By all means. We'll have a further - - -

MR BARNARD: The very great significance of this, your Honour, if this is the correct view of the uses that can be made of these articles, it becomes alarming to think - or in fact - possible to understand how the Oxford Street weekender or the campaign could possibly have any use in these proceedings. They certainly haven't been - even known to anybody in the - the experts - and in those circumstances, in our submission, they would have to be regarded as entirely irrelevant, the issue which arises and that's the state of medical knowledge.

HIS HONOUR: Thank you, Mr Barnard. I'll give other counsel the opportunity of making submissions on that topic at the next convenient point.

AT 11.56 AM THE JURY RETURNED TO COURT

SHELBY LEE DIETRICH:

MR BARNARD: Doctor, I should also tell you - to give an idea

of some of the hospitalisations - in 1960 there was a hospitalisation for a retroperitoneal haematoma, and a right femoral nerve pallet palsy which went from 15 September to 11 October, in other words nearly a month of in-patient treatment, but in 1978 haemorrhages in the gastro and intestinal tract involved hospitalisation for three days. There's two occasions of intercranial mischief, one in 1978 and one in 1980 when there was light headiness, tingling through the body and dizziness and what was thought to be a left retro orbital haemorrhage. Now, Doctor, if I could also ask you to look at - or be shown exhibit PX6 - - -

HIS HONOUR: PX6.

MR BARNARD: You've got a large pile of cards there. I'm not going to you ask you to look through them all, but if I might tell you that in 1980 the plaintiff had a period when he was treated with the concentrate, and thereafter he was treated with the cryo-precipitate until he was transferred again to the concentrate or home therapy in March 1984. If you could - I hope it's the back of the cards - if you could perhaps have a look at the cards in 1983?---Okay, I've located them.

Yes, 1983 - and what dates are you looking at there - at February - April - I'm sorry?---July.

You can see there the sort of doses of cryo-precipitate that were being received?---Yes, I see.

Are you able to interpret those figures there?---Well, I think what I'm interpreting is that the numbers, various numbers, five, six digit numbers, are the donor numbers from the blood bank.

They'd be blood bank numbers on the right - donation numbers?---Yes, on the right, and the - - -

You see the amount there - - -?---Yes, that's the total number of units or bags.

Bags?---Right.

You'll agree that the recipient of these bags is on fairly high levels of therapy?---Yes.

If I tell you that in fact in 1980 and 1982, the plaintiff was offered the opportunity of going onto home therapy and concentrate and that he declined at that stage, and that in 1984 - March 1984 - decided that he was then prepared to go on to concentrate and home therapy, what do you say is the appropriateness of, at that stage, transferring him to home therapy, having regard to his overall condition?---Well, having regard to his overall condition as well as the fact that in 1980, according to this card, he received six or eight infusions of concentrate, I consider that an appropriate therapeutic decision.

I think you can put the cards down, thank you, Doctor. Did

you yourself have any practice of carrying out T-cell tests on your haemophilia patients?---We began T-cell testing in early 1983, although at that time we had to send our specimens some distance and it was not a routine measure.

Did it ever become a routine measure?---Yes, it became a routine measure in the transfusion safety study. It began in September 1985, it was a routine test, and clinically, about the same time, it became routine.

You mentioned you had to send your specimen some distance - is it right that the desirable thing is that you should take the blood sample and have it straight to the laboratory for testing?---Yes, that is the optimal.

It's not the distance that's the problem, it's the time that's involved?---It's the time.

So you would have thought - considered that in 1983/1984 to be carrying out spot tests of T-cells - - -?---That's correct.

Would that be the appropriate procedure?---That's what we do.

What did you hope to find at that time from your T-cell tests?---Well, there was a great - there were a great many reports in the literature of altered T-cell ratios and numbers and we were attempting to determine which of our patients had these altered ratios and find out more about them.

But you mentioned some problems with this - for example, protein received by the patient may cause changes in the T-cell ratio?---Well, that was one theory, we were just looking. Yes, there was a problem.

But you certainly knew that sunburn caused it, didn't you? ---Yes.

And there were other things which gave you varying results which perhaps explained the changes that were taking place?---At that point we didn't know.

And you really didn't know up until 1985?---That's correct.

Doctor, you told us that before you went to this conference in early January 1983, you spoke to your patients? ---That's correct.

Your patients were living at home, were they?---Our patients lived all over Southern California.

How did you go about talking to them, you called meetings of them?---We called the meeting - I think we had 150 to 200 persons there, and we explained what we knew, which is what has been in MMWR, which has been discussed already - about this situation, and we had Dr Michael Gotlieb explain clinically what AIDS meant.

Did they have some organisation of their own, some society, your patients?---Yes, there is a local Southern California Haemophilia Association Foundation.

Do they involve themselves in organising these meetings with you?---No, we organised the meetings ourselves.

Incidentally, were you able to carry out regular reviews of

your patients at that time in 1983?---Regular what? Reviews - did you carry out regular reviews of your patients - did you bring them in three monthly or six monthly? ---I see what you mean. Yes, we had annual reviews of all patients, we're very comprehensive. In the interim between annual reviews, patients were brought back according to their individual needs.

Presumably you would have some patients that may have very little therapy, may only require it once or twice a year?---That's correct.

Or even less frequently?---Or even less frequently.

And the severe haemophiliacs were requiring it all the time? ---That's correct.

For somebody who was requiring it all the time, they'd have to come to your hospital to get their Factor 8?---Yes.

And get concentrate?---They had a comprehensive - very comprehensive exam once a year, but they had to come to the hospital as - every eight to 12 weeks to pick up concentrate.

It's all of these people that you would've called in to this meeting, is that so?---Every - that's correct. All the people were called in.

When you spoke to them - later on I think you suggested in your evidence to Mr Sher - every three or four months you had a further meeting?---That's correct.

Was this the way in which you kept the patients advised, was it?---This is the fashion we kept the patients advised, plus the individual physician/nurse

contacts.

That's when they came in for review, was it?---Exactly.

You didn't call them in?---We didn't - called on them, no, no, we did not.

Through the 70s you no doubt had considerable experience with the problems of hepatitis?---Yes.

Through the 70s when you were having this problem with hepatitis, were you using some cryo-precipitate at that time?---Very little - we used very little precipitate.

Were you aware from other experience from cryo-precipitate in the United States that it was also a carrier of hepatitis?---Yes. I was aware.

Was it the fact that you viewed cryo-precipitate and concentrate as being equally capable of carrying hepatitis?---No. I viewed concentrate because it is a pooled product, as being more likely to carry hepatitis. Particularly non-A, non-B, but I still chose concentrate.

Incidentally, if you were carrying out a surgical procedure, could you tell us what sort of usage of cryo-precipitate would be involved in some sort of operation that the haemophiliac might have to go through?---The usage pre - before the surgery would be 20 to 30 bags and then thereafter, 15 to 20 bags every eight to 12 hours.

Would it be right that with a significant operation that you might be involved in exposing the person to 500 donors?---Yes. Easily.

On the other hand, you could do it from - with concentrate you could treat them with concentrate from the one batch?---From one lot. Yes, you could do that.

Incidentally, you've told us as to how you kept your patients on the concentrate. What was your view if a person had been on large quantities of concentrate, in other words, been subjected to large numbers of donors say prior to 1984, would that affect their susceptibility to become infected in the future if

they weren't already infected?---Well, the best I can answer that is that our view was that by that time if there was an infectious agent in concentrate, no matter what it was, they had been exposed to it. They wouldn't be either more or less susceptible to a new agent.

It wouldn't affect their - you say they'd been exposed to it in the past?---That's right.

If a person had been on concentrate for a long period of time over a number of years, would you say the same in relation to them?---Yes.

With respect - what if they had been on cryo-precipitate over a large - - - ?---If a person had been on cryo over a long period of time we would have the same attitude or perspective, with that many donors that that person had probably been exposed to every transmissible agent that - in cryo or in concentrate.

You've seen the exposure, on the cards that were before you, of the plaintiff in this action. Would you regard that as significant exposure?---Yes. I - it is a significant exposure.

Would you yourself have any view as to the result of that exposure prior to March of 1984, so far as he is concerned?---I would regard that individual with that much cryo exposure as in the same category as our individuals who had had a great deal of concentrate exposure. Already exposed.

In other words, you are saying you would regard him as having been exposed to the HIV virus and other viruses?---Well, I didn't know HIV existed but I would regard that individual has having been exposed to whatever is in there.

Which we now know to be HIV?---Which we now know.

You would regard him as having been exposed to that prior to him going on to the concentrate in March of 1984?---Yes.

So, it's likely that he would - in your view - it would be HIV positive prior to March 1984?---Well, in retrospect I would regard that as possible. In March 84 I didn't have that information to make that judgment.

Nobody did?---No.

You spoke to - talked to Mr Sher - you were speaking to Mr Sher about tests - false negatives - - - ?---Yes.

In testing for the HIV virus, what's your experience of the occurrence and false negatives and for that matter, false positives?---Our experience is that the specificity of that test is over 99 per cent correct. However, false negatives occur when persons are tested before they form the antibody, that's called the window period. False positives occur in persons - women and men - who for some reason of some protein in their blood that reacts with that, and it's not HIV proteined.

So far as false negatives occur, do they occur also where the person isn't within the window period, do you get false negatives for other reasons?---Not to my knowledge. I have never known of a false negative in a person who subsequently became positive or a person who remained persistently negative, and really had infection, I've never heard of that occurring.

What do you regard as the window period, the length of the window period?---I regard the length of that period where before the antibody appears, but after

infection has occurred as being up to six months - 24 weeks.

Is there a bottom limit to it?---Well, I have read reports of antibody formation within two weeks after exposure. We have never personally had that kind of documentation, but I've read it in the literature.

Doctor, you've been asked about the disadvantages cryo-precipitate as compared to the concentrate. I think one witness here that the plaintiff called, described the advantages of the concentrate as overwhelming, would you agree with that?---I'd agree with that.

If I might just go through these, and see whether you agree with these that I list. The cryo cannot be adequately assayed for its Factor 8 as can the concentrate?---Correct.

The cryo-precipitate cannot be quality controlled for bacterial contamination as can the concentrate? ---That's correct.

The volume to be used, and I think you mentioned this, to achieve the required therapeutic level may be so great as to cause fluid overload in the recipient? ---Yes.

And I think that's what you were referring to when you were referring to children, is that so?---Yes, with children.

We've discussed home therapy, and of course the cryo-precipitate may have an antigen overload which can

contribute to immune dysfunction?---(No audible reply).

You agree with that?---Well, that's a theory, I'm not sure if that's theory's really true but that's been proposed that that antigen overload contributes to immune suppression. I - I don't agree with it.

You don't agree with it?---No.

I think you do agree that the - if the concentrate contains an infected donation, the virus contained therein is considerably reduced in their (inaudible) by virtue of the dilution during process, is that not so?

---That's a possibility.

But on the other hand you regard the chances of an infected or contaminated bag of cryo-precipitate an infecting a person would be of the order above 90 per cent, is that right?---Yes, because of the inoculum size. In other words, if the bag is infected, then there's going to be much more of whatever virus in it than in a similar amount of concentrate.

Now, the plaintiff in this case went on in September of 1984 to have a manipulation of his knee and elbow. That was carried out by an orthopaedic surgeon. Would you regard that as being improper treatment in his circumstances, having regard to what you know of his history as a severe haemophiliac and his exposure to Factor 8 over the years?---No, assuming the orthopaedic indications were present for manipulation. I would consider that appropriate treatment.

So far as you're concerned, in your hospital if the orthopaedic indications were present, would you have deferred it at that time?---No, we would not have deferred such procedure.

Why wouldn't you have deferred it?---Well, if the orthopaedic indications were present and the patient wanted it and this patient had already had a great deal of both cryo-precipitate and concentrate, there was no reason to defer it. Assuming good general health.

Doctor, you were telling Mr Sher of a Dr Montenier and your listening to his address in Paris. You viewed his

reason as not acceptable to you scientifically, is that so - you were not satisfied?---I viewed it as preliminary and not proof of anything.

Would you explain that a bit more, I think you haven't explained it in the past?---Well, okay. The Dr Montenier presented electron micrographs - photographs of a virus which he had isolated, and said that he had - I mean, he presented evidence he'd isolated this virus, I believe from the lymph nodes of a boy with haemophilia in Europe, and he showed various data about this virus. But this was one case report, and one case report can - is interesting and preliminary and provocative, but it doesn't prove anything. It didn't prove that that virus and those lymph nodes had caused that whole lymphadenopathy and what was later called AIDS.

You've no doubt heard the suggestion made - possibly made flippantly - that his work wasn't accepted because he was a Frenchman - there's no basis for that, is that so?---Well, in my opinion there's no basis for it.

But on the other hand, Gallow extended that work and did produce satisfaction?---Well, what Gallow did that Montenier couldn't do, given all the French American problems aside, was Gallow managed to make the virus grow, and Montenier couldn't. Then Gallow, having managed to make it grow in cultures, could develop an antibody test, and that was the whole

breakthrough - were the culture an the antibody test.

When you've got it growing, you know you have got a virus?

---Then you know you have a virus and you can replicate it, test it, look at it, inoculate it and so forth.

Doctor, you told us that you came to the conclusion that the AIDS virus was blood born in about January or February 1984?---Yes.

When you say you came to the conclusion, presumably you - you weren't convinced of it at that stage, were you?---I wasn't totally convinced but I was heavily leaning in that direction.

Before that, you'd been - - -?---Before that, I had heard all these theories and I still had them in my mind but, by January and February, I was fairly sure it was blood born.

What convinced you was Gallow's address?---I think it was the increasing number of cases, and in January we experienced at my hospital our first case, and I reviewed that first case - that's AIDS - I reviewed his history carefully and it seemed to me I could see a pattern of infection and I guess I became convinced. Just at that point, we then had several more cases and I was sure it was blood born.

Mr Sher asked you about some questions about warnings on packages and you gave some answers in relation to that. To what extent where you yourself familiar with blood banking procedures in 1983 and 1984 in the blood banks from which you got your blood?---Well, I was familiar. In fact, I think I'd been a blood donor for a friend, so I was familiar with the procedures.

Were you familiar with the extent to which they were

screening?---I believe I gave blood in 1983 in June or July, so I could see what the screening was like.

Apart from doing it yourself personally, was that information transmitted to you by the suppliers of blood products to you?---Well, we have to make sure we're talking about the same thing. The concentrate information came from the manufacturers. The blood information would come from the Red Cross blood bank. So there are two sources of information.

So far as the manufacturers were concerned, I presume they were getting their blood primarily from paid donors, is that - - -?---That's correct.

Were you getting information from them as to what screening - - -?---Yes, we were getting information from them as to what screening they were implementing.

How was that information provided to you?---I believe we received written bulletins from the manufacturers and the National Haemophilia Foundation sent out frequent bulletins which covered all the manufacturers.

They were bulletins directed to who - the National Haemophilia Foundation?---Well, the National Haemophilia Foundation directed its bulletins - they had two kinds of bulletins. One went only to physicians and the other bulletin went to patients and consumers and I read the physician one.

Of course you, as a user of blood products, regard it your

responsibility to know from the manufacturer what it was doing, is that the - - -?---Yes, I did regard it as my responsibility.

Throughout your years in practice, you would have kept in contact with the manufacturers?---Yes.

Their means of informing you was through these bulletins?---And through their representatives, salesmen or detail men, as they're called in the United States, who called on us very frequently, very frequently to tell us exactly what was going on.

You say "detail man"?---That's the term used in the United States a "detail man". Or a sales representative is the real - is the proper term.

When you say "Tell you what was going on". What sort of things would they tell you?---Well, they would tell us that their company was screening donors and just generally what was going on across the country.

Did the bulletins pass on information as to how the manufacturer saw the risk of infection - AIDS in them?---Well, the bulletins would inform us what the screening practises were, what the National Haemophilia Foundation was doing. What the current advice was. It was informative.

The - you've told us that the paid donor's gave you an adequate supply of concentrate. Were you using concentrate for prophylactic purposes?---Yes, we were.

Could you tell us how far you'd known that?---Prophylaxis means the administration of concentrate to prevent bleeding rather than to treat a bleed. Certain children and adults with very severe bleeds we would treat on a prophylactic basis meaning concentrate every other day or even daily for a limited period of four to six to eight weeks. We did not endorse or encourage prophylaxis over months and months simply because of the expense. But we did use prophylactics on a limited basis and we still do.

Do you view that as helping the enjoyment of life or the

welfare of the - - - ?---Prophylaxis in those individuals meant a great deal to quality of life, work, school and so forth, decrease in pain and improvement in joints.

On the other side if you don't have that and if you don't have treatment quickly, what's the down side of not having either prophylaxis or quick treatment?---Well, the down side is the bleeding into joints and the joint destruction. That's the orthopaedic down side. The medical down side is internal or intracranial bleeding.

HIS HONOUR: Mr Gillies.

CROSS-EXAMINED BY MR GILLIES:

MR GILLIES: Doctor, Mr Barnard was asking you some questions about manufacturers and the contact you had with manufacturers. Am I right in saying in the United States the manufacturers are often the blood bank as well as the manufacturer?---I don't understand your meaning of the word "blood bank".

A blood collector?---Yes. That is true in the United States. The manufacturers run these plasma stations in many cases.

So, that when you are talking about manufacturers talking about screening procedures that were in place, you were really talking about manufacturers who'd collect their own blood. Talking about what their self exclusion screening procedure was?---Yes.

You mention in relation to concentrate that it was regarded as

something of a wonder preparation when it first became available as a successor to cry-precipitate. Is that so?---That's so.

