Friday, 12 November 2021

(10.00 am)

Presentation by Counsel to the Inquiry on Dr Harold Gunson (continued)

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: Today we'll continue with the presentation on Dr Gunson. Before I start, I just want to make a correction to something that I said yesterday. Sir, I took you to a memo written by Dr Gunson to the then Chief Medical Officer, Dr Acheson, dated 18 October '83. I'll read the reference for the transcript but we don't need to go to it, it's NHBT0001066_004.

There was a reference in that memo -- I think it was called "Five years backwards and five years forwards" or something like that, and there was reference in the memo to Dr Gunson having brought some information to a consultant advisers meeting earlier on about AIDS, and it's been pointed out to me -- and I made a submission that it was clear from that document that Dr Gunson had provided some advice to Dr Acheson about AIDS previously, and it was pointed out to me that Dr Acheson had actually only been in post 1 October '83. So while advice may have been given to the Chief Medical Officer, it may not

necessarily have been Dr Acheson, depending on when that meeting took place. I'm afraid I haven't been able to find --

SIR BRIAN LANGSTAFF: I think he -- my memory is, because I wondered about his being in post at the time, that he signed it "Chief Medical Officer designate", I think. But this is purely from memory so I may be confusing it with another document.

MS SCOTT: The short point is, sir, that it may not -- that advice may not have been given to Dr Acheson about AIDS, although it would have been given -- if that document is accurate, information about AIDS was provided to the Chief Medical Officer by the consultant adviser.

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: Sir, I just want to go to a couple of documents before I pick up on the AIDS testing issue. The first one is WITN2050047.

SIR BRIAN LANGSTAFF: Just -- I made a note at the time, actually, that he was CMO designate. That's how he described himself. This is NHBT1066_004.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: 18 October 1983.

MS SCOTT: Exactly, yes.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: So this is -- if we could go to page 2 of this, please, this is an entry from the British Medical Journal, 12 September 1987, and on Tuesday when I was doing a presentation in relation to the history and structure of the Blood Transfusion Service, I read extracts from the letter we see on pages 1 to 3 of this document from Professor Cash, and I don't intend to go back over that, but in short, Professor Cash described the Blood Transfusion Service as a "fragmented and disorganised shambles".

What I didn't refer to then but do now, are the responses to that article, and there's one response which we see at page 5. We can see at the top there, on "Correspondence", it's 19 September, so this is a week later, and we can see that there is a letter there, sir, "The blood transfusion service and the National Health Service".

If we go over to the following page, we can see right at the top that that is a letter from EL Harris, Chairman of the Advisory Committee on the National Blood Transfusion Service and the Department of Health and Social Security. I'm not going to go into that letter but below that, we can see there's another letter, and if we go over to the top of the middle column we can see that that's a letter from Dr Gunson

while he was director of the Manchester North Western Regional Transfusion Service.

I just want to draw your attention, sir, to that and just read out some short extracts from that.

He starts off the letter:

"Sir, I would not disagree with Dr John Cash that there are problems within the National Blood Transfusion Service in England and Wales."

Then if we skip down to the next paragraph:

"Individual Regional Transfusion Centres have responded to changing circumstances in blood transfusion medicine over the past decade. It is important that patients have confidence in their treatment and that they may be reassured that blood and its components that they receive from the National Blood Transfusion Service are of the highest quality."

Then, again, skipping down to the next paragraph:

"Dr Cash describes the National Blood Transfusion Service as a 'fragmented and disorganised shambles'. This is hardly an apt description of a service that provided an increase in available blood supplies of 23 per cent between 1975 and 1985 and an increase of several hundred per cent in platelet concentrates."

Then, again skipping down to the next paragraph, at the bottom of that column:

"There may be organisational shortcomings in the National Blood Transfusion Service that lead to operational difficulties from time to time, but these are being addressed and I am confident that a solution will be found. Dr Cash, however, presumably to drive home this argument, exaggerates. The danger inherent in his comments is that they will lead not to rational debate and improvements but to a loss in confidence in the transfusion service by hospital colleagues, donors, and patients. This is neither justified nor in the interests of the National Health Service."

So, sir, a somewhat measured response to what might be seen to be quite an inflammatory article from Professor Cash and Dr Gunson there making it clear that his concern, his primary concern, is to maintain confidence in the blood service.

One further document before we get on to AIDS, SHPL0000163_033. We can see that this is a WHO Expert Committee on Biological Standardisation report, and if we -- it's not a very clear copy, this -- but if we turn to the next page, we can see that it's an annex to a report and it's "Requirements for the collection, processing and quality control of human blood and

blood products".

If we go back to the front page -- it's not very clear, you can't see the date there, in fact.

SIR BRIAN LANGSTAFF: It looks like 1978.

MS SCOTT: I think it's -- yes, 1978. Yes, that's exactly what I think it is.

Then if we turn over to page 33, please -- 31, that's why. That's what I meant to say. 31. You can see "Appendix 1. List of authors", and about halfway down there we can see that Dr Gunson, while he was director of the Oxford Transfusion Centre, is one of the contributors to this report or the annex to this report, which is what we're interested in.

Then if we can turn, please, to page 7, we can see that there they set out some information about the collection of blood and blood components and the selection of donors, and they look, first of all, at donors of whole blood, and then we'll come on to look at plasmapheresis donors. So, on that right-hand column, "A.5.3 Medical History", it says this, under "General", so this is for donors of whole blood:

"Before each donation questions shall be asked to determine that the donor is in normal health and has not suffered, or is not suffering, from any serious illness, eg malignant disease, diabetes,

epilepsy, hypertension, renal disease."

Then the next section deals with "Infectious diseases":

"Donors shall have a negative history of viral hepatitis, of close contact with an individual with hepatitis within the past six months, of receipt within six months of human blood or any blood component or fraction that might be a source of transmission of viral hepatitis, or of tattooing within six months."

Then there's an entry about acupuncture that we don't need to concern ourselves with.

Then at the bottom there:

"Any donor shall be permanently excluded if a previous blood donation given by him was the only unit of whole blood or of a blood component administered to a patient who developed hepatitis within six months and who received no other blood fractions capable of hepatitis transmission during this period."

Then, over the page:

"Donor population showing a prevalence of acute or chronic hepatitis higher than that found in the general population should be avoided for collection both of single donor products (whole blood and its components) and of plasma for pooling for the

manufacture of plasma fractions known to be capable of transmitting hepatitis, such as clotting factor concentrates.

"Countries a low incidence of hepatitis should not use whole blood or blood products obtained from source material collected from an area in which there is a high incidence of hepatitis."

Then it makes a reference to hepatitis B surface antigen testing, and it says:

"National health authorities shall develop policies designed to prevent the transmission of other infectious diseases based on the prevalence of [other *(sic)*] diseases in the donor population and the susceptibility of recipients to the same diseases."

Then it goes on to give some information about malaria and so on.

So that's what it says in relation to donors of whole blood.

If we then turn on, please, to page 9, we can see what it says about donors for plasmapheresis, and I'm going to pick this up in the second paragraph under A.5.6:

"In addition to these criteria, donors participating in a more frequent plasmapheresis programme shall be examined by a licensed physician on

the day of the first donation, or no more than one week prior to the first donation. This examination shall include urine analysis and blood sampling for liver function tests, a serological test for syphilis, and determination of plasma proteins by electrophoresis or another suitable method.

"On the day of each donation, in addition to meeting the requirements for whole blood donors, plasmapheresis donors shall be shown to have a total serum protein of no less than 60 g/l.

"The medical evaluation of plasmapheresis donors shall be repeated at regular intervals, as specified by national control authorities. The interval between physical and laboratory examinations shall not exceed four months."

Then over into the next column it says, just above that indented para:

"In general, plasma collected by therapeutic plasmapheresis shall not be used for fractionation."

So, sir, I draw your attention to those provisions of the 1978 WHO publication because the issues that that raises will be issues that we will be returning to in the forthcoming hearings.

Turning now then to the question of AIDS and testing for HIV, the first mention that we have of

Dr Gunson and AIDS is from an internal Department of Health and Social Security minute on 16 July 1982. We don't need to look at that now but for the transcript the reference for that is DHSC0002219_009, and that sets out that Dr Gunson is being given information about AIDS from a Dr Joe Smith at the NIBSC, who in turn has got his information from the American Bureau of Biologics.

I'm going to turn to Dr Gunson's statement that he provided for the HIV litigation and see what he says there. It's NHBT0020196. I'm going to look, first, at what he says about his knowledge of AIDS and when he became aware that it was caused by blood and blood products.

So can we go first, please, to page 18. So at the top of that page, he starts that first paragraph:

"During 1982 it was not, in my view, proven conclusively that Factor VIII concentrates were the cause of AIDS contracted by haemophiliacs. Again, to quote Dr Peter Jones, in his presentation at the meeting in 1986, reported 'however, when in July 1982, the Centers for Disease Control (USA -- my brackets) reported unusual opportunistic infections in three men with haemophilia, the possibility of a viral aetiology was thought less likely than an immune response to the

constant barrage of extraneous denatured protein involved in treatment'."

Then he goes on to say:

"The first case of transfusion-associated AIDS was reported in 1983 in an infant transfused in December 1982 and this will be referred to later in the statement."

SIR BRIAN LANGSTAFF: Just going to back to the previous extract, normally one would read the last lines after the first sentence as demonstrating that the composition in the first sentence is correct, but what Jones appears to be saying is that, one way or another, Factor VIII concentrates are the cause, the risk -- the cause -- the reason why Factor VIII concentrates are the cause is more likely to be the constant barrage of extraneous protein than it is a virus.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: But he's not saying, as I read this extract, as relied upon by Professor Gunson, he's not saying there's not Factor VIII concentrate. So it doesn't seem to follow from the first sentence.

MS SCOTT: I think that's right, sir. I think what he must mean is he agreed that it's not a virus in the blood.

SIR BRIAN LANGSTAFF: So what he's really talking about isn't so much that Factor VIII concentrates were the cause of AIDS contracted by haemophiliacs but that a virus carried by Factor VIII concentrates was.

MS SCOTT: Indeed, that must be right.

He goes on to say:

"The first case of transfusion-associated AIDS was reported in 1983 in an infant transfused in December 1982 and this will be referred to later in the statement."

I think what he's referring to there is the San Francisco baby case. For the transcript, the reference for the article in the -- well, the reference for when that was first reported MMWR --

SIR BRIAN LANGSTAFF: That was 10 December.

