IAN DAVID GUST, sworn:

EXAMINED BY MR GILLIES

MR GILLIES: Is your full name Ian David Gust?---It is.

Do you reside at GRO-C ---Yes, I do.

Are you by occupation and discipline a medical virologist?---I am.

Would you explain that discipline to the jury, please?---I am a medical practitioner who specialised in pathology and the sub-specialty pathology that I work in is the study of diseases caused by viruses.

How long has that been your specialised interest and area of practice?---Since about 1970.

Am I right in saying that your academic achievements include a Bachelor of Science from Melbourne University, a Bachelor of Medicine and Surgery from Melbourne University?---They do.

Do you also have a Diploma in Bacteriology from London University, and in 1971, were you admitted as a Fellow of the Royal College of Pathologists of Australasia?---I was.

In 1974, were you awarded a Doctorate in Medicine from the University of Melbourne?---Yes, I was.

In 1977, did you become a member of the Australian Society for Microbiology?---Yes.

In 1978, did you become a Fellow of the Royal Australasian College of Physicians?---Yes.

In 1987, were you elected to the Australian Academy of Technological Sciences?---Yes, I was.

In relation to positions held by you - I won't take you to them all but I'll pick out a few - from 1968 to 69, were you the registrar at the Regional Virus Laboratory in Glasgow?---I was.

Were you there pursuant to a World Health Organisation Fellowship?---Yes, I was.

From 1970 until a couple of weeks ago, were you a medical virologist at the Fairfield Hospital?---Yes.

Were you also a director of the World Health Organisation Collaborating Centre for Virus Reference and Research for the Western Pacific Region?---Yes, I was the Director, not a director.

In addition, were you the - in 78 - the visiting scientist of the Laboratory of Infectious Diseases at the National Institutes of Health at Bethesda, Maryland?---Yes, I was.

Can you tell us something about the National Institutes of Health at Bethesda insofar as it affects virology and your special interest in that field?---It's probably the premier research institution in the United States. It has a very large section devoted to the study of infectious diseases and I was working in one of those laboratories.

Approximately two weeks ago, did you commence at CSL in the position of Director of Research and Development?---Yes, I did.

In 1983, were you appointed a director of the Fairfield Hospital Medical Research Centre?---Again, I was

appointed the director.

Likewise, were you appointed the director of the National HIV Reference Laboratory in 85 and director of the World Health Organisation Collaborating Centre for AIDS in 1985?---Yes, I was.

Were you appointed director of the McFarlane Burnett Centre for Medical Research in 1986?---I was.

What is the McFarlane Burnett Centre for Medical Research?---It's a centre for research into virus diseases of man which is located currently at Fairfield Hospital, has a staff of about 65 people, an annual budget of about $4 or $5 million.

Well, in 1986 did you become the Fogarty scholar in residence at the National Institutes for Health at Bethesda Maryland?---Yes, I did.

Were you in fact in receipt of the Fogarty Foundation Scholarship to enable you to take that position?---I was.

What is the Fogarty Foundation Scholarship?---Well, the Fogarty Foundation is a foundation established by Congress to honour John Fogarty, a senator who was particularly interested in medical research. Each year they invite eight or maybe 10 distinguished scientists to spend a year in the United States in residence at the National Institutes of Health, as essentially scholars in residence.

Were you subsequently appointed the Director of the NH&MRC special unit for AIDS Virology?---I was.

What did that position entail?---It basically involved co-ordinating all the research into the virology of HIV infection in - in Australia. This is a - a group of laboratories which are situated in Brisbane, Sydney, Melbourne, Adelaide and Perth.

In 1989 were you appointed Chief Commonwealth Medical and Scientific Adviser on AIDS?---I was.

HIS HONOUR: Mr Gillies, is that a convenient time?

MR GILLIES: Yes, your Honour.

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

AT 3.12 PM THE JURY LEFT THE COURT

HIS HONOUR: Doctor, you may leave the witness box and either

leave the court or remain in the court for the next 15 minutes.

WITNESS STOOD DOWN

HIS HONOUR: Any matter that counsel wish to raise?

MR GILLIES: No, your Honour.

HIS HONOUR: I'll leave the bench.

ADJOURNED AT 3.12 PM

RESUMED AT 3.26 PM

AT 3.26 PM THE JURY RETURNED TO COURT

IAN DAVID GUST:

HIS HONOUR: Yes, Mr Gillies.

MR GILLIES: If it please, your Honour.

I want to take you know to the Societies that you do belong to. Are you a member of the American Academy of Microbiology and the American Society for Microbiology?---I am.

Are you a member of the Asian Pacific Association for the study of the liver and the Australasian Society for Infectious Diseases?---Yes.

In respect of that, were you President Elect in 1985?---Yes. I was.

Also a member of the Australian Academy of Technological Sciences and the Australian Medical Association?---I am.

Are you also a member of the Australian Society for Microbiology and a member of the Gastroenterological Society of Australia?---I am.

Are you a member of the Infectious Diseases Society of America and the International AIDS Society?---Yes, I am.

Do you also have membership of the Medico-Legal Society of Victoria. The Royal Australasian College of Physicians and in that College are you a member of a specialist advisory committee on infectious diseases?---Yes, I am.

Are you also a member of the Royal College of Pathologists of

Australasia?---I am.

We have a multi page CV, I'd ask that a copy of the CV be shown to Professor Gust?

HIS HONOUR: Yes.

MR GILLIES: Is that a copy of your curriculum vitae current up to June 1989?---Yes, it is.

Your Honour, I tender Professor Gust's curriculum vitae.

EXHIBIT LX7 ... Curriculum vitae of Professor Gust.

MR GILLIES: In relation to your various honours and other special scientific recognition, have you held numerous world health organisation appointments on expert panels particularly concerned with virology?---Yes, I have.

Over what period of time have you accepted special appointments by the World Health Organisation?---I received my first support from them in 1968 and 69. I think I've been on a member of specialist committees and so forth since about 1983.

So far as the committees have been oriented toward the study of AIDS, do some of the committees include the following. Were you appointed World Health Authority temporary adviser on informal discussions, on interactions between World Health Organisation programs on control of AIDS and hepatitis B at Geneva in December 88?---Yes, I was.

In December 1988 did you also attend Beijing in China to assess HIV testing and capabilities in that country?---Yes, I did.

Were you a participant in August 1988 on consultation on laboratory diagnosis of HIV infection again at Geneva?---Yes.

Were you a participant in February 1988 of the meeting of the advisory group on biomedical research on AIDS at Geneva?---Yes, I was.

In December 1987 and at Stockholm, did you attend a WHO meeting on criteria for the evaluation and standardisation of diagnostic tests for the detection of HIV antibody?---Yes, I did.

Have your World Health Organisation positions in fact taken you to numerous continents. I note at random South America, Japan, a number of other countries where you have been asked to go and advise on behalf of the World Health Organisation?---Yes, that's correct.

Over the years have you also had a special interest in the hepatitis virus?---I have.

When was it that you commenced to do active laboratory work connectible to hepatitis?---On my return from post-graduate studies in Britain at the end of 1969.

Am I right in saying that in fact you and your workforce at Fairfield have engaged in pioneering work in relation to hepatitis?---Yes.

In particular, the hepatitis A strain. Is that so?---That's

correct.

Indeed, have you had experience in Peer Review when it comes to presenting findings of a revolutionary nature?---I have.

Was that in relation to the initial presentation of you findings in relation to the hepatitis A virus?---Yes, it was.

Am I right in saying that you have been invited to give lectures on hepatitis and on virology generally in many, many countries in the world?---I have.

Including, not only the United States but Austria, Russia, New Zealand, Asia, Germany and the United Kingdom?---Yes.

To name but a few?---Yes.

Have you over the years, in addition to giving those sort of speeches, also been the invited key note lecturer at National Meetings of a scientific or medical flavour?---I have.

In addition to giving those key note lectures - and are they the main lecture are they, of the given conference or meeting?---Yes, that's correct.

Have you served on numerous committees in Australia relating to drug evaluation?---Yes.

Have you served on the Australian influenza committee the CSIRO Advisory Committee?---Yes.

Therapeutic Goods Standards Committee. Have you also served on the National Health and Medical Research Council?---Yes, on Committees of the NH & MRC.

Have those committees related particularly to virus vaccines?---Viruses and immunisation, yes.

Have you also been on the NH & MRC antibiotics committee?---I have.

Have you been a member of the National AIDS Taskforce between the years 1983 and 1987?---I was.

Were you on the Health Department of Victoria AIDS Committee and the AIDS Liaison Committee from 1983 to 1988? ---I was.

Were you the Chairman of the Victorian AIDS Advisory Committee from 1988 to 1989?---I was.

Who did you advise as a member of the Victorian AIDS Advisory Committee?---The Minister for Health.

Since 1988 have you been a member of the Australian National Council on AIDS?---Yes.

Could you describe that body to the jury?---That's the premier body in determining policy in relation to AIDS and advising the government, and in particular, the Minister of Community Services and Health.

I want to deal now with your university appointments. Are you the Professor of Clinical Virology of the Department of Microbiology, Melbourne University?---Not since last Friday week. That was a position which was linked to being the head of the Clinical Virology at Fairfield. It ceased on last Friday week.

What about your Associate Professorship of the Department of Microbiology at the Monash University?---That's now become a full chair.

That's?---That's a full chair.

In relation to the La Trobe University, were you or are you the Honorary Senior Research Fellow of the Department of Microbiology?---Yes, I am.

Until recently, were you the Fairfield Hospital representative on the Faculty of Medicine, Melbourne

University?---I was.

In addition, since 1988 have you been the Honorary Consultant in Virology and Associate in the Department of Forensic Medicine, Monash University?---Yes.

You are also on numerous editorial boards of learned technical publications?---I am.

In particular, since 1977, have you been on the Editorial Board of the Journal of Medical Virology?---Yes.

Had you also been on the Editorial Board of the Asian Journal of Infectious Diseases and the Journal of Infectious Diseases?---Yes.

The Journal of Clinical Microbiology and the Journal of Therapeutics?---Yes.

Journal of Patient Management, the (inaudible) Science Publishers and the Journal of Virological Methods? ---I have.

Are you presently also on the Editorial Board of the Journal of Gastroenterology and Heptology?---Yes.

Does your CV also list numerous prizes that you've won, and named orations?---It does.

What are the named orations in terms of medical or scientific honours - how does it fit in as part of your CV - perhaps you could describe what a named oration is and how it is an honour?---Well, it - it's usually an oration which is endowed by a particular learned society to commemorate somebody who's made a particular achievement in that field, and it's delivered either by a local or an invited speaker

from overseas who's regarded as having some eminence in the field.

Is listed on page 7 of your CV something like 10 or a dozen prizes and named orations such as those you've just described?---Yes.

In addition, have you written books on the subject of AIDS and hepatitis?---I have.

Have you authored or co-authored numerous publications and articles in learned medical and scientific journals? ---Yes, I have.

Is there a total of something like 250 such articles that you've authored or co-authored?---About 300.

You've been busy since June of 89, have you, Doctor?---Yes.

Does your CV that we've just tendered in evidence and which is to date up to June 1989, run to 45 pages?---Yes, it does.

Now, I want first Professor to take you to the question of your acquisition of knowledge of what became known and identified as the AIDS virus. Am I right in saying that in March 1982 you attended a meeting of the Australasian Society for Infectious Disease?

---Yes, I did.

And was there a United States speaker at that meeting that had something to do with you acquisition of knowledge on the subject of what was then a mystery infection?

---A mystery disease at that time. It wasn't clearly defined as an infectious disease at that time.

What was said that triggered your curiosity about this development?---It - it's the first recollection that I have of - of really hearing about AIDS or - or - or having it discussed in public. It was just that this person who was then working in the United States was describing what he'd seen, that was a number of people with this unusual disease, and speculating about what the cause might be, and it was a kind of corridor gossip rather than a presentation at the meeting where people were just sitting around and chatting about it, and saying "How odd, how interesting. What could it be?" And at that stage there wasn't a consensus in the group that I was in that this was an infectious disease, and in fact that the predominant feeling at the time was that it was probably a toxin of some sort or

another.

What's that, a poison?---A poison of some sort, yes.

And what were the disciplines of those who attended the meeting, you were there are a virologist, what were some of the other - - - ?---Primarily they were physicians who specialised in infectious diseases, some public health people with a relatively small contribution from pure scientists.

What was thought of the United States connection with that curiosity?---Well, it was - it - I think the feeling was that this was something interesting that was happening in the United States. It was unusual and peculiar to the United States, and it was just a fascinating observation and we ought to keep an eye on it, and - and see what happened.

When was the next step in your acquisition of knowledge of learning on what later became discovered, and identified?---I think all of us were subject to a large number of different sources of information. From that time on we became in contact with scientists who'd been overseas, and physicians who'd came back. We read the newspapers, we read the medical journals. I think there was a constant flow of information about the disease through 1982.

What about in 1983. I appreciate that it's an evolutionary acquisition - - - ?---Yes.

Of knowledge, but say by half way through 83 what was your state of learning on this health disorder?---I think

by mid - by mid 83 those of us who - like myself - had a background in infectious diseases or in virology had come clearly to the view that this was almost certainly an infectious disease, probably caused by a blood borne agent simply because the pattern of infection that was being observed around the world bore so many similarities with some other blood borne infections, particularly hepatitis type B.

In November 1983 did you attend a World Health Organisation meeting at Geneva?---Yes, I did.

Did learning acquired at that meeting significantly supplement your knowledge of the subject?---Certainly. What happened at that particular meeting was that Luke Montenier from the Pasteur Institute in Paris presented some of his preliminary data on - his claim to have discovered the virus that caused the disease, and I believed him. I was - I was convinced by the evidence that he'd produced at that meeting that he was right, but it was - that was not the universal view of the people who were in the room. In fact there was a great deal of scepticism about his claims.

Well, in short, what did Dr Montenier say that he had discovered?---What he said was that he'd collected a lymph node from a person who was in the - what seemed to be in the early stages of the disease and that he had demonstrated antibody present in the blood of a number of people with the disease against an antigen which he found in that lymph node material and that he had some evidence that the lymph node contained a virus which he thought was the causative agent. It was preliminary data. He certainly hadn't dotted all the "i"s and crossed all the "t"s, and many of the scientists who were present at the meeting were very quick to point out the flaws in his argument but I was - was very convinced that he was correct.

You mentioned the scepticism. Was that something like the scepticism you had experienced yourself with your work in presenting your findings to the international community concerned with Hepatitis A?---Well, there were parallels. The - in our case, the difficulty we had was getting acceptance by the British scientific community who probably thought that it was unlikely that a discovery of any importance could be made in the antipodes, and in this particular circumstance, I think the feeling was a little the other way around. The Americans and the British, I think, assumed that no discovery of such magnitude would be likely to be

made by a Frenchman.

Did you get to know Dr Montenier?---Yes, I sat next to him at the meeting.

Then subsequently during 1984, did you continue to communicate with Dr Montenier particularly with a view to your organisation acquiring some cells of the virus?---Yes, I did. I thought that the way to proceed with - when somebody made an observation like that or certainly had a claim, the aetiologic agent was to try and confirm it as soon as possible independently in another laboratory, so I asked him for supplies of the material that he was working with and he was only too pleased to provide them and he sent them to us on two occasions, but unfortunately viruses are often very fragile, and when - he was sending them in living cells and the living cells perished on both occasions because they had to be transported over a long - - -

How many attempts were made by the Pasteur Institute to send out living cells to your organisation?---I'm not sure whether it was two or three. It was at least two, it may have been three.

Why is it necessary to effectively research to have the living cells?---Well, it was the only source of virus which would serve as antigenic material in a diagnostic test. At that stage, there was no other way of amplifying the virus other than by growing it in cell culture.

Did you get those dead cells in your possession before or after the Gallow announcement of May 84?---We would have received our first shipment prior to the Gallow announcement.

And the second after that?---I believe so, yes.

Talking in terms of antigen, what's the scientific significance of that - what is antigen?---Well, it - an antigen by definition is any substance which stimulates an antibody response in an individual when it's injected into the individual.

What is the antibody?---Antibodies are proteins which are produced by the body which attach to the antigen and neutralise it, immobilise it, then allow it to be eliminated from the body. They're part of the normal defences that we have against infectious and other diseases.

Why were you anxious to share in the research of Dr Montenier by obtaining living cells?---Well, the starting point for the scientific investigation of any new disease is the identification of the causative agent. Once you've got the causative agent, you can develop specific laboratory tests that help you to differentiate between people who are infected and people who are not infected, and in that way, you can begin to plot the spread of infection through the community, work out how it's transmitted from person to person and study the natural history of the disease. It's the beginning of the scientific

study, so without the virus, we couldn't begin that study.

There are the two or three shipments from the Pasteur Institute which were useless because they were dead. What did you then do to try and effectively set up a research in Australia?---Well, first of all it takes a little while after you receive the cells before you are able to determine that they are of no use to you. You try for a long time to try and resuscitate them. That took us a number of weeks and in fact on a couple of occasions, a couple of months or more. What I then did, by about the middle of 1984, when I thought that we were not proceeding properly, was to convince the Commonwealth Department of Health to provide us with some money so that I could send a technician to the United States to work on the test to learn the technology and then bring back some reagent with them. I think that was about August of 84.

You mentioned that you attempted to resuscitate the dead cells. How do you resuscitate or attempt to resuscitate an ailing cell?---Tender loving care basically. What happens is these are living cells which come in bottles or tubes, and they are surrounded by all sorts of nutrients, food for those cells, if they have been badly damaged in transit as they often are because they are trans-shipped on the way and sometimes subject to extremes of temperature, you try a variety of tasty delicate morsels to get them going again, but we failed.

You sent someone to CDC and we've heard how that's a centre of learning on the subject. What was the brief that that officer had in going to CDC in the United States?---The brief was to learn the techniques that were required for establishing a diagnostic test for infection with the causative agent of the disease. If possible to learn how to culture the virus and if possible to bring back with them reagents which would enable us to establish the technology in Australia.

I think you mentioned that in fact the scientist was sent in August or thereabouts of 84?---Yes.

What was his name as a matter of interests?---Robby Pringle.

Did you remain in contact with Mr Pringle while he was over there?---Yes, we were in regular contact by telephone.

When did he eventually return to Australia?---I think he was away for about two weeks or two and a half weeks.

He successfully brought back living cells, did he?---My recollection of that is uncertain. I recall certainly that he brought back with him antigen. He brought back sufficient antigen for quite a number of serological tests. I can't recall. I can easily check whether he brought back the living cells with him at that time. I think he probably did.