You mentioned that among patients it was regarded with great - I think you mentioned overwhelming enthusiasm?---That's correct.

That was largely because from a patient's viewpoint it would be a much more convenient form of therapy?---That's right.

I want to ask you some questions about enthusiasm of the physician for the product. Technical reasons for enthusiasm about the product. You mentioned at page 4703 of the transcript that the advantages including raising the deficient Factor 8 level from 0 or 1 per cent to a normal, or at least a level high enough to achieve blood clotting or haematosis without drowning the patient in fluid. Would you elaborate on that clinical advantage of cryo-precipitate - I'm sorry concentrate, over cryo-precipitate?---Well, the concentrate comes in little bottles and each little vial has on it a certain number of units and then enough units are calculated according to the patient's weight and according to the patient's Factor 8 level, it is a formula, and according to the severity of the bleed. More concentrate is given for a suspected bleed in the head than say a bleed in the ankle.

Yes?---With concentrate one could make those calculations very precisely, and administer the amount of concentrate needed to take care of that situation. The worst one could do would be to over treat. If removed - concentrate removed the fear of under treatment, and both patients and physicians - I think - lived with a fear of the unknown and under treatment.

In the management of a case of a severe haemophilia, am I right in saying that concentrate really is the only prudent modality of treatment?---Well, it's the - it's certainly the most - the more acceptable and prudent course where no concentrate is available as in the third world, one has to get along.

When you've got a choice, and you've got a severe haemophilia what's the preferred - - - ?---The preferred mode of treatment is concentrate.

And in relation to the concept of safety of a patient from his own bleeding disorder, how critical is concentrate as a necessary regime?---Would you rephrase that question?

Yes, when one adverts to the consequences of a bleeding disorder not properly arrested by the preparations be they cryo-precipitate or concentrate, how strongly do you favour concentrate as the preferred regime?---Very strongly. I feel we can prevent joint destruction.

And also in respect of the life threatening consequence of cerebral bleeding, does that apply as well in that

- - - ?---It applies even more emphatically in the case of inter cranial bleeding.

Why is it therapeutically desirable to able to treat quickly as opposed to postponed treatment by half an hour, or an hour?---The - when bleeding begins in a haemophiliac it usually beings fairly slowly as a ooze, but as minutes and time progress this oozing turns into significant bleeding. This is a joint delays simply - well not simply - but delay of bleeding - of treatment of a bleeding joint brings more bleed in a joint, more pain, more joint destruction. Delay in treatment of an internal bleed into the stomach, or into the brain can then permit a significant amount of bleed to be lost, and pressure within the brain from the accumulation of blood then can cause death.

Why was it that you almost exclusively opted for the concentrate as a preparation over and above cryo-precipitate in your treatment of haemophiliacs? ---Because we had - we could calculate the dose, patients accepted it, the staff accepted it and we knew where we were haemostatically.

In your required knowledge with the passage of time of there being a risk of there been a transmissible infectious agent in the blood, and therefore in the concentrate, you nevertheless continued to treat with concentrate?---Well, we realised by 1974 or five, that hepatitis was being transmitted.

Although we had no deaths from hepatitis and actually very little serious illness, but from liver tests and minor illness we knew it was there. Nevertheless we proceeded.

Likewise, when knowledge of the risk of the infection that later bore the tag AIDS - when knowledge of the risk of a blood born infection became publicised during 1983 and 1984, you nevertheless opted to continue with the concentrate?---I analysed the decision very carefully. I made out a list of risks and benefits of concentrate treatment and, having made out a list and presented it to my colleagues, we decided the benefits outweighed the risks.

We have in evidence a bulletin of the Haemophilia Society of Victoria - that's in book 2B and I'd ask that this be handed to Dr Dietrich, your Honour - book 2B, tab C7.

HIS HONOUR: 2B, C7.

MR GILLIES: 2B, tab C7 - Doctor, you'll see that that's what it purports to be, a Haemophilia Society of Victoria Newsletter dated March 1984 - do you have that document?---Yes, I have it here.

I want to take you to the page numbered 3, and on page numbered 3, you'll see the heading "Australian Federation Meeting", a note authored apparently by Jenny Ross?---Yes, I see it.

It mentioned, I think, that Jenny Ross was an Australian representative on an organisation chaired by you, is that right?---That's correct.

I want to take you to the subheading of "AIDS" - you'll see that in the right-hand column?---I see it.

You'll note the first paragraph, that "All States report that

the subject of AIDS is being treated realistically and sensibly", then "All States accept the policy of the WFH" - is that the World Federation of Haemophilia?---That's the World Federation of Haemophilia.

"All States accept the policy of the World Federation of Haemophilia's medical board, chaired by Dr Shelby Dietrich, that the dangers of withholding treatment are far greater than the possible dangers of treatment." Is that illustrative of the point you've just made before the jury?---It is.

Then the observation "With one donor blood supply in Australia, any such dangers are lessened considerably" and that sentence also corresponds with your view in your evidence in this case?---That does.

In relation to the question of purity or comparative purity of the Australian blood supply, we've heard evidence that as late as October 1984, Professor Bloom - is he a gentleman whose name is familiar?---Yes, I know Dr Bloom.

He gave a lecture in Australia in October 1984 in relation to this question of purity of the Australian blood supply, and the evidence is that he stated the opinion that the AIDS risk was not significant in Australia because of the purity of the blood supply. Do you regard that as a view, at the time, that was reasonably open to him?---It seems reasonable.

I want to ask you now some questions about heat treatment. You have given evidence that you, at your hospital, commenced to use heat treated concentrate - heat treated for the inactivation of the AIDS virus as opposed to the hepatitis virus - in about November 1984 - is that so?---That's correct.

And do you say that in so doing, you acted as quickly as was humanly possible, having regard to the unfolding of scientific learning during that year?---That's correct.

In November 1984 you implemented the heat treatment program - or more accurately, the use of heat treated products - but you were not able to do so across the board at that time?---No, we were not able to do so across the board.

How long was it before you in your hospital were able to offer everyone - every haemophiliac - a concentrate that was heat treated to inactivate the AIDS virus?
---Well, to the best of my recollection, we had completely either removed or used all the non heat treated by March or April of 1985. We also had patients who had stocks of concentrate non heat treated at home, and some of those patients just continued to use it and did not bring it in for exchange.

The evidence has been, and will continue to be in this case, that in Australia, CSL - my client - uniformly heated its concentrate for the inactivation of the AIDS virus from November 1984 on. You would regard that as an impressive statistic if - - -?---Yes, I - I regard that as quite impressive, because even toward the end of 1985 there was non heat treated concentrate still present in some outlying hospitals. I know that by personal knowledge, not

hearsay.

Has it been within your clinical experience that patients on cryo-precipitate have in fact contracted the HIV? ---Yes. Within my clinical experience, patient - a patient - more than a patient - several patients on only cryo-precipitate have contracted HIV.

And in any case has that progressed to fully blown AIDS with mortal consequences?---In the first case the infection progressed quickly to full blown AIDS and death.

That was a patient who had been treated entirely with cryo-precipitate?---It was a woman with Von Willebrand's treated entirely with cryo-precipitate.

In relation to the question of warnings - warnings on inserts or on packages, am I right in saying that during 1983 and 1984 you knew of no American manufacturer or manufacturer-blood collector who had a warning insert in relation to AIDS or HIV?---Well, to my knowledge, I didn't know the warning was there, if there was one.

We've heard from European witnesses that as far as Germany was concerned, the witness had no knowledge of warnings of that sort, and we've heard from an Englishman and from a Dutchman who've given evidence in relation to their countries. Do you know of any European manufacturer during 1983 and 1984 that was warning against the possibility of AIDS being transmitted in a blood product?---I know of none.

We've had two copy inserts put in evidence by Mr Stanley, the senior counsel for the plaintiff - he's put into evidence what appears to be an insert from the Armour organisation and another insert from the Cutter organisation, and I desire now to show you each of those inserts.

Your Honour, the two documents are to be found in book 4 at pages 53 and 54 of book 4.

HIS HONOUR: Yes, book 4, pages 53 and 54.

MR GILLIES: Perhaps you could turn to page 53 firstly, Doctor. You'll see a section of that highlighted in a coloured crayon, Doctor?---Mine isn't highlighted.

Let me take you to the section that relates to warnings. Do you see the section headed "Warnings"?---Yes, I see.

This is the alleged Armour insert - - -?---Okay, I have the "Warnings" section.

Do you see that, Doctor?---Yes, I see it.

These documents were put in through Dr Engleman, who's already been mentioned to you. Dr Engleman later said in evidence that he didn't know about these warnings in 83 or 84, and in fact he'd only discovered the fact of warnings very recently. Now, I'll take you to the material part of the warning, commencing "The possibility". "The possibility exists that Acquired Immune Deficiency Syndrome, AIDS, an immunologic disorder with extremely severe consequences may be transmitted by blood and blood products and blood derivatives, including clotting factors. However, the causative agent has neither been isolated nor identified - this information should be considered in determining patient care and treatment." Now, I suggest to you, for your comment, Doctor, that really that statement of warning is really stating the obvious and self evident, isn't it?---Yes.

You didn't know at the time that Armour had a statement to that effect in its insert, did you?---I didn't read

package inserts.

We'll get to that, because Dr Engleman's also given evidence that he had no confidence in package inserts, but let's assume that you had, during 1983 or 1984 - in fact the suggestion is that this commenced in October 1983 because there's a date on the document - let's assume that you'd read that on some date after 1983. I suggest that you, as a treating haematologist, would simply say "So what, everyone knows that?"?---That would be an accurate description of my reaction.

Could I now, Doctor, take you to the next insert - the Cutter insert. That's on page 54, and you'll see the boxed section with a subheading "Warnings"?---Yes, I see it.

Could I take you to the last paragraph of that, because that's the part that's relevant for the purposes of this discussion. It reads: "Isolated cases of Acquired Immune Deficiency Syndrome, AIDS, have been reported in haemophiliacs who have received blood and/or coagulation factor concentrates - including Factor 8 concentrates. It is not known if the disease is due to a transmitted specific agent secondary to multiple antigenic exposures or to some other mechanisms. The physician and patient should consider that Factor 8 concentrates may be associated with the transmission of AIDS and weigh the benefits of therapy accordingly." Again, had

you looked at that insert say in 1984, and had you read it - had you absorbed the information contained in the last paragraph of that "Warnings" section, would you have said "So what"?---That's correct.

Because it is just a statement of what any reasonably well-read doctor, should know?---That's correct.

You mentioned that you yourself didn't find inserts all that useful. Would you elaborate on that please?---You mean package inserts?

Yes?---Well, package inserts are required by Food and Drug Administration Regulations in the US, they are meant - they are useful for the physician who has very little to no experience with that particular product and needs the information on dosage, side effects, warnings and so forth contained. For the physician who is familiar with whatever product, the package insert is redundant.

In Australia and maybe the world, but in Australia, the evidence is that all haemophiliacs are treated by haematologists. Specialist haematologists. Is it your view that for an insert to suggest something of a technical nature to the haematologist is simply repetitively asserting something that ought to be second nature to the haematologist?---I would consider the same situation to apply here. As I just mentioned that any person haematologist experienced would not refer to the package insert and it would be redundant and repetitive.

You've heard from Professor Engleman who said that he himself didn't espouse the giving of warnings in 1983 and 1984, but that he himself paid little heed to package inserts, that he didn't read them. Would

that be consistent with your view of an expert's treatment of package inserts and information contained in them?---Yes.

No further questions, your Honour.

HIS HONOUR: Yes. Mr Rush?

CROSS-EXAMINED BY MR RUSH:

MR RUSH: Dr Dietrich, you said in your evidence that you believed the Australian blood supply to be safe in 1982/83?---Yes.

That's a view that you have always held is it?---Always.

You hold it now and you've always held it?---I held it up until - until I read the case report in Lancet of the infants infected in Australia from blood donor and I don't remember the date of that report.

Didn't you read Dr Dietrich, an article by Riccard in Lancet?---Yes, I certainly did. I was aware - - -

In July of 1982?---Yes. I have read that article and I knew the hepatitis findings reported in that article.

After reading that article in 1982 I suggest, in your opinion, your opinion was that the much vaunted voluntary blood supply in Australia wasn't as good as it was cracked up to be?---Well, I wasn't surprised at the finding because hepatitis B is so prevalent.

But in relation to the question I asked you which is about the volunteer blood supply, I suggest your view on reading that article was that the volunteer blood supply just wasn't what it was cracked up to be? ---Well, I wouldn't be - phrase it in quite that manner - I was not surprised at Hepatitis B findings, because it's so prevalent in the general population. I was - I did consider the blood supply safe from HIV.

You - as you told Mr Sher - gave evidence in Sydney last year in a case, didn't you?---Yes.

You were asked questions about that Riccard article that you read in July 1982?---Yes.

And I suggest to you in answering the questions you told the court in Sydney in 1989 that the much vaunted volunteer blood supply, and your opinion wasn't all it was said to be?---Well, in regard to hepatitis it certainly wasn't.

Because you're not a great proponent of volunteer blood against paid blood, are you, you don't believe there's a great deal of difference - in relation to the risk of infections?---I am a proponent of the paid plasma donor, because of supply demand - are problems. As far as the volunteer donor for whole blood and blood components far multiple reasons I support the voluntary system.

But in relation to your view and your opinion that's held say in 1982, Dr Dietrich?---Mmm.

It was your view that as far as the risk of infection is concerned, let's say Hepatitis B, that the risk of infection was much the same with the volunteer blood supply as it was with the paid blood supplier?---Yes.

And so as far as the risk of Hepatitis B is concerned, in 1982 you made no distinction between volunteer on the one hand, and paid on the other?---Yes, as far as concentrate's concerned I made no distinction.

And as far as the general attributes of those of the volunteer against paid side by side, the blood from the volunteer system and the blood from the paid system, it was your opinion in 1982 that the risk of Hepatitis B infection was about the same in both? ---Yes.

So as far as saying that because Australia had a volunteer blood supply, it was in some special position in 1982 as far as infection is concerned, that's just not the position, is it, as far as your opinion is concerned?---As far as hepatitis infection.

And you agree, don't you, that Hepatitis B had similar attributes as to infection as the AIDS virus? ---Well, in 1982 I didn't know any of that information.

But you agree now, don't you?---Well, hindsight's a great teacher.

Sure?---In 1983 at the January meeting we discussed the similarities between transmission of hepatitis B and

the new syndrome were discussed, and I knew about it.

Doctor, I just want to take you before lunch if I may to some evidence you gave in the United States. Doctor, I suggest to you - you're a pretty experienced witness, aren't you?---Yes.

You've given evidence for a couple of laboratories in the United States?---Yes.

You've given evidence for CSL in Sydney?---Yes.

And you're giving evidence here for the Red Cross?---(No audible reply).

And in a case of Gallagher in the United States - - - ?---The case for?

Gallagher?---Gallagher, yes.

Do you remember that one?---(No audible reply).

August 15 1986 you gave some evidence in that case, didn't you?---(No audible reply).

In August of 1986?---Well, I'll take your word for it, I don't remember it.

Did you maintain when you gave evidence in that case you'd given on oath in the United States?---Yes, it was a deposition.

Did you maintain when you gave evidence in that case that the risk of transmission of AIDS in the volunteers against the paid blood supply there was any difference, or did you think it was the same?---I think it was the same.

So when you gave evidence in 1986 back in the United States of

American, it was your opinion that the risk of AIDS infection was the same in a volunteer blood supply as it was in a paid supply?---The risk of AIDS - - -

Yes?---Not hepatitis.

Risk of AIDS?---In 1986 - yes - I thought they were the same at that point.

And I suggest to you what you were being asked about was the period in 1983, the risk of AIDS against the volunteer against AIDS, the risk of AIDS in 1983 was the same, wasn't it?---Yes. Well, in hindsight but in 1983 I did not believe that.

You drew a distinction, did you, Doctor?---I drew a distinction.

I suggest to you, you were asked this question, Doctor, in that case of Gallagher. "Okay, would you say that the statistical chance of being infected with the AIDS virus would rise with the number of donors to whom the patient was exposed?" and you answered "Yes" to that. Do you agree with that?---Yes, I agree with that answer.

And then I suggest, Doctor, you were asked - over the page - "Do you have an opinion as to whether there is a greater chance that a volunteer donor as opposed to a paid donor is more likely to be a carrier of the AIDS virus?" and your answer was "You said more likely to be a carrier, which means you're asking me is the population from which volunteer donors is drawn more likely to be carriers than the population

from which the paid donor is drawn". And the questioner said "Just the reverse?" and you answered "In my opinion that is not true. Both populations may contain carriers"?---That's true.

Why would you - why was that not the position in 1983?

---Because in 1983 I knew very little about the risk groups, and I thought that the paid donor was much more apt to be an HIV drug abuser than the volunteer donor, to come from a lower social economic social level, to be in street terms sort of a bum, who went into a plasma station and sold his plasma.

But despite that, Doctor, you were prepared to divert or stop your surgery, and warn patients in January 83?

---Despite what?

Despite just what you've said about the distinction that you're drawing between the paid donor, and the volunteer donor, you stopped your surgery, you counselled your patients in January 1983?---Yes, we did, pending further information.

If your Honour pleases.

WITNESS STOOD DOWN

ADJOURNED AT 1.05 PM

RESUMED AT 2.20 PM

SHELBY LEE DIETRICH:

HIS HONOUR: Mr Rush.

MR RUSH: Dr Dietrich, I think before lunch you'd agree with me that as far as you were concerned in 1983, Hepatitis B was equally as likely to be found in the blood of paid donors and volunteer donors?---That's correct.