MS SCOTT: Exactly, 10 December 1982, and that's PRSE0003276. We don't need to go to it.

SIR BRIAN LANGSTAFF: What I think he may be talking about here is a subsequent report in The Lancet --

MS SCOTT: Indeed, which was --

SIR BRIAN LANGSTAFF: -- which may not have come out until 1983.

MS SCOTT: Yes, that was on 30 April 1983 and, for the transcript, the reference for that is PRSE0000317. Indeed, it may be that that's what he's talking about

there.

So then we go on, over the page, please, to page 19 and a paragraph 92(g). Just to be clear -- so I think that's (q), actually -- what Dr Gunson appears to be doing here is making comments about the particulars of claim in the HIV litigation. That's what I understand the reference to para 92(q) to be.

"During 1982, the correlation between the transfusion of blood and blood products was not proven, nor was it known at that time that a virus caused AIDS, although investigations were being undertaken in this regard. The first proven case of transfusion-transmitted AIDS was reported in 1983 in an infant given a transfusion of blood and blood products in December 1982."

Then he goes on -- can we then go on to page 27, where he says at paragraph 92(y), at the bottom half of that:

"I first became aware of the emergence of HIV/AIDS from the information in the Scientific Literature from the USA."

So that's suggesting that, actually, he was reading literature from the USA not simply from England:

"The first reports were of the finding of

Kaposi's sarcoma in homosexuals. No-one knew what the implications were at that time for the BTS. As the reports began to accumulate, it was clear that the immune deficiency related to this disease was a major problem. The medical staff in the RTC discussed each new development as any department would discuss such major developments in another field. In 1983, as soon as we knew that this virus was transmissible by blood products, we were aware that the disease would have a major impact on the work of the Blood Transfusion Service."

Then he goes on, in the next paragraph, to talk about keeping himself informed by reading scientific literature, attending meetings, going to seminars and teaching sessions, and so on. Then he says, at that next paragraph:

"I first suspected the link between haemophiliacs and AIDS during 1982, when there were instances of haemophiliacs contracting immune deficiency. However, it was not known at that time that AIDS was caused by a virus and when this was established, it was thought initially that the AIDS virus was not so virulent in haemophiliacs and only one per cent of those who had HIV seroconverted would develop AIDS. This, of course, has now been found to

be entirely wrong. There were times, until the proof that AIDS was a viral infection and that it could be transmitted by blood products, that I doubted the link with haemophiliacs; other colleagues also had these doubts."

Then he goes on to say:

"Before the emergence of its cause by a transmissible virus, other theories were put forward for the origin of AIDS in homosexuals ..."

Then he sets out what those are:

"Until proof was available that blood transfusion could be a cause of AIDS, it was difficult to take specific action within the BTS. From that time, I held no doubts concerning the significance of blood transfusion in relation to AIDS and acted accordingly."

Then he says at the bottom that he is aware of articles in The Lancet on 15, 22 and 29 January 1983, I don't intend to go to those but I will just read into the transcript the reference of those articles. It's PRSE0003790, PRSE0000315_021 and RLIT0000201.

So it's clear then that, from 1982, he knew there was a link between AIDS and people with haemophilia but the turning point for him seems to be the San Francisco baby case. The question about

whether or not he would have known about that when it was published in America or whether he would only have known about that in April 1983 when it was published in The Lancet is not made clear by this document. If we go on to look at another couple of documents, it may assist you, sir, in coming to any conclusion in relation to that, should you need to.

So the next document is NHBT0039762_031. This is a letter that Dr Gunson wrote to Dr Walford on 17 February 1983, and we can see from this letter that he -- that first paragraph that he's enclosing some information for her on the AIDS situation and he says this, in the second sentence:

"I think that we will have to carefully watch this situation and perhaps when I come back from Washington at the end of February, we could meet to discuss it, because the most important recommendation that is coming from the USA is the question of whether there should be an increased usage of cryoprecipitate, and if this philosophy takes off in the UK it will have considerable implications for the Regional Centres and for the plasma supply situation."

So just pausing there, what we get from this, of course, is that at some point in February Dr Gunson is in America. Whether that assists you in identifying

whether he would have known about the San Francisco baby case at that stage or not, I don't know, sir.

SIR BRIAN LANGSTAFF: Well, he had some contact with Dr Cash, one supposes, and Professor Cash has told us, or we heard yesterday, had copied the MMWR, 10 December and sent it in early 1983 to Bloom. So if he had talked about the matter -- we don't know, of course, we can't know -- but one might have supposed that it's quite possible, maybe likely, I will have to make my mind up on that, that they would have discussed the possibility, or the risk, that blood products transmitted AIDS --

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: -- or whatever was the cause of AIDS.

MS SCOTT: Then, while we're on this document, he goes on in the second paragraph to discuss the fact that there are defined groups of haemophiliacs who will benefit from cryoprecipitate, according to the information that he has from America: newborn infants and children under 4, newly identified patients and patients with mild haemophilia. He says:

"In the North West Region we still do maintain this policy ..."

That, sir, is consistent with some of the

information that we saw yesterday about the north western policy for treatment for haemophilia, which is actually in the HIV litigation statement of Dr Gunson:

"... although I do not think that this is universal throughout the country. This does have an effect on plasma supplies since in the current financial year we will manufacture some 19,000 cryoprecipitates and, of course, this limits the plasma that one can send for Factor VIII preparation since this is about 20-25% of total usage."

He goes on to say that he understands that haemophilia directors have met earlier in the week to discuss the situation but had not drawn any conclusions.

So that's the first document. The second document is CBLA0001703 and this is -- we can see this is the working party on transfusion-associated hepatitis, 27 September 1982, and we can see that Dr Gunson is the Chairman of that meeting. Then if we go over to page 2, under paragraph 5, we can see at the bottom there we can see this is a report produced by Dr Gunson and Dr Barbara on 28 April 1983, and we can see under 5 he says:

"The Working Party has followed carefully the information from the USA on AIDS and has considered

the recommendations with respect to donor screening and use of cryoprecipitates. To date there have been no cases reported following transfusion of blood or blood products. It has been agreed that, until further information is available, the Working Party will not recommend changes to present practices for donor selection or use of blood products."

That's a slightly odd entry with that date on it but perhaps if he'd only seen the report in The Lancet on 30 April, this pre-dates it by two days.

SIR BRIAN LANGSTAFF: It may mean no cases in the UK --

MS SCOTT: It may do.

SIR BRIAN LANGSTAFF: -- because there had been cases reported in the United States --

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: -- and that he plainly knew and would have been taken to know. So this must, I think, mean we haven't had a case in the UK which suggests that the route of infection came through transfusion or infusion of the blood product.

MS SCOTT: There's no other sensible reading of that because it simply ignores so much of the information that was coming from America.

SIR BRIAN LANGSTAFF: It's a very crude way of putting it, saying, "Well, this is a problem in the

United States" --

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: -- "for now".

MS SCOTT: Yes.

Then if we go to PRSE0001182 moving forward a few days to 5 May 1983, what we've got here appears to be a note, and it's not clear who took the note, but a note taken -- in fact, it is clear who took the note, forgive me.

It's a note taken on a telephone discussion with Dr Harold Gunson on AIDS, and if we go to the bottom we can see "DBL McC", so we think -- I think that is Dr Brian McClelland, who is the -- was the Director of the Edinburgh Transfusion Centre.

The telephone discussion seems to be Dr Gunson setting out to Dr McClelland what the Department of Health and Social Security's stance on AIDS is. So:

"DHSS does not plan to take any drastic measures with respect to restricting imports of American factor VIII.

"The following actions have been discussed by HG with the Department, in relation to the approach to UK blood donors:

"(a) Add to the donor questionnaire more specific questions to elicit shivering, general

malaise, unexpected weight loss. No changes in the routine physical assessment of the donor is proposed.

"(b) Avoid collecting blood in high risk locations such as prisons or locations where there is known to be a high proportion of homosexuals or drug abusers in the population.

"(c) Prepare an information leaflet to be made freely available to donors at blood collection sessions. The precise content of the leaflet has not been discussed, but I confirmed with HG that this would specifically make the request to high-risk groups to refrain from donating blood.

"(d) National publicity, perhaps in the form of an article for a publication in 'Gay News'.

"(e) Screening of donors -- I understand no recommendation will be made to the English Directors on this point."

Then at the bottom there:

"Dr Gunson states that the decision has been made to propose [actions] (a) and (b) [so that's adding to the donor questionnaire and avoiding collecting in high-risk locations]. Option (c), the production and issue of a booklet for donors, is, he suggests to be held back for a few weeks until it is clear whether the present high level of media

attention is to continue."

It's unclear what that means or why the high level of media attention is relevant to the question of whether or not there should be donor -- information given to donors in the form of a leaflet or a booklet.

But if we read that letter -- sorry, that note, that document, together with NHBT0001067, which is a letter from Dr Gunson to Sir Henry Yellowlees, then the Chief Medical Officer, dated 9 June 1983, it may assist in trying to understand that.

The first part of that letter is setting out the background to the disease, and so on, and then he sets out, at the bottom of that first page, what the policy decisions are, first of all:

"(1) To ensure that persons in a high risk group with respect to AIDS are not enrolled as blood donors."

He says to achieve that:

"... Regional Transfusion Directors, with the agreement of Senior Medical Officers at the DHSS have prepared a pamphlet which gives information to donors on AIDS and asks those persons [over the page] in high-risk groups not to donate blood. Additional questions are to be asked of donors with respect to their health, but it is unanimously agreed that the

sexual practices of donors cannot be questioned directly."

(2) goes on to talk about the Factor VIII concentrate that approximately half of that used in treatment in England and Wales is derived from American plasma. He says this:

"The Press have been keenly interested in this aspect and there is, in my view, no alternative to the continuation of this point short term."

Then the next paragraph down, he says this:

"AIDS is not a major problem in this country at present and, frankly, we do not know whether it will be in the future. However, it is being taken seriously in European Countries and the Ministers of the Council of Europe are to be asked to approve recommendations designed to minimise the effects of AIDS. These recommendations are not in general incompatible with the measures being taken in this country."

Then he goes on to say this:

"Although the situation with respect to the transfusion of blood products and the incidence of AIDS has been closely observed by the transfusion service for some time, it has to be admitted that press publicity, albeit some of it ill-informed and

alarmist, has resulted in a reconsideration of this problem and the formulation of the policy outlined above."

