

the request of the patient's practitioners. It was supplying to Mr PQ product with the knowledge that he was a haemophiliac, under the care of an experienced expert haematologist. A haematologist with whom the Red Cross were familiar and with whom they worked from time to time and whose understanding of the problem was the same as theirs. So, why they should have to go further and tell Mr PQ that there was a risk when his treating doctor, knew what they knew, we say is a theoretical argument of no substance.

So, you will hear some evidence about how the Red Cross operates in that way. It keeps records of the product - they have already gone into evidence, but it doesn't deal with patients directly, it deals with their doctors. I think that is it members of the jury. That is what the defendant, Red Cross' case is about. That's the evidence that we will call. So, I'll now ask Mr Wodak who is helping me in this somewhat lengthy task to call our first witness.

MR WODAK: Call Dr Wagstaff.

WILLIAM WAGSTAFF, sworn:

EXAMINED BY MR WODAK

MR WODAK: Dr Wagstaff, would you tell the court your full name please?---My name is William Wagstaff.

Your address?---My professional address is the Regional Blood Transfusion Centre. Lumley Lane, Sheffield in the

UK.

Your occupation?---I am the Medical Director of the Transfusion Centre in Trent Region in England.

So, medical director of the Regional Transfusion Centre at Trent?---Yes. Trent is the name of the Region.

The township is - - - ?---Is Sheffield.

That's in the County of - - - ?---South Yorkshire.

For those who may not be familiar with the geography of where Sheffield is in relation to London, roughly what distance and how far?---About 180 miles north of London.

That's the home of people like Geoffrey Boycott is it, Yorkshire?---It is, yes. But I'm a Lancastrian, so I don't talk what things like that.

It is good to start off on a good note like that. Doctor, would you tell the court please what qualifications you have. You are medically qualified?---I am medically qualified, yes. I qualified as MBCHB, which is the basic qualification in the UK.

MBCHB?---Yes.

What does that stand for?---It stands for Bachelor of Medicine. Bachelor of Surgery. That is out basic qualification.

Did you graduate with those qualifications from Manchester University?---That's correct, yes.

When was that?---That was 1957.

That's the basic qualification for a doctor in the United Kingdom, is it?---It is, yes.

Do you hold other qualifications beyond that?---Yes, I'm a Fellow of three of the Royal Colleges within the UK.

Would you tell the court please what those qualifications are?---That's Fellow of the Royal College of Physicians in London. Fellow of the Royal College of Physicians in Edinburgh and Fellow of the Royal College of Pathologists.

Royal College of - - - ?---Pathologists.

Did you - when did you obtain those qualifications?---Fellow of Royal College of Pathologists would be 1977. I was elected to Fellowship of the two colleges of physicians two years ago in Edinburgh and this year in London.

Do you have any qualifications apart from those, Dr Wagstaff?---I have a Diploma in Tropical Medicine which I obtained as part of my service in the army.

You obtained that in London did you. In 1960?---In London. In 1960, yes.

You've told the court that you are the Director of the Regional Transfusion Centre at Sheffield, that's for the region of Trent?---Yes.

For how long have you held that position?---I have held that position since 1974.

Apart from that position doctor, do you have any other appointments or professional positions at the present time?---At the present time - part and parcel of that appointment is an honorary teaching arrangement with the University of Sheffield. So, I am an Honorary Clinical Lecturer in the University of Sheffield Medical School.

Doctor, apart from those positions - - -

MR GILLIES: There's a problem of the jury being able to hear the witness. We are certainly having some trouble too.

HIS HONOUR: Are you. Are the jury having difficulty?

MR FOREMAN: Your Honour, we do have some difficulty.

HIS HONOUR: Yes. Would you lift the microphone up as high it will go and if you keep as close to that as is comfortable?---Thank you.

HIS HONOUR: Yes.

MR WODAK: Doctor, apart from your professional appointments, are you a member of any professional bodies or association relating to the medical aspects that you are familiar with?---Yes, I am a member of some learned societies. I am a member of the British Society for Haematology. A member of the British Blood Transfusion Society and a member of the International Society of Blood Transfusion.

Are you a member of the - I withdraw that - were you a member of the Board of the Faculty of Medicine of Sheffield University?---I was for a period of time sir, yes.

Are you at present on the committee of the Regional Transfusion Directors - National Regional Transfusion Directors?---That particular committee is rather in abeyance since the formation of the National Directorate within the UK. I have replaced that, as it were, with membership of the Management Committee of the National Directorate of the Blood Transfusion Service within England and Wales.

HIS HONOUR: Excuse me Mr Wodak. Are the jury hearing better now?

MR FOREMAN: I think the difficulty is more hearing Mr Wodak rather than the witness.

HIS HONOUR: Very well. Mr Wodak, will you lift your voice a few decibels. Are you hearing the witness Mr Gillies?

MR GILLIES: (Inaudible) Mr Wodak, we can hear the witness alright your Honour.

HIS HONOUR: Very well.

MR WODAK: Doctor, perhaps you could repeat what you have just said. You are now a member of the National Directorate of the Blood Transfusion - - - ?---I am a member of the Management Committee of the National Directorate of Blood Transfusion in England and Wales, which is a different organisation to Scotland.

When did that National Directorate come into being?---It came into being in October two years ago. It has been in existence for two years.

Do you hold any position on that National Directorate?---I am just a member of the Management Committee.

What's the function of the Management Committee?---To advise the National Director in his position as co-ordinator of the transfusion services based at regional level throughout England and Wales.

Doctor, perhaps you can explain to the court how the blood transfusion service operates throughout England and Wales?---Traditionally, England and Wales is divided into 14 health regions. Each of these health regions has a transfusion centre, which traditionally has been based at the sight of that regions teaching hospital. Medical school. Funding arrangements go down from the Department of Health to regional health authorities. With one small exception. All transfusion centres are regionally managed services. Effectively that means that our budget comes from the Regional Health Authority. To that extent we have a certain degree of autonomy, one from each other. This is the newly created job of the National Directorate. To co-ordinate our activities.

That system has existed, I think you said since 1988?---Of the National Directorate, yes.

Before that, there was a national committee, was there?---Before that, there was a committee of the directors of each of these Regional Transfusion Centres, yes.

How often would that committee meet?---That committee used to meet every two months.

Was that the situation in the period of 1983 to 1984?---That was exactly the position.

Doctor, amongst your various appointments, are you an Honorary Consultant in Blood Transfusion to the British Army?---I am, yes.

Have you held that position - for how long?---It must be something like six years now - five or six years.

Doctor, apart from those appointments and the matters that you've already told the court about, have you published any original works of your own in relation to the areas of your speciality?---Yes, most of my interests over the years have been in the field of alternation within blood transfusion and - - -

What does that term mean, please, alternation?---Beg your pardon. Many of the tests which we carry out at transfusion centres on donor blood are repetitive tests and so far as possible, to cut down chances laboratory error, we would try to use various machines and devices to alternate these tests and this has been one of my prime interests since I went into the field of transfusion medicine.

Have you from time to time published articles in journals such

as Transfusion?---Transfusion is probably the one that I haven't. In most of the others, yes, I think.

What - Vox Sanguinous, is that - - -?---Vox Sanguinous, yes.

Lancet?---No, these have been specialist journals which we use within our field, mainly Vox Sanguinous, things like the Journal of Clinical Pathology and that type of journal rather than the general medical journals.

Doctor, have you had prepared for the purposes of giving evidence here, a curriculum vitae?---I have, sir.

If I could ask you to look at this document, please - is that a copy of your curriculum vitae?---Yes, it is.

Your Honour, I would seek to tender that into the general file. Does your Honour have a copy of the curriculum vitae?

HIS HONOUR: No, I don't. I've got the copy that's just been handed up, but I don't have one for my own use.

MR WODAK: I think your Honour now does have such a document.

HIS HONOUR: Yes, I do, thank you.

MR WODAK: I think, your Honour, book 3 is the relevant book for that.

HIS HONOUR: Beg your pardon?

MR WODAK: The general file, book 3, I think, your Honour, is the - where that document should appear.

HIS HONOUR: Three - do we have a book 3? Well, book 3 hasn't started yet. Book 3 was the book that was to be a general file which was available for anyone who didn't have any other books, but no-one's fallen



into that category. Do you want this to go before the jury?

MR WODAK: No, your Honour, no, that's not necessary.

HIS HONOUR: You just merely want one copy to go in the exhibits?

MR WODAK: Yes.

HIS HONOUR: Right, well, it merely goes in as an exhibit.

MR WODAK: Yes, your Honour.

HIS HONOUR: Yes, very well.

EXHIBIT RX5 ... Curriculum vitae of  
Dr W. Wagstaff.

MR WODAK: If your Honour pleases.

Doctor, I'd like to ask you some questions about the Regional Transfusion Centre of which you are the director. You've indicated that that's located in the town of Sheffield?---Yes.

City of Sheffield, I apologise?---City of Sheffield.

Could you tell the court, please, what population is served - roughly, the size of the population served by the Regional Transfusion Centre?---We serve approximately five million people.

The range of activities carried out by the Regional Blood Transfusion Service - firstly, does it include collection of blood?---It does.

Does it include the processing of that blood at all?---It includes processing to produce components which are available for use other than fractionated components, yes.

) So what is it that's produced at the Regional Transfusion Service?---For direct use on patients we would produce a multiplicity of types of red cells - red blood cell suspensions, cryo-precipitate, fresh frozen plasma for individual patient use and platelets. Those are our main products.

Apart from those products which you produce yourself, do you also collect products which are sent elsewhere for manufacture?---We do, we collect plasma from donors which we sent to the - what is now known as the Bioproducts Laboratory - this is just outside London and is the fractionation laboratory for the National Health Service, and plasma sent to that place from the 14 centres in England and Wales is processed into fractionated products such as Factor 8, Factor 9 and so on, and then returned to the regions for distribution to hospitals.

The activities that you've just described, Doctor, were those activities being carried out by the Regional Transfusion Service during 1983 and 1984?---They were, yes.

C In the same way that you've just described?---In the same way I've just described.

And the plasma that is sent to the bio - I'm sorry, what was the name?---Bioproducts Laboratory.

Bioproducts Laboratory?---Yes.

That was then made into, I think you've said, amongst other things, Factor 8?---Yes.

And returned to the 14 regional centres for distribution to hospitals?---That's correct.

Now, the plasma that was sent off to the Bioproducts Laboratories was collected from donors in 1983 and 1984 in what way?---In 1983/84 it was collected from donors by harvesting from whole blood donations. At that time we had not started plasma phoresis as a routine way of obtaining plasma from donors.

So what you're saying is that donors were bled in the normal way?---Donors bled in the normal way and then plasma obtained from those donations at the centre are frozen and sent to the fractionation laboratory in the frozen state.

Doctor, over the years in which you've been involved with the Blood Transfusion Service, have you had occasion to visit the other regional services that you've described in your evidence?---I have. I think I've been to all of them except one.

Apart from visiting them, have you had meetings from time to time with the directors and other personnel involved with running those regional services?---Yes, we had the - the routine meetings every two months of the Regional Transfusion directors in addition to scientific meetings that would be held normally as part of our every day life, yes.

Apart from the experience that you've gained in your own regional centre, do you have a familiarity with the operation of the other regional centres?---Yes, in

fact I worked in the regional centre in Manchester before I went to Sheffield, and of course I've seen the proceedings of most of the other centres as well.

Now, Doctor, during 1983 and 1984 were you in the habit of reading learned medical journals?---Yes, yes.

What sort of journals were you reading?---They were mainly of two types - there would be the general medical journal such as the British Medical Journal and the Lancet, and the more appropriate journals associated with our own profession like (inaudible) Transfusion and some - British Journal of Mutology and one or two other specialist pathology journals like the Journal of Clinical Pathology.

Whilst reading those journals during that period of 1983 and 84, did you become aware of the AIDS syndrome?  
---Yes, indeed, yes.

As a result of that awareness, were any steps taken by your Regional Blood Transfusion Service in relation to the blood supply - the collection of blood?---Yes, in common with all other regions in England and Wales, steps to allow self exclusion of donors who were at that time deemed to be in high risk groups were taken by the issue on a national basis, of an advisory leaflet to blood donors, based on the advice given to us by the expert advisory group on AIDS which by that time, in 1983, had been formed within the Department of Health.

The Department of Health that you've referred to is of the United Kingdom Government?---It's strictly England and Wales - the Scottish system has slightly different department.