And you were influenced, as far as Australia was concerned, by what you'd read in Dr Riccard's article from July of 1982?---Yes.

Because Dr Riccard's article in effect showed similar levels of Hepatitis B infection in the Australian volunteer blood supply as what you'd expect in your paid donors in America?---Yes. I don't recall the exact level, but they were similar.

They were similar levels, weren't they?---Yes.

Now, I read to you transcript of a trial where you gave evidence in 1986, and in that case in 1986 you didn't distinguish between the chances of getting AIDS from a volunteer blood supply or from a paid blood supply?

MR SHER: Well, the question, with respect, is unfair. Firstly, my learned friend's got a copy of the deposition transcript and Dr Dietrich hasn't, and secondly, Dr Dietrich has made it clear from her answer that it depends when you're asking her opinion as to what she thought in 86 with hindsight

or what she thought at the time, and she has said before lunch that what she said in 86 was with the benefit of hindsight. My learned friend is putting it differently to that. In my submission that's not appropriate.

HIS HONOUR: Mr Rush, will you bear in mind those comments?

MR RUSH: Yes, your Honour.

And in 1986 you gave evidence, didn't you, Dr Dietrich, that as far as the risk of transmission of AIDS is concerned, it was your belief then that it was equally as likely in the paid system as it was in the volunteer system?---With the knowledge I had then.

With the knowledge you had then you distinguished, did you? ---No, I mean by 1986 I had that opinion.

But Dr Dietrich, you became a reader of the Morbidity and Mortality reports, didn't you, in late 82?---That's correct.

And indeed, if you said in a previous case that it was July 82, would you argue with that?---That's correct.

It was July 82?---July 82's when I - first report appeared that I read.

But you became a reader of it in July 82?---Between July and December I became a regular reader.

In November of 1982 the Morbidity and Mortality reports put out a whole issue in relation to the safety of laboratory personnel handling potentially AIDS infected blood, did they not?---I remember the title

of the issue, I don't remember the content clearly.

The content of that issue, I suggest to you, clearly drew the attention of the reader to the fact that Hepatitis B was transmitted in a similar way to AIDS?---I accept your statement.

Did you accept it then?---Well, that isn't - I - what I believe that issue drew to the effect to was the epidemiologic pattern was similar in the two - Hepatitis B and AIDS, and because of the similarity, caution was - cautionary measures were advised in lay personnel.

So you accepted that the distribution, if you like, or the epidemiological pattern, showed a similarity between the Hepatitis B infection and AIDS infection?---A similarity.

Surely wouldn't that extend, Dr Dietrich, to the blood supply - it'd be a similar pattern of distribution between the volunteer blood carrying Hepatitis B and the paid donation carrying Hepatitis B?---It pointed to a similar pattern but it did not establish any proof that there was a transmissible agent in AIDS.

But no one had any proof, did they, Doctor?---Not - no, no one had any proof.

That didn't stop the MMV - the Centre for Disease Control putting out recommendations as to how potentially contaminated material should be handled, did it?---No.

They didn't have any proof of what AIDS was or how it had been transmitted, did they?---No.

Yet they were sending out a clear warning, weren't they, to the United States and the people that read this material of the risk of infection of AIDS being similar to Hepatitis B?---They were sending out a warning.

Didn't you, Dr Dietrich, in late 1982, hold the view that as far as the blood system was concerned, there was no difference, as far as AIDS infection is concerned, between the paid and the volunteer blood system?---No, in 1982, I don't think I held that

view.

So you believe the volunteer system was safe?---Yes.

Dr Dietrich, in 1982 - in 1983, early 1983, you suspended elective surgery?---Yes.

In your hospital. You counselled your patients about the use of concentrate, did you not?---Yes.

You were attempting to reduce their consumption or their rate of use of concentrate?---Yes, we were.

In 1982, you could have, for instance, got volunteer blood, could you not?---Well, we had all volunteer blood as far as whole blood and blood components. As far as concentrate, we had concentrate. If we'd used cryo, it would have been volunteer.

The cryo-precipitate that you had available to you in your hospital, that you could have used in your hospital in early 1983, would have been from volunteer blood?---Yes.

You say that that blood had less of a risk of transmission of AIDS?---Nationwide.

Nationwide, not in Los Angeles?---Not in Los Angeles.

Because Los Angeles was a centre for AIDS, wasn't it?---Los Angeles was termed a high prevalent area for AIDS.

So when this morning you spoke about the one patient on cryo-precipitate getting AIDS, was he getting his cryo-precipitate from Los Angeles?---Yes.

So his - if he'd been getting it from Milwaukee, where the incidence of AIDS was a lot less, it'd be less

likely that the cryo-precipitate would give him that infection?---It would have been less likely.

But nevertheless, despite the fact that volunteer blood in your opinion in early 1983 was safer, you kept your patients on concentrate?---That's correct.

Known to you at the time to be more likely to give the infection of AIDS?---Assumed to be more likely.

Assumed by you to be more likely?---Yes.

When did you sort of decide, Doctor, that the volunteer system and the paid system would equally have the rate of infection?---First, let me explain that applies only in our case to cryo-precipitate and concentrate. I believe I came to the conclusion the volunteer system was equally likely to transmit - I just - let me think a minute before I answer the question - in 1984 probably. I don't think in 83 there was enough evidence in my mind to make that conclusion.

Doctor, what about the situation then, you've drawn the distinction between concentrate and cryo in giving your answer. What about where you've got a paid system to blood to make the concentrate, and the volunteer system for making the concentrate. Did you think there was any difference in those two things where you've got the paid system, and the volunteer system for concentrate and the risk of AIDS?---Well, the only place I knew that that system existed was Australia, and I believed in 1983 and up until early 1984 that Australia was safer.

That wasn't the case, was it?---Well, in hindsight it was not the case, but that's what I believed then.

Because you know, don't you, that Australia has the sort of - haemophiliacs in Australia have the sort of incidence of AIDS percentage wise, in severe haemophiliacs, as your patients at your former hospital in Los Angeles?---You mean as far as they're HIV?

Yes?---I know that now, yes.

So the volunteer system you know now gave no protection as far as the risk of AIDS is concerned compared to your paid system in Los Angeles?---I'm aware of that now.

Doctor, you said I think in your evidence that you decided to continue your people on concentrate in 1983, because you believed whatever was in the blood they had, is that right?---Because I believed that if there was anything in it unidentified they'd already been

exposed to it.

They'd been exposed to the Hepatitis B?---Yes.

They'd been exposed to the other strains of hepatitis?

---Right.

Other viruses in the blood, and so you drew the conclusion in 1983 that if AIDS was in the blood they'd been exposed to it?---Yes, by and large.

And you wouldn't criticise a doctor in Australia for doing exactly the same thing, would you?

MR SHER: How can the Doctor answer that question. The Doctor's given her opinion as to what her view was with her knowledge of the American system, unless it can be shown that she was well acquainted with what was happening in Australia, how can she express an opinion about an Australian doctor's performance?

HIS HONOUR: What do you say, Mr Rush?

MR RUSH: What I say, your Honour, is that Mr Sher - Mr Barnard at least has sought the opinion of this doctor in relation to the conduct of the Alfred Hospital. Mr Sher has sought the opinion of this doctor in relation to the manner of donor screening on the basis - I think - one visit. In my submission, your Honour, I'm entitled to put to the witness what an Australian doctor did as far as the use of concentrate with his patients, compared to what this witness did in Los Angeles.

HIS HONOUR: Those pieces of evidence were not objected to. I uphold the objection on the basis that insufficient

material has been put at this stage before the doctor.

MR SHER: If your Honour pleases.

Tell me, Doctor, I'm going to put some evidence to you that's been given at this hearing and ask you to comment. This question was asked of Dr Vaughan - - -

MR SHER: If your Honour pleases I want to raise another objection. I think I should in fairness raise it in the absence of the jury.

HIS HONOUR: Very well.

AT 2.39 PM THE JURY LEFT THE COURT

WITNESS STOOD DOWN

MR SHER: I think what I have to say really won't affect the witness, but - - -

HIS HONOUR: I think before I can hear this, Mr Rush would you read to me the full passage you propose putting to the witness.

MR RUSH: Yes, your Honour.

MR RUSH: I am reading, your Honour, from page 2055 from the transcript, where Mr Sher put to Dr Vaughan "In any event when did you first realise down at Geelong that you actually had some people with HIV infection?" Dr Vaughan, said:

> On the basis of the treatment
>
> . . . . . (reads) . . . . .
>
> AIDS and several of them have.

Question: "So, this was an assumption that you came to that the whole blood system was contaminated?"

> Yes, and therefore everyone
>
> . . . . . (reads) . . . . .
>
> chances were still quite small.

Your Honour, in my submission I am entitled to put that transcript to this witness in the light of her evidence as to that type of practise and I am entitled to put that in cross-examination as a test for the witness and it is going to lead on to some other cross-examination your Honour in relation to what this witness did, as far as her patients were concerned in 1983.

HIS HONOUR: Yes. Mr Sher?

MR SHER: Your Honour, I would have said this if it had been necessary in relation to the previous matter but it wasn't necessary. It is clear what this cross-examination is directed towards, and it is directed towards one topic only and it is try and destroy the credibility of Dr Vaughan. In other words, my

learned friend is trying to elicit evidence from this witness not relevant to any issue in this case other than the credibility of a witness called by the plaintiff. It is clear from what my learned friend has just said that is his purpose. It has nothing to do with an issue in this case. It is not as though anyone in this case's conduct thus far, falls into this category.

Furthermore, your Honour there is no evidence to suggest that this witness is qualified to give such an opinion as a forerunner to yet another series of questions all of which would appear to be directed towards, under the guise of attacking her credibility, seeking to establish the credibility of Dr Vaughan. Your Honour, there is no issue in this case, that relates to this witness' opinion of assumptions that ought to have been made in 1982, I think the period is, or 83, because this plaintiff was treated in this manner in March of 84. So, what's actually happening is, that under the guise of trying to make this appear to be of some relevance they are trying to reinstate the shattered credibility of Dr Vaughan. That's all that it is directed towards. It is not the first time an attempt has been made in this case to - - -

HIS HONOUR: Mr Sher, I think past tragedies don't help much now.

MR SHER: Accept this your Honour, that one has to be

constantly on one's guard here to ensure that the rules of evidence are observed. In my submission, this is clear that this is no more than a device and that's why I asked to have the jury sent out because it seemed to be that it needed to be debated in the jury's absence. It can't possibly be suggested that this witness' view about this matter, firstly that she is qualified to express it unless she knew a great deal more than she has thus far said about the Australian blood supply system. Secondly, even if she did in our submission it is irrelevant because it only goes to Dr Vaughan's credibility.

HIS HONOUR: Mr Rush. What do you say to that, bearing in mind the fact that the witness has already said clearly what course she took in the sense that there's not any doubt about the course she took. What do you say as to whether this goes - these further questions go to a relevant issue as distinct from going to the credit of Dr Vaughan?

MR RUSH: Your Honour the period of time referred to by Dr Vaughan - I'm just searching the transcript your Honour, I thought it was 1983 - by the end of 1983, that's on page 2055 "I had treated" he thought they had AIDS by the end of 1983. Your Honour, this witness is attesting to something that went on in January/February/March of 1983 as to her patients, in her opinion having AIDS then. In my submission your Honour, this evidence in relation to the time

period of deciding Dr Vaughan's putting 1983, she's putting the end of 1983 - she's putting early 1983 and that's a question of significance it is submitted your Honour, in relation to - - -

HIS HONOUR: I can well understand you reason for desiring to put it but does it go to any issue other than the credit of Dr Vaughan?

MR RUSH: I can only say, your Honour, that I would put it in the manner in which I've put it to your Honour plus the basis of an appropriate way of treating patients at the end of 1983. We've established with this witness that that's what she was doing at the beginning of 1983, and the cross-examination can be directed in this manner, to the end of 1983 as to an appropriate way of cross-examining this witness as to what she was doing, from the transcript, and in that manner.

If I can say something else, your Honour - after that cross-examination, the distinction that I wish to put to the witness, - the difference between someone that has been treated in that manner, been on concentrate all their lives and someone that's been on cryo-precipitate all their lives and changing over their treatment.

MR SHER: I probably wouldn't object.

HIS HONOUR: Well, the second issue seems to me to fall into a different category - what you've just said.

Mr Rush, my opinion is that substantially your question is directed to the credit of Dr Vaughan, and for that reason is not admissible.

MR RUSH: If your Honour pleases.

HIS HONOUR: I uphold that objection. What I've said has no relation to what you last said.

MR RUSH: Thank you, your Honour.

HIS HONOUR: Bring in the jury.

AT 2.42 PM THE JURY RETURNED TO COURT

SHELBY LEE DIETRICH:

HIS HONOUR: The objection which was taken was upheld. Yes, Mr Rush?

MR RUSH: Doctor, by March of 1983 you decided to keep your patients on concentrate?---Yes.

That was because you, in your mind, said that large amounts of concentrate all their lives, or for the majority of their lives, and if they're going to get the virus, they'll already have it?---Basically, yes.

So that was the decision that you made and the basis of the decision to keep them on concentrate? You've got to answer?---Yes.

HIS HONOUR: It's not on the transcript unless you articulate your view.

WITNESS: Yes, that was our decision.

MR RUSH: Doctor, prior to lunch I asked you about being an experienced witness and you agreed that you were an experienced witness. You have given evidence for Cutter Laboratories, haven't you?---Yes, I have.

What is Cutter Laboratories?---Cutter Laboratories is a pharmaceutical company which manufactures or prepares concentrate from human plasma, as well as other drug products - but that's the main activity I'm concerned with.

So Cutter Laboratories is a manufacturer of concentrate? ---Yes.

They collect blood in the United States from paid donor

centres?---They collect plasma from paid donors.

And they also buy in plasma from other people, do they not?

---I can't answer how much Cutter buys from outside their own donor centres.

You remember in questioning from Mr Sher this morning that you were asked about blood being Red Cross blood that may be bought by fractionators or people in the blood industry?---Yes, that's correct.

And Cutter Laboratories buy blood from the Red Cross in the United States, do they not?---I don't know that I have an accurate answer to that. My knowledge is that only Hyland Laboratories, which is another company, uses recovered plasma from the Red Cross.

So of your knowledge Hyland Laboratories uses recovered replacement from the Red Cross?---From my knowledge, that's the only fractionator which does - - -

The Red - - - ?---They don't buy it, it's given.

Isn't there a transaction that takes place by way of payment to the Red Cross?---Well, what happens is that the Hyland serves only as the agent to make the concentrate which is returned to the Red Cross, and sold under their label.

So the concentrate that Hyland make is sold under the Red Cross label?---Some of it. Most of it's sold under there own label.

You have actually had a position as an adviser to Cutter Laboratories, haven't you, Doctor?---That was sometime in the 70s, yes.

Without asking you when it was, that's the positions, isn't it?---It was a medical advisory committee position, yes.

You have held a position as advisory to Cutter Laboratories - - - ?---Yes - - -

A medical adviser, and it was for approximately two years in the late 1970s, was it not?---I believe it was.

Now, Dr Dietrich, in addition to - I withdraw that. You're

not an immunologist, are you? We've had immunologists in this court, you're not one of them? ---No, I am not.

You're not an epidemiologist?---I learned epidemiology some after I started the transfusion safety study, but I'm not one by training.

And you're a paediatrician---Yes.

Do you hold any qualifications as such in haematology?---No.

Doctor, you're not a blood banker?---No.

Really the issue of blood banking's been very much secondary to your care of your 450 patients over the years, hasn't it?---It has been a secondary concern.

And as we established before lunch, you're here today to give evidence for the Red Cross?---Yes.

You were in Sydney last year to give evidence for the Commonwealth Serum Laboratories?---Yes.

And in the United States on a number of occasions you've given evidence for the fractionator again, Cutter Laboratories, haven't you?---Yes.

Doctor, Mr Sher asked you questions about the evolution of knowledge of AIDS, and your particular knowledge, and he took you to some of the literature and I'd like you to go to the plaintiff's folder, and to tab number 7 - is the plaintiff's folder number 1, book 1.

HIS HONOUR: Yes.

MR RUSH: It's tab number 6 actually, Doctor, I'm sorry - - -

HIS HONOUR: Which book?

MR RUSH: Book 1.

HIS HONOUR: A6, is it?

MR RUSH: A6, your Honour.

Doctor, you said that that was the first document, or the contents of that document was the first thing that really sort of brought to your attention the problem of AIDS with haemophilia?---That's correct.

And you know about that before it was written, didn't you?

---No, I did not.

Didn't you have a conversation with Dr Alledort about two weeks prior to the issuing of that journal?---Well, if I did I - - -

You've forgotten it?---Forgotten it.

Well, at any rate that refers to three haemophiliacs who have come down with AIDS, they're heterosexual and they all use large amounts of Factor 8 concentrate?

---Yes, that's what the article says.

MR SHER: It's not quite accurate to say AIDS. It refers to pneumocystis carinii.

MR RUSH: Doctor, as far as the patients are concerned, I think it was put to you yesterday by Mr Sher, they came from New York, they were fairly widely distributed, weren't they - - -

MR SHER: That is incorrect. I think I did put that but the witness - I corrected myself and then the witness corrected me - - -

HIS HONOUR: Yes.

MR SHER: The third one came from Ohio I think - - -
WITNESS: Yes, they were widely distributed.

MR RUSH: Well, one's Denver, Colorado, one's from New York, and if the other one's from Ohio, I'll accept Mr Sher's word for it.

MR SHER: It's in the transcript.

MR RUSH: But - I'm happy to accept your word for it - now, Dr Dietrich, there was a bit more to this MMW report than it merely being sent out, wasn't there - you got a letter from the CDC, didn't you?---A letter from the CDC?