How did he do that. On his knee in business class or - - - ?---Yes. In his knee in economy class he was travelling on a Government Fellowship. You

bring them in a small - the sort of little styrene box that some people would use to hold six cans of beer.

You then had something when Dr Pringle with the material and you could commence your research?---Yes, we did.

When was that. Are you able to recall the approximate date upon which you could gear up with the material that Mr Pringle had brought back?---The first test that was undertaken in our laboratory was the 16 September.

What was the test which you implemented on 16 September, 1984?---It was a test designed to detect antibody in the serum of people who may have been exposed to the virus and infected with it. It is a test that goes under the name of an enzyme linked immuno absorbent assay, or ELISA for short. That was the particular type of test that was used.

How did you acquire the technique to effect that test. Was that as a result of what Dr Pringle had told you?---The technique was not unusual the virus that we were looking for was unusual so it was an established technique. He had learnt certain of the tricks of the trade whilst he had been away but it was a technique with which he was basically familiar.

Were the tests performed with the reagent upon stored sera?

---Yes, they were.

Would you explain what stored sera is?---Sera which have been placed in small glass tubes with a screw cap, and then stored in refrigerators usually at minus 20 degrees centigrade which freezes the serum solid, and maintains it for a very long period of time. You can maintain sera in frozen form for decades without any loss of antibody activity or with negligible loss of antibody activity.

What was the object of the research and experimentation in relation to testing stored sera?---The - the first thing - the first object of the test was to determine whether it was working satisfactorily and we had what are known as control sera in it. Sera from people who are known to be infected, and some people who were known not to be infected, but I think the first scientific question that we asked was whether infection was present in the community, or whether or any people in the community in Melbourne had antibodies to this virus.

By October 1984 had you reached any conclusions in relation to the extent to which our community had the infection in it?---Yes, there were two groups which were - were helpful. We were able to offer the test to men - homosexual men with multiple partners who wished to be tested on an experimental basis, and we found in our first studies of a few hundred in such men

that in excess of 10 per cent - between 10 and 20 per cent of them had antibody which we assumed was equivalent to infection in - in those people. The second group that we looked at was - who stored sera for people with haemophilia, mild and moderate and severe haemophilia, and again we found quite a high prevalence of antibody in people with haemophilia. There was however an argument at that time as to whether the significance of antibody in haemophilia - people with haemophilia was equivalent to the - had the same significance of the presence of antibody in homosexual men.

What was the way that argument proceeded?---Well, there were - there were some people who thought that the process of producing clotting factor may damage virus which was present in the original plasma, and in fact destroy it. So that the infusion of clotting factor rather than leading to an infection in the recipient might have actually immunised that person, and rendered them resistant to infection.

What was your opinion at that time. Was that wishful thinking or - - - ?---My - my opinion was that that was wishful thinking, yes.

When you reached conclusions as to the percentage of haemophiliacs tested who were HIV positive did you advise anyone of those results?---Yes, I did but it was common knowledge within the institution. We had regular clinical meetings in which those things were

discussed, but also I discussed with the people who provided us with samples. In particular Dr Sawers at the Alfred - at the Alfred Hospital and I contacted my colleagues at the Commonwealth Serum Laboratories who were involved in plasma fractionation. I - I think it likely that I in the course of conversation I spoke to other people in the blood fraternity, but I couldn't tell you all of them by name.

In those tests conducted by your laboratory between 16 September, and October 1984 what percentage of haemophiliacs tested were found to be HIV positive? ---Well, we - we were able to be a little more sophisticated than just simply take a cross section like that. We had access to sera which had been collected at different points in time from 1981 through till 1984, and the prevalence of antibody differed according to the year at which the sample were collected. I was just referring to my notes about that - - -

I'd ask that the Professor have to leave to look at his notes for those statistics, your Honour.

HIS HONOUR: No objection?

MR BARNARD: No, your Honour.

HIS HONOUR: Leave's granted.

MR GILLIES: Thank you?---In 1981 there - there was no antibody in the samples that we tested - sorry - that the samples which had been collected in 1981,

or the samples collected in 1982 just under 10 per cent - 9.8 per cent contained antibody, and those collected in 1983 nearly 12 per cent - 11.9. 1984, 31 per cent.

So it's 31 per cent of haemophiliacs tested or whose 1984 sera was tested - it was a 30 per cent proportion who were found to be HIV positive?---Were found to have antibodies against HIV.

Is that an inept way of treating positivity?---No, I don't think it is now, but I think at that point of time there was still some argument about it.

At that time, how many laboratories were there in the world that were testing for evidence of infection for HIV in the manner that you were?---Very few. I would say less than 10.

In relation to the report which you made in respect of the findings that you've just detailed, were there any earlier reports in any other part of the world reporting on the prevalence of HIV amongst haemophiliacs?---I'm not aware of any, and I don't believe that anyone had access to the same kind of historical collections of sera that we did. I'm sure that other people would've looked at selected sera from people with haemophilia, but I doubt that the same panels of sera were available.

Do you know of any akin to the report which you gave in relation to the percentages of haemophiliacs who had the antibodies?---I certainly don't know of one that preceded it.

What can you tell Mr Foreman and members of the jury as to your liaison with CSL and with haematologists during this period of research in 84 - September and

October?---Well, I - I tried to keep all the relevant people fully briefed about what we were doing and what the implications were and what the limitations were in terms of - of the amount of antigen that we had present day. The physicians who were involved in managing the patients with haemophilia at the major teaching hospitals - both the adult and the - and the paediatric - the physicians who look after adults and who look after children, were informed, and I informed the Blood Transfusion Service and I informed Peter Schiff and his colleagues at CSL.

Did you, during October, in addition to carrying out the tests on stored sera, did you then commence to test the CSL plasma pools?---Yes, I - we did. I'm not sure of the exact date, I think it could've been a little later than that. It may have been November of - of that year. What - we were in a situation where we had very limited amount of antigen, and it was unlikely that we were going to get any more, and what we - we had two options, I guess. We could've continued trying to define the pattern of infection in the community, or we could've tried to use that antigen for the best possible purpose, and we decided on the - the latter course. Given that we didn't have enough antigen to screen all blood donors, we thought that maybe if we made the test available to CSL to being to screen pools of plasma

that were going to be used, that might be the best possible use of that antigen and that's in fact what we agreed to do.

What was the machinery of that - how was it that you were able to use what antigen you had to test the CSL plasma pools?---Well, basically they sent pools across to us as they were preparing them, prior to fractionation, and asked us to test them for the presence of - of antibody.

Does that meant that they would take samples from batches and ask you to test that?---They were able to - to provide us samples and batches, and if required, the individual components which were - which would go into batches.

Was the CSL plasma tested in that fashion by you until the commercial kits became available later on in 85?

---Yes, it was.

Was anyone else in the world doing that?---I don't believe so.

By anyone else, I mean, any other manufacturer of concentrate having its pools tested for the HIV infection in the manner that you were testing CSL's?---I think the answer to that is almost certainly, no.

Would you tell Mr Foreman and the members of the jury, what other work you did in that period from November 84 to January 1985, with a view to protecting the Australian blood supply?---Well many things. I guess the first thing was to convince the then Minister of Health that we needed to try and introduce routine screening of all blood donors in Australia as rapidly as possible and not to be left behind in the race to introduce that around the world.

If I could hold you up there, that is introducing a test at the blood donation level?---At the level of - - -

Blood bank level?---That's correct. In the middle of 1984 the United States government made available to five test manufacturers a sample of the virus and gave them the challenge - - -

MR STANLEY: Your Honour, I rise to object to this question on the grounds that it is not relevant to anything that was done by CSL during the relevant period. It is not CSL we are talking about. This witness was not employed by CSL. He had nothing to do in a professional way with CSL. What was done through 1985, or whenever in relation to the AIDS problem in

my submission is irrelevant so far as the CSL's case is concerned.

HIS HONOUR: How do you put it, Mr Gillies?

MR GILLIES: Your Honour, part of the criticism of CSL that Mr Stanley has made is that CSL did two little too late. In my submission, it is very relevant to our case to lead evidence of the relationship between CSL and Dr Gust's group and for Dr Gust to explain just what difficulties did present themselves throughout the period in bringing the Australian blood supply to a situation of safety. All of these matters are relevant, not only to the allegation that Mr Stanley makes relating to tardiness in developing a HIV antibody test as well as tardiness in heat treating the product. We say it is all very relevant to those two criticisms and to the rejection of those two criticisms which my learned friend has made on behalf of his client.

HIS HONOUR: Yes. I'll permit the questions.

MR GILLIES: You were mentioning that the US government had in fact licensed, I think six American pharmaceutical companies to research for the HIV antibody test as well as for peripheral learning on the subject. Would you elaborate on that please?---In fact it was five companies. We were very concerned at the time that if these companies brought the test to fruition quickly that they would not be able to keep up with the demand that was required world wide. There was

a great danger that they would first satisfy the US market and then perhaps certain other markets and that there might be an unacceptable delay before the test was introduced into Australia. So, we persuaded the then Minister of Health that this was a matter that required urgent attention. He went to the United States and made representations to the relevant authorities in the United States, as a result of which we were able to join with the Americans in the development process and in the evaluation process, which meant that we were able to introduce the test in Australia, essentially simultaneously with the United States and we were - - -

That's an example of the collaboration that you at Fairfield and the United States pharmaceutical companies engaged in?---Yes, that's correct.

What's an example of it just to pick an example?---As the companies were beginning to develop the test with record speed, they had to be evaluated to determine whether they were of adequate sensitivity and specificity and whether they produced, reproduced results between the periods that you mentioned. I organised a study in Australia which remained the only study - remains the only study in which all of those manufacturers products were independently evaluated in five different centres on a very large panel of sero, the same panel of sero being used in

each case. On the basis of that we made our decisions in Australia as to which tests would be licensed. Much of that information was used as the basis of the licensing applications that the companies made in the United States and I think that shook - - -

MR STANLEY: Your Honour, when the witness gives an answer to (inaudible) word "we", in my submission it is misleading. He should specify precisely who it is that is making these decisions, so that we can ascertain whether CSL had anything to do with them at all, or whether it is the royal "we" or whether he is referring to Fairfield Hospital or the government.

HIS HONOUR: I think that's a fair comment, is it not, Mr Gillies?

MR GILLIES: Yes, of course, your Honour.

HIS HONOUR: Yes, I uphold that.

MR GILLIES: Plainly when you're talking about "we", you're talking about Fairfield, are you?---Well, I think I've used "we" in more than one context. I've sometimes used it to describe myself and my colleagues at Fairfield, and I've sometimes used it to - to refer to the situation in Australia at the time.

What's an example of information - research information - which you at Fairfield were able to send back to the United States pharmaceutical companies which had been licensed, which assisted them in their applications for a licensing of the HIV antibody test or heat treatment - whatever it was?---Basically it - it was information on the reliability and the reproduceability of the assays. Two of the five assays that we - were evaluated at that time were of high quality, some of the others were not of equally high quality, and it was possible to select those two as the test of choice.

You've mentioned the simultaneous testing that you engaged in. What of the setting up of a system in Australia between blood banks, public health laboratories and State reference laboratories - did you do anything from an organisational viewpoint in that

regard?---Yes, I - I did at the summit meeting of health ministers, which occurred in that era and was brought on as a result of the Queensland baby incident. I was asked by the then Minister of Health to propose a system of testing, and in conjunction with two other colleagues, I suggested a three tier system of - of testing.

Approximately when was it that you suggested the three tier system of testing?---It was immediately prior to the federal election. I can't recall the exact date, but it was only a week or so prior to the - to the election in that year. It was the end of 1984.

What was the system that you proposed - firstly, in relation to blood banks?---Well, there are a number of facets to it. Firstly, our suggestion - "our" being myself and my two colleagues - suggestion was that the tests should be provided free of charge in the country so that it would be equally available to everybody. It should be introduced simultaneously into the blood banks and into public health laboratories in every State so that people had an option of being tested, and that every unit of blood which was collected, or every donor who presented to donate blood, would be tested for the antibody. Because of the importance of the result, we suggested that each State establish a reference laboratory so that any tests which were found to be positive in either the blood bank or the public

health laboratory, would be referred on to a reference laboratory for confirmation, so that no positive results were inadvertently given to somebody who was not - not infected.

So it was a back-up, was it?---It was a back-up - a bells and braces approach. Then at the apex of the pyramid we established a National AIDS Reference Laboratory - that lab not only had the responsibility for evaluating all the tests, but agreeing on criteria for interpreting the tests, training people to work in the different laboratories and establishing a quality control and proficiency testing program.

Was the Gust three tier system accepted by the minister?

---Yes, it was.

And was it subsequently implemented?---It was.

Did it work?---It has, it's been the envy of most countries, I think.

Has the World Health Authority in fact held it up as some sort of a model?---Yes, it - it has, and very recently it's been - it's been regarded in the United States as the model of things to go as their testing system has got a little bit out of control.

In relation to this period, was it necessary for Fairfield to recruit extra staff to cope - not only with the organisational load, but also with the load of testing the CSL plasma pool?---Yes, we - we recruited a number of additional people in the - in the interim period. We coped by transferring some

of our existing staff to that - to that task, and also working very hard.

How feverish was the activity over that period?---It was very feverish. We - most of us gave up our Christmas holidays that particular year. I could tell you some anecdotes about it, but I - it's probably not the appropriate place.

HIS HONOUR: Would that be an appropriate time, Mr Gillies?

MR GILLIES: Yes, your Honour.

HIS HONOUR: Mr Barnard?

MR BARNARD: Your Honour, I wonder if I could ask my learned friends for an indication in relation to tomorrow for Dr Riccard.

HIS HONOUR: Yes. Mr Gillies, how long would you expect the evidence-in-chief to go?

MR GILLIES: I would think that I would conclude the evidence-in-chief in an hour, an hour and a quarter.

HIS HONOUR: Mr Sher, what time would you expect - - -?

MR SHER: Well, I may have quite a bit to ask Professor Gust, your Honour. I just don't know, it depends on what he says in-chief. I would've thought - being realistic and bearing in mind the issues, that the whole of the day would probably be taken up with Professor Gust.

HIS HONOUR: Well, Mr Stanley, I expect you or Mr Rush will have some questions to ask?

MR STANLEY: I expect there'll be some questions, your Honour. I hope not too many.

HIS HONOUR: Mr Barnard, I don't think that we need trouble Dr Riccard tomorrow.

MR BARNARD: Thank you, your Honour.

HIS HONOUR: Adjourn now until a quarter past 10.

WITNESS STOOD DOWN

AT 4.17 PM THE MATTER WAS ADJOURNED
UNTIL FRIDAY, 23 NOVEMBER 1990

IAN DAVID GUST:

MR GILLIES: Your Honour, might the Doctor be handed book 7, in particular at tab D10 - D10, book 7.

HIS HONOUR: Yes.

MR GILLIES: That's the bulletin from the World Health Organisation press. Doctor, you mentioned yesterday how in November 1983 you attended a World Health Organisation meeting at Geneva. Do you identify the WHO press bulletin dated 25 November 1983 as being the bulletin that followed that meeting?---Yes, I think it's the press release that followed the meeting.

You mentioned also there was a sinicism in relation to Dr Montenier's paper. Does that press release contain any information about the views of Dr Montenier as he announced the matter at that meeting?---No, it does not. I think the - the feeling was one of scepticism, and that that's reflected in the - in the press release which says the - the epidemiological pattern is consistent with transmission by an agent which is most probably a virus, the cause remains unknown. So that the consensus for that particular meeting in that point of time was that he had not provided conclusive evidence that the agent that he'd identified was the cause of AIDS.

Turning over from that you'll see the list of participants?

---Yes.

At page 430. Just running through that list, do you identify numerous scientists and medical men who were authorities in the field of immunology and virology?

---Yes, there are but the participants were a mixture of people, some of whom were eminent in the fields that you've mentioned. Some of whom were representing countries or - or populations in which AIDS was a particular problem at the time.

Would you just take a few names at random from that as men who were in fact experts in the fields of immunology, haematology, or virology?---Walter Dowdell who chaired the meeting was for many years the head of the American AIDS Program, but is now the Deputy Director of the centres for Disease Control. Allister Clayton was in charge of the - of the Laboratories Services in Canada, and was in charge of their - has been in charge of their - of their AIDS program. Jim Curren became the most senior scientists in the - in the AIDS program, particularly concerned with epidemiology of AIDS in the United States. John Francis is probably the person who altered the world to the possibility of - of HIV being transmitted by blood or blood components. Dr Fay is very well know. Dr Chernoff from the NIH is extremely well known. Dr Connent from California - - -

It's on the next page, Doctor, M.A. Connent, is it?---Yes, Dr Connent. Dr Lakular from Geneva. Luke Montenier from - from the Pasteur Institute. Maurice Hellerman probably the most the influential person in the field of vaccine development over the last 20 years. Ron Penney from Australia who's very well known from Sydney. John Petriciani who at that stage was responsible for licensing the new products through the office of virologics at the - in the United States, so it's a pretty eminent group.

Would you turn to the front of that, and in particular to page 21 - that's A21 of book 7. Right at the front immediately behind tab A, Doctor?---They seem to go backwards.

Yes?---Am I looking in the right place?

I believe that's a chart which is made up of matters which are common ground as far as the batch numbers are concerned. You'll see the batch numbers in the left hand column, they being the batches of concentrate received by the plaintiff in this action between 6 March 1984 and 24 September 1984 and you'll see under the second column which contains the dates. You'll also see figures in brackets under the dates, they represent the number of bottles administered on or about the dates mentioned there. We've heard evidence that batch 543 was contaminated with the HIV and we've heard evidence that batch 584 was contaminated. Would you care to take notes as I put this? I propose putting certain facts and figures to the doctor and I'd ask that he be permitted to make notes as I put the evidence to him, your Honour.

HIS HONOUR: Yes, that could be done. Do you have a pad available to you, Professor?---Yes, I do.

MR GILLIES: The evidence is that those two batches were infected and there is no evidence that any of the other batches listed there was infected. In dealing with the question of which batch, which infected batch is more likely to have infected the plaintiff than the other, I want to take you firstly to the fact that on 29 March 1984 the amount administered was 10 bottles whereas in August 1984 the amount

administered was four bottles. What do those facts tell you in deciding whether one of the two batches is more likely to infect the plaintiff than the other?---Well, it depends on the amount of virus that's present in the starting pool. If we assume that the amount of virus in the starting pools was identical then clearly the more bottles of material that you're exposed to the more likely you are to be infected.