So that letter would suggest that part of the driver, in any event, of the measures that were taken was press coverage.

The mention Dr Gunson made in that letter of the recommendations coming out of Europe can be seen at DHSC0000716.

Sir, this is a letter from Dr Gunson to Dr Walford dated 16 May 1983 in which he's reporting his participation in the Council of Europe meeting that he had just attended, and he says in the third paragraph down:

"With respect to AIDS, there was a long discussion and I append a copy of the summary report for most of the European countries."

Then sets out what was happening in Belgium. Then at the end of that paragraph:

"Most countries reported additional cases following preparation of their reports but there are very few cases following transfusion, even in [West] Germany."

Then he sets out there's going to be a resolution and he gives Dr Walford the gist of it:

"1) To expose the recipient to a minimum number of donations of blood in the case of transfusion of cellular and coagulation factor products.

"2) To achieve national self-sufficiency in ... coagulation and factor products.

"3) [Avoid importing] plasma and coagulation factor products from countries with high-risk population.

"4) To provide information to all donors so that those at risk will abstain from donating.

"5) To inform all attending physicians and selected patients groups of the potential hazard and the possibilities of minimising this risk."

Sir, you have seen the recommendation coming out of that meeting on a number of occasions.

Then he says this:

"You can see what they are leading to is the greater use of cryoprecipitate, and we saw two years ago that this tends to be the standard product in many European countries. Although I put forward the UK view of this product the consensus was against us. Like you, I do not think BPL could change to freeze-dried cryo rapidly and the logistic problems would be considerable. The CBLA is going to have to consider the interim period before the completion of

the new plant very carefully and I am not sure yet, until I can give the matter more thought, what would be the best solution. Fortunately everyone here was in agreement that it was vital to present a balanced view of this problem and to avoid emotive over-reaction (my phrase which will appear in the report of the meeting!)."

While he was at that meeting, the Regional Transfusion Directors, at their meeting on 18 May 1983, decided to create a pamphlet explaining AIDS to donors and to put some publications in the newspaper. We don't need to go to that but it is CBLA0001707. And it's unclear, because Dr Gunson wasn't attending that meeting -- he was at the meeting in Europe -- what input and what consultation there was with him in relation to that decision. He says this about the AIDS leaflet in -- in fact, I don't think we need to go to that.

Yes, so if we could then turn back to what he says about this in his HIV statement, which is NHBT0020196_001. If we go to page 19, please, picking it up at the bottom of that page, last paragraph there:

"The regional transfusion directors at their meeting in May 1983 decided to prepare a leaflet

asking donors to self-exclude if they belonged to certain categories of activities which increased the risk of contracting AIDS. The leaflet was issued in [over the page] September 1983 and in the NW region this was distributed to prospective donors with their call up letters for donation and was distributed to factory donors on recruitment."

So we know that that was left to -- the method of distribution was left to the Regional Transfusion Directors' discretion, and we can see here what Dr Gunson chose to do.

If we then go over the page, please, in the last paragraph there he's talking there about donor selection policies. He says:

"I did indeed adopt a policy of destroying or marking for non-use blood offered by donors who on enquiry revealed or gave the impression of being homosexuals, bisexuals, intravenous drug abusers or other high risk donors. This was part of the standing operative procedure. The majority of such donors were rejected on sessions, but of those who donated, the resulting donation was withdrawn from use and destroyed. This was done in conjunction with Mr P Howell. The policy was instituted in 1983. A system was arranged so that when sessions were

completed and blood returned to the regional transfusion centre, any comments that a particular donation came from an at risk person was reported by the sessional doctor to me in confidence and this to the donation being removed from those prepared for issue."

SIR BRIAN LANGSTAFF: I think the word "led" must be missing.

MS SCOTT: Yes.

"This was co-ordinated with the sending of the leaflet. The system was maintained until the test was instituted, when a new set of operating procedures based on the test results was instituted, whilst still maintaining the previous reporting arrangements."

So there seemed to be a sort of two-stage system. Some people would have been excluded before donating blood as a result of the information given to them at the session but there seems to be a sort of an additional layer, if you like, where, if there are some concerns about a donor, this would be reported in confidence to Dr Gunson and the donation would be removed and destroyed.

I'm going to move now to 1985 and can we look, please, at CBLA0001989.

This, we can see, is a letter to Mr Pettet of

the Blood Products Laboratory dated 18 January 1985, and if we look at the bottom there we can see it is from Dr Gunson. This is a letter in relation to heat-treated product. So what Dr Gunson is there saying is that it had been decided in the region by that date, by 18 January 1985, that:

"... all commercial Factor VIII concentrate to be used from the present time will be heat-treated. However, it is not yet clear whether we will be able to maintain a haemophilic therapy on heat-treated material since it will depend upon the number of emergencies that are admitted between now and the 1st April. Routine non-urgent surgery on haemophilic patients has been postponed until supplies of heat-treated material become more readily available."

He therefore says he has reviewed the stocks of untreated material held at the Centre and doesn't want any more of that because he doesn't want to incur wastage in the future. So therefore he cancels the allocation of untreated material that was going to be sent to him but says that he would still like his allocation of heat-treated material and makes it clear that if they run into difficulties they may have to order some unheat-treated materials in the future.

Then he says at the bottom:

"As you can imagine with the suspension of surgery, there will be a build-up following April and I think that we will be able to receive the number of bottles which you would then allocate to us subsequent to the availability of heat-treated material following 1st April, 1985. I recognise, of course, that this will not be the same number of units due to losses during heating."

So that suggests that there was a policy of suspending surgery in the north-west region.

Then, turning to the question of screening, can we look, please, at DHSC0000406.

We can see here that this is a report from the working party of the Regional Transfusion Directors' Committee on "Screening of blood donations for anti-HTLV III in regional blood transfusion centres", and we can see that Dr Gunson is a member of that working party.

We can see at paragraph 2 that:

"The contents of this document have been approved at full meetings of ... [RTD] Directors' Committee and the SNBTS Directors' Committee."

We can see at 3 that it says -- what it says about the introduction of the screening test:

"It was agreed that routine screening tests for

anti-HTLV III should not be introduced until the following had taken place:

"3.1 The proposed evaluation in the NBTS of different test kits has enabled satisfactory system(s) to be selected.

"3.2 The establishment of Reference Centres for the purposes of carrying out nationally agreed confirmatory tests on sera giving positive results upon screening.

"3.3 The establishment of alternative venues for anti-HTLV III tests on members of the General Public who are not blood donors."

Then it says:

"It was further agreed that the introduction of anti-HTLV III testing in Regional Transfusion Centres should take place throughout the UK over the shortest period practicable following the agreed starting date."

Then the document sets out the process that will be undertaken during the screening procedure, what will happen if somebody tests negative, what will happen if there is a positive reaction to the test.

Can we go over then to page 3, the "Procedures for the health care of donors":

"5.1 All donors will be notified before donating,

by being sent or given a leaflet, that their donation will be tested for anti-HTLV III ... Donors will be asked to confirm that they agree to the test being carried out ..."

The information that is given to the blood donors and the consent form are both annexed to this document.

So it's clear that the process that was agreed was that the donors would be consenting to their blood being tested for HTLV-III.

Then it goes on to talk about donor counselling:

"5.2 On receipt of the first CONFIRMED positive result for anti-HTLV III the donor will be sent a letter by a member of the consultant staff at the Regional Transfusion Centre."

A specimen letter is set out and we don't need to turn to it but it's expressed in these terms:

"Dear donor,

"Examination of your blood has shown that it contains properties which may be important to your health. We should like you to attend to see Dr [blank] to discuss this and take a further small sample of blood."

They are asked to then fix an appointment.

So they're alerted by letter that there is

a problem, called in, and then -- rather than being told by letter that they have tested positive for HTLV-III.

Then it says:

"An early point will be arranged for the donor to be interviewed by a doctor from the Regional Transfusion Centre, who has been trained in counselling."

Then:

"During this interview the significance of a positive anti-HTLV III result will be explained. The donor will be asked for the name and address of his Family Doctor and every effort will be mad to ensure that the donor receives further medical consultation and that the results of the tests can be reported to his/her Family Doctor. A further sample of blood will be collected from the donor and sent to the Reference Centre where the original confirmatory tests were carried out."

So the process covered confidentiality, it covered informing the donor of their infection and doing so in person. Then, if we go over the page, the point about sharing of information about the infection has been touched on previously, reporting it to the family doctor, but at 6 it says:

"Systems will be developed within the RTCs to ensure confidentiality of records. Staff within the RTC will have information on a 'need to know' basis."

We can then see -- so that's the national policy. We can then see a document that relates to the policy implemented in Manchester, NHBT0113679.

This, we can see, is a departmental memorandum from Dr Gunson to Mrs G Oates dated 19 August 1985, and it's titled "Introduction of routine anti-HTLV III screening for blood donations". It says -- at the beginning it makes it clear that the DHSS has written to the regional general managers asking that financial provision be made for screening for anti-HTLV-III, and the north-west region created a reserve for this purpose. So this suggests that there was no central funding for HTLV-III testing.

It then goes on to talk about the fact that the test kits are being evaluated, including at Manchester, but the results of those evaluations are not yet ready but it's hoped to commence routine screening throughout the UK by October 1985 and the purpose of the memorandum is to set out the process that will take place in the north-west region.

Then we can see the "Procedure for screening donations". Reference is made to the leaflet that has

been created by the DHSS and that that will be provided with call-up cards or letters.

Then if we go down to paragraph 2.3 the arrangements for confirmatory tests are set out. So because there are false positives confirmatory tests will be sent to:

"... PHLS Withington [Public Health Laboratory Service in Withington], which has been designed as a Reference Laboratory. The donor will not be informed of a positive test unless the BTS screening tests have been confirmed by the PHLS.

"The initial contact with a donor [at 2.4] whose positive result has been confirmed will be made by a doctor of the BTS who has had special training in counselling for such an event. To this end, I have arranged for Dr Douglas Lee (Lancaster) and Dr Vanessa Martlew (Manchester) to attend a course for consultants at St Mary's [if we go over the page] Hospital, Paddington. The course has been especially designed to cover the problems involved in informing donors that they are anti-HTLV III positive.

"On their return, they will hold meetings to impart this information to other medical staff in the Transfusion Service.