Yes?---I have no recollection of receiving a letter.

Didn't it say - if you turn over the page - and you see down the bottom of the page there, right at the bottom paragraph - are you looking at the right one - you've got the July 16?---Yes, I have July 16.

If you go over to page 2?---Okay, I'm on page 2 then.

If you look down the first half of that page to the bottom paragraph - and you see the bottom paragraph, it commences "CDC has notified directors of Haemophilia Centres about these cases and, with the National Haemophilia Foundation, has initiated collaborative surveillance. A public health service advisory committee is being formed to consider the implication of these findings. Physicians diagnosing opportunistic infections in haemophilia patients should not receive antecedent state health" - I can't read the rest - "immunise suppressive therapy are encouraged to report them to the CDC through local State Health Departments". Now,

Doctor, didn't you get a note to your Haemophilia Centre from CDC?---I don't recall a note to our centre. It's possible we received it and I simply don't recall it.

But Doctor, you took part in that survey, didn't you?---The first notice I remember from the CDC arrived in November.

But Doctor, didn't you take part in a survey from the National Haemophilia Foundation and CDC?---Not between July and November 1982, we didn't.

I put to you, Doctor, that you were reporting seven or eight patients of yours that had the lymphadenopathy syndrome and you reported them to CDC in late 1982?---In December.

Are you sure it's not November?---Well, it could have been November or December, but it was not in July.

That was pretty significant, in your opinion, wasn't it?---Well, it was certainly interesting and it was certainly of great concern - - -

You were - if we got the impression from your evidence that you concern commenced in 1983, that'd be wrong because you - with your patients - because you were reporting on your patients in 1982, weren't you?---In November or December.

You are able to trace back a patient that you recognised as having the lymphadenopathy syndrome to 1979?---Yes, that's the patient I reported.

So you knew at that time that the blood supply that was being

used at your orthopaedic hospital in Los Angeles had probably been contaminated since 1979?---I think that's a great assumption and leap of what I might know now versus what I knew in 1982.

You reported that - you knew of that patient and you put him under a lymphadenopathy syndrome in 1982?---That's correct.

You reported on that patient at a conference in mid 1983?---In Stockholm.

At the Stockholm conference where you didn't find Dr Sawers?---That's correct.

That must have suggested to you - as part of the reasoning why you didn't take your haemophiliacs off concentrate - it must have been a factor in you saying "Well, look, we had this chap back in 1979, that's had lymphadenopathy - it's probable that this has been in the blood supply for some time"?---Well, that is what we thought by later in 1983. In late 1982, when we described that patient plus a few others, what was clear and apparent just wasn't clear and apparent of what was going on. I mean, it sounds easy now to say that, but in all honesty, I don't think our conclusions were that clear then.

But they were clear enough for you to make what must've been a pretty vital step to continue your patients on concentrate in early 1983?---Well, it was clear enough for us to make a judgment that that was the better course to follow.

Weighing up all these considerations?---In weighing the risks and the benefits.

One being that this agent, whatever it was, had probably been in the blood supply for sometime?---Yes.

Doctor, I think - correct me if I'm wrong - but the next major piece of medical literature that you came across was - if you just go to tab 10 in that folder - which is the update on the syndrome from the MMWR. You read that in December of 1982?---Yes.

That reported that there'd been three deaths among those four patients initially reported. If you go just four lines down?---Yes, I - I've read it.

And four additional heterosexual patients?---Right.

Four additional heterosexual patients, haemophiliacs who were users of Factor 8 concentrate?---Correct.

And again, I think Mr Sher's Ohio patient is case number 3 here, if we go to page 2.

MR SHER: He wasn't my Ohio patient, I've never even been there.

MR RUSH: We've got them from Ohio, from Missouri, from Pennsylvania, from Alabama. This was widespread around the United States, wasn't it, Doctor?---Yes.

To isolate the problem to California would've been a mistake

for a treating physician, wouldn't it?---Well, it was clear the problem in haemophilia was widespread, or at least disseminated across the country.

Doctor, if you go over one tab, we've got the next part of that MMWR report - tab 11?---11?

Eleven. It deals with an infant having the possible AIDS syndrome from California, who'd been transfused with platelets. You read that, didn't you?---Yes, I read that.

You said - and I'll just get the transcript to make sure I'm right - to Mr Sher yesterday, at page 4712 of the transcript. Mr Sher asked you: "What did these documents convey to you as a practising haematologist?", and one of them was this document concerning the infant. You answered:

> I guess these reports you have
>
> . . . . . (reads) . . . . .
>
> an isolated case report.

That's what you said?---That's correct.

That's what you said yesterday, isn't it?---Mmm.

Is that your view, Doctor?---Yes. One isolated case report, of interest and concern as it was, did not prove an epidemiologic point.

Doctor, I want to read you some evidence that you gave in Sydney last year. About this time last year, wasn't it?---Just about.

It's at page 546 of the transcript. You were being asked questions about the accumulating knowledge of AIDS.

This question was put:

It started accumulating, you

. . . . . (reads) . . . . .

in 1981, did it not?

You answered "No, I disagree with that." Then the question was asked: "Well, when did it start accumulating?" and you answered:

The first evidence occurred

. . . . . (reads) . . . . .

a blood borne infection.

How do you reconcile that evidence, Dr Dietrich, last year, with the evidence that you've given the court yesterday?---I think that I failed to note last year that all I said was true, but it didn't prove conclusively it was a blood borne infection.

Dr Dietrich you've told this court that you came to the conclusion that it was a blood borne infection in early 1984?---Final conclusion yes. In 1984.

What was your opinion in 1983 - early 1983?---Undecided.

I suggest doctor, that evidence you have given in other cases is that you came to the conclusion that this was a blood borne disease in early 1983. Do you agree with this or not?---I think 1983 was a period of great uncertainty and my state of mind in 83 is difficult. My degree of certainty is not my state of mind, but my degree of certainty is uncertain to me at the moment. I know in regard to haemophilia, in 1983 I was still considering all the various opinions that were then current hypothesis. I was not immediately or even indirectly at that time concerned with recipients of blood and didn't think about it as much.

Doctor, I think we have established that you gave evidence in this case of Gallagher against Cutter Laboratories in August of 1986 and I'll just read to you the questions and answers that you gave to the questions from the transcript of that case. The question "Okay, even though you stated a few moments ago that the earliest date that you recall being aware of a correlation between AIDS and blood products was when you had your conversation with Dr Eladort in July of 1982?" Answer: "Yes". You've forgotten about that conversation?---I've forgotten the conversation yes.

The question. "So did you accept that information then as evidence suggested that AIDS was in blood products?" Answer: "Yes I did". Question: "So you say by the fall of 1982" - is that about now?---That's about now, yes.

"So by the fall of 1982, October of 1982 you really still weren't convinced?" Answer: "I wasn't convinced it was a transmissible agent such as a virus." Question: "But was it in blood products?" Answer: "Yes". Would you like to have a look at the transcript doctor?---No. Because I think the explanation is that something else could have been in blood products like proteins, unknown viruses what not.

The question is about AIDS being in blood products that I read to you doctor?---Well, AIDS is a syndrome, I guess I'm think of more infectious agent.

I'll just read it to you again so you don't misunderstand. The question: "So did you accept that information then as evidence suggestive that AIDS was in blood products?" Answer: "Yes, I did". Question: "So you by October of 1982, you really still weren't convinced?" Answer: "I wasn't convinced it was a transmissible agent such as a virus". Question: "But it was in blood products?" Your answer "Yes". You were talking about AIDS then weren't you doctor?---Yes, I was.

You were saying that AIDS was in blood products?---Whatever -

that's right.

You were saying AIDS, I suggest doctor, was in blood products in October of 1982?---Whatever produced the syndrome was in blood products, but it wasn't necessarily a transmissible agent.

But as far as the syndrome - as far as AIDS - as far as this thing that's - the MMWR reports on is concerned - in your opinion, in October of 1982 that was in blood products?---Yes.

Doctor, you say that you were finally convinced - when were you finally convinced that it was transmissible by blood products?---In an infectious epidemiologic sense, I was convinced about January 1984.

But you held a suspicion before that, did you?---Yes, I held a suspicion.

Your conviction was based on Gallow, was it, or Montenier or someone else?---Well, I had heard informally that Gallow was at work, and I had all the other series that were then current about haemophiliacs. It couldn't be proven and there were increasing number of cases, including the first two in our own centre and then I was absolutely convinced.

You have said before that you have some epidemiological evidence or experience, is that right?---After I began the transfusion safety study, yes.

What about Dr Gotleib, what's his specialty?---Dr Gotleib's an immunologist.

And the immunologist - the specialist immunologist you got to address your patients?---Yes.

In January 1983?---That's correct.

And the immunologist would have a special relationship with establishing viruses, and looking in to blood related viruses?---I don't think I could answer that question. What an immunologist special interests would be - I don't think it would be viruses.

Do you know what immunologist special interest is?---Yes, immunology, the function of the immune system in the body.

Does that bring him to play viruses like AIDS or - - - ?---It may or may not.

You don't know?---Well, I - I know - I know on certain

occasions it brings in viruses, but there are many many disease the immunologist is concerned with that are not a viral origin.

Dr Gotleib at this meeting, he was pretty interested in viruses in January 83, wasn't he, because he addressed your patients about the virus?---He described what the syndrome was, and I don't know what he said about viruses.

He suggested to your patients that this AIDS was a virus?

---Well, he may well have.

Don't you remember it, Doctor?---No, I don't remember his precise words.

Well, I'm not asking you to remember his precise words. What about the flavour it, the consensus if you like, it's a word that's been put to you in examination. Did he talk about a virus?---In January 1983 on that evening I don't know. I - all I remember that fascinated me was his description of the immune changes in the blood, and the opportunist to confection, and his speculations about viruses I don't recall.

Just going back to August 1986. Was your memory a bit better at January 83 then, Doctor?---It was probably a lot better in 86 or 83 than it is now.

This question was asked of you I suggest. "Okay, do you recall a point in time when it was first suggested in the medical literature or data that AIDS was due to a viral agent?" Your answer again "It was the

January 1983 meeting where the speakers suggested that the epidemiological evidence was consistent with a virus". "And that was the first time that you've heard that connection made?" "To my recollection it is" - - - ?---May I correct your assumption from that deposition. That evidence - that link was made at the CDC when I went to that meeting, not by Dr Gotleib - my recollection.

So that was the CDC meeting?---That was the CDC.

And Dr Gotleib, did he speak about it?---I don't know.

Did you accept it was a virus from the CDC meeting?---No, not completely.

One of the speakers at the CDC meeting - or the CDC Hepatitis Branch - was suggesting a surrogate test, wasn't he?---Yes, they were.

Doctor, if I can just summarise your position by the end of 1982. You had reported seven or eight cases of the lymphadenopathy syndrome to the Centre for Disease Control at Atlanta?---That's correct.

Perhaps if we go on to January and February 1983. You called a meeting of all your patients?---Yes.

Of which 150 or so attended?---That's right.

You had 450?---That's right.

Now, 150 of the 450 attended for the purpose of explaining to them the problems, and as much as you could about what was affecting haemophiliacs in the United States?---That's correct.

Because it'd be very important to keep your patients in touch

with what was happening?---And our patients were subjected to media reports all the time, TV, newspaper and so forth.

And you held these patient meetings quite regularly, did you not?---Every three to four months.

Because, as a physician and a treater, you believed it was important to have your patients up to date with what was going on so that they and you could make decisions concerning what was best for them? ---Correct.

And you would agree, would you not, with this proposition, that it's important for a doctor who's treating a patient, to inform the patient about his treatment so that they can jointly come to decisions?---Well, either in a meeting or in a personal contact.

For the patients that didn't turn up at your meeting - when they came in for their concentrate or their medicals, you informed them of the problems, and jointly you came to a decision?---Sometimes that was done by the physician, and sometimes by the nurse.

Were you director of the centre at the time, Doctor?---Yes.

It would be part of your responsibility - whether it's done by you or the physicians - you would want that done, wouldn't you?---Yes.

Because it's important that the patient knows what's happening in his treatment?---Yes.

You decided in early 1983 to continue on with concentrate? ---Yes.

You had no experience, I take it, at the Orthopaedic Hospital at Los Angeles, with cryo-precipitate?---We had some experience, but not a great deal.

You didn't treat your patients with cryo-precipitate prior to them going on to concentrate?---No, we did not. We did not have a transition.

There's some problem, Doctor, about producing cryo-precipitate in Los Angeles, is there not?---There was a reluctance on the part of the Red Cross to devote the facilities and manpower needed to produce enough cryo for us.

So one of the considerations that you had in keeping your patients on concentrate rather than changing them all over to cryo-precipitate - was the fact that the Red Cross was reluctant to produce cryo-precipitate? ---Well, it was a consideration, yes.

HIS HONOUR: When you reach a convenient spot, Mr Rush.

MR RUSH: That is, your Honour.

HIS HONOUR: Very well, the jury may go to the jury room for 15 minutes.

AT 3.12 PM THE JURY LEFT THE COURT

HIS HONOUR: You may leave the witness box for 15 minutes, Doctor.

WITNESS STOOD DOWN

HIS HONOUR: Mr Gillies?

MR GILLIES: Your Honour, we join in the objection but have nothing to add.

HIS HONOUR: Yes. Mr Sher?

MR SHER: I've been present in court, I've heard the evidence of Mr Barnard. I've nothing further to add, your Honour. We join in it.

HIS HONOUR: Mr Stanley?

MR STANLEY: Nothing to say, your Honour. We rely on what we've previously put to your Honour.

HIS HONOUR: Mr Barnard, I expressed my appreciation to you for putting those authorities before me. I will look at them and give due consideration to them. There's one matter that I wish to raise with regard to one of the exhibits. It's exhibit PX22 - I ultimately decided that PX22 was to consist only of two inserts. Now, in the document as it now is there are three pages at the front which commenced with material referring to Moxacin, and I'd like to pass it to counsel to be informed as to whether that is part of an insert, or whether that's some separate document. There was another document which was excluded by me, because it had the date 1916 to 1986 on it - you'll remember.

MR STANLEY: Yes, your Honour.

HIS HONOUR: That was a different one from that. Mr Stanley, I pass to you just to refresh your mind, the one that was excluded, because of the date that it had on it.

MR STANLEY: Your Honour, there was also - I thought - a Hepatitis B vaccine - - -

HIS HONOUR: That's another exhibit, that's - - -

MR STANLEY: That's just a separate exhibit.

HIS HONOUR: That's exhibit PX23, insert marked CSL related to Hepatitis B vaccine. Can you hand that to Mr Stanley also. Mr Stanley, really the question I think for you is where are those first three pages, are probably described as part of an insert. My impression is that they're not.

MR STANLEY: I would agree with that, your Honour.

HIS HONOUR: Yes - - -

MR STANLEY: They don't appear to be and I can't recollect

- - -

HIS HONOUR: I can't recollect - I haven't got a clear recollection. I've looked back over my ruling which doesn't clarify it more.

MR STANLEY: My learned friend's instructor's note is that exhibit 22 is a brochure and two exhibits. There was a third page that we extracted, that's right

- - -

HIS HONOUR: But the brochure I think is the one that had 1916 to 1986 on it.

MR STANLEY: Yes, that was a different one, and that was - - -

HIS HONOUR: No, at the time the original description of the exhibits was PX21 marked for identification. Brochure and two inserts for CSL dated September 1981 and February 84 relating to Moxacin. When I went through the bundles of documents that were with me, I excluded an insert which was a duplication of one of the others, and I also excluded the brochure which is marked 1916 and 1986.

I don't recall dealing with those first three pages at all. I don't think they belong in the exhibit, but before I took any action I wish to refer it to counsel.

MR STANLEY: Your Honour, could we have a - I'd rather talk to Mr Gillies about it and see if we can sort it out. My recollection is very imprecise and my note doesn't help me.

HIS HONOUR: Very well. The ruling appears at page 4136 and I'll hand that down to you Mr Stanley and you and Mr Gillies can use it if you like. I think you are the two that have the most - main interest in this. Mr Gillies, I was going to invite you to start your argument but there's not very much time left so I won't do that.

MR GILLIES: May it please your Honour.

HIS HONOUR: I'll leave the bench for - - -

MR WODAK: May I draw a matter to your Honour's attention fairly shortly?

HIS HONOUR: Yes, Mr Wodak.

MR WODAK: It arose out of the document Mr Barnard was kind enough to hand me this morning, in which he reminded your Honour that your Honour had been at the Australian Bar Association Conference in Darwin and it is quite clear your Honour that this is a learned journal and it is my submission that this should be in evidence absolutely. What it is your Honour, it is a presentation at that conference by a gentleman on his appointment to the bench and it reads as follows:

Let me say barristers should

. . . . . (reads) . . . . .

in the most presentable form.

In my submission that should go into evidence absolutely your Honour.

HIS HONOUR: I think that should be PHLXX?

MR WODAK: In the general exhibit.

HIS HONOUR: As usual you have been most persuasive your Honour. I'll leave the bench.

ADJOURNED AT 3.22 PM

RESUMED AT 3.30 PM

HIS HONOUR: Gentlemen, I will deal with those exhibits at 10 past four, not at this stage. Yes, Mr Rush?

SHELBY LEE DIETRICH:

MR RUSH: Dr Dietrich, prior to the break we were trying to establish what you knew about AIDS in early 1983, end of 1982, and I suggest that one of the things that you knew was that your - in deciding that your patients had this disease, had this infection - was that you could only get it by concentrate?---I'm not sure I could agree with your statement of what I knew then because we had patients on cryo-precipitate. We also had patients who'd received whole blood for various reasons and I do not think I believed - in fact I'm quite sure I did not believe - it was exclusively in concentrate.