Would you go to the total donations column and you'll see that in the total donations column there were 2052 donations that went into batch 543 and 2628 donations that went into 584. Again in relation to this question of which batch is more likely to be the culprit what do those donation figures or a comparison of those donation figures tell you?

---Well, again if we assume that both batches contained only one unit of infected material and that the titre of virus on those two units were similar, there's a slightly greater chance of the earlier batch being involved than the latter simply because the dilution is less.

Would you keep the chart open in front of you because I'll come back to it in a second. Would you explain to Mr Foreman and members of the jury the phenomenon of antibody build up in a person infected with HIV?

---Yes, if somebody is unlikely enough to be exposed to the virus that causes AIDS, for example as a

result of blood transfusion, what usually happens is that at about two weeks or perhaps three weeks after they've come in contact they develop an acute illness and that illness is a little bit like the flu and then from that point their body begins to develop antibody which can become detectable in the blood. But in this particular disease the develop of antibody tends to occur relatively slowly so that it's not uncommon for it to be six or eight weeks after that acute illness which remember it's two weeks after they've been exposed before antibody becomes detectable, and then it usually builds up to peak level or its highest level over the next few weeks or even a couple of months.

Now you are familiar with the testing of the blood of the plaintiff in this action aren't you?---Yes, I am.

We've heard evidence how on 24 October, 1984, tests conducted at your laboratory demonstrated Mr PQ to be HIV positive.

MR STANLEY: Your Honour, that's not correct.

MR GILLIES: I'm sorry that the blood was taken on 24 October, 1984 and was tested at your laboratory and was subsequently found to be HIV positive, is that so?---Yes, that's my recollection.

Did you participate, not only for testing of Mr PQ's blood and a reviewing of the results of the tests but also numerous other people whose blood was forwarded to your laboratory for HIV testing?---Yes, I did.

What is the method of testing a sample of blood for the HIV?---Well, the screening assay that we used is an assay that has a long name, it is called the enzyme linked immuno absorbent assay.

HIS HONOUR: Would you mind spelling that out for the benefit of the transcript?---Enzyme. E-n-z-y-m-e-l-i-n-k-e-d immunoabsorbent, i-m-m-u-n-o-a-b-s-o-r-b-e-n-t assay, a-s-s-a-y. So known colloquially as the ELISA - it is an assay in which you mix patient's serum with a protein known as an antigen and you detect the binding of an antibody in the patients serum to the antibody, by releasing a colour change, so that the intensity of the colour in the solution is proportional to the amount of

antibody that is present. You start off with a solution that is colourless, almost like the water here, or having a very pale colour and if antibody is present the solution goes an orangy colour and if there is a lot of antibody present it goes very orange. You are able to measure the intensity of the colour change with a machine so you don't have to do it with the naked eye. (Inaudible) that intensity is registered on a scale from zero to two, with the zero being no colour whatsoever and two being the maximum amount of colour that is detectable by the machine.

MR GILLIES: What shade of colour produces the conclusion of HIV positivity?---Well, you have to include in each test a number of controls and there isn't an absolute number which can be carried from test to test but in the tests that we were doing at the time the cut off point which differentiated a negative from positive serum was between .4 and .6.

In the case of Mr PQ what shade did the solution turn?---I don't have the information with me at the moment, but my recollection is that on that particular occasion the first positive sample that we got that it was in excess of two. That it was in the scale of our test it was off the scale.

It was off the scale?---Yes.

What did that tell you about the titre or intensity of antibodies in his blood stream?---That he had a high

titre of antibody to the virus.

In relation to a high titre such as that, as a probability what period of time would need to efflux between infection and that sort of a score?---In general, it is unusual to see that titre of antibody in less than three or four months after exposure of the virus. It is not impossible but it is unusual.

Taking that piece of information and returning to the chart, what does the high titre of Mr PQ tell you in dealing with this question as to whether 543 or 584, the March dose or the August dose was more likely to have infected him?---Well, I think it is much more likely that he was infected by the earlier rather than the later.

Why does the test conducted by you point you in that direction?---Simply by - because of the level of antibody that we found, it would be unusual, not impossible, but unusual to have antibodies of that level some eight weeks after exposure to the virus.

I desire to put some further pieces of evidence to you - - -

MR STANLEY: Your Honour, I rise to object to this evidence. Under the rule in Brown and Dunn, to which reference has been already in this case, it's obligatory upon counsel to put matters to witnesses called on behalf of the other side where they propose to call that evidence themselves so that the other side may have an opportunity to answer to that, and none of these matters that Mr Gillies is now putting to this witness were ever put to witnesses that were called on behalf of the plaintiff, and there were a number of experts called including two of the persons who in fact carried out the test at Fairfield Hospital and other doctors who were expert in relation to the question of infection and prognosis of the plaintiff's illness, and we object strongly to the fact that none of this was put to our witnesses and, in the circumstances, we submit my learned friend should not be permitted to lead it from this witness.

HIS HONOUR: Well, Mr Foreman, this raises an issue in which I'll have to investigate. Would the jury have their morning break at this early hour? Would that be

convenient? The jury may now go to the jury room for 15 minutes.

AT 10.33 AM THE JURY LEFT THE COURT

HIS HONOUR: Professor Gust, you may have a break for 15 minutes, though no hot water and coffee is provided for you. You may go outside the court.

WITNESS STOOD DOWN

HIS HONOUR: Mr Gillies, what do you say as to what Mr Stanley has objected?

MR GILLIES: May it please, your Honour. The plain reality is the evidence has been called and it's part of the plaintiff's case that he had HIV positivity. No virologist has been called on behalf of the plaintiff. No witness called on behalf of the plaintiff has dealt specifically with the height of the reading and, in our submission, we're entitled to use the evidence that's been called in presenting our case. It's not a case of fresh evidence being called. It's a case of meeting the case that's been put by the plaintiff. In our submission, what we've done is appropriate.

It would have been inappropriate if a virologist had been called and given a different view, if my learned friend had sought to further explain the evidence which he had called, but in our submission, the rule in Brown and Dunn is completely inapplicable to this sort of situation and we would submit that the conduct in leading this evidence is

further instructions, but also making the decision as to whether or not it's forensically desirable at this stage of the trial for me to reopen our case on this one specific issue, so it's a matter that we would prefer to have the opportunity to consider before any application - before being required to make any application, and certainly before the matter's ever raised in front of the jury.

HIS HONOUR: Yes, so you're saying in effect that I can relax for the time being, that I don't need to have to make any decisions.

MR STANLEY: I think that's probably so, your Honour.

HIS HONOUR: That's the irresistible blandishment to a judge, Mr Stanley.

MR STANLEY: If your Honour pleases.

HIS HONOUR: I'll reserve my decision until I'm asked by one of the parties to take some action.

AT 11.15 THE JURY ENTERED THE COURT

HIS HONOUR: Mr Foreman and members of the jury, it's not been necessary for me at this stage to give a ruling on the matter that was raised. I may need to give some ruling on it later.

IAN DAVID GUST:

MR GILLIES: Professor, if you'd take out your pen and pad, I want to put to you some pieces of evidence for your comment in relation to whether the donor to batch 543, donor 36 was likely to be infected as at the date upon which he made the donation. If the

evidence is that donor 36 made a donation of blood on 29 August 1983, donor 36 having subsequently found to be infected with HIV. That particular donation on 29 August 1983 was what's being classified as a split donation, that part of the it, the plasma was sent to CSL for the manufacture of concentrate, and that the - or some of the red cells were infused into a person known as 18 for the purpose of this case. In dealing with 18, 18 subsequently developed HIV. Six units of red cells were infused into 18, and the Red Cross Look Back program in respect of the donors of those six red cells has unearthed the following information. That including donor 36 there were six donors whose blood made six units of red cells that went into 18. Of the six donors four have been tested for HIV antibody and four of the six have been shown to be negative. There is one who is classified as an unknown in the sense that the - who's a male - and that person has not been tested, but the recipients of his blood have been tested, and they've been found to be HIV negative. The sixth donor is of course donor 36 who has been found to be infected. Now, confining yourself to that data, and in the knowledge that donor 36 is known to have contributed to batch 543, that is the batch that was administered to the plaintiff in March 1984, what is your opinion in relation to whether or not as at the

date of donation by the infected donor 36, that is 29 August 83 he was infected with HIV?---I think it very probable that he was. Am I allowed to ask for any clarification?

Certainly?---They ask whether recipient 18 was a male or female.

A male?---And also whether in the case of the unknown donor in amongst the six units, the other recipients that you've referred too who were not infected were people who'd received blood from that person subsequently.

Yes?---Yes, I think it very probable that the - that the person was infected on 29 August.

I'll put this information to you relating to another donation of donor 36. On 3 May 1983 donor 36 made a donation of blood which was transfused into a woman who we'll call 64, and that was transfused - the transfusion took place on 4 May 1983. 64 was subsequently tested and found to be HIV positive, and the amount of transfused material that she received in May 83 was four units of red cells, and Mrs Learmont of the Red Cross has given evidence in respect of the donors of that four unit batch, and has given evidence that there was a total of four donors for the four units, including donor 36. That of the four donors two have been tested and found to be HIV negative, and the one that has not been tested is a male, and he is a person known to have given blood previously and whilst he himself has not been tested for HIV, the people who have received his blood are not believed to have been infected. So, dealing with that case, case 64 what is your opinion in

relation to this question of infectivity of donor 36 as at the time when he made the relevant donation in this case, namely 29 August 83?---The conclusion that one would reach was that he had been infected sometime earlier, and was infected also on 3 May - sorry - was infectious at the time of 3 May.

Then on 30 December 1982 he made another donation, and that donation in part was transfused into a woman, page 23 - but we call 83 - she received that transfusion on 30 December 1982, the same day as the donation. The evidence is that the 23 year old woman contracted fully blown AIDS, and had died on 29 April 1987. The transfusion which she received in December 1982 was 98 units of red cells, there were thus 98 donors that contributed to that transfusion, and of that total, 47 have been tested and found to be negative for HIV?---Mmm.

Then 22 men and 28 women, the residual 22 and 28, 22 and 28 all have been found to have donated blood on other occasions and not infected anyone as a consequence of their donations of blood, so that of that total of 98 donors the only donor incriminated with the HIV infection is donor 36. What do those further facts tell you of the infectivity of donor 36?

---I think you'd have to say that on the balance of probability that the source of infection in that case was donor 36 amongst the 98 and you could probably also surmise that the teeter of virus in donor 36 was quite high in view of the relatively short incubation period between infection and death in the recipient.

I want to put another case to you, the case 98, patient 98 for the purposes of this trial. That was a donation made on 30 December 1981. Numbered 98 received a transfusion on 2 January 1982, donor 98 was later found to be HIV positive but without symptoms and coincidentally 64 and 18 although they tested positive for HIV were without symptoms. In respect of the quantity transfused into case 98 there were 11 units of whole blood and two units of red cells. A total of 13 donors, of the 13 six were tested for HIV antibody and found to be negative. Of the other six or of the six of the remaining seven, D36 being of them but of the other six they've been found to have donated blood on other occasions and not been

found to infected any donee of that blood. So again donor 36 is the only one found to be HIV positive in that group of 13 donors. What observation do you have to make about those facts?---I think again on the balance of probability is that donor 36 is probably the source of infection in that circumstance.

I want to take you to two other cases of people who have received donor 36 blood or blood products. On these occasions they're donations after the material donation of 29 August 1983. The first one is case 49 and that was a donation on 16 May 1984. The transfusion into case 49 was on 9 June 1984, case 49 was found to be HIV positive and without symptoms. The quantity of the transfusion was six units of red cells, coming needless to say from six donors. Of the six one of whom is D36 and thus HIV positive, of the remaining five four have been tested and found to be HIV negative. The other one who's not been tested is female and has donated blood on other occasions and the recipients of that blood on other occasions have not been found to be HIV positive. What does that tell you about the infectivity about donor 36?---I think again it highly probable that the source of infection in that situation was donor 36 and that donor 36 had been continuously infectious for others over a period of three years.

If I could put the final case to you the sixth case, of course the seventh is Mr PQ, but the final case is case 54. There the date of donation was 24 July, 1984. The date of transfusion was the same day, 24 July, 1984 and case number 54 became HIV positive but without symptoms. As to the quantity of the transfusion we have got 14 units of red cells, one unit of cryo-precipitate and one unit of fresh frozen plasma. 14 red cells, one of cryo-precipitate and one of fresh frozen plasma. Of that total of 16 donors 10 were tested and found to be HIV negative. Of the remaining six, donor 36 being one of course and HIV positive, but of the remaining five on top of that - the remaining five we have got people who have donated blood on other occasions but without infecting the donee on each occasion. Mr Barnard has consulted with his computer. Apparently 11 were cleared. The question was put by Mr Wodak "Is it 10 or 11 Mrs Learmont that were all clear" and she said "Eleven". So, in respect of the balance apart from Mr PQ, they were, whilst not tested, discovered to have given blood on other occasions and not infected the recipients of that blood or any product derived from it. What does that tell you of the degree of infectivity of donor 36?---Again, it is most probable the source of infection in that situation was donor 36, and that he has been continuously infectious over a period of three years, and if we

make that assumption then it has got a 100 per cent strike rate everybody who has received blood or some component of that donor's blood over that period of time has become infected.

Taking that information into account together with the other factors that you have adverted to, in dealing with this question of which, as a probability is the culprit dose which has produced Mr PQ's HIV positivity, what is your opinion. If you go back to the chart on page 21 of book 7?---My opinion is that there is a strong probability that he was infected by the earlier of those two batches that he received. That is batch 543. Several reasons for that. Clearly donor 36 is highly infectious and probably has a high titre of virus in his or her blood, therefore it would be very likely that on the first occasion when somebody was infused with that material that they would become infected. There were other matters that were referred to earlier, the smaller size of the donor pool the higher titre of antibodies that were discovered in the tenth month, I think all point to the same conclusion. The probability of the person having been infected by the earlier batch rather than the later batch, if I had to put a figure to it, I'd say it would probably be - conservatively, it would be 80 per cent.

80 per cent?---Eight out of 10 chance.

That's a - you mentioned - a conservative estimate, eight of 10?---Yes.

In relation to the chances of a given infected person infecting somebody else, what is the situation there - it would take an infected donor making a donation and then his blood being used - are you able to assist us with the question of what's the percentage prospect of a person being infected and themselves becoming HIV positive as a consequence of the infected donation being made?---Yes,it's extremely high. If you look at it in a theoretical risk, it's - it's rather like your chance of getting a threepence in your Christmas pudding. It depends on how many threepences are put into the pudding so that the chance of infection depends on the amount of virus in the donor's blood. But in a high proportion of cases, there are a high titre of the virus in the blood, and therefore the risk of the recipient of the contaminated unit of blood becoming infected is very high generally, more than 90 per cent.

What of the situation relating to a top-up infected dose - and I invite you to assume for the purpose of this question, as I have, that there were only the two infected doses, namely 543 and 584 - what is your opinion in relation to whether PQ, having been infected by 543, could suffer any further consequence by having dose 584 administered to

him?---My reading of the information that's available at the moment is that the answer to that is no, that the only time that he would have come in - where it would have been a problem - would be if he had escaped infection on the first occasion. If he had escaped infection on the first occasion, he may well have been infected on the second occasions, but if he had been infected on the first occasion, meeting the virus again does not appear to have any adverse effect.

I want now to take you to a different topic, Professor, and you can discard folder 7 if it assists you with elbow room on the table in front of you. I want now to ask you some questions relating to surrogacy, surrogacy in the context of surrogate tests for HIV prior to the HIV antibody test becoming available. We've heard evidence relating to a Hepatitis B core antibody test as being an appropriate surrogate test for the infection. In 1983 and 1984, what was your opinion in relation to the reliability or feasibility of the Hepatitis B core antibody test being used?---I didn't think that it would be a reliable marker of HIV infection in the Australian context and that it would probably lead to discarding the large number of units of blood which could otherwise be used for transfusions to save people's lives.

Why did you not regard it as being a reliable surrogate

test?---Well, because the prevalence of infection with Hepatitis B in the donor population was something of the order of five to 10 per cent, whereas we believed that the prevalence of infection with HIV in the donor population was extremely low and that there would be a poor correlation between the two. On one occasion, a scientist in the New South Wales Blood Transfusion Service sent me about 800 serum samples, which I think were consecutive samples from donors who had been found to contain antibody to the Hepatitis B core antigen, and we tested those with the assay for antibodies to the AIDS virus and none of them were positive. If there had been a surrogate test for anti HBC in place at the time, all of those 600 units of blood would have been discarded. The donors would presumably have been counselled in some way that they were potentially infective to their partners and so on, and not one HIV infected person would have been identified.

What did that tell you about the lack of specificity of the hepatitis B core-antibody test?---I didn't believe that it was an appropriate test to introduce routinely into blood donation populations in Australia.

We've also heard evidence of T-4, T-8 ratio assay as a surrogate test. That of course being a test that could only be performed upon red cells, but what do you say the state of learning was in 83 and 84 relating to the worthwhileness of the T-4, T-8 ratio assay as a surrogate test?---Well, it is an area in which I'm not especially expert other than that it is a test performed on white blood cells and not red blood cells. But at that stage it was essentially a research tool, it wasn't a test that could be used in a routine setting and it was also a test with a great degree of non-specificity. It wasn't a reliable marker of HIV infection. The changes in those ratios tended to only occur in people with advanced disease, rather than people who were in an incubation period. Also changes in the ratio were described in other diseases other than infection with HIV.

I want to turn now to the question of heat treatment. What is your opinion in relation to the speed of reaction of CSL in implementing heat treatment procedures. Firstly, your laboratory facility and secondly the commercial kit of the variety which was later on

implemented. The HIV antibody. Heat treating for the HIV infection?---Well, I think there were two separate questions there. Firstly, in relation to use of the HIV antibody test. I believe they used that as soon as it was available and sooner than any other comparable group around the world, they had access to that technology months before any other group that I'm aware of in the world. Regarding heat treatment, as soon as the information was available to CSL they began to do some in-house tests to determine whether or not the particular treatment that had been demonstrated to inactivate the virus would damage the clotting factors. Because there is trade-off between technology which will destroyed the virus and the stuff which will destroy the clotting factor. As soon as they reassure themselves that the heat treatment would not seriously damage the clotting factor, they introduced heat treated clotting factor and if my recollection is correct, once they introduced heat treated clotting factor they withdrew non-heat treated clotting factor.

Which country was the first in the world to give its public a heat treated - completely heat treated product in respect of inactivation of the HIV?---I think Australia was.