So excluding Scotland - - -?---Yes, yes.

That advisory group, did it make recommendations?---It did, indeed, yes.

Now, so far as the Trent Regional Service was concerned, did it accept those recommendations?---We accepted the recommendations that the leaflet produced on the benefit of their advice should be made available immediately on issue to all people coming forward in our region to give blood.

Can you recall - and was that leaflet then distributed or what happened to it?---It was, sir. Our method of getting people to come to give blood is on a postal call up of people from our donor panel. That forms up to 90 per cent of the way in which people come to give blood in my region. From September 83 when these leaflets first appeared each call up letter has been accompanied by the AIDS leaflet or by an extract from it. In September 83 we sent the leaflet itself to all donors called to sessions. Anyone who walked into a mobile donor session without being called to do so, whether he was an established donor from another region or one of our own who hadn't been called, or someone volunteering to give blood for the first time was handed a leaflet to be read at the session before he gave blood.

Would you look at this document, please, Doctor? Can you tell the court what that is?---Yes, this is the original AIDS leaflet produced in September 1983 which we sent out to all donors as I have just described.

That, as you say, went out in September 1983?---Yes.

Your Honour, I do seek to tender that leaflet. There will be other documents as well that I'll be seeking to tender through this witness and I'll be seeking to have them go into Red Cross book 5.

HIS HONOUR: Yes.

MR WODAK: I should say folder 5 of book 5.

HIS HONOUR: Yes.

MR WODAK: Your Honour will recall that the only documents presently - - -

HIS HONOUR: You're correct in saying book 5 too.

MR WODAK: Yes, your Honour. It's the folder in which the documents tendered through Professor Seidl have been produced.

HIS HONOUR: Yes, well, those documents seem to be in the right language for that.

MR WODAK: Yes, that's one advantage, your Honour.

HIS HONOUR: These will be supplied in numbers, will they?

MR WODAK: We have copies here, your Honour, and whether it's convenient to deal with them now - - -

HIS HONOUR: I'll leave that to you.

MR WODAK: Yes, perhaps I'll deal with the second document that I produce to tender and then - - -

HIS HONOUR: I'll merely maintain this at the moment and deal with it later. Yes.

MR WODAK: Doctor, the leaflet that you - I'm sorry, you need a copy of it now to look at.

HIS HONOUR: Do you want these put before the jury as you - - -

MR WODAK: Yes, that might be convenient, your Honour.

HIS HONOUR: I think it may be better to put it in now then.

MR WODAK: Yes.

HIS HONOUR: Which part of book 5 do you wish to go into, Mr Wodak?

MR WODAK: Your Honour, we will have a new tab, tab B, and

then the documents will be numbered under separate tabs.

HIS HONOUR: Yes.

MR WODAK: We have those tabs here, your Honour. Perhaps we can hand them out now.

HIS HONOUR: Yes. You have several documents you're asking to be added this stage, do you?

MR WODAK: Through Dr Wagstaff there will be one other document, your Honour, yes.

HIS HONOUR: Yes, very well. Thank you. We'll put these tabs in for a start. This is in book 5 and we'll put the tabs at the end of what's already there which is tab A. That leaflet, do you want that added to - - -

MR WODAK: That should be B1, your Honour.

HIS HONOUR: B1, right. Yes, are those copies available to the jury?

MR WODAK: I think so, your Honour.

HIS HONOUR: You're about to produce eight copies of this leaflet, are you?



FOREMAN: Your Honour, we've only got the tabs.

HIS HONOUR: Yes, we're waiting for the copies to come. We add this under tab 1, is that correct?

MR WODAK: B1, yes, your Honour. Yes.

Doctor, as you can see science and technology has moved to Australia we now seem to be equipped?---Yes.

If I could ask you to look at the brochure, please, Doctor, could you explain to the jury, please, whereabouts in the brochure there is reference to the risk groups?---The risk groups are covered on side 1 of the copy which has been handed around, under the heading "Who is at risk from AIDS" and the risk groups outlined there were the distillate, I think, of the expert adviser group on AIDS from the current knowledge of the disease process.

Current knowledge at that time?---At that time, at that time.

Still on side 1 under the heading "Has AIDS occurred in the United Kingdom", there is mention of about a dozen cases having been reported by about the middle of 1983?---That's correct.

So far as your own knowledge was concerned what do you say about the accuracy of that statement?---So far as my own knowledge is concerned I would consider that statement to be accurate.

Under that heading the next heading is "Can AIDS be transmitted by transfusion of blood and blood products" and it reads "Almost certainly, yes, but there is only the most remote chance of this

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happening with ordinary blood transfusions given in the hospitals - given in hospital. However in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor 8. This is made from plasma obtained from any donors. Should just one of the donors be suffering from AIDS then the Factor 8 could transmit the disease". Was that a statement with which you agreed at that time?---At that time, yes.

Doctor, as you've told the court the plasma that was collected by the Regional Services sent to the Bio Products Laboratories was made into amongst other things Factor 8 and returned to the Regional Service for distribution to hospitals?---That's correct.

For the use in treatment of haemophilia?---Yes.

Was there apart from the Factor 8 that was manufactured in that way, was there in use to your knowledge in England at that time any other type of Factor 8?

---Yes, at that time the capacity of the Bio Products Laboratory was not sufficient to cope with 100 per cent of the treatment of the haemophiliacs within the UK and so there was widespread use of commercial imported Factor 8 Concentrate to make good this deficiency. A certain amount of cryo-precipitate was still being used, the cryo-

precipitated generated within the transfusion  
Services.

The product that you've called commercially produced Factor 8,  
from where did that come?---Mainly from the United  
States with some from Europe, from Immuno in  
Austria.

Was that distributed by the Regional Transfusion Services or  
how was it distributed?---Generally, no. From my  
own experience within Trent region we did not  
distribute the commercial material.

Doctor, you indicated earlier that the Trent Region Service had a population of about five million. Are you able to say roughly how many donations were collected during a year in that period of 1983/84? ---1983/84, I think at that time we were collecting approximately 150,000 donations.

HIS HONOUR: 150,000?---Thousands - donations of blood, yes.

A year?---Yes, sir.

MR WODAK: Now, Doctor, you've indicated that the brochure we've talking about was posted to each donor at the time that they were called in for donation?---That's correct.

And also handed to a donor who came to the centre spontaneously?---That's correct, yes.

In September of 1983, what was the donor required to do upon arriving at the centre to make a donation?---On arrival at the centre or one of our mobile units, the donor would be handed a list of medical conditions which would in any case invalidate him from giving blood on that occasion. This was in addition, of course, to the new AIDS leaflet. He would then sign to say that he had read this list and that he did not suffer from any of these complaints. This also served as a register of attendance and donation, of course.

The list to which you have referred, Doctor - was that a list that had been in existence prior to September 1983? ---Indeed, yes, yes.

Was it in any way changed in September 1983?---In 1983 mention began to be made of symptoms which might be associated with what you might call the AIDS related diseases, to include things like enlarged lymph glands, unexplained loss of weight or sweating.

The donor was required to read that through and then to sign it?---That's right.

Having completed that task, what was the next thing that occurred?---The next thing which occurred would be a check on the haemoglobin level of the donor to ensure that he was not anaemic, and from that point of view, fit to give blood.

And the check of the haemoglobin level was by taking a finger prick - - -?---A finger prick sample, yes.

Sample?---Yes, yes.

Anything else that was done?---New donors would have questions asked of them by the medical officer at the donor session, since all of the sessions - donor sessions - in Trent are manned by a doctor, not just by a nurse. They would confirm that there was no intercurrent illness with the donor which would disqualify him, measure the blood pressure and make a general assessment of fitness. It is not the British system to carry out full medical examination of donors at each attendance at a donor session. Much, or almost all of the health screening in our system is based on this list questionnaire, and on trust with the donor.

Now, Doctor, the brochure that you've referred to, did that continue to be in use for sometime by your Regional Centre?---It did, yes, yes.

Were there any changes made to it?---Yes, it's been changed two or three times over the years. I think the next change was in 1985.

Would you look at this document, please, Doctor. Can you tell the court, please, what that document is?---This is the amended document - amended AIDS leaflet - which was produced for issue to blood donors in January of 1985.

Your Honour, these documents will now be handed around - I'm seeking to tender them, if your Honour pleases.

HIS HONOUR: They'll be added to book 5, tab 2.

MR WODAK: Yes, your Honour.

Doctor - - - ?---Yes.

This document that you said came into existence in January 1985, you mentioned that the first brochure was the result of recommendations by the Expert Advisory Committee - what was the background to the release of this particular document?---This also came from advice from the same expert advisory group in the light of emerging knowledge on the disease process. You can see, for instance, that the major change perhaps is under the section "Who is at risk from AIDS?"

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Yes?---It was realised by this time that exclusion of practising homosexuals on the basis of multiplicity of partners, was no longer thought to be enough. It was brought down to the level of practising homosexuals and bisexual men, irrespective of the number of partners.

Were there any other changes in this document - significant changes doctor?---One significant change so far as we were concerned, was the inclusion of a section on, "Can Blood Donors get AIDS by donating Blood?"

Where does that appear doctor?---This appears on page - on side one of the new document - of the 1985 document. Is that directly "Who is at Risk from AIDS"?---Correct, yes.

That reads, "No". I should read the question "Can Blood Donors get AIDS by donating Blood?" "No, neither AIDS nor any other disease can be contracted from giving blood. All the material is used for collecting blood are sterile and are only used - are used only once". Why was that included doctor?---After the first issue of this document to blood donors, there was a great deal of anxiety expressed. I think mainly because there was a growing link in the popular press between the contracting of AIDS and blood transfusion of one form of another. Particularly, if I may say in the distinction between routine transfusion of blood and transfusion of factor concentrates to haemophiliacs. The

population press in the UK at that time found it impossible to distinguish between these two and with the establishing link between the contraction of AIDS and some form of blood transfusion in the minds of the lay public it began to be thought by some people that they could actually contract AIDS by giving blood. It was a misconception that was quite hard to shake in some areas and so quite deliberately this paragraph was inserted in the second document.

In relation to the distribution of this document doctor was there any difference in the procedure followed at your centre?---None at all, we continued to send this out with every postal call-up.

In terms of the collection of blood from donors were there any changes at the time of the introduction of this document from the procedure you have described?---Not in so far as collecting cold blood was concerned. By this time we had started to set up plasmapheresis. To obtain just plasma.

HIS HONOUR: Sorry - - - ?---Plasmapheresis.

MR WODAK: Perhaps you could spell that for a start?---I'm going to have difficulty with this, I always do.

P-l-a-s-m-a-p-h-e-r-e-s-i-s. Plasmapheresis.

I think you have done very well?---Thank you.

Could you tell the court please, what it means?---It is a process by which a donor would come to one of our clinics and by the use of a separating machine we



can harvest from him his plasma but return the red cells at the same time of donation. In other words, we can take plasma without any risk of rendering the donor anaemic and so can call them to give plasma more frequently than they can give whole blood. The reason for setting up these clinics was specifically so that we could increase the amount of plasma which we were sending to the bio-products laboratory for fractionation.

Is this a convenient time, your Honour.

HIS HONOUR: Yes, certainly.

WITNESS STOOD DOWN

ADJOURNED AT 1.01 PM

RESUMED AT 2.18 PM

WILLIAM WAGSTAFF:

HIS HONOUR: Yes, Mr Wodak.

MR WODAK: If your Honour pleases.

Doctor, during the period 1983 to 1984 did the Regional Transfusion Service at Trent, have any requirement of donors that they make any declaration about being in a high risk category?---No.

Was such a requirement introduced at any time after that period?---There has never been a requirement within the services of England and Wales to declare one way or the other that they were or were not in a high risk group. This was, I think, implied in the documentation, but never a specific requirement.

A test was developed at some stage for detecting the presence of HIV antibodies. Was that introduced in your transfusion service?---It was, yes.

When was that?---On October 14, 1985.

HIS HONOUR: Which year?

MR WODAK: 1985 your Honour.

So, that was after the second of the two brochures we have been talking about?---Indeed yes.

Some nine or 10 months later?---Yes. Yes.

Was there at any stage during the period of 1983/84 did the blood transfusion service at Trent adopt any form of surrogate test for AIDS?---The question of surrogate testing was discussed both within Trent and in the country as a whole, taking into account opinion

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worldwide on the question of surrogate testing for AIDS. It was thought that none of the tests which could be done in a transfusion centre was suitable as a surrogate test for this condition, yes. So, we did not perform any surrogate testing.

