Thursday, 1 December 2011

(9.15 am)

PROFESSOR JOHN CASH (continued)

Questions by MR MACKENZIE (continued)

THE CHAIRMAN: Good morning, Professor Cash.

MR MACKENZIE: Thank you, sir.

Good morning, Professor Cash. I would like to continue with your C2 surrogate testing evidence, please. I think we had reached the letter in The Lancet of July 1987. I think we should next look at a letter from yourself to Dr Fraser of 8 July 1987, which is [SNB0113846].

THE CHAIRMAN: Mr Mackenzie, whilst that's getting up, is everyone aware of the altered times for breaks today?

MR MACKENZIE: I should perhaps say, sir --

THE CHAIRMAN: I count on you to make sure we manage it properly, in case I get so totally engrossed in what's happening.

MR MACKENZIE: We will stop at 10.30 for about ten minutes and then at 11.50 for about ten minutes.

THE CHAIRMAN: Very well.

MR MACKENZIE: I'm grateful.

Professor, this letter refers to a telephone conversation you had had with Dr Fraser and then you set out the following points:

"1. The SNBTS directors do not wish and currently have no intention of introducing NANB surrogate testing unilaterally.

"2. Current views, which as you know were crystallised last March, are being expressed to support our ... PES submission to SHHD for the next five years.

"3. We have no doubt that an important forum for the continued debate is indeed the BTS/NIBSC group(s) and the current NANB debate (which began some two years ago here), and the confused central management attitudes to the Medicines Act and product liability had much to do with driving me to seek the establishment of this joint enterprise.

"4. I really don't believe you should view The Lancet letter as any more than part of a debate, which was initiated in this journal's columns by our friends and colleagues at Edgware. It can also be viewed as yet another attempt to persuade central management (DHSS) to give renewed thought to the way the transfusion services interface with the Medicines Act and forthcoming legislation on product liability, and perhaps even to ways for improving the coordinated management of the transfusion services on a UK basis."

So professor, is it correct that we should consider the recommendation of the directors on 3 March 1987 to

introduce surrogate testing and the directors' letter in The Lancet of July in the context of the matters set out in your letter to Dr Fraser?

A. Yes, indeed, sir. That's quite a good letter, I must say.

Q. Thank you. We move forward to 1988. I don't think you have seen this before but it will perhaps give us an interesting insight into the thinking in the Department of Health at the time. Can we go, please, to [PEN0160216]. At the top right-hand corner we can see this is a memo from Mr Harris in the DHSS to a Mr Bardwell and a Miss Stewart of 29 January 1988. We can see copies to various individuals, some names we recognise: Dr Harris, Dr Metters, Dr Smithies and others. It's headed "Testing blood donations for ALT."

It is worth just going through the memo. If we start with the summary, it states:

"We have a potential problem which could involve writing off £40 million of plasma stock, expenditure on imported blood products of £10 million and a recurrent bill to the BTS of £3 million per annum. There is a good chance this could be avoided if we can find £72,000 to fund a study by 2/3 RTCs."

Paragraph 2 sets out the background as regards the ALT test and the author states:

"It is not therefore a test which we would want to introduce into the NBTS es[pecially] as (a) it is not a good test; (b) our donor pool is likely to contain few carriers (a byproduct of eliminating those at high risk of AIDS); (c) it would cost £3.5 [million per annum]."

Paragraph 3:

"However, all major producers of blood products now use plasma from ALT tested blood."

Et cetera. Paragraph 4:

"This puts pressure on BPL (CBLA). They (rightly) fear that this development makes their product appear second-class. Not using ALT tested plasma could leave them vulnerable if an action was brought against them (albeit that they believe their heat treatment process does inactivate NANBH) under the new stricter product liability legislation (CPA 1987). Given the awareness amongst MPs and the media of haemophiliacs and AIDS, I have no doubt the Haemophilia Society could mount a very successful political campaign to get us to test for ALT. They may not do so, but if they or the clinicians treating them did so then the consequences would be grave. Achievement of self-sufficiency depends on BPL running down stockpiled plasma while RTCs build up to their collection targets. We cannot test this stockpile for NANBH. We would need to continue to input products

to the value of around £10 million, and write off the stockpile which is worth around £40 million.