In so far as heat treatment prior to the identification and discovery of the HIV, what comment do you have to

make about heat treating in the hope that that then undiscovered and identified infection would also be eliminated with hepatitis?---It would have been effectively backing a long shot in a horse race. Not all viruses are susceptible to pasteurisation. There are many viruses which are quite hardy. Particularly in the early days of the epidemic once it was recognised that this was probably an infectious disease and very probably a virus disease the difficulty in identifying the causative virus led many people to speculate that it might be a virus with unusual property. In particular that it might have been one of the group of viruses that we now refer to as unconventional viruses, which have got extraordinary heat stability. Some of these can be heated to 200 or 300 degrees centigrade without loss of activity and clearly that is not a temperature that you could subject clotting factors to. So, the introduction of heat treatment at a time when you didn't know what category of virus you were dealing with really would have been a stab in the dark.

And from a stand point of scientific advisability what do you have to say about that stab in the dark approach?

---Well, it's - it's not the kind of approach that's normally advocated.

I want to ask you about the question of warnings. We've heard of an AIDS working group meeting that took place on Thursday 18 October 1984, and you were in fact one of those present at the meeting, were you not, on Thursday 18 October 84?---I was but I was only present for part of that meeting, I wasn't a member of that committee I don't believe.

We've heard that at that meeting there was discussion in relation to the question of warnings, and Mr Stanley put to another witness that a suggestion was made that perhaps blood products should be labelled with a warning similar to that used on tobacco products, and he went on to put that it felt however that this was not feasible. Do you have a recollection of being there when that discussion took place?---Yes, I do.

What do you say of the content of the discussion at the AIDS working group relating to the question of whether the products should be labelled with a warning?

---Well, I - I don't think that the word "feasible" adequately describes the tone of the discussion. There was no - there no sense that it wouldn't be possible to print a label and stick it on - on the bag or the bottle. I think the sense that I

recollect of that meeting was that it was not likely to be a useful procedure, that it wasn't going to help anybody because people who were in the business of transfusion of blood were highly expert, and were aware that blood was not an entirely safe product, that there were certain risks associated with it. We thought that it would be as unnecessary, perhaps as printing on a surgeon's scalpel that he or she should grasp the blunt end rather than the sharp end, or something like that. It just didn't seem to be necessary or practicable thing to do.

That was your opinion at the time?---Yes, it was.

We've heard that subsequently a month after that meeting, and therefore after the introduction of heat treatment, the CSL label did in fact advert to the AIDS virus, but in the context of there being a heat treatment procedure. What observation do you have to make about that?---Well, the warnings that have been added to products - or the product information relating to Hepatitis B, and HIV are not warnings which relate to - or are - are different sorts of warnings. What they say is that these products have been tested by a particular test, and you must remember that these tests have certain limitations. Don't be fooled into thinking that just because they've been tested they are automatically safe. So, they worked from the premise that people understand that the product initially carries some

risk with it. And then a test has been done it, which although it's reduced that risk hasn't totally eliminated it, and that's the substance of the warning - - -

But there had been an earlier notice relating to Hepatitis B, but in the context of there having been a third generation surface antigen test applied, and the warning was to the effect that there's no completely reliable laboratory test. Do you see that approach as being consistent with the approach that was adopted in relation to heat treatment?---Yes, I do.

And again, the same reason?---Yes.

HIS HONOUR: Mr Gillies, I'll give the jury a brief break in the jury room. Is that a convenient time?

MR GILLIES: Certainly, your Honour.

WITNESS STOOD DOWN

ADJOURNED AT 11.49 AM

RESUMED AT 12.00 PM

IAN DAVID GUST:

HIS HONOUR: Yes, Mr Gillies.

MR GILLIES: May it please your Honour.

Doctor, in conclusion I want to shortly ask you about the question of self exclusion screening. We've heard evidence that in 1983 and up to the end of 1984 the Red Cross had in position a multiple partner male homosexual self exclusion screen. What do you say as to the adequacy and appropriateness of that screen according to the knowledge of 83 and 84?---I think it was reasonably in light of the knowledge at the time and in fact it was the procedure that was adopted in many countries and was recommended by the World Health Organisation at that time.

I have no further questions, your Honour.

HIS HONOUR: Mr Sher.

CROSS-EXAMINED BY MR SHER

MR SHER: If your Honour pleases.

Professor, when you first learnt about AIDS did you have any view from what you heard and read as to what country or countries were affected by this problem?---I think most of the early information that I had was relating to the problem in the United States and that I was aware of a large number of cases in the United States and subsequently became aware of a smaller number of cases in some countries in western Europe.

But did you have any view as to whether it could be characterised as a problem akin to any particular country?---Not at the outset, no.

As you acquired more knowledge did such a view gain acceptance with either you or your colleagues?---I think that the state of knowledge evolved with time and that one came to see different categories in different countries.

Initially at least was this thought to be an American problem? ---Yes, at the outset it wasn't thought to be exclusively an American problem but it was seen to be more of a problem in the United States than elsewhere.

Within any particular groups of people?---Well, initially in the United States it was an infection that was seen most prominently in homosexual men, particularly homosexual men who had a larger number of partners, amongst people with haemophilia and there was a disproportionate number of cases amongst American of Tahaitian origin.

I want to ask you some questions about your knowledge of the Australian blood supply in 83 and 84 and the concept of it being voluntary and the concept of it being in effect self contained, apart from some blood coming from New Zealand for Factor 8 concentrate. What was your view of the concept of voluntary donors and this country being effectively self sufficient as reflecting upon the safety of the Australian blood

supply in 83 and 84?---I thought it was a great advantage for Australia to have a population of blood donors who were entirely blood donors and to be able to satisfy its own blood requirements.

Compared with the US were you aware of the scene in America?

---Yes, but I'm not expert in that area.

But you're aware of the commercial nature of some of the blood collection processes in America?---Yes, I am.

What was your view as to whether or not that bore any relationship to the problem of AIDS and the spread of it?---I thought that societies that had a commercial system for obtaining blood or particularly western society for the commercial system for obtaining blood were likely to run into problems with blood borne infectious agents because the population that comes forward to sell their blood is much more likely to contain - or are infected with blood borne viruses.

Whatever the virus might be?---Yes.

What was your understanding as to the prevalence of intravenous drug users amongst the people donating blood?---Well, my understanding was that in cities in which there were commercial blood donors, that a significant proportion of donors were people who were intravenous drug users.

What was your view in the circumstances in 83 and 84 about the safety of the Australian blood supply for people who were getting blood products?---I thought it was amongst the safest in the world.

Was that a view that you alone held - can you give us some indication of within what circle such a view was held, if at all?---I think that's probably a generally held view amongst people who are involved with blood transfusion.

You're familiar with the steps that were taken in June 83 in Australia to introduce self-exclusion screening which was directed - so far as homosexual males were concerned - to those with multiple partners, also to intravenous drug users and partners of such people and some other smaller groups - what do you say as to whether, to your knowledge, that was what was happening elsewhere in the world and particularly in America?---Yes, I believe that that was what was happening in the United States and also it was the preferred option of WHO.

Did you regard that yourself as appropriate and reasonable

steps to take in relation to self-exclusion in view of the knowledge of the day?---I thought they were reasonable steps.

What do you say as to the growth of knowledge in 1983 about there being some connection between whatever it was that was causing AIDS and whether it was blood borne. Was that clearly apparent, for example to you, in the early part of 1983?---I think that by the middle of 1983, people with my kind of background would have been persuaded that this was a blood borne infection,yes.

About the time when the Australian Red Cross acted in June to self-exclude donors?---Yes.

Was it a clear cut case in your view at that time?---Well, it's easy in retrospect to think that it was, but at that time, there was a lot of controversy about it. People who had, like myself, a background with other blood borne virus diseases saw tremendous similarities in the pattern of infection between HIV and Hepatitis B, for example, and therefore were readily persuaded that it was probably a blood borne virus infection.

What about other reputable members of the medical profession in different areas than your own - did they all subscribe to that same view as yourself?---I don't know. I'd think that they were probably being led by people with the appropriate expertise.

HIS HONOUR: By - I'm sorry - I didn't hear what you said?---I

think they were - - -

They were led by - - -?---By people with the appropriate expertise.

MR SHER: Well, I suppose the problem had two aspects to it, what's causing it and then what to do with it?---Yes.

Now, I'm going to ask you some questions in relation to some evidence given in particular by a witness, Professor Paul Holland - do you know Professor Holland?---Yes, I do.

How well do you know him?---Well, I worked with him, in conjunction with him in - - -

MR STANLEY: Your Honour, I object to this question. How well did this witness know another witness, in my submission is irrelevant and this witness can't give evidence that would reflect upon the credit or credibility of another witness. It's entirely irrelevant how well he knows Professor Holland.

HIS HONOUR: Well, it's not clear to me as to whether the question would have that effect or otherwise. I think I should direct a question to Mr Sher. Mr Sher, is this a question which would breach that rule of cross-examination or is this a question which is admissible?

MR SHER: Well, your Honour, I intend to put to Professor Gust a number of opinions expressed by Professor Holland, and in my submission, it's relevant to the question of whether or not he would accept those opinions or

agree with them, the standing that Professor Holland has in his eyes.

HIS HONOUR: Yes.

MR SHER: That's how it's put, your Honour.

HIS HONOUR: It's put as a matter of expertise.

MR SHER: Yes, it is, your Honour.

HIS HONOUR: That I think would be admissible, would it not, Mr Stanley

MR STANLEY: I think, your Honour, it should make no difference to this expert's opinion as to whether or not something that's read to him is accurate or inaccurate by whom that opinion or statement is made. This witness has to give his own evidence. He's been called an expert, he shouldn't be swayed by whether something was being said by Professor Holland or by Dr Smith, anybody. He's here to give his own opinion and in my submission what's being done here is firstly leading the witness and secondly, leading him in a way that's unacceptable. It's an endeavour to reinforce the opinion of another witness.

HIS HONOUR: I think that if there is a difference in opinion the jury would need to decide as between opinions and would be entitled to decide the basis on which this witness makes a decision. So in substance I reject the objection but I do not purport to be ruling as to leading questions.

MR SHER: I've forgotten what it is that I asked you now that provoked that objection, but I think I asked you how well Professor Holland was known to you and in what

circumstances you knew him?---He's known to me as an expert in the field of blood transfusion and on one occasion I worked at the same institution with him.

Whereabouts was that?---The National Institute of Health.

What's the standing of the National Institute of Health - that's in the US, I take it?---It's in Bethesda, Maryland. I think it problem is the premier research institution of the United States.

I want to put to you a number of opinions expressed by Professor Holland with a view to seeing whether you agree or disagree with them. Firstly in relation to the existence of risk groups and the fact that in America as in Australia the self exclusion screening lasted for quite some time. In Australia it lasted for about a little under 18 months and in America it lasted at least 18 months if not longer, closer to two years and he expressed the view - at page 5888, your Honour. "The risk groups were barely changed over the next two years, two year period and that's speaking from early 83 when the Americans introduced self exclusion screening, because in fact the risk groups remained essentially the same. That is, the very sexually active men, IV drug users, Haitians, and the intimate sexual partners of those individuals and the numbers kept growing but the characterisations stayed almost the same with about 75 per cent being those very sexually active gay men and about 15 or 20 per cent being IV drug users and

some being both, then a small proportion being either the IV drug users, women and Haitians". Now, what do you say firstly as to whether or not that was your understanding of the position in relation to AIDS and the risk groups associated with it?--- Yes, that - - -

MR STANLEY: Your Honour, I object to this question. In my submission it's a leading question and it is directly contrary to your Honour's ruling which appears at page 6172 and following of the transcript.

HIS HONOUR: I don't memorise all my rulings by the page, Mr Stanley, you'd need to remind me.

MR STANLEY: Your Honour, in that ruling - - -

HIS HONOUR: What page was it again, 61?

MR STANLEY: 6172, your Honour. Your Honour said this "In the trial so far there has been much cross-examination in which counsel for" - - -

MR SHER: Your Honour, this doesn't have to be read out - - -

HIS HONOUR: No, I merely wanted to be reminded of which ruling it was.

MR STANLEY: I'm sorry, your Honour.

HIS HONOUR: It was a ruling on Mooney and Jayle, was it?

MR STANLEY: Yes, your Honour.

MR SHER: Your Honour, this is cross-examination. I submit I'm entitled to ask the question and it's the only way it can be asked. If I want to ask a witness whether he agrees or disagrees with an opinion I've

got to put the opinion to him.

HIS HONOUR: Yes, I'll permit the question.

MR SHER: I won't read it again, Professor, but it related in substance to saying the risk groups remained barely changed over the two year period and that's why in effect they didn't change the self exclusion screens. What was your knowledge of the scene - does your knowledge of the scene cause you to differ or agree with or in some way comment upon that opinion?---My knowledge of the scene was just as described.

And that's in America and in Australia?---Well, in - in the United States. We don't have a large Haitian population in Australia.

That's right, and of course in Australia there wasn't a case of AIDS at all until the middle of 1983, that's so, is it not?---I think the first case was 82. I'd have to check - - -

MR STANLEY: I object to my learned friend leading and leading inaccurately.

MR SHER: I'm going to lead inaccurately on purpose, I can - I didn't think I was. If I lead I'll try and do it correctly, but I thought the evidence was it was 83. It's reported in - - -

HIS HONOUR: At least you're not doing anything inadvertently, Mr Sher.

MR SHER: It doesn't matter, I won't bother about that. I want to ask you about this concept of surrogate testing to see whether you agree with this view - 5901, your Honour - "We thought very seriously about using a surrogate test, meaning again a test which we hoped or thought might pick up some individuals who may be carriers of whatever was causing this disease AIDS, and we thought about a number of them, and we thought about the benefits and the possible risks of those, and we encouraged. I was aware of the studies which were trying to find out if any of them were valuable, but I didn't put them in place for two reasons. Primarily, one, there was no

evidence that there were effective or even potentially effective, and two, if you put such a test into place and you call it a surrogate AIDS test then you could make your blood supply less safe. You can attract people into the blood supply, will come into get your AIDS test, there wouldn't be blood donors. And we've evidence of that now, but it was mainly a concern at the time which I believe was very real, and which actually happened". Now, what do you say as to those two risks associated with the suggested surrogate tests?---Those - those were concerns that were voiced at the time and I thought that they were reasonable concerns.

Something to mentioned to Mr Gillies that I want to ask you a bit about. It related to what you told us about the 600 positive core antibody blood samples you tested for HIV when you had an HIV test available, and found all them were negative for HIV. You mention the fact that not only would you have thrown the blood out and not used it, that you would have had to tell - or to counsel - I think's the word you used - donors of that blood that they might be positive for AIDS?---Yes.

Was that a problem as you saw it in using a surrogate test, whatever it was that was not a certain test for AIDS?---Yes, I think that that certainly was a problem, and it was a concern of many people. If you had a surrogate test which was unreliable

marker, then many people would be thought to be potentially infected who were not potentially infected, and you would have no way of discriminating to either two other than the passage of time, and you would have to treat them all the same.

I suppose have to tell them they might have AIDS?---Yes.

As it turned out of the 600 people who donated blood in New South Wales who proved positive, the core antibody test for Hepatitis B had been counselled that they might have AIDS before the actual AIDS test became available, and you could check it. You've had 600 people wondering whether they had AIDS?---Well, you certainly would have had; and it would have had profound implications on their sexual partners, and other people as well.

What about the affect it might have had upon the blood supply in Australia, what was your understanding of how adequate the number of donors were in Australia in 83 and 84?---My - my understanding is that the Red Cross Blood Transfusion Service is always operating right at the - at the margins and that any - any action that it's taken that might reduce the donor population by even as little as five per cent, it would have a substantial impact on - on the Blood Transfusion Service.

I want to ask you something about hepatitis and homosexuals. You've specialised in the study of hepatitis, have

you not?---I have.

How many strains of hepatitis are there?---Well, at present there are at least five.

In this court we've heard about Hepatitis A, which I assume is one of them?---Yes.

Hepatitis B, that's another one?---It is.

That's the one which thus far most witnesses have identified with homosexuals. Is that right?---It is a blood borne viral infection and anybody whose lifestyle predisposes them to blood borne virus infections is likely to come in contact with that virus.

Then we've heard about non-A, non-B which I gather is now called C?---There are two forms of non-A, non-B one of which is blood borne and one of which is acquired by swallowing it and it multiplying in the gut. The blood borne form is referred to as hepatitis type C. The enterically transmitted one is referred to as hepatitis type E.

That's A, B, C and E. What about D?---D is essentially a parasite on B. It is a virus which is only capable of multiplying in the presence of the hepatitis B virus and usually aggravates the hepatitis B infection.

What do you say as a specialist in hepatitis about the prevalence of hepatitis amongst homosexuals?---Blood borne hepatitis infections are common amongst homosexual men. We've got evidence now on a quite high rate of infection of both hepatitis B and hepatitis type C.

A, D and E are not necessarily associated as being a popular form of hepatitis with homosexuals?---We can't yet test for E. It is difficult to test for D. A is more common amongst some groups of homosexual men but not universally of increased prevalence.

What do you say as to whether or not if you were looking for AIDS, before the AIDS virus was identified and a test for it became available, about the usefulness of having a B-core antibody test which I take it will detect hepatitis B. Or the previous presence of it?---Well, it detected both people who are currently infected with are currently infected with hepatitis B or people who had been previously infected with hepatitis B. My thought was that in the Australian context it was likely to be a very unreliable marker of the presence of HIV. Not only, not all HIV infected people be detected by such a system but a very large number of people who were found to have core antibodies to hepatitis C would not be infected with HIV.

In fact your test with the 600 samples from New South Wales proved that very point?---It confirms that yes.

How do you tell if somebody is a homosexual. Is there any test for that?---I think it is a behavioural test.

I mean is there any scientific test, I should say?---Behavioural tests can be scientific, but other than a behavioural test there is no laboratory test for homosexuality.

How would you distinguish then between a promiscuous homosexual and a faithful homosexual who only had one partner?---Well, you are reliant on the person honestly differentiating between those two alternatives.

Professor Holland said this at 5905 "There's no test for homosexuality first of all. Second of all, this test which indicates infection with hepatitis B which would much more likely in there studies to bear this out, would identify health care workers, doctors, nurses, dentists, technician and so on. Would identify people from the Orient, of Japan, China, those areas where hepatitis is much more frequent and other individuals who as far as you knew were not gay. So you would have lost a lot more individuals by this test than just potentially in portion, and only in portion of those gay men who you might want to rule out". Do you agree or disagree with that?---I agree with that. The impact would be greater in the United States than it would be in Australia.