How many patients did you have on cryo-precipitate, Dr Dietrich?---Well, only the patients with von Willebrand's disease and those were probably 20 to 30 people.

What about the patient - didn't you refer yesterday to a patient that didn't like injecting himself?---Yes, he was on concentrate, however.

Any others on concentrate?---Any other what on concentrate?

Haemophiliacs?---Well, all our severe patients - - -

I'm sorry - on cryo-precipitate?---On cryo-precipitate, at that time, no.

Doctor, another case that you've given evidence in in the

United States is a case of Doe v Cutter Laboratories, isn't it?---Of who?

Doe - John Doe v Cutter Laboratories. I suggest you gave evidence in that case on 26 October 1987?---I'm sure you're correct.

Indeed - - -?---But John Doe was a pseudonym so I'm not sure which case.

In the Superior Court of the State of California, County of San Mateo - I suggest that you gave evidence in the case Doe v Cutter Laboratories?---That was a deposition, yes.

On oath - deposition on oath of which a transcript's taken?---Right.

Doctor - I suggest to you, Doctor, that you gave this evidence. On that date, 26 October 1987, you gave evidence about the CDC - Centre for Disease Control - National Haemophilia Foundation survey that you had participated in in late 1982 - that's right, isn't it?---That's right.

The survey to establish haemophiliacs with sweats, fevers, lymphadenopathy syndrome?---That's correct.

Because that had been associated with - as a precursor to AIDS, hadn't it?---That's right, it had.

In late 1982 - and you said this "The CDC NHF investigation certainly helped our thinking in the direction which I am discussing and our thinking that there was a new disease present. It was new to everyone. It wasn't simply an unrecognised disease making itself

evident, and that our patients already had this new disease and the only way they could get it would by concentrate"?---Well, I think that was a mistake on my part to say the only way would be by concentrate because I'm sure I knew much earlier than that that cryo-precipitate and blood could have - at least cryo-precipitate could have transmitted it.

So do you want to have a look at the transcript - - -?---No.

Or do you accept what I've read out is correct?---I accept what you read.

So as far as you saying that the only way your patients could get it would be by concentrate, when you gave that evidence in October 1987, that was a mistake?---Yes, it was because by that time we'd had the patient die who had received only cryo-precipitate.

Tell me, Doctor, what percentage of your patients in January 1983 did you think had this AIDS, this problem?---Well, no patient had AIDS because that was defined as a syndrome. As far as what percent had lymphadenopathy, those minor findings that were then at that time called AIDS related complex, about 10 per cent or less showed some evidence.

So 10 per cent of your patients - 10 per cent or - - -?---Of 400 would be about 40. That's probably too high. We counted the seven or eight we reported and then, in January, I believe we could count some additional cases, up to 18, so that's not 10 per cent. That's more like five per cent.

And that increased through 1983, did it?---That increased.

So five per cent of 400, 450 patients, had the AIDS related complex - this lymphadenopathy in early 1983?

---That's approximately correct.

You believed that that was the precursor - that's what you got before you got AIDS?---That's what the CDC had described in their diagrams of an iceberg - as the lymphadenopathy being one of the pre - early signs.

So did you think that all your patients would go on to get this problem?---We - I did not think at that time - I had no way of knowing who was infected or who had what at that time, to - the patients with lymphadenopathy with obvious physical signs of some problem - I was afraid would go on - but did not know. The remainder of the normal looking, normal appearing patients, we assumed to be normal. "Assumed" might be also phrased "hoped".

You made a mistake when you said the only way your patients could get it is by concentrate?---Yes, I made a mistake.

Because if the only way they could get it was by concentrate, one thing that you could've done was change them over to cryo-precipitate to reduce the risk of exposure to donors, couldn't you?---Well, if that had been what I really believe, that's true. But I clearly made an error in that deposition.

Doctor, have you told this court everything that you said to your patients by way of alternatives for treatment

when you met with them in January and February of 1983?---We told our Factor 8 patients - let me review and make sure I've covered this - that they could reduce their use of concentrate, but with safeguards, they could switch to cryo if they asked us.

I think that's the one you might've missed out yesterday, that they could switch to cryo?---No, we offered the option.

Let me explore that, Doctor. You certainly didn't give that in your evidence yesterday, did you?

MR SHER: Well, Mr Rush, she wasn't asked, you know.

MR RUSH: I'm asking the question, Mr Sher.

MR SHER: Well, the suggestion in the question's an unfair one. The witness wasn't asked, your Honour. I was the one asking the questions. If you've got a passage in the transcript that you have in mind and you can correct me, I'd be happy if you would. But my recollection is that the witness wasn't asked what - what I asked her is what did they do, not what they told their patients at this meeting. I don't think I asked her what she told the patients. I may be wrong - if I'm wrong, correct me - but I don't believe that the witness was previously asked, Mr Rush.

HIS HONOUR: Well, I don't purport to remember exactly.

MR RUSH: Your Honour, it's my submission that it's not an improper question as to whether that was given in

evidence yesterday. Mr Sher has said that he asked "What did you do?".

MR SHER: You're suggesting that she failed to mention something at a meeting, and my suggestion is that she wasn't asked what she mentioned at the meeting.

HIS HONOUR: Well, I would not be able to rule on that unless I looked at the passage.

MR RUSH: Yes, your Honour.

You offered your patients cryo-precipitate, Dr Dietrich, is that correct?---We offered them the opportunity. I certainly - if I've - didn't make that clear yesterday, it was with no intention of concealing anything. We offered them safeguards, cryo-precipitate, for Factor 8 patients the option of doing nothing was clearly really too dangerous to offer. That's as I recall what we did in 1983, and the surgery which I've already mentioned.

At these meetings, Dr Dietrich, in January and February of 1983, one alternative that you put to your patients was to change over from concentrate to cryo-precipitate?---We mentioned it as a possibility. I must say in all honesty we did not endorse it enthusiastically or even push it.

You mightn't have pushed it, but that was certainly on offer, wasn't it?---It was an offer.

Because you knew that by offering them cryo-precipitate, they would be exposed to single donors - not the great pools of donors that made up the

concentrate?---That's correct.

And thereby greatly reduce their chances of becoming infected with AIDS?---Well, I'm not sure I believed that, but the National Haemophilia Foundation had suggested that be an option, so we attempted to follow a very conservative middle course and offer all the options - feasible and possible.

Doctor the last - you've expressed an opinion about what was proper to do with Mr PQ in March of 1984, and you said it was quite proper to change him over from cryo-precipitate to concentrate, and here you are in January and February of 1983 offering your concentrate patients, that you believed all had this condition, you are offering them cryo-precipitate?---That's a - - -

Is that the position?---That's a year later.

A year later much more was known about this problem wasn't it?---By a year later our perspective had changed.

A year later much more was known about this problem?---Well, at least enough for us to change our whole perspective on the concentrate/cryo question.

A year later the evidence was much greater that it was transmissible by blood?---Yes, it wasn't much - there was much more evidence.

A year later it was much more evident that those that were in the high donor pools - the large concentrate pools, were more likely to get AIDS than those that were on the cryo-precipitate?---Well, that's given taken only the risk of cryo versus concentrate and not considering the recipient status.

A year later that was known, wasn't it doctor?---That the pool products carried a greater risk to the person who had never been treated.

With a pool product?---Yes.

What pool product had the plaintiff been treated with in March

of 1984?---Did the plaintiff do what?

What pool product had the plaintiff been treated with, Mr PQ, the plaintiff that you have offered an opinion about in this court, what pool product was he treated with prior to March of 1984?---He was treated with cryo-precipitate as I looked at those records, with multiple bags of cryo.

In your opinion doctor, Australia was two years behind the United States as far as the development of this problem was concerned wasn't it?---Two years?

Two years?---I don't think that interval was quite two years because I remember the Australia case of the children - the infants as appearing in the literature in 1984. So, it seemed that Australia was more like a year behind.

Doctor you have contributed to a book have you not, that amongst others has been written by doctor or Professor Gust and Patriciani and Hoppy and Cringen, is that right?---Yes that was a meeting and the proceedings from a meeting in Geneva.

I suggest to you that you wrote in that book that countries outside the United States were about two years behind the United States in the development of the epidemic?---Well, that's probably what I said in 1984/85, when that was written.

I think it was a bit later than that doctor?---I've really forgotten the date.

It was published in 1987?---The meeting was held in 86, yes.

Two years behind the United States. That's what you wrote isn't it?---That's what I wrote.

You also had something to say about the risks in relation to the volunteer blood supply, didn't you?---I've forgotten. Perhaps you can refresh my memory.

I suggest in the chapter that you wrote or contributed to the book, you said the rates of sero positivity - what's that mean - amongst haemophiliacs?---That's the percentage of patients reacting to HIV with a positive antibody test.

That's when you can tell that they've got the virus?---Well, that they've been exposed to it, yes.

They are HIV positive. That's the terminology?---That's what that means. HIV positive.

You said the rates of sero positivity among haemophiliacs in countries outside the United States, seemed to be a function of the source and amount of clotting factor products used, rather than geographic location. Haemophilia centres with low rates of HTLV 3 infection, have generally used locally produced blood factor products, usually cryo-precipitate or fresh frozen plasma obtained from low risk donors. In Australia however, the prevalence of antibody in Factor 8 patients has been steadily increasing, even though imported blood products are prohibited. What were you writing about the Australian blood supply when you said that in 1987, or when that was published in 1987?---Well, as more and more patients

were tested more were found to be positive.

What you were saying doctor, is despite no paid donations and a volunteer blood supply, it was surprising to you that Australia had such a high rate of haemophiliac infection. Isn't that right?---Yes, it was surprising to me and disappointing.

And that would suggest to you, would it not, that the sort of screening procedures that you gave evidence about this morning were totally inappropriate, they weren't working?---I don't know that I can draw that conclusion. It was obviously - Australia had a problem, and I recognised it. What caused the problem I'm not sure I can speak - - -

What caused the problem quite obviously, Dr Dietrich, was a contaminated blood supply, is that not correct?---Well, there were donors infected in the blood supply, yes.

In the Australian blood supply?---In the Australian blood supply.

And when you say, Dr Dietrich, that in Australia however the prevalence of antibody in Factor 8 patients has been steadily increasing even though ~~important~~ essential blood products are prohibited, what you're saying is that in your view that's very surprising?---Yes, I'd agree with that.

Because there's something to be said against the voluntary blood system, a criticism in effect made of it, isn't there?---I think it's also a reflection of my feeling in 1983 that Australia wa safe from this problem, and my subsequent disappointment that it was not.

To go back to 1982, Doctor, you've already agreed that Dr Riccard's Hepatitis B figures?---Mmm.

And the amount of it were the same as what you'd anticipate in

the USA?---That's correct.

Doctor, when you put your patients on concentrate - or continued them on concentrate - there was no test to see if they were HIV positive?---There was no test.

You've criticised Dr Jane De Forge in court yesterday, didn't you, the article that she wrote in the New England Journal of Medicine?---I'd say I took exception with her views, I didn't criticise her.

You have said that this article, that it was written from someone in an academic ivory tower, haven't you, Doctor?---Yes.

Perhaps if you go to the article, it's tab 13 in the plaintiff's book.

HIS HONOUR: Book 1.

MR RUSH: Book 1, your Honour.

HIS HONOUR: A13, is it?

MR RUSH: Yes, your Honour.

Doctor, there's just a couple of passages I want to take you to, and if you go down to the third paragraph of this article. I'll read it:

> The risk associated with exposure to plasma from multiple donors however has long been a concern in the care of these patients, primarily because of the evidence of virus induced liver disease.

Is there anything wrong or way out academic about that statement?---No.

If you go down to the next paragraph:

> Now we are becoming aware that treating haemophiliacs with Factor 8 preparations may exact a high cost. Reports from the centres for disease control include three haemophiliacs among cases of acquired immuno deficiency syndrome.

There was no doubt that the use of concentrate was exacting a high cost, was there, Doctor?---Well, one had to define high costs on a - - -

What I mean by that is that the haemophiliacs were dying from the use of Factor 8 concentrate?---Well, that's three patients.

Three patients?---Three.

And all yours - you believed at the time this was written - had whatever it was?---No, that's not true, sir. At that time we had the cases of lymphadenopathy and we didn't know what was going to happen to those.

But when you got the meeting in January, February 1983 you believed that whatever was in the blood your patients had been exposed to?---Exposed to?

Yes?---But that's doesn't necessarily mean acquired, but exposed to.

So you distinguish on that, do you?---Yes, I do.

And over the page the doctor says - just into the first paragraph about eight lines, Doctor, she says:

> Patients receiving lyophilised commercial concentrates of Factor 8 appeared more likely than those receiving cryo-

precipitate to have abnormalities of T-cell sub populations. In view of this finding current modes of treatment must be scrutinised.

That's what you were doing, wasn't it?---Yes - - - Scrutinising your treatment:

> Concentrates are prepared from pool plasma, from 2000 to 5000 donors. Lyophilised and packaged in phials containing 200 to 1200 IU. Cryo-precipitate on the other hand is prepared in the blood bank from the plasma of individual donors. Each bag finally contains about 100 units of Factor 8 in a relatively small volume.

Further down she says at the end of that paragraph:

> The difference between those receiving concentrate, and those receiving cryo-precipitate does not seem to be explained by the fact that there was less treatment in the latter group, but one may wonder whether exposure to fewer donors is crucial.

That was pretty sound sort of stuff, wasn't it, Doctor?---As far as it went.

That's what you were looking at. The very issues wasn't it?---Yes. That's fair enough. Exposure to fewer donors may be crucial.

Then she goes on a little bit more doctor down to the second last paragraph at the bottom of that "The present program has been extremely successful and will be given up by physicians and patients only with great reluctance. Yet it is time to consider doing so even though we may not have enough evidence to demand such a radical change. The fact that haemophiliacs are at risk from AIDS is becoming clear. If the use of cryo-precipitate will minimise this risk the current home infusion program needs to be revised". What was wrong with that?---I disagree strongly. I did not feel our current home infusion program needed to be revised and revised can be read, either rejected or stopped because cryo-precipitate we would not allow to be used at home.

Isn't what this article saying, is have a look at what you are doing?---We did have a look at what we were doing and we came to other conclusions.

That's what this article is saying isn't it. It's putting forward an equally valid and legitimate view, isn't it?---Depends on whose view it is.

It is a view that was right though, isn't it?---Well. I'm not sure I would agree with that fact - that view was right because many deaths and much crippling would have occurred if we had done what this article

suggested.

Do you ever read the medical journal of Australia doctor?---No.

I'd just like you to have a quick look at it and it is C6 I think doctor in the same folder, which is right towards the back?---What number did you say?

C6. You obviously know who Ian Gust is?---Yes, I know.

This is an editorial in the Medical Journal of Australia that he co-authored doctor, in June 11 of 1983. If I can just read the first paragraph to you. It says "Since June 1981 when it was first reported, the required immune deficiency syndrome, AIDS, has reached epidemic proportions among certain groups in the US. It appears to be a new condition and may well be infectious. Over 13,000 cases had been reported by March 1983 from most parts of the United States and from at least 15 other countries". You knew of that information doctor, I take it?---I knew that.

That it was spread into 15 other countries?---I'm not sure I knew that.

Just go over the page doctor. Page 541. If you go to the third paragraph on that page. Dr Gust with Dr or Mr Mutton says "Concern over the haematological transmission of AIDS could create problems for blood banks. It is now recommended that individuals at risk should not donate blood, while the risk to persons with haemophilia can probably be lowered by

replacing pool La Fallar's Factor 8 concentrate with single donor cryo-precipitate. A formidable exercise". That recommendation of Professor Gust is something you also disagreed with I take it?---Yes.

But doctor, you disagreed with it on the basis that it was a change from concentrate to cryo and you didn't see that as being on?---I'm sorry would you repeat - - -

It is a change - you disagreed with the change from concentrate, large pools, back to cryo-precipitate single pools?---Yes.

Where in the literature can you point to Dr Dietrich's, that recommends a change from single pools to thousands of donations for concentrate?---I don't know that I can point to a literature source. I think experience is the source of changing from single donor source to a pool source. Experience would include the status of the patient, the needs of the patient and the previous exposure history.

Doctor, you - from what's been read to you - are you in a position - as you have to Mr Barnard - to give opinions on the type or the course of treatment for Mr PQ in March 1984?---You mean insofar as his blood product therapy?

Yes?---Well, I have read his history - - -

Read his history?---I mean, I've read what was presented here on those cards that he had multiple bleeds and literally hundreds of bags of cryo-precipitate.

But you don't know how he was coping with cryo-precipitate, do you?---No, I don't know how he was coping but - - -

You don't know whether it was easy or hard for him to go to the hospital to have his cryo-precipitate?---I can only assume that he made multiple trips - - -

I'm not asking you to assume anything, Doctor. I'm asking you do you know - has anyone told you about that?---No.

You don't know whether he had a convenient road into the hospital, that the cryo would be thawed when he arrived there, that the infusion was readily available to him - you don't know that, do you?---I don't know those circumstances.

You don't know much about Mr PQ at all, do you, Doctor?---Only what I've read in a brief report.

You offered your patients cryo-precipitate in January/February 1983 as a choice to concentrate - that's right, isn't it?---In 83, early on.

You come to this court and say that what happened to Mr PQ in March 84, when he was changed over from

cryo-precipitate to concentrate, was good medical practice?---I think I understand the reasons for the change, not in 84.