At any stage during that - - - ?---At any stage.

Now, you have told the court that from the blood that was collected by your regional transfusion service, some of it was made into cryo-precipitate, red cells and other product?---Yes.

Some of the plasma was sent to the bio-products laboratories and made into, amongst other things, Factor 8?---That's correct.

Which then came back to the regional centres for distribution. During the period of 1983/84, did the regional transfusion service give any warnings in relation to any of those products, in relation to AIDS?---By way of the written warning on the product itself or with an inclusion, no sir.

Not on the product itself?---No. No.

Otherwise than on the product?

C HIS HONOUR: Would you mind repeating that. I didn't hear that. Would you just give that again?---I'm sorry your Honour. A warning - a written warning on the product or on any documentation accompanying the product was not given.

MR WODAK: By the blood transfusion service?---By the blood transfusion service, yes.

That's during 1983/84?---Yes.

Doctor, you have told the court that you were familiar with the operation of the blood transfusion services in the other regions - - - ?---Yes.

In England. What do you say about the practices that those other regional transfusion services adopted compared to your own. First, in relation to the brochures that you have told the court about. During the period 1983/84?---In almost every case the brochures were despatched by post in a like manner to Trent region. In every case it was ensured that every person coming to give blood was in the possession of a leaflet before actually going to donate.

In relation to the use of the antibody test, was that introduced in the other regional services?---It was introduced over the country as a whole on the same date.

In relation to warnings, were any warnings given by any of the other regional centres - - - ?---No sir.

During the period 83 - - - ?---It was national policy that this was not done.

That was national policy?---Yes.

As far as the leaflets themselves were concerned. Are you familiar with the contents of the leaflets used in the other regional services during that period?---These were identical leaflets provided by the Department of Health to every region.

Doctor, having regard to all of those matters that you have

just given evidence of, what do you say during the period 1983/84, as to whether or not the steps that were taken by your regional transfusion service were reasonable or not in the light of current knowledge - medical knowledge?---In the light of knowledge current at that time we thought that the actions being taken both within Trent and within the country as a whole were perfectly reasonable.

HIS HONOUR: Mr Barnard?

CROSS-EXAMINED BY MR BARNARD

MR BARNARD: If your Honour pleases.

I may not have heard properly and not fully understood, but you spoke of the concentrate Factor 8 being imported from the US and some from Europe?---Yes, sir.

Who imported that?---The general run of events in the United Kingdom and in Trent in particular, which is my own knowledge, was that these materials were bought directly by the Haemophilia Centre directors, in clinical charge of the patients.

So, your organisation at the National Transfusion Service were not itself purchasing the concentrate?---We were not sir.

The only concentrate that you distributed was your own?---Was the material made from our plasma by the Bioproducts Laboratory, yes.

Was the imported concentrate viewed during 1983 and 1984 as more likely to involve risks than the local concentrate?---In as much as at that time it was still current practice for these commercial materials to be made from plasma donated by paid donors, the consensus of opinion was, yes, they were more likely to be at risk.

Were warnings distributed accompanying that concentrate or sent out in relation to that concentrate, the imported concentrate?---Not by the Blood Transfusion Service, no.

So far as the Factor 8 concentrate distributed by your organisation, all of that was from voluntary donors, is that so?---That's right, sir.

Was that sold or sent to patients or sent to hospitals or who does it go to?---It was delivered to the hospitals by our transport simply as an expediency.

Yes?---But on demand from the Haemophilia Centre directors - the medical directors of the Haemophilia Centres would, as it were, place an order for an amount of material to be delivered to them.

I should get that in more detail. A hospital might require concentrate to get to its patients - - ?---Indeed.

Is that so?---Indeed.

Was it sold by you to the hospital incidentally or was it

supplied free - - -?---No, sir, just a direct supply, no question of selling.

So that the hospital ordered it and you delivered it to the hospital?---That's correct.

Was that what - main general hospitals, main public hospitals or how would you describe them?---The UK system is to have a number of hospitals recognised as haemophilia centres. Within my region there are one, two, three, four, five haemophilia treatment centres and it would be our practice to distribute the available material to them in accordance with their orders to us.

When you speak of a haemophilia treatment centre, is that a section of a hospital - - -?---This would be a section of a fairly major hospital, yes.

Are these haemophilia centres run under the auspices of the government?---These are national health service organisations, yes.

There is a central body which organises and represents these haemophilia centres, is that so?---They have the same degree of autonomy as I've described for the transfusion centres and there is an organisation whereby their medical directors will meet and discuss items of interest to them, but the financing of these individual centres will come from the funds appropriate to the major hospital concerned, not centrally from government.

The centres came together and had a body which - upon which

each of them was represented?---That's right, sir, yes.

I think Professor Bloom was president of that body or chairman of that body at one stage?---At the time in question, Professor Bloom was chairman of the Haemophilia Centre directors, yes.

So that the persons to whom you supplied the concentrate would all necessarily be members of this haemophilia - I withdraw that - would all have been haemophilia centres, which would be represented on the central body?---I think that's correct, yes.

Now, you were asked about warnings in relation to the product. Did you in any way pass on information as to how blood was collected to the haemophilia centres or the central body?---Yes, I did, sir. I was responding a question about a written warning with the products - - -

I'm sorry - you were responding to - - -?---I was responding to a question on a written warning with the products.



Yes?---What we did in my region in Trent was to call a meeting between myself and my other consultant colleagues at the Transfusion Centre, and the consultant haematologists working in the haemophilia centres within Trent to discuss at that time the use of the various forms of Factor 8 which were available - with cryo-precipitate and both types of concentrate factor - the NHS material and the commercial.

What was the purpose of such a meeting?---Really to discuss with them their requirements under those circumstances - whether they wished us to carry on putting all of our efforts into making plasma for concentrate, or whether they wished to use more cryo-precipitate or - those are the only ways in which we were concerned.

At these meetings no doubt the question of the risk of blood or blood products being infected would be discussed, is that so?---Of course.

In your brochure which is B1 in folder 5 - that's your brochure of September 1983 - you'll recollect the heading on the third page "Can AIDS be transmitted by transfusion of blood and blood products?" and under that heading it goes on to say "In the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS". At that time you believed that the infection with AIDS in the US was slight, is that so?---With regard to transmission to

haemophiliacs, I think that was the case, yes.

Do you remember what you believe the figures were as at September of 1983?---No, sir, it would be unfair for me to try and guess.

It went on to say "Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor 8. This is made from plasma obtained from many donors, and should just one of the donors be suffering from AIDS, then the Factor 8 could transmit the disease". That suggests that at the time it was your belief that Factor 8 could transmit HIV infection, is that right?---At that time, sir, evidence was beginning to accrue that an infectious agent may be concerned.

No doubt these were matters that you discussed with representatives of the haemophilia centres within your area?---Yes, yes.

Were you referring to one meeting with the representatives of haemophilia centres, or were you referring to a regular meeting?---These are held at irregular intervals, but not infrequently.

Can you - - -?---Two or three times a year.

Three times a year?-- Two or three times a year.

You were with the National Blood Transfusion Service - part of a national organisation, is that correct?---Unfortunately, no, sir. Although it's nationally named, it is not national in fact, and we are still regionally managed organisations with only the

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loosest connection on a national basis.

Was there any body representing the centres in England and Wales?---At this time in question, sir, there was a meeting of the Regional Transfusion directors, which was entirely an ad hoc meeting called by themselves with no executive authority in any shape or form.

But this would've been a meeting which you would've attended?

---Yes, sir.

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Well, between that body of regional directors - was there communication between that body and the body representing all the haemophiliac centres?---No, sir. The traditional link with the body representing the Haemophilia Centre directors was the director of the - what is now the Bioproducts Laboratory.

) The?---The Bio Products Laboratory. The laboratory which manufacturers the commercial Factor 8. Traditionally its medical director would be invited to the committee or the haemophilia centre directors.

You spoke about the laboratory, I think you mentioned earlier where it was, did you?---Elstree, yes. At Elstree, on the outskirts of London.

Can we spell that perhaps for the transcript?---El-s-t-r-e-e, Elstree.

So that it was the director of that laboratory who was charged with the responsibility of communicating with the haemophilia centre directors, representative body?  
---He was allowed to be present at their committee meetings, yes.

So that in other words if there was any risks associated with a product he was charged with the responsibility of conveying information associated with the product to the persons responsible for its use?---I'm afraid that I'm in no position to say so whether he was charged or not, undoubtedly he would do that but not to my personal knowledge.

You say there is no doubt he would do it, is that what you said?---I'm sure he would but I have no personal knowledge as to whether he was actually to so do it.

And you have no personal knowledge of what communication took place, is that the position?---No, no.

I take it the question of the advantages of the Concentrated

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Factor 8 products over cryo-precipitates are not really your specialty, is that right?---That is, as you say, sir, not for me to decide. That is for the clinician in charge of the case to decide.

We were speaking of the possibility that Factor 8 or other blood products may be capable of transmitting the HIV infection, when was it so far as you were concerned that evidence came forward to establish that that in fact was the fact rather than merely a possibility?---The virus was isolated towards the end of 1983 and the first publication which I saw in common with my colleagues would be the announcement by Dr Gallow at the beginning of 1984 that this virus had been isolated. Until that time the presence of an infective agent was still conjecture.

Gallow in, I think, April/May 1984 identified it as a virus but then it was some time after that that you were able to - before you were able to carry out tests?

---That's correct.

To establish that in fact users of Factor 8 had been infected?

---That's right, sir.

When was it that the results of those tests first became known to you in your area?---The test began to be used towards the middle of 1985 on cases. It was not used on blood donors until the end of 1985 in the UK. Now, from personal knowledge of cases being tested we're referring now to the middle of 1985.

So before you could produce conclusive that infection had in

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fact occurred you're into 1985?---I think that's correct, sir.

This September 1983 brochure which spoke of in the US a very small number of patients suffering from haemophilia having developed AIDS, to the views, to the number of people who had been haemophiliacs affected change at that time or when was it that you first had an appreciation that it was a more significant problem than a very small number for haemophiliacs?---It began to be recognised by those in my field in the UK as an increasing problem during 1984 when the first cases began to - reported authenticated cases reported in the UK and it was then realised that this was not just a small epidemic confined to San Francisco.

) And continued to do so throughout the - - -?---Continued to do so, yes.

Thank you.

HIS HONOUR: Mr Barnard, do you have any questions arising from that?

MR BARNARD: No, your Honour.

HIS HONOUR: Mr Gillies.

MR GILLIES: May it please your Honour.

CROSS-EXAMINED BY MR GILLIES

MR GILLIES: Doctor, during 1983 in the United Kingdom was the infection which later was discovered to be the AIDS infection, it was then unidentified infection regarded as fundamentally a Californian homosexual disease?---That was certainly the impression we were given in 1983, yes.

t wasn't until mid 1984 or thereabouts that the evidence changed as far as knowledge of the UK was concerned?---I think the first case in Europe was described in early 1984 and we began to realise that it had spread to the UK during that year, yes.

So that as far as Europe was concerned as distinct from UK alone, during 1983 the European view was that the then unidentified infection was fundamentally a Californian homosexual anomaly?---That I think is possibly the consensus except at that time we had been given warnings from California that the disease may have spread from outside that State. You'll see reference on the leaflets distributed to Haiti it

MR GILLIES: Well, in our submission that's - - -

HIS HONOUR: Mr Gillies, would that be of any assistance -  
would the answer of that be of any assistance to the  
jury?

MR GILLIES: Of course, your Honour. If it's been contended  
by my learned friend as he opened the case that in  
Australia steps were taken but too late, plainly  
it's a very precise relevance in our submission to  
demonstrate that Australia was ahead of the world in  
many respects.

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

MR GILLIES: You would agree, would you not, if we put the  
question again, Doctor, that if the Australian Red  
Cross reacted in June 1983 by placing its first  
donor self exclusion screen in position that would  
be a quick reaction to the American step?---I think  
in retrospect that would be fair comment.



Yes?---At the time we didn't know what was happening, but in retrospect, yes.

Of course, I'm asking you to judge it by the knowledge of the day?---Yes.