"After this initial interview with the donor,

provision will be required for the donor to attend a specialist outside the BTS for further advice and treatment if required. I understand that the RHA are considering the provision of such services through the *ad hoc* Committee chaired by Professor Longson."

It then goes on to talk about confidentiality of records within the Transfusion Service and then, at 2.6, it says this:

"Alternative venues for anti-HTLV III tests. It is important that by the time the BTS is ready to commence screening of blood donations that facilities are available for persons other than blood donors to have samples taken for HTLV III tests. If this is not available there is a danger that such persons may ignore our request to avoid donating blood and present as blood donors just to find out if they are anti-HTLV III positive. They may have the effect of rendering the blood supply less safe than at present since there could be a percentage of these persons who have the virus in their blood but who have not yet developed the antibody, which is all we can detect. Such blood would be regarded as safe for use and yet be infective."

So we can see the plans being made by Dr Gunson in August in advance of the screening coming in for his

region and all the different elements at play there.

If we can then turn, please, to NHBT0004296, and we can see here a letter from Dr Gunson to Dr Smithies in the Department of Health and Social Security, dated 28 October 1985, and he says this:

"I write to confirm that we commenced testing for anti-HTLV III on 17th September, 1985, in order to fully establish the procedure before the due date. This has enabled us to have all products now available in hospitals and the Centres at Manchester and Lancaster tested for anti-HTLV III and none are being issued without testing, unless specifically ordered in an emergency for which responsibility is taken by the person in charge of the patient.

"The small amount of fresh frozen plasma that was lodged at hospitals prior to testing has been withdrawn and replaced."

Then if we just turn back to his statement for the HIV litigation, NHBT0020196_001, and if we go, please, to page 24. At the bottom of that page:

"When anti-HIV screening was commenced on 14th October 1985 [so he is giving there a national date], all other donations held in the RTC and Lancaster Centre were tested, so that all blood issued from that day had been screened for anti-HIV."

Then if we go over the page:

"There was still blood in hospitals which was untested on this date, but the hospitals usually only had 2-3 days supply and so we were sure that tested blood would soon become exclusively available in this region."

So slightly different account given there from the one we see in the letter to Dr Smithies. The account in this statement suggests that there may still be, for two or three days after 14 October, blood being used in the region that was not screened, whereas the letter to Dr Smithies suggests that, because they had started screening from 14 September, that that would be unlikely.

SIR BRIAN LANGSTAFF: They didn't -- but as of 14 September, they didn't say they were screening all donations, did they?

MS SCOTT: No, that is true. That is correct, yes.

SIR BRIAN LANGSTAFF: So it's not necessarily inconsistent.

MS SCOTT: Sir, having looked at that again, sir, I think you are right about that. The two can be read in a consistent way, yes.

SIR BRIAN LANGSTAFF: The consistent way would be we started trying to out what it will look at but we're

not doing everything at the moment.

MS SCOTT: Exactly, and so there would still be some products in use after 15 October that were untested, for two to three days.

Then just lastly on AIDS and HIV, can we go please to NH -- no, sorry, BPLL0010094, and if we go to page 2 of that document, please. We can see this is a minute of a meeting of experts to advise on the disposal of the plasma stockpile at the BPL Elstree, held on 16 January 1987. We can see Dr Gunson was one of the attendees of that meeting.

If we look at what it says at the Chairman's introduction:

"Dr Abrams from the chair explained to the group that they were being asked to advise DHSS on the disposal of the stockpile of 50 tonnes of fresh frozen plasma ... and 126 tonnes of time expired plasma ... presently held in cold storage at BPL and untested for HIV antibody. He asked that the group should give advice based on scientific principles and leave financial, resource and political considerations for DHSS consideration."

Then it goes on:

"Feasibility of Retrospectively validating FFP [fresh frozen plasma].

"Dr Gunson tabled a paper which reported the results of a feasibility study to determine whether the current HIV antibody status of donors who had contributed plasma to the FFP stockpile could be determined. He concluded that 65% to 70% of the sample of single donations of FFP examined was obtained from donors who had donated again after 14th October 1985 and who had been found anti-HIV negative."

So there is then a discussion about whether or not, if you could identify which donations they were, you could release those for use:

"The Chairman [over the page, third paragraph down] summarised the consensus view that it would be safe (for some purposes ...) to use [that plasma] which was obtained from donors subsequently shown to be anti-HIV negative", and subsequently referred to as "retrospectively validated [fresh frozen plasma]".

Then they go on, over the page to -- they then consider what use the retrospectively validated fresh frozen plasma could be put to and Dr Gunson -- if we look down at paragraph 5, at the bottom there:

"... Dr Gunson felt that since the plasma would effectively have the same status as normal donations it should be used for Factor 8 as well", and they were

having a discussion about as well as for albumin production.

There is a difference of view in relation to that but, if we go over the page -- I'm sorry. Sorry page 4. I've gone one page too -- back to page 4. They agree -- "All agreed this plasma could be used", if we go up a bit, above 7:

"All agreed this plasma could be used for commissioning the new plant for which some 15 tons plasma would be required."

They then go on to discuss uses of the unvalidated fresh frozen plasma, and whether or not it can be utilised, at paragraph 8, in the early stages of commissioning non-sterile equipment:

"The consensus view on scientific grounds was it would be acceptable to use the plasma for this purpose although reservations of a practical nature were held by several members."

Then they go on to have a discussion about the use of time-expired plasma, and they agreed that it was unacceptable that it should be given to patients abroad where it wouldn't be acceptable for use in the UK.

So, sir, those were all the documents I wanted to draw your attention about HIV and AIDS. There are

many more documents referred to in the written presentation that accompanies this oral presentation.

Sir, the next topic I wanted to address was the response to non-A, non-B hepatitis, or hepatitis C, and I'm going to refer you to a handful of documents that are relevant to surrogate testing and Dr Gunson's role and views, insofar as we can elicit them, on surrogate testing.

We know from the documents and, indeed, from Dr Gunson's statement for the HCV -- for the *Re A & Others* hepatitis litigation, which we will be looking at later on today, but we don't need to turn to now, but for the transcript it's NHBT0000026_009, that he and Dr McClelland made an application in 1981 to the Medical Research Council Blood and Transfusion Research Committee, of which Dr Gunson happened to be the chair, for a grant to set up a prospective study to investigate transfusion-associated non-A, non-B hepatitis.

That grant was refused and the committee was disbanded in 1982. So there were early attempts by Dr Gunson to study, as I understand it, the prevalence of non-A, non-B.

We do know that the DHSS did fund a multi-centre trial of surrogate testing and, in fact, I am going to

look at the statement now, sorry, NHBT0000026_009. That's the front page of the statement. If we turn, please, to page 23, I think it is -- no, 24 -- we can see the part that Dr Gunson played in that:

"In April 1987 I submitted an application to the DHSS for a grant for a multi-centre study of ALT and anti-HBc screening of donations. It was proposed that the three RTCs in England -- Manchester, North London and Bristol -- and one in Scotland -- Edinburgh -- would carry out the study. The plan was to test 12,000 donors in a period of six months and, by interviewing the donors with elevated ALT levels and those who were anti-HBc positive, to determine not only the rates but also any aetiological factors contributing to elevated ALT values and the significance of anti-HBc positive donors."

Then if we go down to paragraph 64:

"The DHSS approved my application on 28th April 1988 and the trial proceeded in the English RTCs. 3,000-3,600 donors were tested for ALT and anti-HBc at each RTC. The study was managed by a steering committee, of which I was a member. The Chairman was Dr Marcela Contreras, [Dr John Barbara and Dr Rafaat were also involved]."

We don't need to turn to these now but, for the

transcript, the proposal for that study is PRSE0002161 and the results are PRSE0000290.

The Council of Europe held a meeting of the Committee of Experts on blood transfusion and immunohaematology in May 1987, which Dr Gunson attended, and we can see -- if we have a look at SBTS0003040_001, we can see this is a document which has an extract -- you see Council of Europe, European Health Committee. In fact, extract -- it's below "Extract from the report of the Committee of Experts on Blood Transfusion and Immunohaematology, 10th meeting ... 19-22 May 1987".

If we go over the page, we can see the title "Non-A, Non-B Hepatitis -- testing of blood for indirect evidence of infectivity", and then the report sets out the synthesis of the replies from the members, and I don't intend to look at that in any detail, but we can see from this that, at page 3, what Dr Gunson was reporting was the position in England at that time, two-thirds of the way down:

"Dr Gunson told the committee that in the United Kingdom a study on a cohort of donors in four centres had been proposed. Each donor would be ALT and anti-HBc tested and those with abnormal results would be assessed clinically in order to try and establish

their potential risk in respect of the transmission of [non-A, non-B]. This study would also yield important information on the loss of donors and donor management."

Then he says:

"Proposals for a prospective study on patients transfused with blood with normal and raised ALT levels had not received ethical approval."

So a recipient study was not going to go ahead.

Then we can see the conclusions of the working group at page 5:

"On the basis of this information the working group concluded that:

"1. The use of non-specific test for the purpose of reducing the incidence of transfusion-associated [non-A, non-B] ... and its possible value as a public health measure remain controversial issues.

"2. If a stance is taken that blood should have maximum safety then the tests would be introduced but the benefits derived from this testing would not be uniform throughout every country. Also, there is no guarantee that, in a given country, there will be a significant reduction in the transmission of [non-A, non-B] hepatitis.

"3. The introduction of non-specific tests could lead in some countries to a severe depletion of blood donors which may compromise the blood supply and this is a factor which must be taken into account.

"4. When non-specific testing is introduced in a country, provision must be made for the interviewing, counselling and further medical examination and treatment that may be required for donors found to have a raised ALT or who are anti-HBc positive.

"5. The committee cannot give a general recommendation on the introduction routinely of non-specific tests for evidence [non-A, non-B] infectivity of blood donors. Individual countries will have to assess the situation locally and decide on the appropriate action to take."

Then Dr Gunson wrote a report arising out of this meeting, which we don't need to go to but for reference it is NHBT0008816_002.

Sir, I'm about to jump forward a couple of years in the surrogate screening story, so I wonder if now is a convenient time for a break?

SIR BRIAN LANGSTAFF: Yes, it is. We will take a break then until 11.45.