Tell me, would you have spoken to him about it if you were his doctor?---Well, I would have had much more information if I were his doctor, in making a decision to change him, and then I would have discussed it.

You would have discussed it, wouldn't you?---With him?

Yes?---Yes, I would.

You would have told him about the problems that were associated with the blood supply?---Well - - -

The use of concentrate?---I would have explained the advantages and disadvantages of each form of treatment.

Tell me, Doctor, you were doing the T-cell tests in December 1982, weren't you?---Only on very rare occasions.

But nevertheless you were doing them, weren't you - having them done?---We had them done, yes.

And continued to have them done on not so rare occasions through 1983?---On selected patients, we did.

It was quite possible to do a T-cell test on Mr PQ here in Melbourne in 1984, wasn't it?---I don't have the information to know whether it was - I just don't know.

T-cell tests show people that are immunosuppressed, don't they?---Well, they show changes, yes.

And that was one of the reasons that you had them done in December 1982 - was looking for those changes?---That's right.

Because that was a sign that the people had this disease, had this problem?---Well, that's right.

So that was a test in March 1984 that could have given some indication, if it was done on Mr PQ, as to whether he was infected or not?---It would have given information.

Tell me, Doctor, did you know that blood was taken from Mr PQ in March 1984 when he was changed over from concentrate to cryo-precipitate?---I saw a record of his serum samples and I believe one of the dates was March 84.

What did that serum sample say, with the record that you saw?---I would - you know, I'd rather answer after I saw the record. I believe it was negative but I can't be positive.

You believe his blood, as sampled, was negative in March 1984?---Well, I'm trying to recall all the records I've looked at.

You agree that one test that could have been done, as an indication of his status in relation to AIDS in March 1984, was a T-cell test?---Yes, a T-cell test.

It was the sort of test that you would have done before you made such a dramatic change in treatment, isn't it?---In hindsight, yes, I assume in 84 I would have done it. We didn't have that situation presented so.

When you spoke before about what you were doing with your patients, speaking to them and meeting with them and making decisions in relation to concentrate or cryo-precipitate - when you were doing that with your patients, you'd expect any physician to do that, wouldn't you?---Well, any person treating a number of haemophiliacs, any physician of experience.

And the same goes for elective surgery, does it not?---You mean discussing the pros and cons?

Yes?---Yes, we discussed the pros and cons of elective surgery.

Putting before patients the sort of thing that they'll need - haemophiliac patients - that they'll need a lot of blood if they have surgery?---A lot of concentrate, yes.

A lot of concentrate?---Mmm.

Exposed to many thousands of donors?---Right.

Doctor, you've been asked questions in this court about heat treatment. You knew, I suggest, that in 1983, Cutter Laboratories had developed heat treatment, is that not right?---It was Hyland Laboratories that had developed heat treatment 1983.

Cutter had developed it too, had they not?---I didn't know that then.

I don't want to go through all the transcript, but I suggest in 1986 you gave evidence that Cutter had heat treated product in 1983?---Well, I knew it by 1986, but I didn't know it in 1983.

Hyland Laboratories had been putting out heat treated product since approximately September of 1983?

---Approximately.

And you used that product - - -

HIS HONOUR: What was your answer?---I said yes, they had, yes.

MR RUSH: You used that product, did you not?---We used it in

limited amount, yes.

And the reason you used it was because it was recognised that heat treatment could kill the virus or any virus that was in blood?---Well, that's an over simplification. There was controversy about the use of heat treated concentrate. First of all, there were fears that the heat treatment itself would change the protein around and cause some side effects such as antibody to the Factor 8. Secondly, - that was one great reservation - the second was - antibody formation was the first, the second was the presence of what's called D nature protein in concentrate where they would have some sort of unknown side effect on kidneys and liver. There just wasn't enough data about it to answer those questions, so we did use it hoping that it was safe from hepatitis, but the data from Europe was small in number, actually.

But nevertheless, it was enough for you to use it on some of your patients?---We used it on some of our patients, right.

The reason being that if AIDS was a virus, there was less risk of transmission with the heat treated product?

---Well, that was really not the major question why we used it. We hoped that what they were saying about the European data was actually true, was safe from hepatitis, and children and infants who've never been exposed to hepatitis - one likes to

protect them.

Doctor, you are aware of the heat treated blood products being used in Europe since 1981?---I'm aware of it, yes.

There was nothing new, this heat treatment business, was it? ---Well, it was new to us and I approached things very conservatively. It's very unwise to rush into the mass use of a new product without a lot of data.

I'm accepting that you approached things conservatively - what I'm suggesting to you is that as far as a process for heat treatment is concerned, it had been available, to your knowledge, in Europe since 1981? ---I was told that it had been available, yes.

Doctor, why do pharmaceutical companies put inserts in things like Factor 8 concentrate?---Well, first reason, it's a regulation, and the second reason is to inform the person who's using it about the product.

There was no regulation from the FDA - the FDA in the United States, what's that?---That's the Food and Drug Administration. They issue the regulations.

They didn't issue a regulation in 1983 about warning for the dangers of concentrate, did they?---I don't know what they issued in 1983 as far as package inserts are concerned.

I think in your evidence this morning you said that there was a regulation from the FDA about warnings, you can't say whether that's the case or not - - - ?---I know there's a regulation. You said did I know what it said. I said no I didn't know what it said.

What I'm putting to you, Doctor, is there was no regulation from the FDA in the United States to put a warning on concentrate package inserts at anytime in 1983? ---Well, there had been hepatitis warnings all - for sometime. Now, as far as AIDS, I really don't know what the FDA did or did not do.

Cutter Laboratories and Armour Laboratories, the inserts that you were shown this morning, they - those laboratories put the warnings on their inserts without any direction from the FDA, did they not? ---I don't know whether they were directed to or did it on there own.

You just didn't read the warning?---I didn't read the insert.

And you didn't read any warning?---Well, I had all my information in some other fashion.

Tell me, Doctor, surely there's some purpose in the FDA - surely there's some purpose in the people that make the concentrate writing warnings on their inserts? ---Well, it's a - it's a legal protection for them, number one, that's the major reason, and secondly those products can be used by any physician who's licensed anywhere in the United States that it's available, and the package insert contains all the

information necessary for a physician to use it - theoretically.

At any rate you knew?---I knew without reading - - -

You knew it was dangerous - the concentrate was a risk - I should say - you knew that?---I knew that.

And you knew at that stage that it could be transmitted - that this disease could be transmitted by the concentrate by September 1983?---Yes.

And I guess because of those reasons if you'd been in charge you would have made sure there was a warning?---Made sure there was a warning to whom?

Because you knew it was dangerous, because you knew there was a risk of transmission by concentrate, if you'd been in charge you would have made sure there was a warning on the package insert?---Well, I - it's difficult for me to know what I would do if I were a federal regulator. I just don't think I can assume to know that.

Doctor, you've given evidence from the position of a treater of haemophiliacs in Los Angeles about the appropriateness of Australian donor screening this morning, that's right, isn't it?---I - - -

Blood donor screening?---The donor screening I was informed about of exclusion of males with multiple homosexual partners.

But you were asked about a situation in 1983, were you not, as far as Australian donor screening was concerned?

---(No audible reply).

You were asked to express an opinion by Mr Sher on the - - - ?---Yes, I was, right.

From your vantage point of a treater of haemophiliacs at the Los Angeles Orthopaedic Hospital, that's the vantage point that you - - - ?---That's my perspective.

You don't think it was a bit risky from that perspective offering an opinion about what was going on in Australia?---Well, based on my knowledge of the US I'm simply equating the two.

Because they were pretty similar?---Well, human behaviour is probably similar in the two populations.

Human behaviour as far as it would concern the homosexual population?---Yes - as far it concerns peoples ability to tell the truth on voluntary screening.

You wrote a letter to Dr Riccard, didn't you, in June 1983 about - in which you put views held in the United States about donor screening?---I don't recall, but if you have it I'm sure I wrote it.

Didn't you write Dr Riccard a letter in preparation for this World Haemophilia Conference in Stockholm?---I wrote - I wrote a great many people, yes.

In that letter that you wrote to Dr Riccard you gave information about what was happening with donor screening in the United States?---I don't recall the contents of that letter.

I might have given you the wrong date. May 9 1983 I suggest you wrote a letter to Dr Riccard from the - in your position as chairman of the World Federation of

Haemophilia, and you enclosed in that a summary of the position as of May 1983, do you remember that?
---Well, I remember all the letters but I don't know what the - I don't recall the contents in detail.

Do you agree that you wrote him a letter and you enclosed a summary, as far as the World Federation of Haemophilia was concerned of the position in May of 1983?---I don't know whether I created the summary or copied it from someone.

Would you like to have a look at this just to check that you signed it. Shelby L Dietrich MD. Chairman of the Medical Advisory Board and the enclosure that was put in?---What is the enclosure?

World Federation of Haemophilia. Summary as of May 1983?---I'd like to see if I copied that from the CDC. This attachment which goes on for pages I copied from, I believe the National Haemophilia Foundation of the US. I didn't create it de novo, I copied it until I got to the last point where I posed the questions.

I see. Could you hand that back to me?---Certainly.

You certainly agree after looking at that that that's a copy of the letter that you wrote to Dr Riccard?---Yes.

With the attachment?---Right.

That you have gone through as being part of it?---Right. I agree.

HIS HONOUR: When you get to a convenient point Mr Rush.

MR RUSH: I'm happy to finish here, your Honour.

HIS HONOUR: Mr Foreman and members of the jury earlier during the plaintiff's case there were three exhibits which were marked for identification but not admitted into evidence, those have now been the subject of some

debate before me and I am now admitting the following documents into evidence.

EXHIBIT PX21 ... Three reports of Commonwealth Serum Laboratories for the years 1982-1983, 1983-1984, 1984-1985.

EXHIBIT PX22 ... Two inserts of CSL dated September 1981 and February 1984 relating to moxacin.

EXHIBIT PX23 ... Insert marked CSL relating to hepatitis B vaccine.

HIS HONOUR: Those exhibits will be handed to you and you can briefly look at them when you retire to the jury room. The court will now be adjourned until 11.15 tomorrow morning.

WITNESS STOOD DOWN

AT 4.14 PM THE COURT WAS ADJOURNED
UNTIL FRIDAY, 5 OCTOBER 1990

SHELBY LEE DIETRICH:

MR RUSH: Dr Dietrich, before we go to the Riccard - the letter that you sent to Dr Riccard, can I just ask you a couple of things concerning your evidence yesterday. You had patients on cryo-precipitate in early 1983?---Yes, we did.

And how many patients, Doctor?---Perhaps 10 or 15. Other than the von Willebrand patients who were always on cryo for medical reasons.

So, there were 10 or 15 haemophiliacs that were - - - ?

---That's right - - -

Were on cryo-precipitate?---At the most, yes.

And they stayed on cryo-precipitate, did they not?---No - - -

During 1983?---I can't give a precise answer. I can - I do remember that as 1983 went on - into 1984 - most of the those patients converted back to concentrate, unless they were small children. The adults who'd been on concentrate went back to concentrate. The children stayed on cryo-precipitate - children under four - until heat treated concentrate was available.

You changed - didn't you have long term users of cryo-precipitate that were severe haemophiliacs?---Not to my recollection - we had none - - -

You don't - - - ?---We had no long term users - severe haemophiliacs - who used cryo-precipitate.

There were some children that you kept on cryo-precipitate

---Yes.

And you kept them on cryo-precipitate and didn't put them onto concentrate until the heat treated concentrate was available?---That's correct.

It was your view, was it, when you changed them onto the heat concentrate that that greatly reduced their chances of being infected with AIDS?---Yes.

And it was your view that by keeping them on cryo-precipitate rather than putting them on concentrate, that that also would greatly reduce their chances of getting AIDS?---I don't know that I'd say greatly reduced. I would modify that to say minimise or reduce. By the later - latter part of 1983, or during 83 it was clear Los Angeles was an area of high AIDS prevalence, so that safety was very relative in Los Angeles.

So if you were getting your cryo-precipitate from Los Angeles it was of a much higher - that because of the blood supply, and the people donating in Los Angeles it was greater risk of the cryo-precipitate?---That's correct, yes.

But you changed them over to the heat treated concentrate, not to any other type of concentrate - not to the normal concentrate?---No, we changed the children to heat treated. The adults changed themselves to whatever they wanted.

Dr Dietrich, yesterday when Mr Gillies was asking you some questions about the advantages or lack of

disadvantages of concentrate as opposed to cryo-precipitate, he asked you this question:

> In the management of a case of a severe haemophilia am I right in saying that concentrate really is the only prudent modality of treatment? -

and you answered:

> Well, it's - well, it's certainly the most - the more acceptable and prudent course where no concentrate is available as in the third world one has to get along.

Now, the position is, Doctor, isn't it, that cryo-precipitate is used in lots of countries that could not be considered to be third world countries? ---Yes, it is.

And if the impression was left after your answer there, that it was basically third world countries that used cryo-precipitate, rather than what we might consider to be the developed world, that would be an incorrect impression?---Yes, I didn't mean to lead that impression with that statement.

Because in Australia in 1983 certainly cryo-precipitate was widely used, wasn't it?---I think so, and my knowledge of how much concentrate and how much cryo is used in Australia's really somewhat limited.

Were you aware of the home treatment program at the Royal Prince Alfred Hospital in Sydney?---Yes.

For cryo-precipitate?---I was. With cryo-precipitate?

Yes?---I'm not sure I was aware of that. I can't answer definitively.

It was used exclusively in Finland was it not?---Yes, I was aware of Finland.

Doctor, the National Haemophilia Foundation in the United States in 1983. It was asking the producers of concentrate to avoid taking blood for concentrate products from the high risk areas, wasn't it?---Yes.

What the Haemophilia Foundation was doing, is saying to the concentrate manufacturers, let's avoid places like Los Angeles or San Francisco, or New York, where there is obviously a high risk of AIDS?---No, that's not quite correct. They asked the fractionators to screen the individual. The fractionators continued and still do have plasmapheresis establishments in Los Angeles and around the bay area.

They might still have them but what I'm putting to you is that the National Haemophilia Foundation was asking the concentrate manufacturers, not to include blood from those high risk areas in the concentrate?---No. I don't think there was a geographic ban. It was an individual screen of the donor. I have to differ with you on that.

Doctor, can I read from a document that Mr Sher took you to and it is the National Haemophilia Foundation

recommendations to prevent AIDS in patients with haemophilia. It is tab 17 in the plaintiff's folder. I don't know that you necessarily have to be shown it because I can read it to you. Perhaps, you might as well be shown it doctor. Book 1 your Honour.

HIS HONOUR: Book 1 A17, is it?

MR RUSH: Yes your Honour.

Doctor Dietrich if you go to what is number 2 half way down the page in paragraph 3 which reads "In addition the manufacturers should cease using plasma obtained from donor centres that draw from population groups in which there is a significant AIDS incidence. It is clear from the epidemiologic data, that the pool of individuals at risk of AIDS transmission is not uniform throughout the country and that a great deal could be achieved by excluding donors from the hot spots". I suggest to you doctor, that when the National Haemophilia Foundation says, "In addition the manufacturers should cease using plasma obtained from donor centres that draw from the population groups in which there is a significant risk of AIDS incidence". They are saying don't take the blood from that centre?---It think that's exactly what they were saying, although that didn't happen in exactly that fashion.

When I put the question to you before you placed another interpretation on this in relation to donors?---Yes.

I see exactly what you are pointing at and I agree that was the inference.

What they were saying is what I put to you and you had misunderstood - - - ?---Yes, I misunderstood.

That's a sensible thing in 1983 wasn't it doctor?---Yes, it was sensible.

Doctor, in talking about concentrate and cryo-precipitate could you just tell us - you've told us of the risks of cryo-precipitate or what may happen to people using cryo-precipitate. What about the risks of concentrate. What risks were attached to the use of concentrate?---The major risk attached to the use of concentrate are the infections transmitted through concentrate and that was hepatitis up until HIV. There are rare minor and even extremely rare major allergic reactions to concentrate. In all my career I've seen only two major and I must have seen thousands, if not more of infusions. But as I said, I certainly have to mention that they have occurred. The minor ones are just that. Very minor. Headache and so forth. The risk of fluid overload is not present. That's a non-existent risk. Sticking to medical risks only I think the risk of transmission of infection is the only true risk. There has been speculation but it has never been proven that concentrate stimulates inhibitor formation, but so does cryo, and I'm not sure anyone has ever quantified the difference in the risks between the two.

Doctor, do you know of Professor Pennington?---By name.

What do you know of him by name?---Well, in all honesty I'm not sure. He's a physician involved in blood banking.

Were you aware that in 1983 he was the chairman of the National Blood Transfusion Committee of the Red Cross?---In Australia?

In Australia?---I'm not sure I was aware of that.

I want to put to you, Doctor, something that Professor Pennington wrote in October, 14 October 1983 after receiving some information from the World Federation of Haemophilia, of which you will remember at the time. Professor Pennington in writing the letter that he wrote to the Commonwealth Department of Health. He said "One point of importance in the World Federation document to which reference should be made is their statement that infusion therapy should never be withheld because of the risk of hepatitis. The transmission of disease by products obtained" - that's the quote from the World Federation of Haemophilia?---Mmm.

I'll read it again. "One point of importance in the World Federation document to which reference should be made is their statement that" and I quote "Infusion therapy should never be withheld because of the risk of hepatitis", that's the end of the quote from the World Federation. He goes on "The transmission of disease by products obtained from pooled plasma is a

real problem. There is a high incidence of chronic liver disease in haemophiliacs who have been managed in this way and it is likely to be a further five or 10 years before we commence seeing cases with haemorrhage of the oesophageal varices"?---Varices.