Likewise in respect of the tests for the HIV antibody, I think you have indicated that in the UK they were commenced on 14 October, 1985. The situation in Australia was that approximately a year earlier the HIV tests was available and being used. Again, you would regard that as being a very good reaction to the problem that had beset the world's blood supplies?---It is a very difficult question to answer sir, because at that time we didn't know the size of the problem. At that time the position in the UK was that we were cautious in the introduction of the test because it was not without fault and it was adjudged that the size - the probable size of the problem in the UK meant that the introduction of a (inaudible) test would give more problems than benefit. Again, with hindsight of course. The answer is yes. But at that time it would have been difficult to adjudge.

I'm not being critical of the English situation. I'm seeking it (inaudible) for the Australian - - - ?---Yes, it is. Indeed.

In relation to heat treatment, I think you have indicated that the heat treated product was first available - the heat treated product for the elimination of the AIDS

virus was first available in the UK in February of 1985. Again, the evidence will disclose that the situation in Australia was that the product was heat treated routinely to inactivate the virus from November of 1984. You would regard that as a good and proper reaction to the problem that had beset the world blood supply?---With the same comment sir, yes.

In relation to the question of warnings, I think you have indicated your answer to this already to Mr Wodak, but am I right in saying that your evidence is that during 1983 and 1984 the blood products laboratory which manufactured the concentrate in the UK during 83/84 the blood products laboratory gave no warnings either on the package or in the package of concentrate relating to the risk of infection with the AIDS virus?---No sir. My reply to council was that the transfusion service did not issue written warnings on the products which it issued. The fractionated products emanating from the bio-products laboratory are a different material entirely. Warnings were issued, have always been issued with those products on the question of possible viral transmission. I know that a specific warning about the possible transmission of AIDS was introduced by the bio-products laboratory, but I am unaware of the exact timing of that introduction. All I can say is that it is some time during 1985.

) So that what I'm putting to you is correct. In 83 and 84, there was no warning in relation to the risk of AIDS, either on or in the product?---Viral transmission was mentioned, AIDS wasn't.

So you're agreeing with what I'm putting?---Yes.

Is that so?---I think so, yes.

You had mentioned the opinion that paid donations - as opposed to purely voluntary donations - paid donations were regarded as being more dangerous from an infection viewpoint and that was a generally held view, was it?---That was a generally held view, sir, yes.

( Why is that, why are paid donations and why were they perceived to be more hazardous than purely voluntary donations?---They have traditionally been perceived to be more hazardous because payment as an inducement to give blood has tendered in the past - perhaps not in the moment, but in the past - to bring forward people who may well have been identified as one of the risk groups we've been discussing today.

( We've heard evidence that Professor Bloom gave a lecture in Australia in October 1984 in which he emphasised that in a voluntary, a purely voluntary and self-contained voluntary system of donation, there were great advantages in relation to infectivity and in particular as far as the safety of the product was concerned - does that conform with your own opinion?---I would agree with Professor Bloom's

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opinion, yes.

You mentioned in respect of self-screening that the UK model, or more accurately the National Blood Transfusion Service model as contained in its brochure, was amended in January 1985 to request that all homosexuals refrain from making a donation - is that so?---That's correct, sir.

Again, to put it to you precisely, practising homosexual and bisexual men were described as being at risk from AIDS?---Yes, sir.

That was put in place in January 1985 and we've heard that the American amendment took place in December 1984 - was that something that you were aware of?---I was not aware of that, sir, no.

Again, if the Australian amendment took place in December 1984 or perhaps a shade earlier, you would regard that as a good and quick reaction to the knowledge of the day?---It preceded ours by one month so, yes, yes.

I have no further questions.

HIS HONOUR: Yes, Mr Stanley?

CROSS-EXAMINED BY MR STANLEY

MR STANLEY: Doctor, is this the first occasion that you've had cause to give evidence in a court about these matters?---Yes.

Do you expect it to be the last?---No, sir.

That's because your authority and indeed effectively all of the authorities concerned with the blood transfusion system in the United Kingdom have been sued by - in

a class action - by haemophiliacs that have contracted the HIV virus?---That's correct.

Among other allegations of negligence that have been made against the Blood Transfusion Service conducted by yourself and others is the allegation that you failed - - -

MR WODAK: Please, your Honour, I object to this. In my submission, the making of allegations in other action in another country can have no relevance on what this jury is asked to determine in this action.

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

MR STANLEY: Your Honour, if it's good enough for this witness to give evidence about what was done by him and by others in the United Kingdom, in our submission, it's good enough and proper for us to test that by reference to what's in fact happened because it's being put forward as though it's beyond reproach, beyond criticism. Now, this witness, in our submission, obviously has an interest in the evidence in which he is giving because it's evidence that, if he were to give other evidence, it would be used against him or defendants in other actions in which he's later to appear, and we submit that it's relevant to his credit and it's relevant to the issues that he's raised in his evidence in-chief.

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

MR STANLEY: Doctor, I'm afraid Mr Wodak's question probably caused me to forget my question. I think I was putting to you that amongst the allegations of negligence that had been made in the class action, is the allegation that the Regional Health Authority or District Health Authority of which you are a part, failed to appreciate properly the categories of HIV high risk blood donors and act accordingly? They failed to screen donors effectively - that's one of the central allegations, isn't it?---I have not seen a detailed report of these allegations, these are being handled by the legal profession at the moment.

I understand that, Doctor, but you know, don't you, that one of the allegations that's being made against you is that you didn't do enough early enough to screen donors?---That's - I'm sure may well be the case.

And in particular, that you didn't take sufficient steps to screen homosexuals?---I'm a little bit at a loss as to understand what you mean by screening homosexuals.

I'm sorry - take steps to preclude all homosexuals from donating blood, as distinct from homosexuals described in your leaflet as those who have had - homosexual men who have had many different partners? ---I think, sir, my answer to that is the answer I've already given. That the approach taken in the

United Kingdom in general and in Trent - - -

Doctor, you're not answering my question. The question I'm asking you is, you're aware that the allegation that is being made against the defendants - the relevant health authorities - is that they failed to screen effectively. In other words, they failed to prevent, as far as possible, all homosexuals from donating blood?---I can understand the allegation, sir. In the particular of screening, I am unaware of the content.

You said, Doctor, that you expect to give evidence in a number of other cases, is that the position?---No, sir, I said I didn't expect this would be the last time.

How many times do you expect to be giving evidence?---That at the moment is unknown. You have mentioned - you have mentioned the general case coming under consideration. It's very possible that I would not be called to give evidence at all in the general case. If there's a settlement of the general case, then particular cases involving haemophiliacs in my region would then not come to court.

So there's a major action?---Yes.

Which is a class action brought - - -?---Yes.

On behalf of all the haemophiliacs?---Yes.

And there are other individual actions?---But they are pending the class action.

Have you been concerned or involved in particular, in the actions involving haemophiliacs within your own

district?---No, not at this moment.

So at this moment, your concern has been in the class action?

---Yes.

Doctor, can you tell us how it was that you happened to be here, happened to be chosen to come and give evidence in this case?---Yes, sir. Because at the time in question - 83 to 84 - as I've already said, the major exchange of information amongst transfusion directors was at that ad hoc committee, and I was chairman of that committee at the time.

So far as Trent is concerned, in the overall picture in the United Kingdom, is it the largest or the smallest of the regions?---Within the top third.

The top third?---Mmm.

Of 14, was it?---Of 14. We'd be something like the third largest.

Doctor, does the Red Cross have anything to do with the collection of blood in the United Kingdom?

---Effectively, no, sir.

You have nothing to do with the Red Cross?---No, no.

You're employed by?---Effectively, the government.



Is this all part of the National Health System?---Indeed.  
Indeed.

So that when we talk about the Regional Health Authorities  
they are all part of the National Health  
system?---Yes, that's correct.

All the doctors are employed by the Government effectively,  
through this National Health system?---There are  
some doctors who are totally in private practice but  
the vast majority of us are government employees.

The doctors that are concerned with the issue of  
blood - - - ?---I think it is fair to say that those  
doctors are all Government employees.

The blood transfusion service within each of these fourteen  
regions, at the time we are talking about 83/84,  
each was run separately was it?---Yes.

Is it still?---Yes. In terms of administration of finance  
which is what counts unfortunately, they are  
separate entities.

So, there may be different steps taken by different regions,  
in relation to, for example, the procedures to be  
adopted with - in the screening of donors?---At the  
time in question sir, co-ordination was through our  
Committee of Transfusion Directors, with advice from  
such groups as the Expert Advisory Group on AIDS  
which I discussed in connection with the leaflet. At  
the present moment there is now a National  
Directorate, the National Director would be in  
charge of co-ordination of these activities in the

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autonomous centres.

The fact is, is it not that different regions did take different steps in relation to the steps that were taken in relation to donors back in 1983 and 84?---I'm unaware of that sir.

Was it not the situation that the North London Blood Transfusion Centre introduced a questionnaire as well as the leaflets?---Yes, indeed. Yes.

I'm reading from a statement that was provided to us by the Red Cross solicitors?---I understand that.

Reporting to give a summary of your evidence?---I do stand corrected sir. I was aware of that leaflet.

So, at least one transfusion centre that you have mentioned, as well as the leaflet had a special questionnaire?---Yes.

That was the North London Blood Transfusion Centre?---Yes.

Was there any particular reason why the North London Blood Transfusion Centre should have it, and for example the Trent one didn't?---Yes, sir. At that time it was perfectly evident from general social practice that the problem of homosexuality and drug addiction was a major problem in that area of London and was not mirrored by any other region in the United Kingdom.

Trent didn't have that?---No.

No Gay Mardi Gras in Trent?---No.

But you concede that if homosexuality was a significant problem in the sense that there was a lot of

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homosexual activity and disease, it was a matter that would justify extra steps being taken?---I think the steps taken sir, were adequate to deal with the problem assuming that the co-operation was there.

In fact, that is the reason the step was taken, I take it you agree that that extra step was warranted?---Subsequent publication to that, suggested that it had been warranted.

If there had been a homosexual problem in Trent, particular homosexual problem and you were aware that homosexuals were contributing, let's say up to ten per cent of your blood supply, you would have been concerned about that in 1983 and 84?---I would reinforce what I did sir, which was to contact the gay societies and discuss the situation with them.

) Doctor, if we look at the leaflet that in fact was put out, the first one if we look at, what is it, the back page. This page, Doctor, do you see with the - - -? ---Yes, I have it.

Yes, that page. It starts off "Recently there's been considerable publicity in the newspapers and on radio and television about a new serious but rare disease called AIDS. Since AIDS may be transmitted by transfusion of blood and blood products the National Blood Transfusion Services wants blood donors to have the facts about the disease". Now, is that saying that AIDS might be transmitted or is it saying that it is transmitted or there's that it was transmitted?---Can I refer you, sir, to this second paragraph on the same page on the right hand side where it says "Almost certainly, yes, it can be transmitted".

So what was being told to donors that it was almost certain could be transmitted by blood and blood products?

---At that time could be is what was the expression used, yes.

As you say the answer was almost certainly yes?---Yes.

When was it?---September 83.

Of particular concern amongst those who were receiving blood products was the situation for haemophiliacs, is that so?---Yes, sir.

You were saying in this leaflet, well, there's not so big a risk with transfusion patients but there is a real

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problem, a real risk with patients such as haemophiliacs who require a lot of blood products, is that so?---The paragraph says, sir "Haemophiliacs are more susceptible of AIDS because they need regular injections".

That's injections of pooled products?---Of pooled product, yes.

( So you were comparing on the one hand persons who only get single donor products, whether it's cryo-precipitate or whether it's a blood transfusion, you're comparing them on the one hand with those who receive concentrated pooled product on the other, weren't you?---That's correct, sir.

Because you believed then that there was a far, far greater risk with the pooled product?---This is exactly as set out in the paragraphs, sir, yes.

And that was your belief at the time?---This was our belief at the time, yes.

( Indeed, Doctor, if we look at the first column, the foot of the first column, there's note there that "Patients with AIDS also seem more likely to have suffered at some time from various other diseases such as Hepatitis B, syphilis or other sexually transmitted diseases". Was that your belief at the time?---This was the information given to us by the people with whom we had contact in what you would call the venereal disease clinics, yes.

So you made contact with the venereal disease clinics?---Yes.