(11.12 am)

(A short break)

(11.46 am)

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: I'm going to move on to 1989 now and we can see from a letter that Dr Gunson wrote to Dr Smith at the DHSS -- which we don't need to turn up but for the transcript is NHBT0000014_033 -- he wrote the letter on 6 January 1989, that as a result of the Chiron -- what came to be known as the hepatitis C test -- coming on line that he was suggesting that 1,000 of the samples from the multi-centre surrogate testing trial, so 1,000 of those samples where the samples either had raised ALT or anti-HBc results, should be tested against the new Chiron test, and he describes that as an excellent opportunity for the trial.

Can we then turn, please, to NHBT0000043_002, which is a minute of a meeting on 24 February 1989 of the UK Advisory Committee on transfusion-transmitted diseases, and if we look at the second page we can see that Dr Gunson is an attendee.

Then if we turn over, please, to the fifth page, under "Non-A, non-B Hepatitis", Dr Contreras outlined the results of the study in England and Wales -- so that, as I understand it, is the study we have just been talking about, surrogate testing study. Then if

we go down to 7.4:

"It was agreed that there should be no recommendation to institute ALT testing until the current study was completed in England. However, there was a degree of inevitability about the introduction of the test which was required by regulatory authorities in other countries to determine the acceptability of fractionated plasma products. This would be discussed with BPL in the near future."

So the position then, in February 1989, was: no decision now but inevitable that surrogate testing will be brought in.

Of course, we know ultimately it wasn't and -- well, except in limited circumstances, I'm going to come to that in a moment. It would be helpful to look perhaps at what Dr Gunson says about this in his statement for the hepatitis litigation.

Can we have NHBT0000026_009. Can we go to page 27 of that, please.

He makes the point there at paragraph 66:

"I do not believe that the NBTS should have introduced surrogate testing for [non-A, non-B], whether by screening for raised ALT levels or anti-HBc, at any time between 1988 and 1991."

He goes on to say:

"I do not believe that recipients of blood or blood products derived from donors who had not been so screened -- whether in the UK or in the Netherlands or any of the other countries which decided not to introduce such screening -- were receiving a product which was less safe than they were entitled to expect."

There was, however, surrogate screening brought in in a limited respect, and that was referred to by Ms Richards yesterday, and she gave you the references but didn't take you to the documents but I'm going to do that.

So could we look at the first one, NHBT0000027_011.

This is a letter to Dr Gunson from -- if we go over the page -- Dr Cash, dated 12 January 1990.

Go back over to the first page, please:

"ALT Donation Testing: Plasmapheresis Donations.

"A chance conversation with Marcela Contreras has revealed that a policy decision has been made requiring all NBTS RTCs to commence routine ALT donation testing of plasmapheresis donations on 1st April 1990."

Then next paragraph, second sentence:

"We were both conscious of our (SNBTS) published

professional views on the matter and the subsequent assurance we gave to you that Scotland would not introduce any form of routine surrogate [non-A, non-B] donation testing, unless it was a joint UK exercise and one which, like the HIV-1 donation testing, had Ministerial approval."

He goes on to say:

"On the assumption that Marcela's news is correct, I wonder where that leaves us all?

I suggest, with the deepest and most profound regret, that it looks as through the NBTS and SNBTS must go their separate ways in regard to quality assurance.

I would have thought that with all the emerging litigation associated with blood and blood products, particularly against the background of the new product liability laws, this must surely have signalled the beginning of something so desperately needed for the last 30 years -- a coming together on policy and operational matters of the NBTS and SNBTS."

The reply from Dr Gunson, which we find at NHBT0000027_012, dated 16 January 1990, and he says, second sentence of the first paragraph:

"I honestly thought that you knew all about this development since it was discussed at the Transfusion Transmitted Diseases Committee where I recall I said

that we were under considerable pressure to perform ALT testing for the production of iV Ig [immunoglobulin]. You will recall also that you and I discussed, in some detail, the report that was sent to the DOH on anti-HCV testing and that after some difficulty we agreed the recommendation which appears at item 7.5, viz ..."

Then he quotes from the report:

"'The routine introduction of non-specific tests should be deferred unless this is necessary for the acquisition of product licences in the UK for fractionated plasma products. It is the intention of the Committee to keep this topic under close review.'

"The purpose of the present testing is just for this reason. BPL wish to obtain a licence for iV Ig production and the licence requires the plasma to be ALT tested. We are restricting the testing to plasma collected by apheresis because of the implications of ALT testing all blood donations."

So it would appear that there was some limited testing, surrogate testing, of some plasma, for commercial reasons, to BPL.

I'm going to move on now to hepatitis C testing. I'm going to start by looking at PRSE0002340.

This is a letter dated 18 August 1989 to

all RTDs and it is from Dr Gunson. Then he says, the third paragraph down -- he says in the second paragraph he's forgotten to mention some issues about policy aspects about anti-HIV 1 and 2 and anti-HCV, and he says in the third paragraph:

"It is important that we act in a co-ordinated manner nationally and also with Scotland with the introduction of these tests with respect to the routine screening of donations. There will have to be approval of the DH before they are introduced and the means of obtaining this is the agreement of the DH's Committee on the Virological Safety of Blood ... next [meeting] on 17th October 1989."

Then he goes on at the bottom of that page to say that the:

"Anti-HCV is being evaluated ... in North London and the Glasgow ... [transfusion centres]."

But what he says -- the reason for the letter is right at the bottom of that first page:

"There are many aspects to clarify before routine testing can commence, although I think it would be prudent to include the cost of this test as a development in your budgets for 1990/91."

So the expectation is, at that stage, that RHAs, Regional Health Authorities, will have to find some

money for routine testing of donations for hepatitis C.

We can then pick it up, please, at NHBT0005043, which is a meeting of the Advisory -- ACVSB on 16 November 1989, and this is in Dr Gunson's oral evidence for the A & Others litigation. This he describes as the point -- the meeting at which the decision was made to introduce testing for hepatitis C in principle.

If we can look, please, at page 4 and we see under "Non-A Non-B Hepatitis", paragraph 23, that Dr Gunson speaks to a paper, and he says there:

"The conclusions of the BTS committee that the test will detect a viral marker to [non-A, non-B], a positive test may mean blood is infected (but not always), and that routine testing for anti-HCV will reduce [non-A, non-B], but estimates of the extent of the reduction range from 20%-60%. The problems ... [are] lack of a confirmatory test, and a question mark hanging over the status of the ALT and anti-HBc testing. The recommendations were that routine screening should be introduced only after a confirmatory test becomes available ..."

Is the first condition. Secondly:

"... after the FDA have approved the test and

[thirdly] urgent pilot studies have been carried out in this country."

Then if we go down to paragraph 26 we can see what Dr Metters from the Department was saying:

"[He] explained that although the Department must bear in mind the possible litigation that could arise from a prolonged delay in the introduction of general screening, the NHS Management Executive would want to know more facts and figures before backing such a move."

Then if we go over to paragraph 28 on the following page:

"The feeling of the Committee, as summed up by the Chairman, was that the test represented a major step forward, but that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test. It was agreed that while the UK would not want to go on in advance of an FDA decision, it could prove difficult if the FDA did not decide in favour of the test. Nevertheless, it was felt that if the UK do the test into general use RTCs will need to have had experience with it, and therefore pilot studies should go on in Birmingham, Sheffield and Brentwood, to show the feasibility of adding this test to routine practice."

Then in the following paragraph the Committee comes to the view that there's no case for surrogate testing.

So that was the position in November 1990. The report that Dr Gunson spoke to -- and we don't need to go to that but, just for the transcript, it's NHBT0000188_072. So the requirement there for FDA approval, Food and Drug Administration in America approval, of the test is an issue that we see returned to in the papers and Dr Gunson gave some evidence about that in his oral evidence for the *A & others* hepatitis C litigation.

If we could just turn that up it's NHBT0000148_001. If we could go -- we can see from the first page that this is the oral evidence he gave on Thursday, 26 October 2000 and he is being cross-examined by Mr Brown, counsel for the defendants.

If we go please to page 26 of that, we can see what he says about FDA approval. So if we start, please, at line 1285 -- 1280, let's start with Mr Justice Burton:

"Why did you need to wait for the US domestic test to be done when it seemed FDA regarded it as sufficient to allow you to have it on the

understanding you would carry out your own tests, which you were perfectly capable of doing.

"A. The Department of Health were anxious to have the FDA approval before we started testing, because it was a test that had been developed in the United States and they considered that it would be very embarrassing if we had started testing using this test and the FDA came along and said, 'This test is deficient and you cannot use it in the United States'.

"Mr Brown: I want to look at that, please. Were the Department of Health similarly anxious to restrict introduction of the second generation until it had FDA approval.

"A. No, they were not.

"Q. Why not? Why was there any difference?

"A. Because we had done considerable testing of the second generation.

"Q. If you had done considerable testing of the first generation assay the Department of Health would have been satisfied?

"A. That may well have been so."

Can we go back, as well, to pick something up he says on page 25, about the second -- if we go to 1240, he started that answer explaining what the FDA approval is and why it's required, and then he says at

1240:

"Indeed, with the second generation test, we did not wait for FDA approval and indeed it was late in the United States and they were using the second generation considerably after it had been used extensively in Europe."

Another document, sir, that I wish to draw your attention to, in relation to the condition about -- that we saw imposed at the November 1989 meeting, regarding introduction of HCV testing about confirmatory testing, is NHBT0071870_002, which is a minute of the National Directorate of the NBTS National Management Committee, 4 January 1990, with Dr Gunson in the chair.

If we could go, please, to page 5, this is in the section of the meeting where they are discussing the pilot trial on anti-HCV testing. If we could go to fifth paragraph down it starts "With regard to":

"With regard to the absence of a confirmatory test Dr Gunson advised the Committee that the ACVSB did not see this necessarily as a barrier to the introduction of routine screening but the ACVSB would insist that any test for routine use must have been licensed by the FDA. Some progress had been made towards a confirmatory test using the same antigen in

blot form and this may well be available at the end of January."

So a slightly different complexion put in by Dr Gunson to what's recorded in the minute of that November 1989 meeting, where it seemed to suggest that it was, in fact, a pre-condition of introduction of HCV testing that there should be a confirmatory test. Something slightly different is being said here, and it's not clear which is an accurate summary of what was said at that meeting.

We understand from Dr Gunson's statement in the hepatitis C litigation, which we don't need to turn up now, that the pilot study was completed and reported to the ACVSB at the meeting on 17 January 1990, and we can see that meeting -- we don't need to turn that up but PRSE0001477.