I wonder if you'd just mind listening carefully to something that I suggest you gave in evidence in another case of a like nature to this.

MR STANLEY: Your Honour, I object. In my submission, if your Honour's ruling means anything, it means that there should be no leading of the witness.

HIS HONOUR: Mr Sher how does that not come within my prescription of leading questions.

MR SHER: I'd seek leave to lead this witness your Honour.

HIS HONOUR: What you say is that you admit that it does?

MR SHER: I wouldn't be prepared to argue to the contrary, your Honour, not at 25 past 12 on a Friday.

HIS HONOUR: Very reasonable approach on a Friday.

MR SHER: I'll concede I'm trying to lead the witness.

HIS HONOUR: What's the topic? Well, I don't know what the topic is, what's the topic - - -

MR SHER: I want to ask him (Inaudible) differences between the Australian and the American population from the view point of blood transfusion and I thought it would be a shorthand way of doing it. I can do it without leading. I'll do it without leading.

HIS HONOUR: You've made an application.

MR SHER: All right, I'll - - -

HIS HONOUR: Are you going to give me - - -

MR SHER: Yes, I do apply, your Honour. I thought it would be quicker, that's all. I asked for leave to cross-examine to put to this witness in evidence he gave (inaudible).

HIS HONOUR: It's not been my practise to call in other counsel on this and unless you have particular reason I don't propose to call on you, Mr Stanley. Do you wish to be heard on it?

MR STANLEY: Your Honour, I'll just refer you to the reasons that your Honour gave in your ruling at page 6713. In my submission the fact, the factual situation is met precisely by our present, the position we're presently in. I can read it to your Honour - - -

HIS HONOUR: I'll have a look at that. It may be that that paragraph is not all inclusive but I regard this as being directed to a real issue which impinges upon the Red Cross and I will give lead to put leading questions on that subject.

MR SHER: If your Honour pleases.

Doctor, I'll read this through fairly quickly because there's quite a slab of it and if you want it repeated or you don't follow it would you please let me know. I suggest you said this in a trial in Sydney not so very long ago, but you did give evidence in a case in Sydney, did you not?---I did.

Just as a matter of interest who called you in that case?---I can't recall.

What party I meant. In any event you're talking of Australian blood bankers and you said "They had good reason to believe that the situation in Australia was more likely to be substantially different from the United States and they have been reluctant to introduce measures that might have compromised the Australian blood supply without any evidence which would lead them to realise that they needed to do that". Did you say that?---Yes, I did.

Do you adhere to that view?---Yes, I do.

Question "Why was it in Australia after January 83 assessed by the blood bank, blood scientists that the Australian experience would be likely to be different?" Answer "Well, there are a number of features of the

Australian blood transfusion centre which differ radically from the situation in the United States". I take it you agree you said that?---I do.

These are the differences you said "The blood donor population's substantially different. In the United States there's been a tradition of purchasing blood which leads to a different character of the blood donor than in Australia. In Australia the blood donor population is very largely middle class, very largely well educated, very largely urban populations. In the United States a significant proportion of those people who sell their blood are working class and several proportion of them are intravenous drug users. Some of them are people who prostitute themselves and therefore at an increased risk with other blood borne agents". Did you say that?---Yes, I did.

Do you adhere to that view?---Yes, I do. I think perhaps the term working class might not be the best term to the views to put. A high proportion of them are unemployed.

Unemployed?---Unemployed.

In addition, and this is if I may suggest, right up your alley "In addition in Australia there was another factor that made us different than the epidemiology of AIDS would be different from the United States. We didn't have - we don't have large urban ghettos in which there is intricate intravenous drug user

problems. We certainly don't have the problem to the extent they have in the United States. We've no equivalent of the shooting galleries they have in the United States. There was very little equivalent of the bath house scene which we see in some parts of the United States, so there was a perception that the circumstances which were occurring in the United States would not be directly transferable to countries such as Australia". Did you say that?---I did.

Do you adhere to that view?---I do.

Question, "And among blood scientists and blood bankers generally, the assessment that the experience here of AIDS would be likely to be different, those matters were being discussed - what - very soon after the CDC meeting and its associated divisions reached this country, is that right?" Answer, "I believe so". Did you say that in answer to that question?---I believe I did.

What you were being asked about was the fact that you went to a meeting or heard of a meeting - I'm not sure which - called by the CDC in January 83 in the US?---Yes.

Did you either go to that?---No, I didn't.

But you heard and read about it?---A colleague of mine who works at the same hospital was present in the United States at the relevant time.

What you were saying in answer to these questions was that in Australia amongst blood bankers and people associated with it, people thought that the situation in this country was going to be different from America?---Yes.

Not only was this an American problem, in the first instance at least, amongst the fast track homosexuals, but there were other differences between Australia and America?---Yes, it was thought that the American experience could not be directly transferred to Australia.

In particular, did you express this view, at 797, "The prevalence of infection with certain blood born

viruses is lower in Australia than it is in the United States or Europe or South East Asia"?---Yes.

Is that true?---Yes, it is.

Would you like to elaborate on that and tell us what you meant by that?---Well, I was, I think, referring particularly to Hepatitis type B, and the prevalence of infection with that virus varies dramatically around the world. In Australia, less than five per cent of the population overall have come in contact with the virus and have got antibody, but the prevalence of infection varies very greatly according to the subset of the population that you belong in. If you were to go to North America, the prevalence is considerably higher. If you were to go to Asia, the prevalence is between 80 and 100 per cent.

We've heard evidence in this case from a doctor who ran the Sexually Transmitted Diseases Clinic in Sydney for quite a number of years. He told us that there was a high prevalence of Hepatitis B amongst the homosexuals that he came across in that clinic, but he made the point that the people he was seeing was a subset of the homosexual set. What do you say as to that?---That - I'm sure that that's correct. The risk of coming in contact with the virus, either by heterosexual or homosexual intercourse, depends on the number of partners that you have. If you live in a community in which chronic carriers of the

virus are relatively uncommon, the more partners that you have, the more likely you are to become infected.

Thank you, Professor.

HIS HONOUR: Mr Barnard?

MR BARNARD: If your Honour pleases.

CROSS-EXAMINED BY MR BARNARD

MR BARNARD: Professor, I want to ask you some questions about the infectivity of the batches of Factor 8 concentrate. You know how - certainly when I get a piece of the Christmas pudding, my piece always misses out on having the sixpence in it - threepence, is it - but what's the situation when you get a batch of concentrate, is the infectivity right through it?---It depends on the number of threepences or sixpences in the batch. If there are a lot, then the infectivity is evenly distributed and every recipient of that material would be likely to become infected. If there is a low titre of the virus, then you might find only one in every two bottles - or of units contains infectious material.

Perhaps you might explain what governs the low titre of the virus?---Well, the virus governs the titre of the virus. There's a difference from infected person to infected person in the amount of virus that might be present in their blood. That's part of a kind of natural variation in the same way there are some short people and some tall people.

Yes?---But in any individual who's infected, there are periods of their infection in which they are more infectious or less infectious, and the higher level - the periods of highest infectivity tend - to be at the beginning and at the end of the infection.

Would it make a difference if there was 1000 or 20,000 in a batch - does that make a difference to the infectivity of the batch?---It makes a - it makes a difference at the lower end but not at the upper end. I think once there is sufficient virus in the batch that every - every aliquot that is used contains virus, then you're at the point where every recipient is likely to become infected. When you have a less - a low amount of virus present, then you can end up with a slice of the pudding which doesn't contain a threepence.

Mr Gillies has been asking you about donor 36?---Yes.

From the information that you're given, would you conclude that everybody in a batch to which he was a donor would be likely to get infected - is that the situation?---I think, on probability, the majority of people who received his batch would be likely to be infected.

Yes?---You - you couldn't say 100 per cent without actually knowing the titre, but in - in view of the history you'd think there would be a very high probability of recipients who received that batch who were previously susceptible becoming infected.

Can I ask you - looking at the other side of picture - would you expect - if you knew that a batch of concentrate had been known, and if after a period of six years there'd be no evidence that anybody had been infected or become HIV positive as a result of having received part of that batch. Would there be any conclusion you could draw from that?---If you were able to follow all the recipients of that batch, and if none of them had become infected then you'd be extremely confident that the starting batch did not contain the virus.

Let me put it to you the other way. If a period of six years or more has passed and you haven't bothered to follow any of the recipients but no evidence comes forward to suggest anybody's become infected, would that suggest anything to you?---Well, I think it depends on the - the quality of surveillance system. Whether or not that information would likely - would have been likely to come to hand.

But if a batch was infective you wouldn't expect one single person to get it I assume, would you, you'd expect more than one to get it - - - ?---Yes, if the batch had been given to multiple people you would have

expected multiple people to be infected if the virus was in it.

What I'm asking, surely over - if multiple got it surely over a period of years, such as six years you'd expect somebody to be found out to be HIV positive?---Yes, in Australia certainly.

Professor, can you give me some figures in relation to transfused patients in New South Wales, and we're of 117 transfusion patients that - in fact 48 of them have already died. Now, is there some conclusion to be drawn from that as to the strength or the timer of the dose - virus - they got?---Correct, 117 who'd been transfused were infected.

And it became HIV positive that 48 of them have already died? ---Well, it - I don't know what the time scales were between transfusion and death, but - but if - if those were all transfused and died within a five or six year period that would be on the - on the short side of incubation period, the - the average incubation period tends to be closer to 10 years - a little under 10 years. So, that this - - -

HIS HONOUR: Close to 10 - - - ?---Years.

MR BARNARD: Yes?---So that if this people had been - if the incubation period in these people was - for argument sake - five and six year then that would be rather less than the average, and we know that the incubation period tends to be related to the dose.

Yes?---So that the larger the dose the shorter the incubation period. That would be consistent with those people having received a large dose of virus.

These are the people on the Look Back program, which no doubt you are acquainted with and these were the ones who had part of the - part of a donation or the red cells from a donation and by way of transfusion and they are in the 83/84 period although some could have been earlier than that before they had their computer. So on that basis they are, within the six or eight year period?---Yes.

Does that mean that if 48 out of 117 are already dead, does that mean that out of a blood transfusion you get a very much stronger dose do you?---Yes. Clearly if you are exposed to a whole unit of blood you get much more virus than if you acquire infection as a result of sexual intercourse or shared needles and syringes. It is common with most blood borne virus infections that the time from infection to the onset of disease, or in this case to death, is shorter if you get a larger dose of virus.

Does the same apply if one gets it from the use of cryo-precipitate?---Yes. It doesn't relate to the way in which the virus is present, but just simply to the dose.

It means that you are going to get a bigger dose from a bag of cryo-precipitate than you are from something you get, than from Factor 8 where it has been

fractionated?---Yes, all things being equal the dose in a unit of cryo-precipitate from infected persons, it will be higher than in clotting Factor which has been diluted by several hundreds or thousands of other units.

Professor, you wrote an article with Mr Kenneth Mutton which was published in the medical journal of Australia in June of 1983 and some words in that article have been treated in this court by some as though they were in a statute. Do you - perhaps we should let you have a look at the article. I wonder if it could be handed to you. It is in book 1, C6.

HIS HONOUR: Which book?

MR BARNARD: Book 1. C6.

You might look at the second page of the article in the middle of the first column. You express the view whilst the risk to persons with haemophilia can probably be lowered by replacing pooled lyophilised Factor 8 concentrate with single donor cryo-precipitate. A formidable exercise. Firstly, might I ask you in relation to that, did you write that sentence or was that Dr Mutton?---I really can't recall where it came from.

Have you yourself been responsible for ever treating haemophiliacs?---No neither Dr Mutton or myself.

Were you expressing views about for example, as to whether a severe haemophiliac should be taken off Factor 8 concentrate or not?---No. I wasn't and nor would I

be competent to express such a view.

Perhaps I should ask you. What in fact were you conveying at that time?---Could I just have a moment to re-read it sir.

Yes?---I think in re-reading it what I was trying to do is sound a note of warning for the future rather than - that's the sense that I get of reading it. It's a long time since I wrote it.

It can be clear from that you weren't saying that severe haemophiliacs should be taken off concentrate or for that matter you weren't warning against anybody put off it at that time?---No. No, I wasn't.

But on the other hand you were recognising the possibility of a risk in the blood supply and in particular this particular blood product?---Yes.

I imagine you weren't turning your mind to the question whether in fact haemophiliacs or all haemophiliacs could be treated with the cryo-precipitate?---No, no, I wasn't. That's an area quite outside my expertise.

The reference to formidable exercise was that it was clearly indicating that it was a problem that would be dreaded?---Yes, I recognised the difficulty of replacing which comes from a large pool, something that comes from individual donors.

Professor, in 1984 was there a view that you could be HIV positive and you wouldn't end up getting - you may not end up getting AIDS?---Yes, there was. There was a view held by some people, particularly in the haemophilia community that the significance in antibodies in people with haemophilia was different from the significance of antibodies in other groups.

The argument was that people with haemophilia may have received inactivated virus. The virus may have been damaged in the treatment process and thereby have immunised these people, so that they developed antibody but weren't infected and that was an argument that was quite common in that community at that time.

So the use of blood products - or the risk arising from the use of blood products was seen by these people to be less, is that - - -?---Well, by some people.

Also at that time was there some view about whether you could become vaccinated against AIDS by being exposed to it?---Well, I think that that's the other side of the previous question and that is that there was a hope by some groups of the community that inactivated virus that might have been received in clotting factors would have stimulated an immune response without infecting that disease.

Were these views found by respectable medical practitioners?

---Yes, they were.

So that being HIV positive wasn't seen necessarily to be a killer disease?---No, the situation of that - say there were two elements to that situation. First of all there was the thought that some people who had antibodies present may not have been infected and therefore that there were two sub groups, an infected and an immuno sub group, both of whom had antibody. But secondly, at that point of time we

hadn't been able to follow infected people for a long enough period to be able to determine what proportion of them would ultimately die from the disease. So that the case fatality rate was only a proportion who'd been infected and observed and who had died to that point in time.

Of course at that time it was hepatitis was it, that you could - you could have the virus within you but the virus itself was dead and inactive, and - but you could still record positive?---Yes - well - there was already a hepatitis vaccine and - which with you could immunise people and stimulate antibodies in their blood - they had antibodies - were not infected and was not infectious.

This is back in 1983, 84, is it - - - ?---With hepatitis?

Yes?---Yes, the vaccine was licensed in 1981.

A similar - or the HIV positive was seen by some as involving the same sort of picture, is that so?---Yes.

Professor, you told us of doing the ELISA tests on sera, and this was on old sera that you got from hospitals, and I think you said that it was - needed to be stored and refrigerated at minus 20 degrees?---Yes.

And that this was necessary to avoid the loss of antibody activity?---Yes.

When you say "minus 20 degrees" what happened if it was stored in a normal refrigerator or a lesser temperature than that?---If it was stored at a - in a normal refrigerator or stored at room temperature there would be a danger of contamination with the (inaudible) bacteria or fungi that might be in the air, and secondly even if you managed to avoid that, there's a deterioration in the quantity of antibody with time, and it's proportional to time and to temperature.

If it wasn't stored at the required temperature does that involve you get a false negative?---You may. You may get a false negative. It depends on the titre of antibody originally, that is the decay is relatively slow. It depends on the - the amount that you have present at the beginning and then how long afterwards.

Was the ELISA test in fact reliable or did it show false negatives?---Well, we weren't able to tell at that point of time exactly how reliable it was. However, we've been - we've now been able to go back and look at samples that were tested in those early days with more modern techniques, and we find the test at the time was very reliable.

MR SHER: Your Honour, I forgot to ask one thing of Professor Gust. I wonder if I may before lunch ask - - -

HIS HONOUR: Yes - - -

MR SHER: It was just an oversight on my - - -

HIS HONOUR: Having regard to what you last said the answer's yes.

MR SHER: Professor, you gave us some figures yesterday that you'd tested this sera from haemophiliacs. There were no HIV antibody in the 81 samples. 9.8 per cent in the 82 samples. 11.9 per cent in the 83 samples, and 31 per cent in the 84 samples. Is it the fact that you also tested some sera collected in 1985, and found between 45 and 46 per cent?---Yes, it is.

Have you ever found as much as 63 per cent?---Yes, the prevalence of antibody that - that you find when testing people with haemophilia, depends when the sera were collected and how severe the haemophilia is. Haemophiliacs either mild, moderate or severe and the very severe ones get a lot of clotting factor, and therefore are more likely to be infected, and so the highest prevalence of antibody is amongst people with severe haemophilia, and the lowest prevalence is amongst those with mild haemophilia.

But the figures I've just run through, some of which you'd already given as the new one was 45 to 46 per cent for 85. None of those figures get up to 63 per cent?---No, I think that where we - where we've demonstrated two thirds of a population of - of people with haemophilia are infected it's been where the group that have been selected have been exclusively or largely those with severe - - -

Was that all the haemophiliacs in Australia or just some small sub group of them?---Well, each of these studies has involved a sub set.

Yes?---There are about 1500 people with haemophilia. A high proportion of those are now being tested.

HIS HONOUR: A high proportion are?---A high proportion of those have now been tested.

MR SHER: Amongst severe haemophiliacs in Australia, does the figure get as high as 63 per cent of all haemophiliacs?---I don't have the figures in front of me but my recollection is about two-thirds of the people with severe haemophilia.

What I just want to ask you is - and this is what I meant, that was just preliminary, this is really what I wanted to ask you - having got those figures, you've been able to sort of work out from that when it is that the AIDS virus probably came to Australia, have you not?---Well, I think it's a helpful piece of evidence in terms of the introduction of the virus into the blood donor population. It doesn't necessarily answer the first question.

So if we can't say from that when it came to Australia - which obviously you can't - you can at least say when some of it in Australia got into the blood donor population - was that 1981?---Yes, I think so.

So two years before there was - maybe two and a half years before any AIDS case in Australia, apparently the AIDS virus had come to Australia and got into the donor population?---That's correct.

Yes, thank you.

HIS HONOUR: Yes, Mr Stanley?