So I suppose if you wanted to express an opinion on whether the Australian Red Cross acted appropriately in this regard, you would like to know whether the people who were in charge - the people like Dr Archer in New South Wales and Dr Morris in Victoria, Dr Beale in South Australia - you'd like to know whether they found out about their donor base, wouldn't you, whether they understood their donor base?---I don't know whether I'm in a position to answer that. The interrelationship between the transfusion services and the gay societies or special treatment clinics in Australia is something which is totally unknown to me, and I think it's this personal relationship which counts.

Doctor, what I'm putting to you is a question of general applicability. If you have a blood banker, and you look at the directors of the divisional blood banks in this country - - -?---Yes.

And we take the director of the New South Wales blood bank, Dr Archer - you've already said that in your opinion a good blood banker should know his donor base in the sense that I explained it to you?---Yes.

For you to be able to express an opinion on whether Dr Archer in New South Wales had acted appropriately in this regard, you would have to know what Dr Archer did to find out about his donor base, wouldn't you?---Yes.

Similarly with Dr Morris in Victoria?---Yes.

And if it transpired that in fact Dr Morris had done nothing

to find out about the homosexual proclivities within his donor base, you'd be critical of that, wouldn't you?---No, sir, I think that it would depend entirely on the location and the population concerned. I would need to discuss this with Dr Morris to find out the nature of the problem.

If there was just no homosexual problem here at all, and no homosexuals giving blood, it would not be a problem?  
---It would not be a problem.

If, on the other hand, it was accepted that perhaps 10 per cent of the donor base was homosexual, then you'd expect Dr Morris to be finding out about their problems, wouldn't you?---I would think that Dr Morris would already know, sir.

If he didn't know, he ought to find out?---I will not be critical without discussing it with him, sir.

Well, as a matter of general principle - - -?---I think there - there's a matter of difference in approach in different regions such as ourselves and North London.

Well, Doctor, the Blood Transfusion Service under which you operate - am I correct in saying this, that every new donor, when he comes to give blood, is medically examined?---I explained, sir, that the system of medical examination in the UK is based mainly on questionnaire and trust. The medical examination per se of a new donor would be usually confined to measurement of pulse and blood pressure and a

general quick assessment by the doctor in charge of the session. It would not be a full medical examination.

HIS HONOUR: Mr Stanley, have you reached a convenient point?

MR STANLEY: Yes, your Honour. Could I just deal with one point?

HIS HONOUR: Certainly.

MR STANLEY: Doctor, is the position this, that every time a new donor comes, he is seen by a doctor?---Yes.

So that - - -?---I'm sorry, but so is every donor in my region.

Every donor that comes is seen by a doctor?---The needles in my region are inserted into veins by doctors.

This was the situation in 83 and 84?---Indeed.

So all these thousands of donations are all - every donor is seen by a doctor every time?---Yes.

And when it's a new donor, some sort of an examination - - -?  
---A little bit more attention, yes, a little bit more attention.

And every time the donor comes, he fills out a questionnaire?  
---Yes.

And signs it?---Yes.

And that's whether it's the first, second or 52nd time that he's there?---The signature to the medical questionnaire is combined with a signature of attendance, so we use that as a register as well.

That was the system that was in operation from September 1983 on?---This has been in operation since long before I



went to Sheffield.

But in September of 1983, were there additional questions put in?---In September 1983 we introduced questions on what had come to be regarded as symptoms associated with this new disease, in other words - - -

AIDS?---Lymphadenopathy and - - -

So there'd always been a questionnaire - - -?---Yes, sir.

That had to be signed by every donor - - -?---Yes.

But in September 83 you added specific questions directed towards ascertaining whether the patient was suffering from AIDS or any symptoms - - -?---Right.

That might give an indication that that person might be at risk - - -?---Yes.

For AIDS?---Yes.

Mr Wodak asked you to produce - or produced through you - the two leaflets, but he didn't ask you about the brochure - those questions. Do you have a copy of that?---I'm afraid not, sir, no, no.

You just didn't bring one out with you from England?---That's right, yes.

Were you not asked to bring a copy of the documents, Doctor?

---I brought a copy of the general document, but not the 1983 one.

Doctor, I asked you, were you not asked to bring documents that were relevant to this matter so far as - - -?

---I was - I was - I was asked to bring specific documents, sir, and these I brought.

Were you asked to bring the questionnaire that was used and that referred to the AIDS symptoms in 1983?---No, sir.

You weren't asked?---No.

You didn't bring it?---No.

Would there be very much difficulty in you getting a copy of that faxed over to us, Doctor?---My reason for pausing, sir, is that I'm trying to remember whether this was part of the official document produced by the Department of Health or whether this was a local thing which you put on the desk.

Should it matter in terms of its availability?---In terms of its availability, it might. I know that's criticism, but it might.

Has that document never been forwarded to the legal advisers of the Red Cross in Australia?---To my knowledge, no, sir, no.

Would you be able to make some enquiry to determine whether a copy of it could be faxed out to us?---Whether it is available, yes, I can make those enquiries.

Would this be a convenient time?

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

AT 3.16 PM THE JURY LEFT THE COURT

HIS HONOUR: Dr Wagstaff, at this stage, the jury have a break for 15 minutes and you may remain in court or go outside court, whichever suits you?---Thank you, sir.

WITNESS STOOD DOWN

HIS HONOUR: Gentlemen, may I mention one thing about the mysterious general file that has been perplexing the bar table for some time? The books that have been given designations are the books which contain the multiple copies, the eight copies. Provision was made - following the enquiries I made what the party's intention was - provision was made for book 3 being a catch-all general file for multiple documents that didn't fit any other book, because it was thought at that stage that there may - that may be a course followed by one or more of the parties, but it hasn't - doesn't have any documents in it, and I'm not saying it needs them, but I'm merely indicating that when the parties put in a document which is merely one copy document, it doesn't go in any file. It's just an exhibit and gets an exhibit number. I see Mr Sher's very pleased to learn that - and I leave the bench.

ADJOURNED AT 3.18 PM

RESUMED AT 3.35 PM

AT 3.35 PM THE JURY RETURNED TO COURT

WILLIAM WAGSTAFF:

MR STANLEY: Doctor, the doctors that were under your control, if I can use that word, with your Blood Transfusion Service - we've already established that they're all employed by the National Health Service and all obviously qualified doctors?---Yes.

Are any of them specialist haematologists?---No.

Are they training to be specialist haematologists?---Can I clarify something - whether you mean the doctors who work on our donor sessions - our blood donor sessions?

Is there a distinction?---Yes, there is indeed, yes.

The doctors dealing in the donor section - - -?---Yes.

That's the one that sees the patient - has the one to one contact?---The one - the ones who see the donors on a one to one contact are generally speaking - apart from one or two trainees - are not haematologists.

But as well as that there are other doctors employed by the Transfusion Service that are haematologists?---Yes.

How many of those would there be?---There are four of us in my centre who are trained in haematology.

Is it part of their function to ensure that the doctors who are out seeing the donors - that they know what they're doing?---Yes.

And they follow the right procedures etcetera?---(No audible reply).

So they instruct them - - -

HIS HONOUR: I think you nodded your head then. You meant to say "Yes" to that?---I'm sorry, sir, yes.

It doesn't come over on the transcript otherwise.

MR STANLEY: Well, I take it that before this leaflet was introduced in 1983, there must've been a fair bit of discussion and deep concern by the haematologists in your service - - -?---Yes.

About this problem?---Yes.

About AIDS and what was causing it and what could be done, is that so?---Yes.

It was, I presume, as a result of that discussion that - I withdraw that. Involved in that discussion was the fact that now donors were going to have to answer additional questions related specifically to these issues?---The doctors were informed of that, sir, yes.

So you saw it as part of your function to inform your own doctors in the field, as it were, as to what you were doing and why it was being done?---That is so, sir.

So that every doctor who saw every donor, would've known - because he'd been instructed - of this potential risk of the transmission of whatever it was that was causing AIDS, is that so? You have to answer?

---Sorry, sir, yes, indeed, yes.

And he was instructed as to the sort of symptoms that were associated or thought to be associated with this

condition of AIDS?---That's correct.

So that if, for example, any of your doctors observed lymphadenopathy - swollen glands - on a donor, then that would immediately alert or should've alerted that doctor in view of what he'd been instructed by you?---It certainly should have, yes.

So you regarded your instruction to your doctors as a vital step in trying to ensure that only healthy donors gave blood?---Yes.

And it was vital - a vital step in terms of trying to avoid the risk of having infected persons giving blood infected with whatever it was that was causing AIDS? ---Whatever it was, yes.

So you placed considerable reliance upon your doctors?---Yes.

It certainly just wasn't a matter of some nurse who may or may not have been told about AIDS, seeing the patient, taking the blood and dealing with the whole procedure?---All of the donors were seen by a doctor.

Was that really a fundamental principle?---This has been a fundamental principle of the practice of transfusion in my region for many years.

Do you know whether it's done in Australia?---No, I'm afraid I don't.

If it were not done, it mightn't make it necessary, desirable or advisable, to have taken additional steps when the AIDS scare was on in 83 and 84, wouldn't it?---I think it's - would have been just as necessary to

ensure that the people taking the blood were aware of the situation, no matter what the qualifications would be.

Obviously, if you had a doctor there, you could place greater reliance upon the safety of the blood product?---We would've expected the doctor in any case to be aware of the AIDS situation.

Now, Doctor, the leaflet that you used puts the people at risk from AIDS as homosexual men who have many different partners, is that so?---This was the first leaflet in September 83, yes.

Yes, the first leaflet - how many different partners?---I think that it was precisely because of that question that we changed it to the format of 1985.

Because it's a silly question, isn't it?---Yes.

It's a silly question, a silly statement?---In the light of the knowledge of 1983, it seemed a very reasonable statement, but with two years - well, a year and a half progression, we realised that we knew very little in 1983.

Doctor, let's look at it from the point of view of the person to whom it's directed?---Yes.

Namely, the donor, the homosexual donor - how many is many different partners - what does the homosexual do to decide?---As I say, sir, it was one - that was one of the questions considered by the expert advisory group when they changed their advice on these leaflets as to the question of - - -

Doctor, I'm asking you what your opinion was when this leaflet was put out in September 1983?---In September 1983, it seemed a reasonable statement because, to the best of my knowledge, that was the type of case coming forward.

So you agreed with it?---Yes.

Now, I'm asking you, what did it mean - how many partners should a homosexual have before he should preclude himself?---If you're asking for local interpretation, sir, which I assume you are, more than one.



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It doesn't say that, does it?---No.

Is two many?---Two is multiple.

Did you expect homosexual men to understand that what they're being asked here is whether they've had two partners?---I think so, yes.

When - what was the time frame for the partners - did it mean if they'd had two partners in the last week or last month or last five years - what did it mean?---I don't really know that I'm competent to answer that question.

Well, if you're not competent, Doctor, how were the homosexuals in Trent going to answer it?---It was interpreted by us as meaning more than one partner.

Because it was appreciated that it was a silly question, it was changed in the later leaflet that was put out in January 85 - is that so?---It was changed in view of the difficulty of interpretation which you have highlighted.

Doctor, you've told us of the donors that came to your Blood Transfusion Service - was it 90 per cent or just over 90 per cent were what you called regular - - -?---That's correct, sir.

Donors, and you would write to them or circularise them in the post?---Yes.

How often each year would they receive such a circular?---The routine at that time would be to call a donor twice a year.

HIS HONOUR: Sorry - the routine at that time was?---To bleed

donors twice per year, sir.

MR STANLEY: So you said, I think - was it 150,000 donors you had - so in terms of your regular donor base, you'd have what - about 70,000 odd, would it?---No, sir, no. At that time, we were taking 175,000. The regular donor base would be more than 100,000 because each donor cannot attend each time he's called.

So that would certainly be 90 per cent or more of your donor base being regulars?---Yes.

That meant that every time they were due to come in, they would receive a notification from you?---Yes.

Once this AIDS scare problem arose in 1983, they were sent a copy of this leaflet?---That's correct, sir.

So every single potential donor had the opportunity of assessing the situation in his own home, as it were, and making the decision as to whether or not he should go to the blood bank to give blood or not?---That's correct, sir.

One of the benefits I take it of this system, namely of writing to them rather than just handing it to them when they get there, is that it avoids the embarrassment of the homosexual or whoever it might be, of coming along to the blood bank and then having to go away without having given blood?---That was part of our thinking at the time.

It is a much more sensitive and indeed more sensible approach, is it not?---We thought so.