I just want to turn back to the oral evidence given by Dr Gunson in *A & others* to see what he said the major steps were in the chronology of hepatitis C testing. So go back to NHBT0000148_001. So we're on the same day of cross-examination of 26 October. If we turn please to page 52.

SIR BRIAN LANGSTAFF: Yes, I think you said earlier that Mr Brown was representing the defendants. Plainly he wasn't, if this is cross-examination.

MS SCOTT: Yes, sorry.

So if we go to line 2568, and the question is:

"When do you say, Dr Gunson, that the ACVSB decided in principle -- because that was their task -- to recommend the introduction of routine screening?

"A. I think that in principle was in November 1989."

That's what we've already looked at.

"Q. Thank you. When do you say they made their final decision as it were to go ahead?

"A. July 1990, subject to a pilot trial."

Then, if we go over to page 53, if we pick it up at 2610, or 2609:

"Q. So when did you say a decision in principle was made?

"A. I said the decision in principle that we must test was November 1989."

Then at 2615, the judge says:

"I have three dates on Dr Gunson's evidence: November 1989, in principle; July 1990, go ahead subject to the pilot trial; November 1990, final decision.

"Mr Brown: I am content with that summary, my Lord."

Dr Gunson, as the witness, doesn't intervene and

say no, no, that's wrong. So it's a little bit difficult to follow his evidence but my understanding of that is that that is what his evidence was in terms of the major milestones.

So, just for reference, that meeting in July 1990 -- we don't need to turn it up -- is PRSE0000976.

SIR BRIAN LANGSTAFF: A moment or two ago you told me, I think, that the pilot -- a pilot study was completed and reported in January 1990.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: This date suggests the ACVSB decided to go ahead in July 1990, subject to the pilot trial.

MS SCOTT: Yes, so this is a second pilot and then we'll come on to the third.

SIR BRIAN LANGSTAFF: So is this the second pilot for the second generation?

MS SCOTT: No, this is the second pilot -- so by the meeting in July 1990 there was FDA approval of the Chiron test.

SIR BRIAN LANGSTAFF: I think it might help, at some stage, perhaps as a supplement to the presentation, if a chronology is set out as to what's happened.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Because it's not entirely easy to

follow, dotting backwards and forwards from amongst the documents, and I'm concerned that everyone should be able to track it through.

MS SCOTT: Yes. At the July 1990 meeting, the FDA approval had been granted for hepatitis screening, and the trial that was given the go ahead, if you like, at that meeting was the trial to establish which was the better of the two tests that were available at the time: the Ortho or the Abbott test, and there was discussion about whether or not the Wellcome test would be able to join that trial. So that's the trial that Dr Gunson is referring to in his evidence in July 1990.

Then the final decision, as he puts it, in November 1990, we might just look at. It's NHBT0000073_018. That, we can see, is the ACVSB meeting, 21 November 1990. We can see that Dr Gunson is an attender and, if we turn over to page 2, there's an entry "hepatitis C testing", and we go to paragraph 6:

"Dr Gunson introduced his paper ... on the results of the pilot study, saying that the results of the supplementary testing would be the decisive factor when considering whether one screening test was better than the other; both screening tests could be deemed

to be satisfactory for routine use within RTCs from an operational viewpoint and the choice would be influenced by the equipment available in the RTC."

Paragraph 7, Dr Tedder is speaking and he says, halfway through that paragraph:

"Overall, there seemed little to choose between the two screening kits."

So what they are discussing there is that second trial of the difference between the two tests. Then if we go over to page 3, we can see what Dr Gunson articulated as the final decision to go ahead with testing and we see that at paragraph 10:

"The Committee agreed that it was important to start screening as soon as practicable as a measure which would further enhance the ... blood supply."

Then there's discussions about counselling and so on.

So can we then turn to what Dr Gunson says in his litigation statement for the hepatitis C litigation --

SIR BRIAN LANGSTAFF: Can I just understand this. This meeting is when? This is November.

MS SCOTT: November 1990.

SIR BRIAN LANGSTAFF: November 1990, they have decided that, of the two tests which they have been examining,

either would do, they are both satisfactory tests to be used to see whether -- or to the screen out a real risk to blood transfusion recipients, and the committee says get on with it as soon as practicable and it wasn't introduced until nine months later, ten months later.

MS SCOTT: Quite so. I'm just going to show you some documents because, as you can imagine, Dr Gunson was asked questions about that in the litigation.

SIR BRIAN LANGSTAFF: Yes, so what -- can you take us to what he had to say about that.

MS SCOTT: Yes. So the first period of what might be described as delay or was put to him as being delay then, he deals with in his witness statement. So that is NHBT0000026_009, page 34 to begin with, please, paragraph 81. So he describes, effectively, the meeting 21 November, final decision was made to proceed with HCV testing, and he says this:

"... although that decision had to be confirmed by Ministers, and I was not informed that approval had been received until shortly before 22nd January 1991. The issues thereafter related to implementation."

He goes on to say at paragraph 85, which is page 36, he describes how he was informed:

"On 22 January 1991, having been notified on the

telephone by Mr Canavan of the Department of Health that Ministers had approved the introduction of routine screening, I wrote to all RTDs [and asked] for the earliest date on which testing could begin at each RTC."

Indeed, we do have a letter from Dr Gunson written, so he says, on the same day that he was informed that the go ahead had been given by the Department for screening, to all RTDs asking them precisely that question. That letter, I think there's no need to go to it, Ms Richards went to it yesterday, but for reference that letter is NHBT0000076_006.

We see, indeed, Dr Gunson writing more letters to the Regional Transfusion Centre Directors in February 1991. He writes one on 5 February 1991, again we don't need to go to that, but for reference it's NHBT0000062_027, suggesting at that stage that the screening should start in June. Then ten days later, on 15 February, suggesting that it might start in July, and that is NHBT0000191_077, and we don't need to go to that.

So, certainly, there is activity by Dr Gunson in trying to get the screening programme up and running shortly after -- once he's heard from the Department.

There then -- the next document that I want to

go to, to try and explain this timing point, is NHBT0000073_063, and it's a document that Ms Richards went to yesterday but it's a significant document in terms of the chronology. We can see that it's a minute of the ACTTD, and we can see that Dr Gunson is in the chair.

If we go to page 2 of that, we can see at 4.11 that:

"The proposed starting date of 1st July presented difficulties since it was considered essential that the second generation test from both Ortho and Abbott should be evaluated prior to the commencement of routine tests."

So here we have what seems to be a third evaluation and this is the second generation evaluation, and that decision is made at that ACTTD committee and you may recall, sir, yesterday, we looked at the difference between the two committees, the ACVSB and the ACTTD, and the ACTTD was dealing with operational issues.

SIR BRIAN LANGSTAFF: You say the decision was made. The decision to recommend was made because --

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: -- the various committees we have been looking at all are recommendations, aren't they?

MS SCOTT: Yes. Well, yes. I think that's correct, although this is -- I think, that is correct, sir, although this committee is dealing with operational matters.

SIR BRIAN LANGSTAFF: Well, it's an advisory committee.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: That's its title.

MS SCOTT: Yes. We see that that is communicated, that that decision is communicated to the RTCs on 3 April 1991 and, if we look at that, that helps us. That is NHBT0000073_065 and, precisely as you say, sir, the way that that's articulated, it's to all Regional Transfusion Directors from Dr Gunson, it's an update from his letter from 15 February, when he suggested that the date might be 1 July, and then he says, in the third paragraph:

"The Department of Health has agreed that there should be a 'second-round' comparative evaluation of anti-HCV test kits at ... Newcastle, North London and Glasgow ..."

So the first round comparative evaluation was the June 1991. There was, of course, preceding that, the pilot trial in 1989. So this is called the second-round comparative evaluation and it's of the second generation tests.

So he there, in that letter, suggests that the start date for screening will, therefore, be put back to 1 September 1991.

Now, we get a little bit more about how this came about in the oral evidence that Dr Gunson gave in the hepatitis C litigation. So if we can turn back to the transcript, please, and this time can we go to NHBT0000146_001. This is evidence he's giving on Tuesday, 24 October and, sir, this is evidence-in-chief, so being asked questions by his own --

SIR BRIAN LANGSTAFF: Well, is it in-chief, or is it re-examination?

MS SCOTT: No, it's --

SIR BRIAN LANGSTAFF: It is in-chief, is it?

MS SCOTT: It's in-chief. He was in-chief for several days.

SIR BRIAN LANGSTAFF: Thank you.

MS SCOTT: If we turn, please, to page 91, and if we start --

SIR BRIAN LANGSTAFF: He says there when the decision was taken at the bottom of the page, doesn't he, to answer the question which I was asking you shortly before.

MS SCOTT: Quite. He says orally:

"It was a decision" --

It was put to him the decision to postpone to 1 September was not taken -- this is right at the bottom, 4547 -- it was put to him:

"Now that decision to postpone was not taken either at the ACVSB or the ACTTD, was it?

He says:

"No, it was taken after a discussion between myself and Dr Pickles."

Then, over the page:

"Q. Who phoned whom?

"A. I think I phoned her.

"Q. And the gist of your discussion was?

"A. It looks as though we are going to have a problem completing these tests by 1st July, perhaps we ought to consider a later date, and I suggested 1st September, to which she agreed, and sent a memo to Dr Metters, who was her chief, because she -- it was she I was discussing it with because she was on holiday at the time."

Then the judge says.

"There are two decisions there then, Dr Gunson. I want to be clear about this. There are two decisions. The first decision is: it is an essential precondition of starting routine screening that there be prior tests on about second generation equipment;

secondly, consequent upon that, it is decided to postpone from 1st July to 1st September.

"Now you have told us about the second decision, but who took, and how and when, the first decision, which does not appear, as you have told us, either to have been the express subject of discussion at either of those two meetings?"

The answer:

"It came I think also in that discussion I had with Dr Pickles, how advisable it would be, and I think it then got to essential; it was sort of drift."

So that's what he says in evidence, but of course, having looked at the minute of the March 1991 ACTTD meeting, that doesn't quite --

SIR BRIAN LANGSTAFF: Just at the bottom of the page Mr Underhill, who is representing the Department of State -- I think --

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: -- said -- this is 4576:

"I am concerned both about the time and indeed the stance so that, as your Lordship knows, I have adopted as regards the evidence of things that happened after 1st April."

The date of 1 April is significant for what

reason? Was that the date from which the Department accepted it certainly should have been introduced or not?