<u>CROSS-EXAMINED BY MR STANLEY</u>

MR STANLEY: Professor, you told us that you're now employed

mmonwealth Serum Laboratories, is that
it is.
) - the early 1980s and up until fairly
ou were employed at Fairfield Infectious
ospital?---Yes, I was.
loyee of there?---Of the Health Department
a.
ad under you at that hospital, were they
employed by the Health Department?---No,
't.
oyed by?---Well, they were employed by a
people. I had two responsibilities. One
he diagnostic section of the laboratory,
entirely funded by the Health Department.
ing portion, the research component, were
a variety of grants, whereas the National
erence Laboratory was funded by a block
n the Commonwealth Department of Health.
ck that you and those under you did in
to obtaining the AIDS virus, first from
ier and subsequently from America, that was
te apart from the Commonwealth Serum
y?---Yes, it was.
ith CSL at all?---No, it did not.
done at Fairfield to develop the test, that
by researchers - again, you had nothing to
SL?---Well, it wasn't done by researchers.
ne by members of the hospital staff. Both

ere members of the
not employed -
out the tests, some
evidence in this
ntist, was he, or a
technologist, yes.
erica and he was the
is that so?---Yes,
he had also given
tand.
Stanley?
two.

RESUMED AT 2.21 PM

IAN DAVID GUST:

MR STANLEY: Professor, I want to continue asking you questions to just find out whether CSL or the Red Cross for that matter had any input into the steps that were taken by you, or by those with you at Fairfield in respect of the ascertaining of the AIDS virus, and the testing and so on. Now, you've told us that you first heard Dr Montenier's position in relation to what he believed was the AIDS - or the virus causing AIDS at the WHO meeting in November 82, was it?---83 - - -

You attended that meeting in what capacity?---I was invited by the World Health Organisation. I'm not sure whether it was in a private capacity or as my role as the Director of the WHO collaborating - - -

Was it essentially because of your personal association with Dr Montenier - or Professor Montenier - together with the fact that he must have appreciated that you were one of the believers, that you ultimately were able to obtain the virus and cell line from him?---I think it was simply that I asked him. I - I believe that he made available similar samples to a number of other laboratories at the time, and in fact the centres for Disease Control in Atlanta, and the United States obtained their strain from Montenier.

So essentially you believe it was just a matter of asking for it?---I believe - I believe so.

And if CSL - their research and development department or whatever the appropriate section is, had made such an approach you have no reason to believe that they wouldn't have been provided with it also?---No, it depends a little on the amount of material that was available, and I - normally you have to have some kind of packing order in the distribution of reagents.

Now, so far as the virus that you eventually were able to utilise, was that one that came from the Pasteur Institute through Dr Montenier, or was that one that was obtained from America?---It was obtained from the United States, but it's origin like - like the material we sought to import was from Dr Montenier's laboratory.

That was the virus that Mr Pringle brought out with him? ---Yes.

He was doing that as an employee, was it, of Fairfield Hospital?---He was.

And went it came out here tests were done it by Doctor - or tests were devised by Dr Williamson, and then various tests were carried out by you and other members of the staff at Fairfield?---Yes, the material that they were using in those tests however was not virus, but viral antigen - - -

Antibody?---No, antigen.

In all events it was obtained from the United States, and to this stage CSL and Red Cross had nothing to do with

it?---No, to that stage they had not had any direct involvement.

Would it surprise you if in July 1984 CSL did not even know that you had the virus or the cell line?---Well, we didn't have live virus in Australia at that time.

What did you have?---We had cells that we had obtained from Montenier which had died and didn't contain any vital virus.

Would it surprise you to know that CSL were unaware of that?---No, it wouldn't - that wouldn't surprise me at all. It wasn't public knowledge.

Is there some secrecy or was there some secrecy about it?

---No, there was no secrecy about it. The - there's a mechanism for reporting viruses into the country through - because these are subject to quarantine regulations, and - and it would have been possible to check the relevant quarantine authority.

That was all done formally and open for anyone to check?

---Yes, yes, perfectly - - -

Doctor, you were invited to join a working group - an AIDS working group - set up under the auspices of the Australian Red Cross, is that so?---I was.

And that was - that group had its first meeting in October 1984, correct?---I believe so.

That was the first occasion upon which you'd been, as it were, co-opted on to any committee in relation to the AIDS problem by the Red Cross?---Yes, I think that was the first formal association like that.

Prior to that, had you any discussions about this problem with any of the divisional directors of the Red Cross and, at that time, they would have been Dr Morris in Victoria, Dr Archer in New South Wales, Dr Hart, I think it is, in Queensland, and it may have been Dr Beale, I think at that stage, in Adelaide?---I think - I'd have to check the timing of that, but certainly, I was a member of the Victorian State AIDS Advisory Committee and of the task force and there were representatives, including some of the people that you mentioned, on both the State body and the task force. What I'm unclear about was when those two committees were established.

By the way, the first meeting of the AIDS working group, which I suggest to you the minutes show, was held on 18 October 1984. It was a meeting at which you were present for only part?---I believe at each of the meetings that were held, I was invited along for a component of the meeting but not of the whole of it.

Is it your understanding that in practice minutes of meetings are set out in effect chronologically or in the order in which the matters are dealt with at the meeting?---I don't have great experience in that.

You'd expect that to be the case, wouldn't you?---I don't have

great experience in that at all.

But you would expect it to be the case, wouldn't you, that the minutes would - in terms of the matters they deal with - would be set out in the order in which the matters were dealt with at the meeting?---I imagine so.

Professor, do you - you, in evidence-in-chief, indicated that you were present when there was discussion at that working group meeting about the issue of having a warning on blood products and it was put to you that - the statement was it was felt that this was not feasible - do you recall that - and you then - - -?---Yes, I do, yes.

Are you sure that you were present in fact at the meeting when that matter was discussed - perhaps it might - you might like to refresh your memory by looking at the minutes and you'll see, if you turn to the second page, page 2, about 10 lines from the bottom is the sentence "A suggestion was made that perhaps blood products should be labelled with a warning similar to that used on tobacco products. It was felt, however, that this was not feasible" - do you see that?---Yes, I do.

That in fact was the - and then there was an agreement stated following that discussion. That's the first matter that's dealt with in these minutes, is it not?---It is.

If you turn over to page 11, do you see at the top of the page

the heading is "Application of Screening Tests"?---Yes.

Would you mind reading what it says underneath that?---It says "Dr Ian Gust, who later joined the meeting, agreed that three years was a reasonable period to set back" etcetera.

Well, Doctor, would you agree with me that, by reference to the minutes, there are many factors or matters that have been dealt with before reference to your attendance at page 11 including, if you go to page 3, donors, page 5, donor - or screening, and then notification of results of screening tests, co-operation of private medical practitioners, autologous blood transfusion, recipients of blood and blood products and donor records, female donors, sterilisation of AHF concentrate, precautions for staff handling blood, and then the application of screening tests was the matter I referred you to - in other words, there are many matters dealt with in the minutes after the reference to the warning on the cigarette - such as on cigarette, tobacco products, and yet this reference to your attendance is you'd "later joined the meeting" - can you explain that?---No, I can't without an opportunity to read the entire document, and quickly glancing through it, I've noticed at least one reference much earlier that implies that I was present, but I would need to read the entire document to be able to see

if there are other such - - -

Could you show us - sorry?---There's a reference about confirmatory tests being done in Fairfield Hospital on the bottom of page 6. I think it's unlikely that such a discussion would have been in my absence.

In all events at page 6, even if that was so, it is considerably after the first item that's referred to in the Minutes, namely, the warning?---Yes, it is.

If you look at the front page of the Minutes where it has the list of those present, your name is indicated as - you are indicated as being present for part of the meeting?---Yes, it is.

Doctor, on reflection are you confident that you were there when there was discussion about the warnings?---Yes, I'm confident that I was there while there was discussion about it. I don't know that I was there at the time that the primary discussion took place. It is not uncommon when somebody joins a meeting for the chairman of the meeting to summarise the discussions that had gone before that are pertinent to it, to that person's attending.

So, it may have been a summary of what had been said previously?---It may well have been.

Doctor, by the middle of 1983 you were obviously sufficiently concerned about the problem of AIDS and its spread in Australia to write what you did in the leading article of the medical journal of Australia?---Yes, I was.

I take it what you wrote there was your - it contained your views and the position that you adopted at that time?---It contained our views that were jointly authored.

Your Honour, I seek to tender this article. It is already an

exhibit, but it is an exhibit for a limited purpose only. I desire now to tender it absolutely in effect, as truth of the contents in so far as they are the opinions and express the facts as adopted by Professor Gust.

HIS HONOUR: Yes. You seek to tender it under s.55 do you?

MR STANLEY: Yes, I do your Honour.

HIS HONOUR: Very well. I'll admit it on that basis.

MR STANLEY: If your Honour pleases.

Could the witness be shown book 1 please. C6. Professor this article - I'm sorry, this issue of the journal was one that was essentially directed towards this problem of AIDS wasn't it?---It was.

The cover dealt with it and a number of articles in it and this was the leading article from yourself and Dr Mutton?---Yes, it was.

So, it was obviously a matter viewed with importance by those responsible for the production of the American Journal of Australia?---It was.

In the introductory paragraphs you set out the factual situation as you understood it at that time?---Yes, I did.

I take it that this was issued - this issue came out on 11 June, you would have written it some - what weeks or - - - ?---Some weeks earlier.

We could say the same for the other articles that are contained in the journal. They would have to have been submitted to the publishers, I take it, some weeks before publication?---Yes, frequently they had the date of submission actually as part of the - - -

Yes, I don't think yours don't?---No, not the editorial.

You were in the introductory paragraphs indicating the extent of the problem, that by that time in the United States or by March there was some 1300 cases and also at least 15 other countries and the progression rate, progression rate of reported cases was rising. You stated there were - the view that the prognosis was appalling. I take it that was your view at that time?---Yes, it was.

If we go to effectively the bottom paragraph, it starts "This definition". It's after you've discussed the definition of AIDS, of the centres for disease control, you're in effect saying it's a narrow retyped definition and it's likely that there are many other cases of AIDS that don't meet as yet that strict definition?---I think that's not quite the intent of that paragraph. It was more to say that AIDS is in one aspect a spectrum of the infection, is the final stage in the disease and there may be other people who are infected and at an earlier stage of the disease and do not have the disease

- - -

Among those you specifically mentioned were the haemophiliacs?

---Yes.

One of the reasons you said that is because at that stage the haemophiliacs like the AIDS victims were showing a reversal of their T-4, T-8 cell ratio?---That they - those people or among those people were people formed the disease as well as abnormal laboratory tests which did not meet the definition of AIDS, but were probably we believed part of the same spectrum.

Then if you could turn over the page, in the second full paragraph, the one starting "There is a growing feeling that a novel agent is involved acting directly or with other factors. The epidemiology supports the notion of a transmissible agent spread in a way similar to that of Hepatitis B infection". That was clearly your view at that time, wasn't it? ---Yes, it was.

You were very familiar with the way in which the Hepatitis B infection was spread?---I was.

You then went on to describe the sexual transmission being suggested in AIDS amongst heterosexual persons and transmission by a blood and blood products seems likely on the basis of AIDS occurring in persons with haemophilia, in IV drug users, after blood transfusion and in a baby after platelet transfusion. So you were putting forward there the reasons why you accepted that it was likely the AIDS was being spread by or through blood and blood products?---Yes, I was but I qualified it by saying

it seems likely.

I take it that was your view at that time?---Yes, it was.

That it was likely that that was the case. You then went on in the next paragraph "Concern over the haematogenous 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 replaced pooled lyophilised Factor 8 concentrate with single donor cryo-precipitate formidable exercise". I put to you that what you're doing there is in effect is you are endeavouring to alert the medical profession to a risk, a problem?---Yes, what I think I said earlier was that we were alerting to a risk that we foresaw in the future. When I - I think the statement about replacing lyophilised Factor 8 with single donor cryo-precipitate was merely a statement of the obvious.

When you say a statement of the obvious. What do you mean?---I mean that it - I would have thought that it was fairly obvious to people in that area that the risks from a single unit of material from an infected donor were somewhat different from - if you took the material from a single donor, different from when you had a pool of material from 1000 or 2000 people.

What you are in effect suggesting is that the risk of getting infected is much less if you are on the single donor product rather than the risk of getting some infected batch of a pooled product?---Yes.

That, to use your expression is or should have been "self-evident" to any doctor?---I think that principle was self evident. But was putting both sides of the equation.

In the sense that it would be in your view a formidable exercise?---That's right. I was pointing out the difficulty of implementing such a procedure.

So whilst ideally, it might have been better for everyone to have gone back to the single donor product, for practical purposes it just wasn't appropriate?---Well, I didn't say that, I was simply pointing out the difficulties of doing that. I would have left that judgment to the people who were actually responsible for the Blood Transfusion Service.

To those treating the patients or to the Blood Transfusion

Service?---I think those decisions are usually made in conjunction. So, you would say the decision really rests with both the physician and with the Blood Transfusion Service, the Red Cross.

In my experience, which admittedly is fairly limited of those kinds of decisions which involve a change or a recommended change in the treatment there is usually input from both the manufacturer and also the client at the other end.

You would accept that as the appropriate way for things to be done?---Yes, I think that's the - appropriate is not the only way, but that's an appropriate way - - -

You would certainly expect some input from the manufacturer and/or distributor of the product, as well as the actual physician?---Yes.

Professor, if we go on in the next paragraph you refer to the fact that AIDS has an incubation period of nine to 22 months. Do you see that?---Yes. I'm sorry I haven't - - -

It is in the middle of the next paragraph. The paragraph saying "The outcome of attendance"?---Thank you.

So you are alerting the reader to the fact that one of the problems with this AIDS is that it has this incubation period, which is very long, from nine to 22 months, and that can mean a number of things can't it. Present a number of problems?---I was simply stating the facts as they were known at that time.

I'm asking you, do you agree that the fact that there was such a long incubation period presented the medical profession, those concerned with this problem, with particular difficulties?---Yes, but in the context of - that it is used, in this particular editorial, it refers to the results of negative tests on chimpanzees to date and basically points out that we can't assume that the chimpanzees have not been infected.

Professor, if I could refer you to one of the articles, contained in this same issue, where the incubation period is referred to. I simply want to put to you, and ask your comment on this?---Isn't it a fact that because AIDS was known, as at middle of 1983 to have an incubation period, on your assessment of up to 22 months, wasn't that a factor that caused particular difficulties to those in the medical profession concerned with this problem?---It caused some difficulties in estimating the number of people in the community who had been infected.

It made some reputable people, people very experienced in the field, express the view that the probabilities were that all that was being seen was the tip of the iceberg?---Yes, that phrase was frequently used.

It also meant that the virus, or whatever it was that was causing this AIDS, could be present in the community and in the blood supply for up to 22 months, without anyone knowing?---For up to 22 months without anybody developing disease.

There was no test?---No, there was no test - - -

So without a test it could be there up to 22 months without anybody knowing?---Yes, that is correct.

So, that's what you were telling the medical profession in the middle of 1983?---What I was telling the medical profession is contained in this editorial. I'm not specifically using that information in relation to the chimpanzee experiments.

The whole point of it though, is it not, is to suggest that there may be a lot more there than we currently know about?---No, that - that was not the point what I was stating in the article. The point that I was trying to make in that article was we shouldn't throw away those animals that had been injected on the assumption that they were not infected, because they might be able to report information at a later date.

Doctor, further down that same column, in the last big paragraph on page 541 in the left-hand column "Starting in this issue", do you see that paragraph? ---Yes.

About halfway down that paragraph after referring to the five patients that are described in the issue you say "These cases occurred in Sydney and are the first cases of the syndrome recorded in Australia. Given the similarities said to exist between the Australian, and the United States homosexual sexual communities it's hardly surprising to read these

reports, and efforts should be directed early to try to establish the actual extent of this potential problem in Australia along the lines suggested by Dalgleisch and others" - and Dalgleisch and others were authors of one of the papers contained in this issue, is that so?---They were, but I've - I've forgotten at this point of time exactly what those suggestions were.

I won't embarrass you by asking you but the point is this, you there refer to the similarities said to exist between the Australian and United States homosexual communities, and on the basis of that it's hardly surprising to read these reports. Namely, these reports of people - homosexuals getting this disease in Australia?---Yes.

Now, what did you know about the similarities existing between the Australia and United States homosexual communities in 83?---I guess what I'd been told by members of the gay community in Australia at that time. I'd been told that there was a - a significant homosexual community in Sydney and Melbourne who openly identified themselves as gay and had there own newspapers and pennies and so on. But there was quite high rate of sexual activity in those groups, and that there was frequent contact between members of some of those groups, and similar people on the west coast of the United States.

By homosexuals from Melbourne and Sydney going to the United

States or alternatively the United States homosexuals coming to this country - - - ?---That's more the former than the latter.

But you were certainly aware of the homosexuals seen in Melbourne as well as Sydney at this time, weren't you?---I was - I was becoming aware of it. I was by no means expert in the middle of 1983.

But if people had the idea that Sydney was the only homosexual base in Melbourne - in Australia - that would be quite inaccurate in 1983, wouldn't it?---That would be inaccurate, but there - there were perceived to be very great differences between the scene in Sydney and Melbourne. I think they still sort of - - -

I'm sorry, they - - - ?---They were perceived to be major differences in - - -

Of course - - - ?---Well, Sydney was seen to be the place for homosexual men in - in Australia - in a sense the mecca - many people from other States had gravitated to Sydney because there was a larger scene in Sydney.

You were aware that there was in fact a similar scene so far as homosexual activity's concerned in Melbourne?

---But on a - on a very different scale.

Different in what sense?---Different in - numerically - there didn't seem to be, and we now have some - some evidence that the - that there were either as many homosexual communities in Melbourne as in Sydney or

that the rate of infection were as high.

Doctor, you'd done some work, had you not, in relation to the extent of hepatitis amongst the homosexual communities in Australia - - - ?---Yes, I had - - -

Was that in Melbourne?---Yes, the work that - the work that I did was primarily in Melbourne.

That work showed a significantly high rate of infection with Hepatitis B or indications of past infection with Hepatitis B amongst homosexuals in Melbourne, did it not?---Yes, again I would have to check the information. My recollection is perhaps about a third infected.

I suggest to you that in 1983 the studies that you did showed Hepatitis B markers present in 58.1 per cent of men who'd been engaged in homosexual activity for more than 20 years, almost 60 per cent?---Sixty per cent in that particular sub group of homosexual men. It's very similar to what I described amongst people with haemophilia in which the highest presence of antibody is found in those with severe haemophilia. This was a sub group of men who'd been involved in homosexual activity for a long period of time, but my recollection and I could be wrong about this is that the overall prevalence amongst all homosexual that we studied is closer to a third.

Doctor, I suggest to you that what was published in the Medical Journal of Australia in November 83 under your - or over your name was "Hepatitis B markers were found in 46.8 per cent of subject", does that sound right?---I don't have that paper with me at the moment but I'd be happy to look at it. Thank you.