It was a lot better than simply putting a pile of leaflets on a desk at the blood bank for people to pick up and look at when they came to donate?---That was the opinion in Trent.

It is your opinion too, isn't it?---It is my opinion as well.

Doctor, of the blood that was donated in your service how much of that blood or plasma from it, went to make Factor 8 concentrate?---At that time sir, approximately 50 per cent.

So, half of your blood donated was used for cryo-precipitate, for red cells and so on. The other half went to make concentrate?---No sir. That would imply that all donations were used for some form of Factor 8 which is untrue. It is necessary to have some donations made into other components such as platelets. Half of the material would be made into - plasma taken from the cells, to go for fractionation for concentrate and a proportion of the rest would be used for the preparation of cryo-

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precipitate.

What sort of proportion of your total blood intake would be used to make Factor 8 concentrate?---Concentrate?

Yes?---About 50 per cent at that time.

The blood that you sent to the laboratory for manufacturing into the concentrate, when you got the concentrate back did it come just from your blood or was it pooled with blood from all over the country?---It was generally pooled with plasma from all over the country.

Was that production, manufacturer of the concentrate, done at the bio-products laboratory?---It was then known as the blood products laboratory but it is now the bio-products laboratory, yes.

It was then the blood products laboratory at Elstree?---That's right sir.

Was there anywhere else in England where concentrate was manufactured?---Yes, sir. There was a small plant at Oxford which with the opening of Elstree is used really for research and development.

So, there are two places in - or there were then, two places in England where Factor 8 was concentrated?---There still are in fact.

There were there, that's the - - - ?---So, there was.

The major one being - - - ?---Elstree.

Doctor, it would follow then would it not that Elstree, or the Blood Products Laboratory, would in broadened terms seem to correlate with the role of the Commonwealth

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Serum Laboratory in terms of the manufacture of Factor 8. Are you aware of that?---In my brief understanding of the situation, yes.

So far as the Blood Products Laboratory was concerned, in the early 80s there were some difficulties with that laboratory were there not?---It was undersized.

Undersized?---Yes, sir.

In fact, I suggest to you it was declared as unfit for good manufacturing practise by the Department of Health's Medicine's Division. Isn't that so?---To be honest, I am unaware of that, because to the best of my knowledge they never stopped producing.

Between October 1978 and up until December 1982, that laboratory was managed by the North West Thames Regional Health Authority wasn't it?---That's right, yes.

I suggest to you that during that time, it was declared unfit for good manufacturing practice?---I know sir that manufacturing continued during that time.

I suggest to you that from December 82 on it was managed by the Central Blood Laboratories Authority?---That's correct, sir.

Did you experience any difficulties yourself with what was going on at Elstree?---Only in terms of quantity of supply.

Sorry, in terms of?---In terms of quantity. The old facility was not big enough.

Doctor, I suggest to you that in the early 1980s because of the problems at Elstree the whole provision of Factor 8 Concentrate in the United Kingdom was under very great pressure?---Yes.

With the result that more and more product had to be imported from overseas?---I think your assessment of pressure is quite correct, sir.

Indeed if we come to the early 1980s by far the majority of Factor 8 Concentrate used in the United Kingdom was imported, came from overseas and America in particular?---If I may speak of experiences in my region, Trent, I think that is the case.

HIS HONOUR: You think?---That is the case.

You say that is the case?---That is the case, yes.

MR STANLEY: So for the majority, for most Factor 8 that was - the concentrate that was used certainly in your area, your Blood Transfusion Service had no say or no involvement whatsoever?---More than 50 per cent of the Factor 8 Concentrate used in Trent came from sources outside the health service, yes.

It follows from that, does it not, that your service had nothing to do with that product, as to how it was collected, from whom it was - - -?---That is correct, sir.

Whether the donors had been screened or not?---That is correct.

There was nothing you could do about it?---That is correct.

But you did know, did you not, that the product that was imported from the United States had inserts in it and those inserts included warnings in relation to AIDS?---I am aware in retrospect that they had inserts in according to viral transmission.

I suggest to you they had warnings that were relevant at the time so far as AIDS is concerned?---(No audible reply from witness).

So far as the inserts that were contained in the product manufactured in the United Kingdom at Elstree that insert also had warnings, did it not?---It did, sir.

What was the purpose of those warnings?---To make it quite clear to the clinician prescribing these products that in spite of the best efforts there is still the possibility of viral transmission by blood products particularly made from pools of plasma.

Doctor, Mr Wodak I think asked you whether any declaration was required from your donors. Your answer I've noted it was that you said that was implied but there was never a specific requirement?---That's correct, sir.

What did you mean that it was implied that there'd be a - that

the declaration was implied?---The leaflets to which we have made reference contains a list of people thought to be at extra risk for AIDS and they are required to sign to say that they have read and understood this, but they're not required to sign to say that they are not one of the risk groups.

Doctor, are you aware of the league of Red Cross Societies?

---Yes.

And of a newsletter that was put out by that body entitled "Transfusion International"?---I'm aware of the existence of that.



Well, some copies of that newsletter have been tendered in evidence in this case. There was a newsletter put out in July of 1983 in which the following is stated: "It should be remembered that there are some general means of minimising the hazard of transmission of infectious diseases to the recipient of blood or blood products. The Council of Europe Committee of Experts on blood transfusion and immuno haematology has formulated the following basic principles." The first of those is in these terms: "To expose the recipient to a minimum number of donations of blood when the transfusion is of cellular and coagulation factor products." That was in a newsletter dated July 1983. Do you agree with the sentiments expressed as at that time?---As at that time I think that that is a reasonable statement, yes.

What is it saying?---It's really saying to me - I understand I have not had time to digest the article - it says to me what we have accepted as self evident truth, that the more donors you expose a recipient to, the more chance there is of transmission of any virus.

So it's good medical practice in the sense of whether you're a clinician or whether you're anywhere along the line, to minimise the exposure to donors and blood transfusion or provision of blood products?---So far as compatible with the proper treatment of that patient.

In a later newsletter from the same body, dated October 1983, there again appears under the heading of "AIDS" three basic principles published by the Council of Europe in Transfusion International editorial. They include recommendation that - "To take all necessary steps and measures with respect to AIDS, and in particular, to avoid wherever possible, the use of coagulation factor products prepared from large plasma pools" - again that's in respect of what we've just dealt with?---Indeed, yes.

It then goes on saying that it's particularly important in those countries where self sufficiency of the products has not yet been achieved, and that was the case in England?---Yes.

It also goes on, Doctor - this is a recommendation. "To inform attending physicians and selected recipients such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks." Now, do you agree with that as an appropriate step for those involved in the collection of blood?---That the attending physician should be informed of the risks, yes, sir.

Yes?---Yes, I do.

And also the haemophiliacs. It says "To inform attending physicians" - that's the doctor who's treating the patient, whether it be a haemophiliac or someone else - and also "selected recipients such as haemophiliacs"?---My interpretation of that, sir, if

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I may be permitted to interpret it, would be that  
the attending physician is the one who is in the  
position to warn the haemophiliac.

Because you see the situation that your service, for example,  
would have no - - -?---No direct contact with  
haemophiliacs.

Would you even know the name of the haemophiliacs that you  
provide the products for?---Not necessarily, no.

You don't keep a register indicating the name of each patient  
to whom the particular product is provided for?  
---No, sir, no.

So in your case, would it not be possible for you to be dealing directly with the patient?---No.

So you would see your obligation as directed towards the physician?---That's correct.

Informing him of the risks?---That's correct.

I take it you did that?---Yes.

Doctor, heat treatment of blood products is not new, is it?---Blood products in general, no, not at all new.

Indeed, I suggest to you it's been used for many, many, many years?---For one particular blood product, that's correct.

Which one is that?---That is the product which is composed mainly of albumin.

Mainly of?---Albumin.

When was that first introduced - that is, heat treatment to that product?---Heat treatment of albumin, to my personal knowledge, was introduced in my region in the 60s.

Albumin is a pooled product?---Albumin is made from the same pool of plasma as Factor 8. It's part and parcel of the same process.

What was the purpose of heat treating albumin?---To reduce then the risk of transmission of one of the hepatitis viruses.

So it was to minimise the risk of transmission of - - -?---Viral transmission - - -

A virus?---Yes.

I suggest to you that - perhaps before I get to that - in your

own area, was heat treated Factor 8 available in the 1980s?---In the 1980s?

Yes?---Yes, sir.

When did it become available?---In a bi-phasic mode, I think we would say. The commercial material reached the market in my area by the end of 1984. Heat treated material from the blood products laboratory began to be issued in February 1985.

It is the fact, is it not, that from about 1980 commercial heat treated concentrate was available in West Germany?---I can't speak of that at personal experience.

From Sweden, since March 1983?---I know that efforts to secure an effective heat treated product were going on in the early 1980s, but so far as the UK is concerned and my region is concerned, they were not available until late 1984.

Is this what you're saying, Doctor, that in your region, there were attempts to - - -?---No, no. Attempts were made by commercial manufacturers and by the blood products laboratory.

Outside of your - - -?---Outside of my region, yes. I'm just talking about the availability of materials within my region.

Did you make any - take any steps to determine the availability of heat treated Factor 8 concentrate in early 1984?---No, sir. I think I have explained already that the question of handling imported

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concentrates was not within our (inaudible) and we  
were liaising with the blood products laboratory as  
much as possible for the early release of heat  
treated material made from our plasma.

In terms of actually endeavouring to get it, that was outside  
your area of - - -?---Indeed - - -  
Of control?---Indeed.

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4543

W. WAGSTAFF, XXN

Mr Gillies was suggesting to you that throughout the whole of 1983 that this should have been regarded or was being regarded by you and others you mixed with in the United Kingdom as Californian problem. It is the fact, is it not, doctor, that in August of 1983, a haemophiliac died in England as a result of AIDS?---The first reports began to come through in 1983 sir. That's quite correct.

These were reported in the British Medical Journal and similar journals?---Yes sir.

Doctor, one of the ways of making an assessment of how safe a blood supply is, is to look at the incidence of infection following blood transfusion, is that so?---Yes, sir.

It is a pretty direct association - - -

HIS HONOUR: Did you say - - - ?---Sorry, sir. Yes, I keep forgetting. Yes.

MR STANLEY: Because it is a direct association if you have the transfusion of whole blood or the relevant parts of the blood, it is far more likely to convey the infection from the donor to the recipient, and perhaps even that through a pooled product is that not so?---Monitoring of post-transfusion infection is a valuable way of looking at the situation.

So far as the United Kingdom was concerned, there were figures taken out in relation to this and indeed, they still are aren't they?---Yes.

So far as the - so far as AIDS is concerned. I suggest to you

that by June of 1985, in the United Kingdom, there were a total of 176 cases of AIDS and of those one was from a blood transfusion. Do you accept that. Does that sound right?---This was by when sir?

June of 1985?---1985. I'm not sure whether the first report was of the case of transfusion within the UK. The first reports of AIDS transmission by transfusion within the UK were of people who had been transfused abroad.

Could we just deal with the question of the transfusion association AIDS. Do you accept that there was only one case as at June of 1985?---That's probably correct sir. Yes.

If it was put to you that in fact there were - by May of 1985, in Australia, there were nine cases of AIDS associated with blood transfusion, what would that suggest to you?---In the light of circumstances and retrospective thinking, I think we were lucky in the UK. Again, it comes down to just where the transfusions were given as to the significance of this.

Doctor, what is the current transfusion AIDS percentage in the United Kingdom?---We have something just under 4000 cases reported of which about 30, I think, are transfusion transmitted, excluding haemophiliacs.

It is less than 1 per cent?---Yes.

This is for blood transfusion, exclusion haemophiliacs?---Yes.

You would regard a percentage of, in the vicinity of 5 or 6



per cent as extraordinarily high wouldn't you?---I would just count it as unfortunate, yes.

It would certainly make you suspicious that if you had such a high level, a high percentage it would indicate a very unsatisfactory state of that blood supply?---No sir. May I quote from one case in the UK which will illustrate the fact that that statement cannot be interpreted just literally.

Yes, you may, you may - - - ?---That is that we do have at least one properly authenticated case of AIDS being transmitted by the donor giving blood during what is called the window period.