MS SCOTT: So -- yes, I think that's right, because -- I'm going to come on to look at the admissions made by Dr Gunson in his evidence. What I haven't traced through is what that meant in terms of the legal case. I'm not sure without checking what date they actually plumped for, but that would make sense. That would fit with --

SIR BRIAN LANGSTAFF: It may be useful for this Inquiry at any rate to know what, if any, concessions, albeit in the context of this litigation, were made as to the timing at which it is accepted, or was accepted then at any rate, that screening for all blood donations across the UK should have been introduced.

MS SCOTT: I'm certainly going to look at what Dr Gunson said about that, the admissions he makes, because he talks about it in his written statement and orally.

But just on that point, about who made the decision, who made the decision in principle that the second generation testing was essential, well, we've seen that -- the advice given by the ACTTD to the Department, set out in that 25 March '91 minute, and then we've got this evidence from Dr Gunson saying:

well, the Department made the decision -- well, he and Dr -- what he actually says is he and Dr Pickles, I think, made it together, with a memo to Dr Metters and then, between him and Dr Pickles, they decided to move it from 1 July to 1 September in a telephone call.

I just want to draw your attention, sir, to some other aspects of this oral evidence and pick up the point about the admission. Just before we get on to the admission, if we could go, please -- if we could just look -- sticking on this page, can we just see what Dr Gunson says.

So he's asked, at line 4589:

"... which centres did the testing part before 1st September?"

And he's asked to discount Newcastle. Newcastle, sir, as you are I'm sure aware, was the centre where Dr Lloyd was the Regional Transfusion Director, and we heard from Ms Richards yesterday that he started testing early. So discounting Dr Lloyd.

And the answer is:

"It is in my paragraph 94 [of his written statement]. It began at four English centres around the beginning of June, which are Leeds, Liverpool Sheffield and Bristol, and in the Scottish centre at

Glasgow."

So that would be an issue that we'll come back to in the forthcoming hearings.

Then, on the admission point, if we can go, please, first of all, to Dr Gunson's witness statement which is at NHBT0000026_009, and see how he deals with it there. He says -- if we could go, please, to page 41 and paragraph 95:

"Given the date at which the decision to proceed was taken, with which I have dealt above, and given the importance reasonably attached to adopting a common start state for HCV screening, I am sure that a start-date could not reasonably have been set much ... before 1st July 91. There was a great deal of work for the RTCs to do before screening could have been effectively introduced. The further postponement to 1st September 1991 was the consequence of the decision to carry out a trial of the second generation assays. I am sure that the decision was reasonable, given the deficiencies of the first generation test and the absence of any independent evaluation of its successor. But I accept that it would have been possible to adhere to the earlier date [which I take to mean 1 July 1991], using the second generation test and collecting data from all RTCs until the second

generation test had been fully evaluated. With hindsight, I think that it would have been better if we had done so. However, it would only have meant that tests would have been introduced two months earlier, and in five English centres that had occurred in any event."

Then for the sake of completeness I think it is important, sir, to draw your attention to what he says in paragraph 82 of this witness statement, which is in relation to the decision on 21 November 1990, which has been described as the final decision, and this is at page 34, paragraph 82:

"I do not believe that the decision of 21st November 1990 was one which ought to have been made earlier. The factors which influenced the ACVSB in not making a final recommendation earlier appear from the minutes. But I should emphasise in particular the related problems of false positives, confirmatory testing and donor counselling."

Then he goes into detail about those issues which I'm not going to go to now.

Just note, sir -- again, we don't need to turn to it -- that those -- I am calling them "admissions" in the loosest sense of the word but those concessions, I think would be a better way to put it,

that Dr Gunson made are consistent with a letter that he later wrote or that he wrote on 16 February 1999 to a solicitor at Davies Arnold Cooper. We don't need to turn that up, but for your note is NHBT0088808.

Then if we can now just turn to how Dr Gunson dealt with that orally, if we turn back, please, to NHBT0000418_001. Yes, NHBT0000148. I gave you the wrong number.

Again, we're back on the examination by Mr Brown on 26 October, and could we, please, turn to page 24. So Mr Brown, at 1178, he says:

"I want to try the round-up question, Dr Gunson. You had come back from Rome and made a recommendation. You did not make your recommendation to the deciding body, there was about six weeks or indeed close to two months after you got back from Rome?

"A. It is the first time they met after I got back from Rome.

"Q. Let us assume that that body had arranged to meet immediately after this very important conference. Can we assume that, please?

"A. Yes.

"Q. Let us also assume that before Rome we in this country had done what the French had done and had run some extensive pilots?

"A. Yes. May I say, France was really the only country that reported at Rome to have done that.

"Q. I understand that, but you were striving, as your statements of objectives makes plain, to maintain the highest standards and ensure the maximum safety. So I am imposing upon you your own standards, Dr Gunson. Let us assume first that the Committee had met immediately after this very important conference; secondly that we had done some extensive pilots before that conference; third that Dr Cash and Dr Gillon had got their act together about drawing up donor counselling and documentation; fourth that people like Dr Lloyd had approached their local funders to say, 'We will need some money'; fifth,that everyone had said, 'Well, we will have to wait for the excise licence, the export licence, but we do not have wait for FDA approval'; and sixth, and this is the one where we will perhaps part company and I identify it for you, Dr Gunson, everyone had been prepared to say, 'We think there is a confirmatory test just on the horizon. It is desirable but it is not necessary to have on the same day'. If I make all those assumptions, we could have started, could we not, at the turn of the year?

"A. With those assumptions, yes."

He then goes on to give some evidence in relation to FDA approval, which I think we've looked at and then if we pick it up, please, at page 27, at the bottom of page 27, Mr Brown, 1344:

"The only other matter that you identify, making all the assumptions I did about the best will in the world and moving forward and trying to maintain the obligations you set yourself, subject to the need or the desirability for a confirmatory assay, one could have introduced it at the turn of the year?

"A. If the transfusion centres had been able to do so.

"Q. We have looked at why they could not. It is questions of funding, good will, matters of that kind. They have most moved earlier.

"A. Building, possibly.

"MR JUSTICE BURTON: What do you mean 'if', because you are the man who would know?

"A. When I enquired a year later, my Lord, two centres were carrying out building work prior to the necessary -- before introducing the test. So the previous year that building work may well have been required.

"MR JUSTICE BURTON: Can you see if you can, giving all the experience you have to it, and of

course knowing that at that stage you had not been long in place, give an estimate as to whether, in fact, leaving aside the sixth point which Mr Brown is going to ask you about, practicalities would have been such that on balance of probability all or most of the centres could have had it in place at the beginning of the year?

"A. My Lord, I think I said some days ago that in retrospect you could put forward an argument that we could have started earlier.

"MR BROWN: By 'earlier' you mean possibly as early as the beginning of the year?

"A. That I would not like to be committed on, but certainly early in 1990."

SIR BRIAN LANGSTAFF: So the "here" they have been talking about is 1990?

MS SCOTT: Yes.

Sir, then moving on to the issue that Ms Richards addressed you on yesterday, the Dr Lloyd breaking ranks issue and starting testing in his centre earlier than the agreed date on 1 September 1991. I don't propose to take you to many of the documents and, indeed, Ms Richards took you to some of them yesterday and we will be exploring those issues -- those documents in later hearings. I just

do want to take you to one document, which is the response from Dr Gunson to Dr Lloyd when he discovered what had happened, and that is at NHBT0000074_008.

This is 29 April 1991 to Dr Lloyd from Dr Gunson, and it says -- he sets out the history. He says, at the second paragraph:

"I was sorry to learn that you had taken this unilateral decision to proceed with testing without first discussing the issue, not only with me, but with your colleagues in other RTCs, given you must have been aware of the implications for them of your decision."

Then he says that:

"At [the ACVSB meeting] on 21st January 1991, it was agreed that the UK should introduce testing for anti-HCV as soon as practical and the importance of a common starting date for introduction [through] the UK was stressed."

Then he sets out the history, saying to Dr Lloyd:

"I have been keeping you abreast of what has been going on and explaining to you why the date has kept being put back."

Then, if we pick it up over the page, the fourth paragraph down:

"I have written these details in some length to demonstrate that I had kept you fully informed of the national policy with respect to anti-HCV testing. There are still other matters which have not yet been concluded. These principally concern confirmatory tests, the situation with respect to PCR tests, information given to donors prior to testing and the counselling of donors. Later this week, I am sending to all RTDs the minutes of the UK Advisory Committee on Transfusion Transmitted Diseases, in which these matters are discussed, as part of the consultative process."

Then skipping out the next paragraph that then:

"You gave me several reasons over the telephone why you did not consider that you could follow national policy in this matter, and I will be grateful if you could put these in writing to me."

We will pick up the response from Dr Lloyd in due course.

The report there, the information coming out of the ACTTD, as set out by Dr Gunson in that letter, I don't think we need to go to it but, for reference, its NHBT0002876 and that sets out -- it's a compendium of recommendations setting out recommended practice to be implemented by the Regional Transfusion Centres the

following month, and it covers detailed consideration of management and counselling of donors and the evaluation of confirmatory tests, and so on.

Sir, there is just one more document that I want to take you to in relation to HCV and that's on prevalence, or at least Dr Gunson's views on prevalence, and that is PRSE0002161. In fact, I'm not really interested in this -- this is the proposal for the multi-centre trial study of surrogate testing, and it's actually an annex to this that I want to take you to. So if we could go, please, to page 10 of that document and we can see there Appendix 1, and it's called "Alanine Amino-transferase (ALT) and Hepatitis B-Core (Anti-HBc) Screening of Blood Donations".

If we go over, please, to, page 14, we can see that, at page 5, at the bottom there, page 5 of that appendix, right at the bottom, we've got Dr Gunson October 1986. So if we could please go back to page 1.

So what he is doing in this paper is setting out his views on the prevalence of hepatitis C or non-A, non-B, and I'll go through it in a little bit of detail but, of course, that's one of the questions for the Inquiry, and no doubt this issue will be

considered in due course on a number of occasions, including by the expert group of statisticians.

So what Dr Gunson is looking at is, first of all, prevalence and, secondly, flowing from that, the cost to the donor population from the introduction of surrogate testing.

Looking, first of all, at prevalence, he does a review of the literature and, in the last paragraph of this first page, he looks at -- this is page 10. Sorry, that's why, I'm telling you the wrong page. First page of the annex, I meant. Thank you.