Doctor, the point I'm seeking your concurrence on is this, that studies that you did in 1983 disclosed a high

incidence of hepatitis markers amongst homosexual men in Melbourne?---Amongst one subset of homosexual men attending one general practice in Melbourne, yes.

This is the study you did?---Yes.

It shows, does it not, the figure that I put to you, 46.8 per cent across the board and 58.1 in those who have been having homosexual activity for more than 20 years?---That's correct but also in that article I think there's reference to the fact that they were a select group of men.

It says "All homosexual men attending a general practice between mid September and early April 82"?---If I could have it back for a moment, I think that it also - remember a statement saying that they were selected in a particular way, that they could not be taken to be a cross section of the entire homosexual community at all.

You conclude by saying "It is possible to identify a 'Typical' cross section of the male homosexual community. This group selected itself by attendance at a general practice known to be sympathetic to the homosexual community"?---Correct.

So they're homosexuals who went to a general practice doctor who was known by homosexuals to be sympathetic to them?---Yes.

It simply means they're homosexuals that attend a doctor?---No, that's not the only - - -

Perhaps we - - -?---Selected them, a high proportion of them attended with other sexually transmitted diseases.

Doctor, the position is this, is it not, that you knew and it was generally accepted that amongst homosexuals there was a significantly high level of incidence of hepatitis?---Yes, they were known to be increased risk of all blood borne infection.

That was much the same situation as was revealed by the United States studies?---It was similar but, as I think is pointed out in that paper, much lower than in the United States in the equivalent populations.

So when you spoke in the leading article about the similarity said to exist between the homosexual communities, were you referring also to the incidence of hepatitis?---Yes, I was pointing out that there were a number of similarities and certainly increased risk of being infected with blood borne viruses was one of them.

If I can take you to the next column, the second last paragraph, you deliver what I suggest is something of a warning to hospitals and hospital staff members. You said "Although there's no evidence of AIDS transmission to hospital staff members, those in contact with such patients or with specimens from them should observe certain precautions to minimise any potential danger and these precautions are broadly similar to those against Hepatitis B". Now, this was a warning again for the future, correct?---Yes, it was.

You were saying that the precautions that should be taken are broadly the same as those that should be taken against Hepatitis B?---Yes, that's true.

The precautions that had to be taken against Hepatitis B or should have been taken, these had been well known, hadn't they?---The - in hospital settings they were.

Laboratory workers, hospital workers, doctors and nurses, they all knew the precautions that had to be taken?---Well, they should have known.

Similarly, anyone involved in the collection of blood should have known about the risks of hepatitis and the steps that should be taken to avoid being contaminated by it?---Yes.

Doctor, it was put to you earlier in a question by my learned friend, Mr Sher, that we'd heard evidence from a doctor who had been the director of the Sexually Transmitted Diseases Clinic in Sydney and it was put to him that in about 1983 that male homosexuals aged - of male homosexuals aged 36 years or more, the figure in the literature in Australia at that time was that it was about 80 per cent of those males that had Hepatitis B and he agreed with that?---Well, that may have been his experience in his practice but I don't believe that that was a universal experience, and if you were to seek out the data from other States, I think you would find that that was not so, certainly not universal.

He wasn't expressing his personal view. He said that the figure in the literature in Australia was about 80 per cent?---Well, I don't believe that there would be a figure in the literature in Australia to say that 80 per cent of homosexual men in each State of Australia had serologic evidence of past infection of Hepatitis B, or there may be an isolated group in

whom that figure was found but I don't believe that represents the homosexual population in Australia.

Well, in all events, it had been known for some time before 1983 that, so far as homosexuals are concerned, they had a higher risk than the average member of the community of having hepatitis and it was also known - should have been known - by blood banking people what precautions should have been taken in relation to Hepatitis?---It was known prior to 1983 that homosexual men in some countries of the world were at high risk of infection with Hepatitis B. I don't know when the first published reports in Australia of data confirming that they were at increased risk occurred.

Well, Doctor, you certainly believed, did you not, that by the middle of 1983, steps should have been taken by those responsible for the Blood Transfusion Service with respect to the possible dangers associated with the spread of AIDS in Australia?---Yes, and I outlined them in the leading article.

You earlier expressed the view that you considered the steps taken were reasonable?---I did.

What were the steps that you thought were reasonable?---I think that the donor exclusion form or the quizzing of potential donors was the single most important step that was taken in the early days.

Any others?---The encouragement of women to donate blood so that there would be additional non-male donors.

That wasn't until November of 1984 doctor was it?---I don't recall the exact date.

By you would have thought that would have been a good thing to have done?---I think you were asking me what positive things were done and I'm answering what positive things were done.

I'm asking you about November - sorry mid-83?---Well, I don't have a detailed time sequence in front of me, but I believe that the first step that was taken was to try and discourage homosexual men with multiple partners and intravenous drug users from donating blood.

You've dealt with that. You said the quizzing of donors was the thing that you regarded as relevant or important?---Yes it was.

Anything else?---I don't recall any other active steps being taken at that time.

So is this the position as you understand it that was the only step that was being taken at that time?---I'm not sure if there were any additional steps. There may

have been steps that I was unaware of but they'd seemed to me to be the corner stone, not only of Australia's response but of any other countries response.

When you say the "quizzing of the donors". What did you understand that to mean?---Well, I understood that the precise process varied from state to state and that sometimes it involved giving the potential donor something to read. It sometimes involved some discussion with a potential donor as well.

What about requiring him to sign. Did you have any understanding about that?---I don't recall at what stage the asking them to sign the declaration occurred.

What's your understanding of what the quizzing or questioning amounted to?---I believe that they were given a questionnaire page or perhaps a little longer than that in which they were asked a number of questions which might disqualify them as potential blood donors and their attention was drawn to a number of things. Not just hepatitis and (inaudible) that might disqualify them as blood donors and they were then asked if they fitted into any of these categories to refrain from donating blood.

Do you know anything about what steps were taken to ensure that they read it?---No. I don't. That's not an area that I'm directly involved in.

Or whether they had to mark it or sign it in any way?---I

don't work in a blood transfusion service.

No. But you see doctor. You gave the evidence that in your opinion the steps taken were reasonable. I'm just ascertaining how much you knew about what was actually done?---I think that the question that I was being asked was whether the attempt to exclude homosexual men who had multiple partners was a reasonable thing in light of the knowledge of the day. My answer to that was "Yes".

Doctor, as to how that should have been done. Do you have any views?---I regard that as an operational issue that needs to be sorted out by the transfusion services themselves, and it is not an area that I have been very much involved in.

In all events, you would certainly want uniform steps to be taken in each State wouldn't you?---I think that would be desirable but it is not always possible.

You know in this case it wasn't achieved until the end of 1984, was it?---Uniformly - I believe (inaudible).

That was after the death of the babies in Queensland when the politicians became involved and that meeting that you described as the summit meeting was called in December of 1984?---I don't know if that was the trigger.

You attended that meeting, did you not?---I did, a portion of that meeting.

You're aware that at that meeting the NH and MRC chairman, I think it was, it was Professor Pennington, produced a declaration, a uniform declaration that had been drawn up after the quest had been made of the different divisions of the Red Cross to provide their version of such a declaration. You're aware of that, are you not?---I believe of that, yes.

So you believed that that was certainly a desirable factor, namely that there be uniform steps taken in each State?---I think that that's desirable but it's not always essential that the same information can be transmitted in a variety of different ways.

Doctor, what's your view about whether it would have been appropriate to have asked donors to sign a form indicating that A, they've read and understood the leaflet, the information leaflet that was given to them or alternatively, that they'd understood questions that were asked of them by a doctor or member of the staff?---I think it would have been perfectly appropriate if somebody would have wanted to introduce that. Yes, certainly.

We've been told by your former colleague, Dr Holland, that that's the step that he took at his blood bank at the relevant time in September 83. You'd regard that as appropriate?---Perfectly appropriate, yes, certainly.

Were you aware that in May 1983 in New South Wales the director of the Blood Transfusion Service had directed that all homosexuals should refrain from donating blood?---No, I don't recall that.

Your Honour, could the witness be shown exhibit RX15?

HIS HONOUR: Yes.

MR STANLEY: Your Honour, this also appears I believe in book 7 which the jury would have.

HIS HONOUR: Mr Stanley, it's 10 past three, is a convenient time to break?

MR STANLEY: Yes, it would be, your Honour, and we could - perhaps could I just indicate to the jury?

HIS HONOUR: Yes.

MR STANLEY: It appears in B, book 7, B, and it's the third set of documents after the second green folder.

HIS HONOUR: Seven B, after the second divider.

MR STANLEY: Yes, it has the number 20 on the first page. I was going to refer the witness and the jury specifically to page 13.

HIS HONOUR: Once you've got it to the page you'll release us, will you?

MR STANLEY: I'm sorry, your Honour?

HIS HONOUR: Once you've got us to the page you'll release us?

MR STANLEY: Yes, I shall, your Honour.

HIS HONOUR: Yes, nothing counsel wish to raise with me, is there?

MR SHER: No, your Honour.

HIS HONOUR: Very well. I'll leave the bench for 15 minutes

and the jury will go to the jury room.

WITNESS STOOD DOWN

ADJOURNED AT 3.11 PM

RESUMED AT 3.28 PM

AT 3.28 PM THE JURY RETURNED TO COURT

IAN DAVID GUST:

MR STANLEY: Professor, just before I take you to that particular document, there's just some background knowledge - following on from the middle of 83, the number of AIDS cases and AIDS related syndrome or AIDS related complex cases in Australia was increasing was it not?---Yes it was.

You in particular through your membership of the NH & MRC were advised of the circumstances and particulars of each case?---Yes, I believe we were.

What I'm suggesting to you is that you were able to make a judgment in each case about the individual whether he was a promiscuous homosexual or one that might have had multiple partners whatever that means, or whether he was a monogamous homosexual or whether he said he wasn't a homosexual?---We were reliant on the information that was provided to us. Also, there was a lag between somebody being identified and the paper work catching up. It was often quite some time afterwards that we got a notification.

The fact is, I suggest to you, that it soon became apparent that amongst the AIDS victims in Australia there were included some homosexuals who had many partners, or some who might even be regarded as homosexual prostitutes, and others who would properly be regarded as minimal homosexual

contact?---I'm not sure about that. I don't recall from the original forms that were available whether questions of that degree of detail were asked. They may have been volunteered but I simply can't recall that.

I suggest to you that one of the cases which you got details was - and this is late in 83 - of a - was of a male, 38 year old male, who was a homosexual, never been to the USA, has not to his knowledge had sexual contact with anyone from the USA and described himself as non-promiscuous living with his parents in Sydney. Now, that was a patient who - of Dr Stewart at the Westmead Hospital in Sydney?---Mmm.

If that were the sort of situation that would indicate that we are not just dealing with, necessarily homosexuals who are promiscuous?---I think one of the problems with the word "promiscuity" is the - that it leaves open to the interpretation of the person who is filling in the form.

HIS HONOUR: Person was - - - ?---The person who is filling in the form.

MR STANLEY: What do you mean by that professor?---Well, I mean, that what one person regards as promiscuous might be regarded as normal behaviour to another.

So, what if one - you may have two homosexuals, they may in fact, objectively their sexual activity may be much the same, but one would regard himself as not being promiscuous while the other one may?---Yes. That's

true, and there are also very wide boundaries from what many people would regard as "promiscuous".

Do you believe that it is particularly so amongst the homosexual community?---I think the boundaries are wider than amongst the heterosexual community.

Perhaps I might just get you to amplify that in light of the minor interruption?---Well - - -

You are saying that with homosexuals as to what's meant by promiscuous has wider boundaries. What do you mean by that?---Well, in some groups of homosexual men, very many more contacts occur in the case of say a year, than even amongst the most promiscuous heterosexual people, excluding I suppose extremely busy female prostitutes.

So, you may have a homosexual who may perhaps have a different contact once a month but he wouldn't regard himself as promiscuous?---Well, it would depend on the frame of reference that he had. Somebody who had that many partners might not regard themselves as promiscuous because they had friends who had 100 partners in the same time.

That's the attitude "Well, I'm not as promiscuous as he is" or "He's promiscuous but I'm not"?---Yes, I think that - the problem is that it requires some kind of subjective assessment.

Yes, it requires the homosexual himself to make the assessment of whether he fits that description?---That's correct.

What about the description "with multiple partners" - what do you think about that?---Well, I think that that is a description which is much more restrictive than simply saying promiscuous and begins to take some of the element of chance out of it. "Multiple partners" I take to mean more than one.

Does it mean many?---Well, it can mean many but I - my understanding of "multiple" is more than one.

You wouldn't regard "many" and synonymous with "multiple"?---Its's not exactly the same shade of meaning.

You would regard "many" as being more than - if you said, for example, of a homosexual, described him as a homosexual with many partners, that would have a different meaning to you than a homosexual with multiple partners?---Not necessarily, but when the term "multiple" is used in general, it would include many.

But "many" would not necessarily include "multiple"?---Yes, "many" - it's a fine shade of meaning. I think "multiple" begins from two and goes up to infinity,

whereas in most people's conception, "many" would start at beyond two.

Do you know what the leaflet in the Victorian Blood Transfusion Service - what the leaflet said in relation to homosexuals - the leaflet that was provided to donors between June 1983 up until about September 84?---No, I don't recall the exact wording.

If it said "homosexual or bisexual men who have sexual relations with many partners", that would be somewhat wider than you would have thought appropriate as at the period from June 83 till September 84, isn't it?---It's wider than the alternative term. I don't recall at what stage I would have thought that "multiple" was a better term than "many". It was an evolving situation.

Doctor, if you say that it was appropriate to have - the limitation being on homosexuals with multiple partners, how can you say that it's appropriate to have the limitation as I've just put it to you?---The - as I said, there was an evolving period of knowledge over the time. Early on, it appeared that the group of homosexual men who were at particular risk were the homosexual men who had many partners.

Professor, certainly, if we take it by the middle of 1984, there was no doubt that homosexuals could give this disease, could pass it on, without them necessarily

having many sexual partners, isn't that so?---I think it was always realised that an infected person could transmit the disease without the need to have many partners. It was the reverse of that situation with the risk of an uninfected person becoming infected that was - be under consideration.

Professor, you've had, in a purely professional sense, a lot to do with homosexual men and their - and had to discuss with them their sexual activities, is that so?---No, I haven't. I've had a great deal to do with homosexual men in recent years but I've had very little discussion of their sexual activities.

So far as - well, you've had discussions with them about their homosexual diseases, have you, or sexual diseases?---Yes, yes, I have.

What do you think would be in the mind of the homosexual when they read a leaflet that says "homosexual or bisexual men who have sexual relations with many partners should not donate blood"?---I honestly don't know because I'm not sufficiently well attuned to the sexual practices in the gay community. I think the assumption at that time was that you could divide the gay community up into two groups, people who were relatively monogamous and those who were rather promiscuous. That was probably a great oversimplification but that was probably the way that it was thought of at that time.

Not only was it a great over simplification then it's proved by the events that have occurred to have been grossly wrong, isn't it?---I don't know.

Let's just look at the incidents of AIDS as it's occurred amongst the haemophiliac population. You were involved in a study that was published in the Medical Journal of Australia in 1985, were you not? ---I believe so.

In relation to the incidence of AIDS amongst haemophiliac patients?---Yes, I was.

That study was on 126 patients who were registered in a single hospital in Melbourne, haemophiliac patients with haemophilia A and B?---I don't recall the exact study that we're talking, would it be possible to look at the paper?

What I've just put to you is you'll see in the middle of the - on the first page, the middle column just under the heading "Patients and methods"?---Mmm.

Can you tell us which hospital it was?---I would need to read a little more carefully just to see. If they were adults it would almost certainly be the Alfred Hospital. I presume if they're adults and Kathy McGrath is the senior author that they must have been patients at the Alfred Hospital, but I don't see it actually.

So presumably they would be those haemophiliac patients, including the plaintiff in this action whose serum you tested in the latter part of 1984?---Yes,

probably they would have been.

In all events the results under the heading "Discussion" may be easiest if we go to first. Go to the second paragraph under the heading "Discussion", do you see that?---Yes.

There's reference to 63 per cent of patients receiving frequent treatment with Factor 8 having HIV - or HTLV3 it is there. Do you see that?---Yes, I do.

Your subsequent studies have in effect confirmed that, if anything it's a slightly higher figure?---The overall figure for all people with haemophilia in Australia is about a third but with the prevalence relating to the amount of concentrate that people had received.

As at 1985 when this study was carried and this paper was written, do you see from the last paragraph in the middle column, just below where I was referring to a moment ago, There's the prevalence of antibody in patients receiving home therapy approaches that of patients treated with commercial concentrates in the United States and is much higher than the level found in European patients with haemophilia, 6.7 per cent who were treated with local products". Do you see that?---Yes, I do.

So what you're saying there, is it not, that in effect in Australia amongst the haemophiliacs, those are being treated with frequent treatment of Factor 8 concentrate, they're almost 10 times greater

incidence than in that category of European patients?---I wasn't saying anything in this particular paper. I think I was the last of eight authors on the paper of whom the senior author was a haematologist, Kathy McGrath. My contribution simply was to do the serological test and make it available to the other people in the paper. I don't think that I should be held responsible for the text of the paper.

You are named as an author?---I'm - I certainly am named as an author and my contribution was to have done the sera logic test upon which the descriptive part of the paper hangs.

Would this paper appear amongst your curriculum vitae?

---Certainly it would.

Professor, whether you wrote it or not that's what it says, are you able to dispute the facts as asserted there?

---No, I'm not disputing the fact - - -

It then goes on and says this - this is to explain the high incidence of the HIV amongst the Melbourne haemophiliacs. "This may reflect the popularity of travel between the United States and Australia, and alternatively a higher percentage of homosexual donors in Australian Blood Banks compared with the European counterparts". Did you have anything to do that input?---Yes, I think I probably did.

Did you basically agree with what's stated there?---Those are two speculations. We were - we were speculating about what - how you might explain these observations.

Was it your belief as a result of discussions with those in the blood bank, that Australian homosexuals seem to be more frequent donors than European homosexuals?

---There was a view, and I don't know exactly what time it surfaced, there was a view that homosexual men were disproportionately represented in the blood donor population in Australia. But I - as I say - I

don't recall at what time that view surfaced.

When did you become aware of that view?---I think in discussions with some of the members of the blood transfusion community. I don't - I really have no recollection of a precise date. It - I don't have a recollection of a date.