What's that?---Those are slow and enlarged blood vessels that burst.

So Professor Pennington is saying "It will be five or 10 years before we commence seeing cases with haemorrhage from oesophageal varices consequent on cirrhosis of the liver and later cases of cancer of the liver associated with chronic viral infection. Once these complications become apparent there may well be a major swing back to the use of cryo-precipitate from small plasma pools and more conservative therapy". What about the risk of cancer, Doctor, or the risk to the oesophagus from use of concentrate?---Well, those risks exist. They have to be put into perspective with all the other risks of being haemophiliac. I have seen death, one death from cancer of the liver. I've seen several deaths from cirrhosis of the liver with the complications you've mentioned. I've also seen several times more deaths from - from that I mean three or four fold more deaths from bleeding. Being a haemophiliac is a risk, there is no way to treat haemophilia without incurring some risk. It's not - there is no such thing as totally safe therapy. So one simply has to

decide in the patient's best interests which carries the greater or lesser risk. Cryo I believe does not carry any lesser risk of Hepatitis B transmission at all and non B is now really a field under evolution with a new test. But all summed up I don't think cryo from the hepatitis point of view in a heavily treated haemophiliac carried a significant margin of safety.

But Professor Pennington obviously does because he says the transmission of disease by products obtained from pooled plasma - he's talking about pooled plasma there, isn't he?---I realise that we are differing opinion so I guess that's where we are.

Doctor, you said in answer to Mr Sher that there was a dip, you described it as, in the use of concentrate in 1983/84?---Yes, that's correct.

I just want to put to you what Professor Pennington says about that. He says "In this context, the recent reports of AIDS transmitted by blood products to subjects with haemophilia in the United States have led to a major reversal of practice in many centres in that country in the past 12 months, with extensive dependence upon cryo-precipitate rather than Factor 8 concentrate in the management of haemophilia. Whether the same will occur in this country is yet to be seen, but I believe it is quite possible there will be a change as a result of the appearance of this disease in the Australian community despite the precautions". Now, Doctor, there was a bit more than a dip in relation to the use of concentrate in the United States, wasn't there?---Well, in our centre, the consumption of concentrate went down about 20 per cent during the latter part of 83.

That's a pretty significant dip, isn't it?---Well, you're talking about millions of units of concentrate - yes, it was significant and we were actually quite apprehensive because patients we felt were under treating. Then the assumption again gradually rose.

HIS HONOUR: Here you said "in our" and I didn't hear the next word - will you - - -?---In our centre.

Centre, thank you?---I really can't address the trends in the entire United States with accuracy.

MR RUSH: Dr Dietrich, you used a lot of concentrate in your

hospital, didn't you?---We used about 30 million units annually.

Your patients were over-treated with concentrate, weren't they?---I don't know they were over-treated. In our judgment, that was the proper treatment. That's a perjority of judgment, I would say.

It was a judgment, I suggest, Dr Dietrich, that you were prepared to give in Sydney last year - - -?---Yes.

Just a minute - that your patients were clinically over-treated with concentrate?---I think I phrased that or I would phrase it again today that on home treatment, many patients used concentrate to treat arthritic joint problems rather than true bleeds, and we couldn't distinguish the two. Nor could they.

Doctor, I suggest this was put to you in Sydney in 1989 - this was quoting back in the question what you've previously said in your evidence - the quote of your evidence was "Because, quite honestly, I think our patients overuse concentrate?" and your answer was "Yes". Then the question is said "In other words, concentrate was being administered where it was not clinically necessary - correct?" and your answer was "Uncalled treatment programs, yes"?---What did you say?

"Uncalled treatment programs, yes"?---On home treatment programs, I - - -

"Uncalled treatment programs"?---Uncalled?

Uncalled - page 549?---Well, I'm saying exactly the same thing today I said last year. We did have overuse of concentrate. It was freely available. It was affordable at that time. Patients used it at home because they felt they were bleeding. We told them to do that. We did not over-treat in the sense that we calculated the wrong dose and administered too high a dose.

Doctor, evidence has been given in this court - and I'll just put the question and the answer to you - "In general" - this is to Professor Engleman - "are you able to say what the situation was throughout the United States in terms of the relevant use of cryo-precipitate as against concentrate at this time?" and he answered "Well, the use of cryo-precipitate increased enormously relative to the use of concentrate as a direct consequence of the fear of AIDS, concern about the transmission of AIDS" - is that right?---Would you read that once more, please?

"In general, are you able to say what the situation was throughout the United States in terms of the relevant use of cryo-precipitate as against concentrate at this time?" and you answered "Well, the use of cryo-precipitate increased enormously relative to the use of concentrate" - - -

HIS HONOUR: Mr Rush, you said by mistake "you said".

MR RUSH: I'm sorry, your Honour

HIS HONOUR: Would you rephrase the question?

MR RUSH: Yes, I will. Do you want me to read the question again, Doctor?---No, I think I follow.

Professor Engleman said "Well, the use of cryo-precipitate increased enormously relative to the use of concentrate as a direct consequence of the fear of AIDS, concern about transmission of AIDS". Now, Doctor, you've given evidence of what happened in your hospital, but that's what's happened throughout the United States, isn't it?---I will - cannot really definitively answer. The Red Cross in the United States would have to furnish the figures on cryo consumption.

Doctor, just one other matter on this. You said yesterday you just - you didn't read the package insert warnings, you just - you didn't take any notice of them?---I was already aware of what was in the package insert warnings.

You weren't aware of the warning that was shown to you yesterday - - -?---At that time, I wasn't.

You, whilst not reading the warnings, or reading those warnings, you were prepared to accept what the salesmen from the fractionators were telling you when they came to see you?---Well, I think that's a rather incomplete picture of how information was disseminated. We had multiple avenues of communication through journals, the National Haemophilia Foundation, the sales representatives. I don't think I could say I accepted what sales representatives said as scientific truth. I learned that when I was an intern.

The FDA were responsible for the package inserts weren't they?---They were responsible for approving the wording, yes.

Doctor, next we come to that letter that we came to yesterday the Riccard - the letter that you wrote to Dr Riccard of May 9 and the enclosures that were in it. Doctor, you said to Dr Riccard in the letter of May 9, "By the time you receive the enclosed material new developments or discoveries may have occurred". I take it you said that because all the time, throughout 1983, there was a rapid increase in learning?---I think that was a statement of hope in 1983.

Of hope?---Yes.

In the enclosure doctor that you sent to Dr Riccard in May of 1983, in part of the enclosure in connection with blood and blood plasma donation. What you said

"Because the possibility of acquiring AIDS through blood components, or blood exists, there is intense concern about donation of blood or plasma by persons belonging to the high risk groups". Was that your view at the time?---Yes.

You set out for Dr Riccard the steps that were being taken by the Alpha Therapeutic Corporation in the United States, in relation to their screening of blood donors, didn't you?---I can't recall what's in that letter but I will take your word, that's what I did.

If I can read doctor "The pharmaceutical industry is being extremely concerned and co-operating in attempts to exclude plasma donors at high risk for AIDS. These efforts are summarised in a public service brochure, recently issued by Alpha Therapeutic Corporation". Then you go on to quote the brochure. Question: "What are manufacturers doing to diminish our risk?" The answer: "All commercial producers of concentrate, following Alpha's lead, have taken steps to eliminate members of high risk groups from their donor pools". That's a step that you would agree with, would you not?---Yes.

"Alpha now educates donors about the risk of AIDS." That also is a step you would agree with?---I am aware of that brochure now that you are beginning it.

But it is a step you would agree with?---Yes.

Educating donors about the risk of AIDS?---Yes.

Specifically identifies high risk donors, such as male

homosexuals. Intravenous drug users and travellers from Haiti. Again, that established what the high risk groups were?---That's right.

Male homosexuals. "Staff personnel back-up a self exclusion option with questions designed to identify and exclude high risk donors." A step you would agreed with?---Yes.

Proper blood screening?---This was actually a description of what was happening.

Steps that you would agreed with as being appropriate?---Yes.

"All donors are screened via medical history. Physical examinations and questionnaires for early signs of AIDS." Again, good blood banking practise in your opinion?---I have to point out that all of these steps you are reading, which were carried out just as you are saying, but were in the commercial plasmapheresis stations, not in the voluntary.

They are good blood banking procedures aren't they doctor?---They are good procedures, but there are very valid reasons in the United States, why those same procedures were not implemented at that time in the voluntary blood sector.

Maybe Doctor, but they're good blood banking procedures, are they not?---Yes.

Doctor, were you aware that in May 1983 the commonwealth government in Australia recommended to the blood banks in Australia that no male homosexuals should donate blood?---I wasn't aware of the day - of the date of that recommendation - - -

Were you aware of it?

MR SHER: Mr Rush - - -

MR RUSH: Were you aware of that, Dr Dietrich?

MR SHER: Your Honour, I challenge the assertion - that that's been established by the evidence. There is in my submission no evidence of the nature described by Mr Rush. There is some evidence that touches on it. He has overstated it in my submission. If he wants to put that to the witness he should identify the evidence or the transcript reference from which he gets it.

HIS HONOUR: What do you say, Mr Rush?

MR RUSH: Your Honour, in my submission I haven't got the page reference as yet, but Dr Gatenby gave evidence of the recommendation of the doctor from the Department of Health - Commonwealth Department of Health - at the AIDS Scientific Committee meeting. There is the evidence, your Honour, of the advertisement - there is material in Book 1 from medical practice, and I'll take the witness to that, if that's what Mr Sher desires, your Honour.

I'll go onto something else, if it pleases, your Honour, while that's being found.

Dr. just to go back to the material that you wrote to Dr Riccard. You told him of what was being done by Alpha therapeutic or distributed what they were doing:

> All donors are screened by medical history. Physical examination and questionnaires are early signs of AIDS, such as unexplained weight loss and swollen glands. Alpha does not accept plasma from any suspect donor.

And that also was sound in relation to what Alpha were doing?---That's right.

That as you say, Doctor, they were the producers of the Factor 8 concentrate?---Yes, they were one of the four producers.

Doctor, you gave evidence yesterday of the appropriateness of the Red Cross screening in Australia in 1983. What, Doctor, was your understanding of how the Red Cross - was it your understanding the Red Cross were responsible for blood collection throughout Australia?---Yes, that's my understanding.

That the Red Cross were the only collectors of blood in Australia?---I believe that - that's my understanding of the Australia system, yes.

Yes, you gave your opinion based on that understanding, is that right?---I'm sorry?

You gave your opinion yesterday based on the understanding that the Australian Red Cross was responsible for the collection of blood throughout Australia?---Yes, that's correct.

That's a very different position to the position in the United States, isn't it?---It's a different system, yes.

And it's a very different system, isn't it?---Yes, because the United States system has a dual track of paid donors for plasma, and voluntary for blood.

You have many or different organisations collecting blood around the United States?---Yes, there is Red Cross and then something under other voluntary organisations collecting blood.

They each have their independence?---They're each independent in there own area, yes.

In Australia it's your understanding that there is only the one, the Australian Red Cross?---That's my understanding.

That placed, did it not, in your opinion the Red Cross are in a unique position to be able to institute a uniform system of blood screening throughout Australia?

---Well, to be quite candid I don't think I thought much about Australia in 1983.

But, Doctor, you've given an opinion to this court of what was appropriate for Australia in 1983. Are you saying the opinion you gave probably wasn't appropriate as well?---No, I didn't follow the opinion through to the inferences that there would be one system for the whole country. I certainly do agree, that's true.

Looking at it now you would agree that the Red Cross was in a unique position in Australia to institute a nationwide system for blood screening?---Assuming the basic premise is true, yes.

Assuming the premise upon which you gave evidence yesterday is true?---Yes.

Is that right?---That's correct.

Doctor, were you aware of what went on in any individual State in Australia?---No, I wasn't.

You gave evidence yesterday about surrogate testing. Have you ever been informed of the introduction of a surrogate test by the New South Wales Blood Bank?

---Not to my immediate recollection I don't remember.

When did the Hepatitis B core antibody test, when did that come into existence Dr Dietrich?---Well, as a test, a laboratory test I remember it was available probably by the early 80s as a - just as a - but not as a surrogate test. One could order it for an individual patient.

Whether that was introduced by the New South Wales Red Cross you can't say?---I can't remember.

Do you know Dr Archer?---I've met Dr Archer, yes.

Who's Dr Archer?---He's director of the blood bank in Melbourne or Sydney.

I think it's Sydney?---Sydney.

Does that ring a bell?---Pardon me?

That rings a bell?---Yes, that rings a bell.

What about the director in Melbourne?---I can't remember who that is.

Do you know Dr Morris?---Not to my knowledge.

Are you aware of Dr Archer still being in his position in Sydney as the head of the blood bank?---Yes, I am aware.

Doctor, you gave evidence that when you were at the orthopaedic hospital in 1983/84 you had something like 450 haemophilia patients?---Correct.

How many of those were severe haemophiliacs, Doctor?---As I recall we estimated approximately 300 were severe and 150 moderate and mild.

Doctor, what percentage of those 350 severe haemophiliacs have either died of AIDs - - -

HIS HONOUR: You said 350.

MR RUSH: Yes, your Honour.

HIS HONOUR: The Doctor said 300 severe, 150 moderate.

MR RUSH: 300, is it, Doctor?---That's about right.

What percentage of the 300 have either died of AIDS, have AIDS or are HIV positive?---All told the HIV positivity rate in the Factor 8 severes is about 80 per cent, so 80 per cent of about 225, you see they're Factor 9 patients in the total too, of that 80 per cent of which is over 200, 40 - no, about 50 now have AIDS or have expired of AIDS, which is about close to 25 per cent, I think.

Doctor, you remember yesterday I put some transcript from the case of Doe against Cutter Laboratories, the case that you gave evidence in in the United States, I think it was 1988, October 1988, and you said there was a mistake in the transcript. Do you remember that?---It's not a mistake in the transcript. Apparently there was an error in what I said in that transcript.

I suggest, Doctor, you said that there was a mistake in the transcript yesterday but - - -?---Well, why don't you read to me and we'll decide.

Well look, I"ll just read it to you again to straighten it out, Doctor. Page 16 of that transcript you said "The CDCNHF investigation certainly helped our thinking in the direction which I'm discussing and our thinking that there was a new disease present.

It was new to everyone. It wasn't simply an unrecognised disease making it self evident and that our patients already had this new disease and the only way they could get it would be by concentrate"? ---Well, I said I made a mistake in saying "Only by concentrate". Because that's an error I should have said what I knew which is by concentrate in blood.

Doctor, you have an opportunity with these sort of depositions to correct errors, don't you?---Yes.

Because the depositions once they're typed up are sent back to you so that you can check over for that sort of mistake?---Mmm.

And then you sign them as being correct, do you not?---That's right.

And you signed that deposition as being correct, didn't you? ---I didn't catch the error.

You didn't catch the error?---(No audible reply).

Just going back to this last matter now. I'm reading from C4, your Honour, of Book 1 - I'm sorry - C - - -

HIS HONOUR: C3 of Book 1.

MR RUSH: Doctor, you see the "It's from medical practice" - down the bottom of the page - "of June of 1983"? ---Mmm - I see it.

And at the top of that it's headed "The Commonwealth Department of Health has supplied the following". Headed "AIDS, deficient AIDS, Acquired Immune Deficiency Syndrome". If you down the page to underneath the - see where it says "Unfortunately there are no markers readily available which can be used for screening purposes to identify people who have or have had the disease"?---Yes, I follow you.

And then the next line "At this stage it's considered it would be prudent for male homosexuals not to donate blood". What I want to ask you, Doctor, is that you were aware of any recommendation from the

Commonwealth Department of Health of Australia in late May or June 1983, along those lines?---In 1983 I was not aware of Australian recommendations.

Doctor, if you can just go back in that folder to A17 which is the group of documents at the beginning. You see, it's the National Haemophilia Foundation recommendations of January 14 1983 - back to them again?---Yes.

And you were involved with the National Haemophilia Foundation, weren't you?---At that time I was not directly involved - - -

Did you?---Not under committees, no.

You'd been completing a survey for them?---Well, that survey was run from the National Haemophilia Foundation in the CDC, yes.

Doctor, if you go again to the recommendations, and this time to number 1 "Recommendations for concentrate manufacturers". Recommendation 1 talks about identification by direct questioning, individuals who belong to groups at high risk of transmitting AIDS specifically male homosexuals IV drug users. That's a - would you agree - a similar recommendation to what's just been read from the medical practice note under the heading "Commonwealth Department of Health"?---They sound very similar.

The recommendation, Doctor, was that all homosexuals should be excluded from donating blood?---Well, I suppose by -

it's implied all.

And that there should be direct questioning of blood donors?

---By the Factor 8 concentrate manufacturers.

And they were appropriate recommendations, weren't they, Doctor?---Yes, they were.

HIS HONOUR: Mr Sher?

RE-EXAMINED BY MR SHER

MR SHER: Doctor, you made the point earlier today, and I want to take you to the document that you have in front of you about recommendations in relation to the manufacturer of Factor 8. As far as you were aware was Factor 8 made by other than commercial manufacturers in the US in 1983?---No. All the Factor 8 concentrate was made by the commercial manufacturers.

Did they have voluntary or paid donors?---They had paid donors with the exception of the Red Cross - US National Red Cross - who made concentrate under - who, let me re-phrase this. Who distributed concentrate under their label which had been made for them, fractionated by Hyland Labs from voluntary plasma.

Right?---Is that clear - my answer?

Yes. These recommendations from the National Haemophilia Foundation of January 14, 1983, were directed therefore to the commercial manufacturers obtaining donations from paid donors?---Yes they were.