Last page -- the last paragraph of the first page of the appendix, he reviews the literature, such as it is, on prevalence of non-A, non-B in the UK and he considers the MRC study from between 1968 and 1971, and he considers a much smaller study of 248 patients undergoing cardiac surgery, who received an average of just over six units of blood.

He concludes -- he finds in there, that the MRC study has an incidence of 2.5 -- an overall incidence, we can see, four lines up from that paragraph, the overall incidence of 2.5 per cent and he concludes that the Collins study, the smaller cardiac study, has, three lines up, an instance of 3.2 per cent.

If we go then over to page 13, we can see his

conclusions. I have gone to that paragraph to try and understand his conclusions. The matters for consideration:

"1. Incidence of Transfusion Associated [non-A, non-B] Hepatitis in the UK.

"The best estimate of incidence from published data is 3%."

Now, I don't know where that figure comes from. I'm surmising that it comes from somewhere between 2.5 and 3.2, but I don't know.

SIR BRIAN LANGSTAFF: By "incidence" there, is he talking about the incidence of the hepatitis after transfusion or is he talking about the incidence in the population, the donor population?

MS SCOTT: Again, I don't know, but he is -- well, it's under 1, instance of transfusion associated --

SIR BRIAN LANGSTAFF: Yes, I follow the heading, but what he has been talking about as ranging between 2.5 and just over 3 per cent from the studies of Collins and others is population prevalence, isn't it? Have I got that wrong?

MS SCOTT: Can we just go back, please, to page 10. Yes, so incidence -- so first line there, it's difficult to estimate the incidence of transfusion-associated non-A, non-B hepatitis in the UK and then he comes to

the view -- yes, he talks about an overall incidence of 2.5 per cent. I think that's correct. It's difficult to see because the Collins study seems the way that he's written it seems to suggest it's following transfusion.

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: So he may be looking at two different things.

SIR BRIAN LANGSTAFF: It would be much clearer, I think, if -- looking at the original papers.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: So the figure of 3 per cent may well be after transfusion?

MS SCOTT: Yes. That, I have to say, is how I had read it.

SIR BRIAN LANGSTAFF: That would fit with the heading, you are quite right.

MS SCOTT: Yes. Then, with what he says afterwards:

"If one assumes that the 2.3 million donations in the UK are transfused to 750,000 recipients annually ..."

SIR BRIAN LANGSTAFF: You are reading from a page, which isn't in front of us, so we need to go back.

MS SCOTT: Sorry. Yes, we need to go to page 13. "Matters for Consideration" 1, so we got to the 3 per cent, and then:

"If one assumes that the 2.3 million donations in the UK are transfused to 750,000 recipients annually, (possibly a more accurate assessment should and could be made), then one would expect 22,500 icteric or anicteric cases of [non-A, non-B] hepatitis each year. If the morbidity pattern of the disease is similar to that in the USA then one might expect half of these patients to have chronic ALT elevation 10%, ie 2250, to develop cirrhosis."

Then he goes on to say:

"Projected value of ALT and anti-HBc screening in prevention of transfusion associated [non-A, non-B] Hepatitis.

"If 30-40% of [non-A, non-B] hepatitis could be prevented by the use of the above tests, then the reduction in the number of cases would be 6750-900 per year and by extrapolations; 675-900 cases of cirrhosis."

So I think that must mean 9,000, that first "900". Then he sets out some qualifications.

SIR BRIAN LANGSTAFF: Yes.

MS SCOTT: Then at paragraph 3, at the bottom:

"Effect of ALT and Anti-HBc Screening on Blood Collection.

"From the evidence available in the UK one might

expect that ALT screening will cause the loss of 0.7-0.9% of donations and anti-HBc in the order of 1%."

Again, it's not clear how he's come to that figure:

"[But] Presumably there will be some overlap in the ALT and anti-HBc results but one might expect a loss of donations of approximately 1.5-1.75%."

Then over the page he sets out some qualifications in relation to that.

So clearly this is an issue that the Inquiry will need to look at very carefully but I just bring this, sir, to your attention because this appears to be the view of Dr Gunson on the issue of incidence and impact of surrogate testing as of October 1986.

Sir, I don't intend to draw your attention to any more documents in relation to hepatitis C or non-A, non-B. I do just have one more document which I wish to draw your attention to before concluding this presentation, and that is at DHSC0002941_006.

This is a note of a meeting dated 21 February 1992, and we can see that it's entitled "HIV Infected Blood/Tissue Recipients", and we can see present at the meeting Dr Rejman, from the DH, including -- a number of attendees, including

Dr Rejman, and then we've got attendees from the CDSC and then we've also got Dr Gunson attending from the NBTS.

This appears to be a meeting that's being held by the Department of Health in contemplation of setting up a scheme to make payments to those who have been infected by blood and blood products with HIV or are not eligible for payments from the Macfarlane Trust.

So we knew, sir, from the evidence that we heard to date what actually transpired was that the Eileen Trust was set up, but this was a meeting before that, obviously at planning stage.

So the proposed scheme is set out at the top there:

"... submission ... currently with [Secretary of State] seeking agreement to an outline scheme. [Department of Health] outlined their current thinking", and they set out what their intention is.

So:

"The intention was to pay as soon as possible a first batch of cases which had already been validated."

Then it says:

"Payments would be made probably by the

Department without a handling organisation, in view of difficulties involved in extending the remit of the Macfarlane Trust."

We know that didn't transpire.

Then it says:

"A draft application form was tabled for comments. The form would

"-- be signed by a medical 'sponsor' (more than one medical practitioner may be needed to provide information in respect of the transfusion and the HIV status) ..."

Then if we go down, please, to the bottom paragraph:

"A unit would need to be set up, probably in the Department, to screen applications; anything contentious would be referred to the Panel."

Sir, you will recall the evidence that we heard in relation to the Eileen Trust was precisely that, that the Department made the decision about eligibility, and only once the Department had decided that somebody was eligible for payments under the Eileen Trust did it come to the Eileen Trust.

They then talk about the Department writing a procedure and if we could pick it up four lines from the end:

"It would be for the Panel to decide what further information they required, eg PCR testing and what weight to be put on information about [example] lifestyles in individual cases. DH asked NBTS and CDSC what information was available to them to assist in the validation process."

Then if we go over the page, please, we've got -- if we pick it up at "Information available from NBTS", halfway down the page, so this what Dr Gunson says is available in terms of records:

"Pre 1985 library samples of donations in RTCs would be very rare. RTCs hold stored samples for the last 2-3 years and may have stored samples post 1985.

"NBTS hold the donation number of all HIV positive donations, full records of the positive donations held at RTCs.

"All HIV positive donors who could be traced (about 90%), have been informed of their HIV positivity, and told not to donate again.

"NBTS would be in a position to find the donation number from the hospital and trace back to the donor. Where a donor moves from one RTC to another a transfer note should be held to enable the donor to be traced. Difficulties could arise where perhaps as many as 30 units used in one transfusion

would need to be traced.

"During 1987, Dr Tim Wallington, Bristol ... undertook a look back study, and was able to trace recipients from only one third of the seropositive donors due to resistance from consultants and ethical committees. Clinical opinion about the potential benefits of early diagnosis of HIV was now changing and this together with the potential for payments to the patients concerned should lead to greater cooperation."

So, pausing there, Dr Gunson clearly was of the view that it was the consultants' willingness to co-operate that was the a barrier to identifying successful look-back rather than an absence of records. Then:

"Dr Gunson raised the question of funding the additional work that providing information for validation of claims would create."

So, sir, we can see what's being said about what's available. Precisely how the system from the Government -- precisely how the Government, in fact, set up that panel -- if, indeed, they did set up a panel, how they screened those applications for eligibility for what became the Eileen Trust we don't know. We haven't heard any evidence in relation to

that. That is clearly a matter that the Inquiry will be looking at.

Sir, those were the documents that I wished to draw your attention to in oral presentation. As I say, there is a much longer written presentation which will be published on the website in due course that accompanies this oral presentation.

SIR BRIAN LANGSTAFF: Yes. That will link together the various documents which you have been showing me?

MS SCOTT: Indeed, it will, yes.

And, sir, we will certainly take up the suggestion to publish a chronology relating to, in particular, hepatitis C testing, because it is complex.

SIR BRIAN LANGSTAFF: Yes. That will be, I think, very helpful indeed. Thank you very much. Now, what's next?

MS SCOTT: So next week, on Tuesday, we start with the oral evidence from regional transfusion centre directors, and we will start with Dr Napier, who was the director of the Cardiff centre, and he will give evidence over Tuesday and Wednesday.

SIR BRIAN LANGSTAFF: And he will be giving evidence remotely?

MS SCOTT: He will be giving evidence remotely, yes.

SIR BRIAN LANGSTAFF: Very well. In that case, we break now. After, I hope, you will enjoy a lunch together, those of you who wish to, and I shall see those of you who come back next week on Tuesday, 10.00, Dr Napier. Those of you, who are watching online, it is 10.00 next week, where we start with Dr Napier's evidence remotely from Cardiff. Thank you very much.

(12.59 pm)

(Adjourned until Tuesday, 16 November 2021 at 10.00 am)

MS SCOTT: [57] 1/6 2/9 2/16 2/22 2/24 3/1 6/5 11/18 11/23 12/5 12/16 12/20 12/23 17/13 17/16 19/12 19/15 19/21 20/2 20/4 28/9 38/18 38/21 39/2 47/4 59/1 60/11 60/14 60/18 60/24 61/4 62/23 63/7 63/12 65/23 66/1 66/6 66/8 67/14 67/16 67/19 67/24 69/19 70/4 70/17 77/17 82/15 82/22 83/7 83/10 83/13 83/17 83/23 84/22 90/10 90/18 90/25

SIR BRIAN LANGSTAFF: [59] 1/5 2/4 2/15 2/19 2/23 2/25 6/4 11/8 11/19 12/1 12/15 12/18 12/21 17/3 17/14 19/11 19/13 19/16 19/24 20/3 28/7 38/15 38/19 38/24 46/23 47/3 58/23 60/8 60/12 60/16 60/21 60/25 62/21 62/24 63/10 65/21 65/24 66/5 66/7 67/12 67/15 67/18 67/21 69/16 69/20 70/11 77/15 82/11 82/17 83/6 83/8 83/11 83/15 83/21 84/21 90/8 90/15 90/23 91/1

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'91 [1] 70/24
'earlier' [1] 77/11
'fragmented [1] 4/20
'Gay [1] 21/14
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