HIS HONOUR: During?---The window period. This is the period between infection with the virus and the appearance of a positive test. I would regard that as still a possibility, even given the best of blood supplies because there is no way that any organisation can guard against someone deliberately falsifying his background and giving blood during that - - -

Doctor, I think you may have misunderstood what I was directing your attention to. If you accept that there is five to six per cent incidents of transfusion associated AIDS referable to infection in the period 82/83/84, it would indicate, would it not, that that blood supply in that period was certainly not safe?

MR SHER: That's with the benefit of hindsight.

MR STANLEY: That's the fact?---The fact probably is no, sir, because if these cases were of AIDS during 1982 to 85 then infection probably took place by transmission of blood, in blood taken before anyone was aware of the AIDS epidemic.

Doctor, you didn't listen to my question?---Right.

I've taken that into account?---Right.

I'm asking you to accept that the infection occurred between 82 and 84.

MR WODAK: Well, with respect, your Honour, that wasn't the question as was formulated previously by my learned friend. The question that was put as I recall it was AIDS cases between 1982 and 1984. It's a different question.

HIS HONOUR: I don't recall precisely the terminology. Will you phrase your question, Mr Stanley, and I'll listen carefully to it.

MR STANLEY: Yes, your Honour.

Professor - I'm sorry, Doctor, if you accept that there was a five to six per cent rate of transfusion associated

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AIDS where the infection occurred as a result of transfusions given between 1982 and 1984 it would indicate, would it not, that that blood supply was not safe?---I'm not being asked to comment on the time of infection?

You're being asked to comment upon whether or not the blood supply was safe on the assumption of the facts I put to you?---I don't know, sir, that I'm in any position to accept on assumption the facts that you've given to me.

For the purpose - - -?---Infection of - the date of transmission of infection of a case of AIDS is notoriously difficult to accept to assess.

Doctor, I can understand you having some difficulty with that. The question I'm putting to you is based on evidence that's been given by a Professor John Dwyer in this court?---Right.

What I'm putting to you is the basis of his evidence, I ask you to assume it for the purpose of the question. Does it not indicate that that blood supply at that time was not safe if you had a blood transfusion AIDS related portion of five to six per cent? It was less than one per cent in the United Kingdom, wasn't it?---Yes.

Just over one per cent in the United States, isn't that so?

---I regard five per cent as high, yes, certainly.

HIS HONOUR: Yes?---High.

MR STANLEY: It's extraordinarily high, isn't it?---It's

certainly higher than ours.

HIS HONOUR: It's certainly high?---Higher than ours.

MR STANLEY: It would indicate, would it not, a very unsatisfactory state of affairs so far as the blood supply is concerned?

MR SHER: I object to that, your Honour, it's a meaningless question. If my learned friend wants to make speeches he can make them later, that's when we all make our speeches. It's all based on a hypothesis which is unproven, it's just mere assertion in any event.

MR STANLEY: I think Mr Wodak was taking - - -

MR SHER: Well, I'm taking the objection.

HIS HONOUR: It is in my view a permissible question in cross-examination, I'll permit it.

MR STANLEY: Doctor, it's an extraordinarily high reading, isn't it?---It's much higher than ours, yes.

And indicates a pretty unsatisfactory state of affairs so far as the blood supply is concerned, doesn't it?---It's an unsatisfactory state of affairs at that time, yes.

HIS HONOUR: Mr Wodak, you'll be postponed until tomorrow, Mr Wodak. Gentlemen and members of the jury, I mention that on Friday of this week I will not be sitting until 11.15 in the morning. Adjourn the court now until quarter past 10 tomorrow.

WITNESS STOOD DOWN

AT 4.16 PM THE MATTER WAS ADJOURNED  
UNTIL WEDNESDAY, 3 OCTOBER 1990

pq 2.10.90  
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4549

W. WAGSTAFF, XXN

MR STANLEY: Your Honour, I had effectively finished cross-examination yesterday, but may I have leave to put to the doctor questions in relation to the questionnaire that I asked him about yesterday that he was going to endeavour to get from London, and there's another matter also that I desire to put to him.

HIS HONOUR: Yes.

MR STANLEY: Thank you.

HIS HONOUR: No one had taken over after you - - -

MR STANLEY: No.

WILLIAM WAGSTAFF:

MR STANLEY: Doctor, you recall yesterday I was asking you about the questionnaire that was administered in September 83, were you able to get a copy of that?  
---I was able to contact my centre last night. My recollection I'm afraid was at fault. We did discuss - - -

Doctor, the question is are you able to produce the questionnaire?---The questionnaire that is in the court at the moment is the only copy. The additional information - - -

I'm sorry. It was Mr Sher's interruption, we didn't hear what you said?---The questionnaire which is in the possession of the court at the moment is the only questionnaire we have used. My recollection on the

additional information put on was incorrect.

You were wrong?---I was right in that we had discussed the additional information with our doctors, but not that it had been put on the questionnaire for donors.

You give evidence you'd come out to this country an expert to give evidence about what was done in your own system. You told the court yesterday that in September 1983 this questionnaire was devised - was issued - and had to be answered and signed by every donor - - -

MR WODAK: No, your Honour, that with respect was not the evidence.

HIS HONOUR: What do you say the evidence was, Mr Wodak?

MR WODAK: The evidence was that in September 1983 a leaflet was sent out to all donors, and was given to donors when they came to the centre. His was that a questionnaire had been in use before that time, and continued to be used after that time, and my recollection was that the witness also said that he thought that that questionnaire which had been used before, was amended in September 1983 to refer to the symptoms of AIDS.

HIS HONOUR: What do you say, Mr Stanley?

MR STANLEY: On page 4521 I asked the witness the question "Everytime the donor comes he fills out a questionnaire" - that's three quarters of the way down the page - and the answer was "Yes".

Q: And signs it? A: Yes.

Q: And that's whether it's the first, second or 52nd time he was there? A: The signature to the medical questionnaire is combined with a signature of attendance, so we use that as a register as well

Q: That was the system that was in operation from September 1983 on? A: This has been in operation since long before I went to Sheffield.

Q: But in September 1983 there were additional questions put in? A: In September 1983 we introduced questions on what had come to be regarded as symptoms associated with this new disease. In other words - - -

Q: Aids? A: Lymphadenopathy.

Q: So there's always been a questionnaire? A: Yes, sir.

Q: That had to be signed by every donor? A: Yes.

Q: But in September 1983 you added specific questions directed towards ascertaining whether the patient was suffering from AIDS or any symptoms?

A: Right.

HIS HONOUR: Mr Wodak, I think that justifies the question, does it not?

MR WODAK: It shows your Honour, that my recollection of his evidence was correct and that Mr Stanley had not put the question in accordance with the evidence, with respect.

HIS HONOUR: I'll ask Mr Stanley to formulate the question and I'll listen carefully to it.

MR STANLEY: Your Honour, I object to what my learned friend has just said - it is a question that I put in my submission, was in accord with what I've read from the evidence.

HIS HONOUR: That's certainly my impression Mr Stanley, but I don't wish to get into an argument about it. I don't pretend to remember every word that was used, so if you put the question.

MR WODAK: Your Honour, perhaps I can be specific so that we understand each other. What I was taking objection to was Mr Stanley saying that the evidence that this witness gave yesterday - was that the questionnaire, which he has just referred to, was sent out to the donors. That's my recollection of the question.

HIS HONOUR: Mr Wodak, I've already indicated that I don't propose to take in the time of the court by going into precisely what was said this morning. I ask Mr Stanley to ask his question now.

MR WODAK: If your Honour pleases.

MR STANLEY: Doctor, let's just get it clear. The



questionnaire was not sent out, was it?---No sir.

It was there for every donor to sign?---Yes sir.

There had been a system in operation for a long time whereby donors had to sign this questionnaire which had a lot of questions about their health and so on?---Yes.

In September 1983, you told us yesterday, there was an addition to that questionnaire of specific questions related to the symptomology that was indicative of AIDS. That's what you told us yesterday, wasn't it?---I have heard the transcript sir, and that apparently is what I agreed to yesterday.

Are you now telling us that wasn't the case?---I'm saying that my recollection of the inclusion in that questionnaire of those points was incorrect. My recollection of discussion of those points with our medical officers who see the donors is quite correct, but inclusion in the material signed by the donor was incorrect.

How did you come to this conclusion that you now expressing to the jury?---By contact with my home base.

You telephoned someone last night did you?---Indeed.

Who did you speak to?---I spoke to my secretary who got the information for me.

Your secretary. Is that a doctor?---No. No. This is a secretary.

Just an ordinary secretary?---I think there are secretary and secretaries, but yes.

It was a lady was it?---Yes.

What did she do for you?---She discussed the question with the people in my centre who handle the documentation seen by donors.

Was this done while you were holding onto the line?---No. She got back in touch with me.

So as a result of what your secretary found out from other people, you now believe you were wrong in what you told the court yesterday?---I understand (inaudible).

Did you have a conference with Mr Wodak about this morning in his chambers?---Mr Wodak asked me whether I had been in touch with the centre and I said yes, I had.

MR SHER: What are you suggesting Mr Stanley. Your Honour, that is quite an outrageous suggestion. The clear implication that is being made here is my junior did something wrong. The cross-examination had finished yesterday - had finished and my learned friend had announced he had finished and it is perfectly proper when you are going to re-examination the witness particularly when something has been raised to get instructions. I ask my learned friend to withdraw any suggestion implicit in his question that Mr Wodak had done anything untoward at all. It is quite improper what he has just done. I take exception to it on behalf of Mr Wodak.

HIS HONOUR: Well, I say that if Mr Wodak had a conference with the witness this morning, in my view that was perfectly appropriate. Mr Stanley, do you wish to say anything?

MR STANLEY: No, your Honour, I don't. But there was an order for witnesses out of court - - -

MR SHER: You'd finished your cross-examination.

MR STANLEY: The fact that cross-examination has been finished, in my submission, is of no relevance.

HIS HONOUR: Mr Stanley, I've indicated my view and I maintain that view.

MR STANLEY: If your Honour pleases. I don't desire to say anything further.

Doctor, we've heard mention in this court of the British Medical Journal. I take it that you're aware of that journal?---Yes, I am.

You have some opinion of its standing?---Yes, sir.

What is your opinion of the standing of that journal?---It's a medical journal of international repute.

You've also heard, I take it, of Dr John Cash?---I have, sir.

What's Dr Cash's present position?---Dr Cash is National Director of Research and Development in the Scottish Blood Transfusion Service.

So he's the senior blood transfusion officer - if I can use that term - for the whole of Scotland, is he?

---Medically qualified, yes.

Highly medically qualified?---To the best of my knowledge, sir, yes.

He's the National Medical Director of effectively the Scottish Blood Transfusion Service?---Yes.

You're aware of the article or letter that appeared in the British Medical Journal in September of 1987 from Dr Cash?---Dr Cash has written more than one leading article in medical journals, sir. I would prefer it if you quote - - -

Let me be specific. This particular article, I suggest to you, is entitled "The Blood Transfusion and the National Health Service". It's an article in which he is - to put it mildly - extremely critical of the Blood Transfusion Service in the United Kingdom? ---I'm aware of the leading article you're quoting from.

He referred to the "sustained failure of the Transfusion Services in England and Wales" - known as the National Blood Transfusion Service - and that's your service, is it not?---That's correct, sir.

"The sustained failure of that service over the past two decades to meet the needs of the National Health Service." You recall - - -?---I recall.

The general tenor of this?---I recall the general tenor of the articles yes.

He was critical of a number of aspects - not only its relation to its provision of Factor 8 concentrates, but also about "chronic and occasional severe shortages of blood", is that so?---I remember the reference, sir, yes.

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He was also critical of the fact, I suggest to you, that "the conduct of affairs at the clinical interface of blood transfusion throughout the UK leaves much to be desired", and he laid at the feet of the Blood Transfusion Service, did he not?---I don't think that particular aspect can be laid at the feet of the Blood Transfusion Service, I don't think Dr Cash did. We are not responsible for the clinical interface.

He said this, did he not, "Many general managers" - - -

MR SHER: Your Honour, before this matter goes any further, I'd ask your Honour to enquire of my learned friend what he's intending to do. If he's intending in some way to challenge this witness, then he ought to put to him what the challenge is. If he's asking whether he agrees or disagrees with something, he ought to do that. But what he is endeavouring to do is to try and give evidence from the bar table of what someone who is not called as a witness in this case, and apparently won't be brought into this case, said in an article in 1987.