In your opinion, as at that time, was it legitimate to differentiate between the paid donors and the voluntary donors in relation to voluntary screening?---Yes, it was, in my opinion, legitimate because the paid donor system in the US had a bad reputation.

You were asked a little while ago by Mr Rush some questions as

to why certain steps were not implemented in relation to volunteer donors, and you said there were good reasons for that. Do you recall that question?---Yes, I did say that.

Can you tell us what those reasons were?---Well, those reasons were more legal than medical, but basically the volunteer blood system and the volunteer blood donor is treated in the US with a great deal of respect. It was felt - and I'm sure in Australia - and it was felt that it was an intrusion on civil liberties and privacy to question a person - - -

MR RUSH: Your Honour - I now object based on the evidence as given. In my respectful submission your Honour, she is not in a position to be able to give this sort of blood banking evidence. She is not a blood banker. She is not a blood banker your Honour. I didn't ask her about the intricacies of the question that Mr Sher is putting to her, and in my submission it is going beyond what was asked in cross-examination. It is based on hearsay your Honour in relation to what the witness is now saying. It is not evidence of her own knowledge.

HIS HONOUR: I regard it as rising out of cross-examination. I will permit it.

MR SHER: I'll have to get you to continue on your answer if you can remember the question and what you were saying. You were telling us what the good reasons were why it was not necessary to implement steps, or

there were good reasons you said - steps in relation to volunteer donors?---I'm speaking actually from direct information and not from hearsay. At the January 1983 meeting at the CDC the - a group, two groups I believe representing the gay community made their position very clear that any questioning of donors, volunteer donors, of sexual preference was considered to be an extreme infringement of privacy and civil liberties.

In your experience of blood donors in the United States of America, what was the view about the way in which volunteer donors ought to be treated?---I'm not sure I understand your question, how they should be treated?

Well, was the fact that they were volunteers of any significance?---Yes, that was of great significance in the US. The fact they were volunteers. Blood was regarded as a gift and the volunteer was - I don't know how to phrase it, treated with a great deal of tenderness in order to keep the volunteer coming back.

I want to ask you some questions arising out of some of the matters you were asked?---You were asked by, I think it was Mr Rush, that - and I'm reading from 4814 your Honour. It was put to you that hepatitis B had a similar - had similar attributes as to infection as the AIDS virus. Your answer was "Well, in 1982 I didn't know any of that information". You were

asked whether you agree - it was put "But you agree now don't you?" You said "Well, hindsight is a great teacher"?---I said that.

I want to ask you some questions about that. Back in 1983 it was - I think this was common ground - understood that hepatitis B was a blood borne virus?---Yes.

And therefore transmissible through blood products?---yes.

And one of the risks that people using concentrate were subject to?---That's correct.

Does it follow that anyone using blood products were subject to the risk of Hepatitis B at that time?---Do you mean any person receiving blood or blood products?

Any blood product?---That's true. It was - that's a hazard of receiving any blood or blood product except gammaglobulin.

Mr Rush also asked you about the fact that you knew in 1981 in Europe they were heat treating blood concentrate? ---Yes.

You've told us how it became available in America I think much later than that, I think 83/84?---Correct.

You were talking there about treating concentrate for hepatitis?---That's right.

That's heat treating it for hepatitis. Now, can you heat treat cryo-precipitate?---No, you cannot heat treat cryo-precipitate, it - - -

So was there any way of protecting a person from the risk of hepatitis by heat treating the cryo-precipitate in the way in which in Europe they were heat treating concentrate?---No.

What about other blood products, did you use other blood products in your hospital?---Well, we used packed red cells for transfusion frequently.

Can you heat treat packed red cells?---No.

Was therefore a risk of transmitting Hepatitis B through

packed red cells that couldn't be dealt with by heat treatment?---That's correct.

Nonetheless you used it?---That's right, when medically indicated.

When did you first become aware that heat treatment could deactivate or protect people from the AIDS virus as distinct from hepatitis?---In September 1984.

As far as you are aware were they heat treating concentrate to protect people from what was causing AIDS - or when did they start to do that?---After the data and the experiments at the CDC, Centre for Disease Control were completed.

Were they heat treating anything at all in America or as far as you're aware in the world, to protect people from AIDS before the latter part of 1984?---I think heat treatment was in use in the hopes and the - that it would inactivate what later was determined to be the AIDS virus, but that was based on hope.

When did people know in the medical profession in America that heat treatment could protect you from the AIDS virus?--In September/October 1984 when there were reports from San Francisco and the CDC.

You told us - going now to page 4822, your Honour. You told us in answer to some questions from Mr Rush that - and he was asking you about the fact that you suspended elective surgery and counselled your patients and were attempting to reduce their consumption of concentrate, and he then said to you

"In 1982 you could have for instance got volunteer blood, could you not?" You said "Well, we had all volunteer blood as far as whole blood and blood components. As far as concentrate we had concentrate. If we'd used cryo it would have been volunteered". Do you remember that evidence?---Yes.

How much blood product other than concentrate were you using at the time in - I just want to get some rough estimate of whether it was just a little bit or whether it was more than that, but you describe there namely whole blood, blood components and cryo from volunteers?---For haemophiliacs.

At all?---At all?

Yes?---Well, I was practising in a surgical hospital so we used considerable amount of packed red cells to transfuse surgery patients. For cryo which was used in that hospital exclusively for haemophilia patients since there were no other patients needing cryo, we used a small amount. Other blood components which are platelets and fresh frozen plasma all come from basically blood donation, we used a small amount during that time.

In any event, all of this blood and blood product came, you've told us, from volunteer blood donors?---That's correct.

In those circumstances, where was the voluntary blood products coming from?---They were coming from or supplied to us by the Los Angeles Orange County Red Cross and drawn from donors residing in the Los Angeles - Orange County is right next to Los Angeles - in that area - metropolitan area.

In using these voluntary blood products, I take it you'd have been interested in how the Red Cross was going about collecting this blood from donors?---Yes, I was interested.

Were you aware of the steps being taken in 83 by the Red Cross in relation to screening blood donors?---Yes, I was aware. I met regularly with the head of the Red Cross in Los Angeles and I also became a volunteer blood donor.

Were you aware that the Red Cross were screening in accordance with the recommendations made in March 1983?---Well, I was - yes, I was aware. Those - I was aware the Red Cross were screening in a manner consistent with the volunteer donor system.

I think it's common ground that recommendation and the steps that were taken was to screen amongst homosexual - just the multiple partner homosexuals?---Yes, that's correct.

Are you aware of that?---Yes.

Did you regard that as an appropriate screening process for the voluntary blood donors?---I believe I've already given my opinion on the effectiveness and appropriateness, yes - effectiveness, no.

For the reasons you've told us yesterday?---For reasons I've already mentioned.

When in America, to your recollection, was the voluntary blood donor high risk category of homosexual expanded to include homosexuals other than multiple partners?---I believe in 1985 or 1986, but I can't be precise.

Now, in using blood products from the Red Cross, which were obtained from voluntary donors, during 83 - and I take it used them in 84 as well?---The usage continued.

Were you - did the Red Cross warn any of your patients about any risks associated with using those products?---The Red Cross personnel had no contact at all with our patients. They were in a separate place geographically. They supplied the blood or the whatever was ordered and we had no personal contact with them or them with us.

What's your view as to whether it was appropriate for the Red Cross to be going to your patients and warning your patients?---Well, my view was that any interference or communication between the Red Cross was inappropriate and disruptive to the physician/patient relationship and actually was not

be tolerated in the United States.

And this notwithstanding the fact that the Red Cross blood products in 83 and 84 were obtained from voluntary donors and the homosexuals that were screened from them were multiple partner homosexuals?---Notwithstanding that.

MR RUSH: Better be careful about the leading nature of the questions - - -

MR SHER: Well, I - there is an element of leading in it, but it was all common ground I thought, with respect. All right.

Now, I just want to ask you another question or two about something you mentioned. You used the word "inoculum" in the course of talking about the - I think the risk of transmission of an infection from cryo-precipitate?---Yes, I did use that word.

What's the inoculum, Doctor?---Well, the inoculum is a term applied to the total bacterial or viral quantity in any given substance at any given time. In other words, if one knew that a unit of blood did have an HIV positive unit in it, one talks about the inoculum as the size and quantity of the virus in that one unit.

How does the inoculum in a contaminated batch of cryo compare with the size of the inoculum in a contaminated donor to a pooled concentrate product?---Well, we have discussed that very question at great length and I would say that there is no scientific answer

quantifiable to say "This inoculum is 10 times that inoculum". We always felt that in a unit of blood or cryo, that if the donor was positive - and this information I'm now giving you comes from my experience in the transfusion safety study - that if the unit was positive the patient had received - the recipient had received a very large inoculum and the data really bore out that contention, how large the inoculum was in concentrate, no-one has really ever been able to determine.

What are your chances if you get cryo or any blood product other than concentrate, a non pooled product?---Mmm.

And the donor is HIV positive, what were your chances of getting AIDS or HIV?---HIV. Our data from the transfusion safety based on 100 recipients of blood and components was that 90 per cent became infected.

Your opinion in relation to keeping your patients on concentrate because as you put it at 4832, for the majority of their lives if they were going to get the virus they already had it, that was the proposition with which you agreed, you were there talking of patients who'd had - were you there talking of patients who'd had concentrate made by commercial manufacturers?---Yes, I was.

You were asked some questions about the evidence you'd given in one of the US cases and it was put to you that you'd given evidence that it was - you weren't convinced it was a transmissible agent such as a virus but it was in blood products and having been asked about that evidence by Mr Rush, and this is at 4844, your Honour. You then said this "I think the explanation is that something else could have been in blood products like proteins, unknown virus, what not". Do you recall giving that answer?---Yes, I do.

What did you actually mean to convey to us by that answer in dealing with that evidence you'd given in the American case?---I think I - I know I meant to

convey that at the time of 83 and when there was little knowledge and a lot of uncertainty one of the current theories was that concentrate contained so much globulin and protein that it was suppressing the immune system and that concentrate also might contain the unknown viruses, I mean unknown to anyone, that concentrate was different from cryo-precipitate in blood and that because haemophiliacs had had so much concentrate over the years since it became available that they were now developing this whatever syndrome.

What do you say as to whether that made them the same as other people coming down with AIDs or whether there were differences?---Well, we didn't know. That was really one of the big unknowns, were they the same or were they different and we just speculated but had no answers.

You mentioned also in the course of some questioning by Mr Rush, that - in keeping in touch with patients and talking to them that they had been subjected to media reports all the time. TV. Newspaper and so forth. This is at page 48 and 49. What was it like in the States back in those days in relation to the behaviour of the media and the AIDS problem?---Well, beginning I'd say in 82 - well no, 82 - I don't remember any media to speak of in 82. But in 83 it was like a crescendo. Every single edition of our leading newspapers seemed to have a new story on AIDS. TV programs now featured people getting sick with AIDS and interviewed them. When the blood situation arose there were more interviews with the blood bankers, who were saying essentially what has already been presented about the screening and so forth. The media, particularly TV and radio in the United States are very powerful tools of communication, and I'm impressed with the fact that our patients had such an onslaught of information that we had no control on.

What effect did that have upon what you did?---Well, it didn't have any effect on what we did medically but it did have an effect on our perception we needed to communicate what we knew to our patients as directly as possible.

You told us that you were surprised and disappointed - this appears at 4867 your Honour - when you learnt about

what had happened in Australia, notwithstanding the fact that Australia had a self-contained and volunteer blood donation system?---That's right.

Why were you surprised and disappointed?---Well, I naively thought that a volunteer blood system, somehow would eradicate or - prevent not eradicate - but prevent donors from entering the blood system for pay, I mean to be paid, and therefore would prevent the transmission of this disease which I associated with IV drug abusers?---Yes.

You also told us that, when you were being asked some questions by Mr Rush about this article that Dr De Forge wrote, with which you said you disagreed, that if - and when you came to different conclusions about using cryo-precipitate - but if you had done what was suggested you would have had many deaths and much crippling - if you had done what this article suggested - that is at 4872/3 your Honour. What do you think would have happened if you had taken the advice of Dr De Forge and switched a lot of your patients to cryo-precipitate?---Well, I think first of all, we would have had a patient revolution or uprising because people didn't want to be switched. I think some of our patients would have gone to other doctors and obtained prescriptions for concentrate and wouldn't have been our patients any longer. We would have had a shortage of cryo-precipitate and been forced to

ration it probably for very serious or life threatening bleeds and everyone treated would have had to have come to the hospital which would have overwhelmed the hospital facilities.

How readily available is cryo-precipitate?---In Los Angeles? Yes?---Well, we could order cryo-precipitate at any given time and we'd receive it but in talking about a volume of 100s of bags of cryo that's another matter. It was a matter of scaling up for the Red Cross.

You also mentioned when you were being asked some questions about heat treatment of concentrate that there are some down sides, that there are things about heat treatment that you have to be concerned about. You mentioned at page 4880, your Honour "That heat treatment itself would change the proteins around, cause side effects such as antibody to Factor 8 and de-nature the protein". Would you just elaborate a little more on that for us, for those of us who aren't medical practitioners as to what you exactly mean by all that?---Well, when you boil an egg you de-nature the egg white. That's denaturing protein, it's structure breaks down and heating the concentrate had the same effect. The protein tends to break down at these higher temperatures. Initially because we had no data except limited European data we were apprehensive that the presence in the bloodstream of these breakdown products would be harmful and it was a time of great worry and uncertainty, since we were injecting people, unlike eating eggs, we were injecting this material directly into the bloodstream daily in some cases.

As far as you're aware how long did it take the manufacturers to work out a satisfactory method of heat treating concentrate to protect people from the AIDS virus? ---Well, the Highland (Hyland.) company, the one that was first licensed in the United States had successfully heat treated the concentrate by a license by 1983

but that did not remove the possibility of those side effects that I just mentioned. Actually heat treatment evolved over - I mean methods of heat treatment in general evolved over the next three years from dry heat treatment, which is just heating the powder, to wet heat treatment which is like pasteurisation and heating the concentrate in a wet solution and to another method of treating the concentrate in solution with some chemicals. So this whole field has been an evolving one with new techniques, new methods.

I want to take you - have you got a copy before you of that - I don't think you ever had the advantage of looking at your own letter to Dr Riccard when you were being asked some questions about it. If you'd just look at this, Doctor, and I think you've already told Mr Rush that the letter was composed of a letter by you together with - you'd sent some material that you'd got from another source?---Yes.

I just want to ask you about your views that you expressed in that letter?---All right.

As at 9 May 1983. What were the views that you expressed to Dr Riccard in the commencement of that letter about what was known so far as you were aware about the AIDS syndrome as at that date, that's as at 9 May 1983?---Can I read my own letter?

Certainly?---All right. "The new described Immune Deficiency Syndrome, AIDS, is an enigma and problem of great

magnitude to all those in any way concerned with haemophilia. Although much is known about this syndrome the basic questions of aetiology and transmission still remain unanswered. Enclosed are material" - - -

Was that your view at the time?---That was my view and my letter.

Your Honour, I haven't spoken to Dr Dietrich and I'd like an opportunity just to have a word with her in case there's something in re-examination that she might want to tell me something that I don't know. If I could just have a moment, your Honour, it will only take a minute or two.

HIS HONOUR: Yes, well, I'll leave the bench for a minute or two.

WITNESS STOOD DOWN

ADJOURNED AT 12.45 PM

RESUMED AT 12.48 PM

MR SHER: Well, I'm grateful to your Honour for that opportunity. There's nothing further I want to ask Dr Dietrich and I think she'd like to go back to Los Angeles, your Honour.

HIS HONOUR: Yes - - -

MR SHER: Excused.

HIS HONOUR: Well, members of the jury, during that break, did you think of anything that you wanted to ask of Dr Dietrich?

FOREMAN: Yes, your Honour, we do have one question.

HIS HONOUR: Yes, very well, would you return to the witness box, Professor.

SHELBY LEE DIETRICH:

HIS HONOUR: Would you put the question to me and I'll listen to it and then rule on it.

FOREMAN: The question that we'd like to put to the doctor is, in her opinion, what would be the average life expectancy of a severe haemophiliac, assuming that that person was not HIV positive and assuming that they were of an age equivalent to the age of the plaintiff in this case and assuming that they were receiving appropriate medical treatment for their haemophilia and then how would that life expectancy compare with a non-haemophiliac person?

HIS HONOUR: Yes, you may answer that question.

WITNESS: The answer is that I would expect the life expectancy to be between 65 and 70 years of age and

that would be reduced slightly from that of the non-haemophiliac male of the same age and sex - I mean, the same sex and race.

FOREMAN: Reduced by how much?---Five to 10 years.

Okay, thank you.

HIS HONOUR: Thank you. No questions, I take it, arising from that answer? Is there any opposition to the Professor being excused? You're excused, Professor Dietrich?---Thank you.

WITNESS WITHDREW

MR WODAK: Call Ruth Duffy, please.

RUTH DUFFY, sworn:

HIS HONOUR: Ms Duffy, would you lift that microphone up so it's level? If you can, speak into it because it amplifies the sound?---Thank you.

Yes, Mr Wodak?

MR WODAK: If your Honour pleases.

EXAMINED BY MR WODAK

MR WODAK: Would you tell the court your full name, please?---Ruth Duffy.

Whereabouts do you live?---GRO-C

What is your occupation?---Registered nurse.

Are you employed at the moment?---Yes, I am.

By whom are you employed?---The Red Cross Society, Victorian Division.

Victorian Division?---Yes.

Are you employed at the blood bank?---Yes, I am.

What is your position at the blood bank?---I'm the director of