Doctor, while you've got that there. If you'd just like at the first column on that second page. In the middle of the paragraph there's the sentence starting "The test results", do you see that?---No, sorry, I don't.

About 10 lines down from the top of the page in the left-hand column. "The test results in three patients"?

---Yes - yes.

It says "The test results in three patients who six months before testing had received a batch of Factor 8 concentrate containing plasma from a donor who later developed AIDS were negative"?---Mmm.

Now, what it's saying, is it, that three haemophiliacs received a batch of concentrate, that it was known and in fact had - or been contributed to by an infected donor?---By a donor who later developed AIDS I think is what it says.

So it's in precisely the same sort of situation to the situation that was put to you this morning in relation to PQ?---No, it's not precisely the same situation. The situation this morning as I understood it was that there was evidence that the

person was infected not only at the time that they contributed to that batch of clotting factor, but at several previous times of which they'd donated. There's no information here about preceding - preceding samples - and whether or not they transmitted infection.

But is the point this, whether this establishes it or not - that the mere fact that a batch is infected by an infected donor does not necessarily mean that every person that gets that batch will become themselves HIV positive?---I can't answer that in the context of this paper, because I haven't had a chance - - -

Let me - - - ?---But in general terms the answer is yes.

So in other words you could have two haemophiliacs, put them together, give them both bottles from the same batch which you know has been - as it were - spiked with an infective - an infection of HIV - and one may become HIV positive the other may not?---Yes, that - that can occur.

Is that because of what, some individual difference in the person or - - - ?---It relates basically to the concentration of virus in the starting material.

But if they both get the same - if they get bottles - say they both get five bottles each from the same batch, and they sit down and inject themselves at the same time with it, does it mean that necessarily they will both become HIV positive?---The circumstance where they'd get five bottles the probability is that they

would, but if they were only getting one - one unit each - then there it's the situation like the threepences in the Christmas pudding. If there are not enough threepences to begin with some will become infected and some will not.

There's been some evidence given in this case that although it's fair to say that the results are not absolutely conclusive but that the best estimates are that the infectivity of concentrate is about 50 per cent, is that right or not?---No, I don't think that any - sorry. I don't think that it would be reasonable to put a figure like that on the infectivity of concentrate. The infectivity of concentrate depends, varies from concentrate to concentrate. I would put a range on it and if I were asked that question I would put it between 50 and 100 per cent, depending on the concentration of virus in the starting material.

So in your view concentrate could be so infected as to be, as you say 100 per cent infected?---Yes, yes.

That could come from one infected donor if that donor happens to have a higher titre at the time he donates?

---Correct.

If he has a low titre it may not be as infected?---That's correct.

Does the level of the titre is that the - or the amount of it, is that the equivalent the same as the amount of the virus?---Yes, it is.

The amount of the virus in the infected person, persons with the virus, the higher titre does that mean he's more likely or he's getting closer to developing full blown AIDS?---Well, the highest titres of virus are found at both ends of the disease. The very high

titres are found early on after infection has become established and later on as the disease begins to develop the titres to be lower in the intervening period.

So if for example you had a donor, a person giving blood who was found to have full blown AIDS say within a matter of months for example after the time of donating, would you expect or suspect that that batch would be particularly infected because he would have likely to have had a high titre?---It would be more likely to be, yes.

Do you know anything about the two donors who it's alleged were infected in respect of the two batches that you were asked about this morning?---No, only what I was told this morning.

If I put to you that the evidence discloses that the infected donor for the batch 584, D21.

HIS HONOUR: Book 7, D21.

MR STANLEY: Book 7, A21.

HIS HONOUR: A21, first page in the book.

MR STANLEY: The chart. If you look at that chart you'll recall, Doctor, this morning you were asked the two batches, what I'm putting to you is that the batch that was administered or delivered on 27 August 1984 the donor there who is alleged to have been infected was diagnosed with full blown AIDS by October 1984 and he's now well and truly dead. Now, that would, would it not, lead you to suspect that that

particular batch may have been particularly infected?---That would only lead me to surmise that it was probable that the blood that he contributed at that time had a high titre of virus.

MR SHER: If your Honour pleases, with respect I think the dates that have been given are misleading. It's the date of the donation that's important.

MR STANLEY: I agree with that, your Honour.

MR SHER: Yes, and I don't think you gave that date.

MR STANLEY: Yes, I did. I gave you the date of administration, it should have been the date of donation that's relevant?---Yes.

So the date of donation is - - -?---Eight months earlier.

Yes, about nine months say before the death approximately. Well, that doesn't change your view, does it?---If somebody is in the terminal stages of their illness they're likely to have quite high titres of virus present.

MR SHER: I'm sorry to do this but I think my learned friend has stated the date wrongly about the date of death.

HIS HONOUR: I'm just looking for where one finds the date anyway. I thought I could find it easily but I - - -

MR SHER: My learned friend's, I think - - -

HIS HONOUR: Is it on the chart?

MR SHER: I think my learned friend said he was well and truly dead by October 84.

MR STANLEY: I didn't say that, your Honour.

HIS HONOUR: Before you get to that. Does that chart tell us the date of the donation?

MR STANLEY: Yes, your Honour - - -

HIS HONOUR: Whereabouts?

MR STANLEY: It would be under - if we look along the line, the Sydney donations were between 4 November and 18 January and so on - - -

HIS HONOUR: Yes.

MR SHER: But there is precise evidence of this. I'll just tell my learned friend what we understand the evidence to be, and - - -

MR STANLEY: Your Honour, I'm sure I don't need that. If what I put to the witness is incorrect well so be it, the answer is of no benefit, but what I put to him is that the - - -

HIS HONOUR: Why don't you gentlemen have a quick talk about it instead of - we won't need to send the jury out. Have a quiet talk about it and see if you can sort it out. If you can't - - -

MR STANLEY: I'm sure we can, your Honour. I was just trying to save time.

HIS HONOUR: Save time in that way.

MR STANLEY: Doctor, the position is this, apparently the donation was on 29 November 1983, the patient was found to have fully blown AIDS by October 84 and he died on 25 December 1987. Now, in that situation the probabilities are that at the time he donated

the - the blood that he donated would have had a high titre, would it not?---Well, the situation is somewhat different from the way I - I had understood it. If there's - if there's a period of four years between the time that the donation was made and death, then I wouldn't have necessarily expected such a high titre of virus at that time.

What about if he develops AIDS, full blown AIDS within 10 months or so of donating?---Yes, the - the probabilities are that in both the donors case the high titre of virus was present. As I understand it 100 per cent of - of recipients of either donors blood have become infected.

Doctor, so far as the donor to batch number 543 is concerned, the evidence as far he's concerned is that - - -

MR GILLIES: Your Honour, I've asked my learned friend to go directly to the evidence. I appreciate what my friend said before that if he's got it wrong then he'll have to - - -

HIS HONOUR: Yes.

MR GILLIES: But the - in our submission - - -

HIS HONOUR: Mr Stanley hasn't had a chance to get it wrong yet. Give him a chance.

MR GILLIES: I'm just being consummately careful as he does, your Honour. We submit that on matters like this - - -

HIS HONOUR: Mr Gillies, is not appropriate - before Mr Stanley has done more than open a phrase of a

question to raise an objection. If there's something wrong in the question the time the question is asked before it's answered is the time to object.

MR GILLIES: May it please, your Honour.

MR STANLEY: Professor, if the position is that the donor is believed to have been infected in respect of batch number 453 is still alive, and is still A symptomatic as at a few months ago. Whereas on the other hand the donor to the batch number 548 has died in the circumstances that I described to you a moment ago, isn't it more likely if you had to pick between the two that the second batch - the batch 543 - sorry - the second batch 584 would have been the more infective?---No, I don't believe that you can draw that - that conclusion, because that's only one piece of evidence that we've been - is available to us. I think that both donors are clearly highly infectious in that they have succeeded in transmitting infection to each recipient of their blood.

Doctor, what about the donors to batch number - let's say batch number 564 in May - that was given to the plaintiff in May 84, what can you tell us about their infectivity?---Well, I have very little information about that on the sheet here.

Do you know anything about whether or not any of the donors to that batch were infected?---I haven't been given any

- any information.

What about say batch number 592, have you been given any details about whether any of the donors to that batch were infected?---No, I haven't.

Indeed professor, the only way that one could say that a particular batch was not infected would be if every donor was in fact tested. Isn't that so?---If every donor or every recipient was tested.

If one looks at batch 592, it appears that 119 bottles of that batch were given, so that if by any chance there was any infection at all in that batch, the fact that so many bottle are given would greatly increase the risk of infection, would it not?---Yes, it would.

Professor I'm sorry. You were asked some questions about - - -

HIS HONOUR: Mr Stanley are you leaving the question of infection at the moment?

MR STANLEY: Yes, I am your Honour.

HIS HONOUR: Professor I would like to ask you a question which I'm sure someone else has answered during the case but I just don't remember it. When a person receives an infection of HIV, do they become immediately liable to infect someone else, or not?---Yes, they do, within a period of a couple of weeks of coming in contact with the virus. They are potentially infectious for other people and they remain so for the remainder of the time that they survive.

MR STANLEY: Professor the position is this, is it not, that you are unable to say, without a great deal more information about every one of these batches, as to which one of them in fact caused the infection of Mr

PQ?---Yes, one can't make a conclusive statement about it, one can only talk on probabilities.

But even apart from that, the fact is you know nothing at all about any of the other batches apart from the two that you have been specifically directed to by Mr Gillies, isn't that the position?---It is. I'm making an assumption I think. I'm making an assumption that given the level of surveillance that has existed in Australia in the last few years, that it is unlikely that people who have been infected as a result of these other batches being used, would not have been recognised.

Have you made an assumption that of the infected transfusion cases that have been studied for the Look Back program, say in New South Wales, that all of the infected donors have been located?---No. I think the assumption that I was making when I was being taken through the history of donor 36 for example, was that it was extraordinarily unlikely that if all those recipients had acquired their infection in some other way, other than through the common exposure to his or her blood.

But so far as the batch either before or after that is concerned, you know nothing?---I haven't been provided any information.

Professor, just taking you very briefly to the issue of surrogate tests. You know of Dr Ian Fraser?---I do.

You know that he, back in 1984, was carrying out a prospective

study of 100 or 101 homosexuals in relation to the development of AIDS?---Yes, I do.

You know that he screened his group for the hepatitis B core antibody and that he found 80 per cent positive?---It wasn't around that but I know that he has screened people.

MR SHER: I have an objection.

HIS HONOUR: Yes, Mr Sher.

MR SHER: This is exactly the same sort of evidence to which objection has been taken before your Honour, unless it is going to be put as a notorious scientific fact, it is hearsay. The way to prove this is to call the person who did the work and then we can ask him about it.

HIS HONOUR: Mr Sher, this falls directly within the category of scientific fact, does it not.

MR SHER: With respect - - -

HIS HONOUR: Before you actually object to the professor said he was aware of it anyway.

MR SHER: I beg yours - - -

HIS HONOUR: The professor said he was aware of it anyway. It is always open to a witness to put to a witness another scientific fact just as you can put a text book with another opinion.

MR SHER: That's - is this an established scientific fact or is it just somebody else's work.

HIS HONOUR: The professor seems to regard it as a scientific fact.

MR SHER: Frankly your Honour, I wasn't noticing was he was saying, I was trying to articulate an objection. So, perhaps he did but in any event I object to it your Honour.

HIS HONOUR: Yes, well, how do you put it, Mr Stanley?

MR STANLEY: Your Honour, perhaps I can circumvent it by tendering - calling on my learned friend to produce a letter from or a memo from Dr K McGrath, the assistant director of the Victorian Blood Transfusion Service, addressed to Dr Morris dated 10 September 1984.

MR SHER: You're asking me?

MR STANLEY: Yes?

MR SHER: Well, that's the first I've heard of it, your Honour, and strangely enough, I can't product it.

HIS HONOUR: Well, Mr Sher, he thought you wanted to get in the act someway. He didn't want to leave you out - - -

MR SHER: Well, I'm into it now. I can't product it, your Honour. I mean, that was the first I heard of it, but it wouldn't really make any difference even if I could.

HIS HONOUR: Well, it would be convenient, if this doesn't interfere with your order, Mr Stanley, to leave that matter over until Monday morning.

MR STANLEY: I'd certainly hoped to finish with Dr Gust within a matter of minutes - - -

MR SHER: Well, I withdraw my objection to the earlier parts of it.

HIS HONOUR: Yes, yes, very well.

MR STANLEY: If I suggest to you that Dr McGrath informed Dr Morris that Dr Fraser had found 80 per cent

positivity and if that were the position - well, firstly, what are you able to say about that result?---That four-fifths of the people that he was studying in that particular group had current or past infection with Hepatitis B. That was an unusually high prevalence but it was a specially selected group.

HIS HONOUR: Mr Stanley, in all the excitement I forgot what the question was. Who were these people? Were these haemophiliacs or homosexuals or who?

MR STANLEY: These were 101 haemophiliacs - sorry - homosexuals, your Honour - 101 homosexuals who were being screened for the Hepatitis B core antibody which was what we have been referring to as one of the surrogate tests.

HIS HONOUR: Yes.

MR STANLEY: And of these homosexuals, Dr Fraser found 80 per cent positive for Hepatitis B core antibody.

If that were the case, Professor, it would, would it not, be relevant in determining whether or not surrogate test by way of Hepatitis B core antibody should have been adopted?---Yes, it would if that was not a piece of evidence taken in isolation, which I believe it was.

Let me show you the memorandum that I'll tender in due course - Doctor, isn't the position this, that if there were an 80 per cent positive rate, that would be very relevant in determining whether or not it

was appropriate to institute a Hepatitis B core antibody test?---If the prevalence of anti HBC in homosexual men throughout Australia was of that level, that would be so, but it neglects the fact that the group that Dr Fraser was studying at the Royal Melbourne Hospital was a very specially selected group of people who were thought to be at especially high risk of being infected with HIV. They were recruited for just that purpose.

Well, Doctor, when you're working out - determining whether you should have a surrogate test or not, it's a matter of seeing how far you can limit the test to make it relevant and you found in your study that of the 600 or whatever it was that had been done, none of them were positive but they were - to HIV - but of those 600, how many of them were housewives?---I don't know.

HIS HONOUR: How many were?

MR STANLEY: Housewives, how many were women?---I don't know.

How many were homosexuals?---I don't believe that that information is available.

But would you let us say, by early 1984, would you have wanted donating to a blood supply, a single male, unmarried male, aged between 20 and 45, who lived within an area of say - a radius of say 5 kilometres of the hot spot, the middle of Kings Cross in Sydney. Would you have wanted that person to be donating blood to the blood transfusion service.

MR SHER: Your Honour, could my learned friend add to that, in the light of current knowledge, or in the light of the knowledge of the day.

MR STANLEY: As at early 1984, if you had this person who was living there and who was found to be hepatitis B core antibody. Would you have wanted that person to have donated blood?---I think in the light of my understanding of the disease at that time, if you had asked me whether I would have preferred to have that person's blood transfused into me or another person's blood transfused into me, I would have chosen the latter.

Professor the fact is, is it not, that if your opinion had been sought by early 84, in view of the problems that were then about both in relation to hepatitis and the AIDS virus, or whatever it was that was causing AIDS, you would not have wanted, or you would not have advised accepting the blood of such a person into the Blood Transfusion Service would

you?---I don't recall exactly the state of my opinion at that time.

That's not what I'm asking you though. I'm asking you if you had been asked, your answer would have been I suggest, knowing what you knew then, that you would not have wanted that person's blood in the blood transfusion - - -?---I don't recall being specifically asked that question, or giving an answer to that question.

I take it, if you didn't want it for yourself, you wouldn't wish it on anybody else in the community would you?---I'm talking about my recollection of what - of those events. Partly that's coloured by what I've learnt since that time.

Professor, if you didn't want it for yourself, you wouldn't want it for anyone else in the community would you?---Probably not. Probably not.

HIS HONOUR: Mr Gillies.

RE-EXAMINED BY MR GILLIES

MR GILLIES: If it please your Honour.

Professor, in 1983 and 1984, what was the general consensus of scientific and medical opinion in relation to the appropriateness and adequacy of the multiple partner male homosexual self-exclusion ban?---I think it was generally regarded in the United States and Western Europe which were comparable areas, as the most appropriate form of exclusion to introduce. As I think mentioned earlier, it was also the

recommendation of the World Health Organisation.

In relation to the question of input from manufacturer or pharmaceutical distributor, Mr Stanley asked you some questions relating to whether there should be input in a situation of changing regime of treatment for example. Concentrate to cryo-precipitate. What did you mean by input in that situation?---What I mean by that is, if any major change is contemplated which is going to have an impact downstream, it is always wise for there to be discussion at the outset, so that the implication and major are understood by the clients.

What sort of change did you envisage when you were talking about input?---Well, the sort of change where, if for example, CSL was going to change from unheated to a heated product and that would lead to 50 per cent less product being available. I think that's something that would have to be - the implications of that would have to be discussed very carefully with the people who were going to use it.

Was that what you had in mind when talking about changes?---Yes, I was thinking of a major change which had an implication for those who were the users of the product.

Finally, I think you've mentioned your knowledge of the degree of surveillance over the last two years or so, of HIV carriers, and the tracing procedures. What is your knowledge of the intensity of surveillance that

has been in place over the last couple of years that you adverted to in answer to Mr Stanley?---I think it has varied from State to State but there's been an extensive Look Back program in some States and in addition I think we were referring particularly to the risk of becoming infected from clotting factor. Virtually all patients with haemophilia in Australia have now been tested and those that have been infected, it has been possible to look back and check what batch of the clotting factor they have received.

We've heard that of the batches on the table there are only two that have been found to be infected. With your knowledge of the intensity of surveillance what observation do you have to make about your ultimate opinion in relation to the probability, the eight out of 10 probability of the culprit batch is 543?

---Well, I think it unlikely that other batches were infected if we don't know about it at this time and if we assume that those two batches that were mentioned are the only two that have been known to contain an infective donor, I think that my original estimate holds but I would put a very probability that the earlier, not the latter batch was involved.

Your Honour, I have no re-examination of Professor Gust. May he be excused if no-one has any questions?

HIS HONOUR: Any questions, Mr Foreman and members of the jury? Very well, no objection. You're excused Professor Gust.

WITNESS WITHDREW

HIS HONOUR: I think before adjourning I should congratulate the jury on passing 10,000 pages of transcript today. The case will now be adjourned until quarter past 10 on Monday morning.

AT 4.16 PM THE MATTER WAS ADJOURNED
UNTIL MONDAY, 26 NOVEMBER 1990