Now, your Honour, I object to it. In my submission, it's not a proper way of cross-examination. If my learned friend wants to challenge the witness on some issue, he should do so, but this is just a means of trying to get something in evidence. My learned friend has objected to us trying to put in evidence articles after 1984 and he's doing exactly what he objected to us doing.

HIS HONOUR: Mr Sher, the position is that much is left to the discretion of counsel in cross-examination and I assume that counsel are and will proceed properly, and until it's demonstrated that that's not so, that's my approach.

MR SHER: Well, in my submission, your Honour, that point's been reached. This witness hasn't been asked. All my learned friend's doing is reading out an article.

HIS HONOUR: Well, I am not assuming that Mr Stanley is doing this without bringing the matter to a proper conclusion. I do not make that assumption about any counsel before me in this case. Yes, you may proceed, Mr Stanley.

MR STANLEY: Thank you, your Honour.

Doctor, what I'm putting to you is that here, from a senior person in the blood transfusion world, is an article or a letter published in this journal that is extremely critical of your blood transfusion service, is it not?---That article is critical of

the organisation, which I will submit is a different thing. Professor Cash was putting forward his views on the formation of a national service as against the regional service which presently exists.

In particular, he was critical of - among other things, I suggest to you - of the fact that you had these regional centres conducting the blood transfusion service rather than a central body conducting it?---That was my statement.

Indeed, I suggest to you he said about that, that the National Blood Transfusion Service is a fragmented and disorganised shambles - that was his criticism, wasn't it?---The words are well remembered, sir.

MR SHER: Well, your Honour, I object again. I now ask the question what has that got to do with this case? It's just a means of bucketing this witness by reference to something said by another doctor in an article some years later, who's not going to be called and whose views we can't test, and it's improper in my submission. It's not put to any relevant evidence of this witness has given. It's just a wholesale attack, just throwing mud through the mouth of somebody else who's not going to be seen in this court and whose evidence can't be tested, at this witness and that's the whole purpose of this exercise and, in my submission, it shouldn't be permitted.

HIS HONOUR: Mr Stanley, are you taking this matter further or

have you completed your cross-examination on this aspect?

MR STANLEY: No, I hadn't quite, your Honour. There are other matters in this other aspect of the criticism that I wanted to put to this witness.

HIS HONOUR: Well, are you - you heard what I said earlier and you know the basis on which I'm proceeding.

MR STANLEY: I'm not sure that I'm completely clear, your Honour. I don't want to run foul of any - - -

HIS HONOUR: Well, I'm proceeding on the basis that I assume that some specific allegation will be put as arising from this article. Is my assumption correct?

MR STANLEY: In as much as I've already put some, your Honour, and I'll endeavour to put them further. Your Honour, the relevance of this evidence is that the witness has been called to give evidence about what was being done in the National Blood Transfusion Service as though that was pre-eminent body and that what it did was appropriate in the circumstances. Well, we would submit that in a number of respects, and relevant respects that body was criticised - has been criticised - by the persons who were in a position to know and who would be in a position of some degree of authority and responsibility themselves so that it, to some extent, may throw some doubt upon the validity of the claim that's being made by the defendant, that the British or the National Blood Transfusion Service was one that was



in fact pre-eminent and one that should - that it was appropriate for Australia to follow.

HIS HONOUR: Mr Stanley, so far as this article is concerned, the only use you can make of this is a use which you can make if you lead the witness to modify his evidence in the light of that. It's not nearly enough that it be mentioned that there was that article. It's necessary, if that's to carry any weight, for you to take the matter further with the witness to obtain, if you are able to, concessions from the witness.

MR STANLEY: If your Honour pleases.

Doctor, you were aware, were you not, way back in 1983 and 84 of criticisms of the National Blood Transfusion Service on the basis that it was run as regional centres rather than a unified body?---No, sir, there was no such criticisms voiced in public.

I didn't say anything about voiced in public. I'm asking you whether you were aware amongst the medical profession?---Amongst the medical profession there was one school of thought which believed that it would be better to have a national service rather than a regional service.

And the basis of that was that it was regarded as being fragmented and disorganised?---No, sir. The basis of that was that funding was thought to be better from a central source than from 24 different sources.

Now, it was purely a matter of funding, was it?---Mainly a matter of funding, yes.

What else, apart from funding?---The increased efficiency which might come - and I stress might - because we don't know from the question of national organisation.

Thank you, Doctor.

RE-EXAMINED BY MR WODAK

MR WODAK: Doctor, you were asked some questions yesterday about a meeting that was held in Trent with consultant haematologists to discuss the use of

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cryo-precipitate in concentrate products, do you recall being asked about that?---Yes, sir.

During the period 1983, 84 and confining yourself to your own knowledge of what was occurring in Trent Regional Transfusion Service, are you able to say anything about the comparable amounts of cryo-precipitate and concentrated products used by haemophiliacs?

---During the period in question the proportion of cryo-precipitate against concentrate did not change in any material way.

Can you say what those comparable amounts were - roughly? Was there more one used - - - ?---More use of concentrates than cryo-precipitate - - -

And you said that was right through the period in question?

---Yes.

1983, 84?---Yes.

Now you were asked some questions about the North London Centre, and a form that was introduced by it. Do you recall being asked about that?---I recall it, yes.

And you said in your evidence that the population of the area served by the North London Centre had some differences from your own at Trent?--Yes.

What were you referring to there?---I was referring to - in the main - the homosexual population and the use of hard drugs.

That was something that was - - -

HIS HONOUR: I missed a little bit of that sentence. Would

you give that again, please, Doctor - you were referring to?---Yes, sir. It's the question of the homosexual population known to exist in London as against the rest of the country. The proportion of people known or thought to be using hard drugs in London.

MR WODAK: Doctor, would you look at this document, please?

---Yes.

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W. WAGSTAFF, XXN  
RE-XN

Are you able to say what that document is?---Yes, sir. This is the additional small questionnaire which has already been referred to in court, used in North London, because of the increased awareness of homosexual activities in (inaudible).

Is that the document that you were referring to in your evidence yesterday?---Indeed, sir, yes.

I tender that, if your Honour pleases, as part of book - it would go under tab B3 in folder 5, your Honour.

HIS HONOUR: Book 5, B3.

MR WODAK: Doctor, are you able to say when that document was distributed by the North London Blood Transfusion Centre?---This document began to be used in the central Westend Clinic in July of 1984, and was used in some of their other clinics in the following year - 1985.

So commencing from July 1984?---Yes.

It starts off by asking whether the donor had read The Age leaflet?---Yes.

Are you able to say what AIDS leaflet was being referred to?

---In July 1984 - - -

MR STANLEY: Well, your Honour, this witness has told us that he at the time was involved with the Trent Blood Transfusion Service. He's being asked here about a different transfusion centre altogether - a different area. In my submission he would have to show a lot more before he would be able to answer these questions - they would have to be based upon

hearsay, in our submission.

HIS HONOUR: He was asked questions about this very document in cross-examination, wasn't he?

MR STANLEY: He was asked whether there was a questionnaire administered, your Honour.

HIS HONOUR: I would permit the questions.

MR WODAK: Do you want the question repeated, Doctor, or can you recall it?---If you please.

The question was this - the questionnaire starts off "Have you read the AIDS leaflet?" and what I was asking you was do you know what leaflet was being referred to? ---In July 1984 that was the leaflet before the court dated 1983.

HIS HONOUR: Would you say that again?---The leaflet dated 19 - September 1983.

MR WODAK: Now, Doctor, in relation to your own regional service at Trent, in 1983/84 were you aware whether amongst your donor base there were any homosexuals? ---At the beginning of that period, sir, no. There is no way that we could've been sure - apart from a supposition that there would be by the normal distribution.

I want to take you to the question of medical examinations of donors about which you were asked some questions yesterday. You indicated that a doctor is always present every time a donation of blood is given in your regional centre, is that so?---That's correct, sir, yes.

The doctors who are present on those occasions, I think you said, were not specialists?---The majority of them are general practitioners.

What was it that they did on the occasion of a donor being bled?---Physically their task was to carry out the venipuncture and - - -

That's inserting the needle?---Inserting the needle into the vein. They're also asked, as was discussed yesterday, to act as a medical screen of the health of the donor.

How was that task carried out, the medical screening task?---The majority of medical screening in my region as in most of the UK is based on the use of questionnaires. This questionnaire is available at the desk as the donor arrives at the session. Any cases of doubt or difficulty are referred through to the doctor for discussion with him, as to the donor's suitability to give blood. He would take action accordingly.

Was there any physical examination carried out?---The only physical examination that was carried out as a routine was - is measurement of blood pressure which of course incorporates pulse and measurement and these being general practitioners, they are extremely useful in assessing - - -

HIS HONOUR: Extremely?

MR WODAK: Useful, your Honour?---In assessing the apparent general health of the individual presenting as a donor.

If a patient presented with lymphadenopathy which was the matter that you raised yesterday?---Yes sir.

Would you tell the court first what's meant by lymphadenopathy?---Lymphadenopathy is a swelling of the lymph glands of the body which occur in various groups around the body.

Whereabouts are the lymph glands located doctor?---Generally speaking in the folds of the attachment of the limbs.



The armpits?---The armpits.

In the groin?---In the groin and large chains of potential lymph glands in the neck.

Whereabouts in the neck. Can you perhaps demonstrate with reference to your own neck?---Running down from behind the ear downwards on both sides of the ears.

Behind the ear - - -

HIS HONOUR: The witness indicated behind his ear and moved his hand back diagonally at about 45 degrees downwards?---Thank you your Honour.

MR WODAK: Towards the base of your neck?---It is towards the base of the neck. Yes sir.

HIS HONOUR: That's so that it is in the transcript, doctor?---Thank you sir.

Anyone else looking at it would otherwise be unaware of what you had done?---Thank you your Honour.

MR WODAK: Those are the places where the lymph nodes are located is that so?---These are the major groups of lymph nodes which are easily accessible.

If a person suffers from lymphadenopathy, what effect does that have on those lymph nodes?---They swell, usually visibly, particularly in the neck and are easily visible to a trained observer.

When you say a trained observer, who do you have in mind by that?---I have in mind, in this particular instance the doctor who is conducting the blood donor session.

Would a nurse in a blood transfusion centre be able to discern

that?---Yes, I think a trained nurse would be able to do this.

Doctor, you asked the questions about the September 1983 leaflet that went out and the expression "Many partners" was used in that leaflet?---Yes sir.

I think you agreed in your evidence yesterday that by 1985 it had become apparent, I think you said you agreed with the - that that was a silly question?---It was a question which was impossible to interpret easily.

Was that an understanding - when was it that you reached that understanding?---I think it was mainly that point which precipitated the production of the new leaflet in January 1985.

At the time that the leaflet went out in September 1983 what was your view about the appropriateness of that expression?---The view at that time was that it was quite appropriate in as much as it was based on the experience coming from San Francisco again, that this was a disease usually associated with a high degree of male promiscuity.

Doctor, the blood that was collected by your regional transfusion service during 1983/84, I think you said in your evidence yesterday that approximately 50 per cent of it was used for the manufacture of concentrate?---Yes sir.

END TAPE 7. Do you mean by that 50 per cent of all blood collected or 50 per cent of the plasma or what were you referring to?---I'm sorry if this was unclear.

We would take the plasma from approximately 50 per cent of all the donations and send that for fractionation purposes.

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W. WAGSTAFF, RE-XN

All of the plasma?---All of the plasma taken from each donation, yes.

In relation to heat treating, Doctor, you were asked some questions about the heat treating of blood, and it was put to you, I think, that it was heat treated as from the early 1980s - some blood - sorry, I perhaps should rephrase that - Factor 8 was heat treated as from the early 1980s?---The investigations into the feasibility of heat treatment began in the early 1980s, that's quite right.

Was that - were those investigations for any particular purpose?---They were initiated because of the known risk of transmission of the hepatitis virus groups in these pooled concentrates.

In relation to heat treatment for the human immuno deficiency virus, when was heat treated product introduced, to your knowledge, in your region?---During the end of 1984, we began to see the use of imported commercial heat treated material in my region.

I have no further questions, your Honour.

HIS HONOUR: Yes.

MR WODAK: May Dr Wagstaff be excused?

HIS HONOUR: Mr Foreman, is there any particular question which the jury wish to ask of the doctor before he's excused?

FOREMAN: No questions, your Honour.

HIS HONOUR: Thank you. Yes, Dr Wagstaff is excused.

WITNESS WITHDREW