"5. We could reduce the likelihood of pressure from haemophiliac centre directors and the Haemophilia Society by attempting to demonstrate (a) the low incidence of NANB carriers in the NBTS donor pool and (b) the low utility of the ALT test. Dr Gunson, CMO's consultant adviser, has put forward proposals for a study to do this. Such a study could, against all expectations, prove the need for the ALT test. Even so it would then have provided scientific justification for the resulting expenditure. Even having a study in train would give ministers a valid reason for not being 'bounced' into accepting ALT testing.

"6. The R&D programme cannot find room for this study -- cost £72,000. In view of the serious financial consequences for the HCHS, can it be exceptionally found from the HCHS central fund?

"7. I feel that ministers would not thank us for failing to head off this folly."

As a matter of detail we see in paragraph 6 the author had stated:

"The R&D programme cannot find room for this study ..."

If we go back over to the first page, the

handwritten note, someone has written:

"Paragraph 6 overleaf is not entirely correct. The fact is DRC did not give this priority against the other bids."

I think the difference between not giving priority to something against the other bids and not finding room for this study is perhaps a subtle one, I think. I take it professor, you wouldn't have seen this memo before?

A. No, I haven't, sir.

Q. Were you aware of any of the matters set out in the memo before in terms of the thinking it indicates from the DOH?

A. I wasn't aware of the level of this detail but I was aware through Harold Gunson that -- and I don't know if you recall the last day we discussed all this -- that finally, eventually, Brian McClelland and Jack Gillon did put in, after a fair amount of pressure to our chief scientist chaps, their component bit of this trial, and the outcome was exactly what I thought would happen. And in fact to be fair, so did Brian. But its scientific content -- this is the Scottish Chief Scientist's office -- and we had been warned by Boyd Moir as well it wasn't going to run -- it fell and I thought it -- the study was deeply flawed, and I think one of the Scottish assessors used that very same word.

And in discussing all this with Harold Gunson, it became clear to me that -- it's very interesting they had set it a higher priority. My gut feeling talking to Harold was the CSO -- and they all worked together, these people -- the CSO people in London had actually come to the same decision as the Scottish team.

The fact that they put it in terms that it didn't reach priority and so on, this is a well-known -- you know, the MRC and so on, "Sorry, we haven't given you a grant," and so on and so forth. But in some of the assessors it was regarded as deeply flawed. So I was aware of that, sir.

Q. Yes. It does seem that funds were eventually found in England for the English part --

A. Not from the scientist's budget.

Q. Indeed, from a different budget.

A. From a political budget.

Q. Yes. And the study then did proceed in England. Thank you.

THE CHAIRMAN: Do you recognise the handwriting on that document?

A. No, sir.

THE CHAIRMAN: You do not?

MR MACKENZIE: Yes, it appears, sir, to be "JJM". We can perhaps speculate but I don't think I can go beyond that

today.

THE CHAIRMAN: I think we would all speculate to precisely the same effect.

MR MACKENZIE: The next document, please, professor -- we will come back to Scotland and the Scottish directors -- is [SNB0027321]. The minutes of a directors' meeting on 12 April 1988. Can we go to page 4, please? I'm simply here continuing the chronology of surrogate testing.

A. Yes, sir, I understand.

Q. We can see paragraph (e):

"Surrogate testing for NANB."

If we go to the fourth paragraph down, we see:

"It was confirmed that it had been agreed not to introduce ALT testing in Scotland until it had become UK policy, but directors wished to reserve their position on this matter in the light of reports of the commencement of ALT testing in at least one E/W RTC."

I think we had asked you, professor, whether an England centre had commenced surrogate testing. I think you said you were unsure. It may simply have been rumours.

A. On reflection, I'm almost certain the rumour was it was Birmingham, the director of which was a close personal friend of mine. The director of which was then summarily removed as chairman of the Advisory Committee

on Transfusion-transmitted Diseases, so it stacks up, I think, fairly well.

Q. The reference to "UK policy", that may become, I think, clearer when we look at another document shortly.

The next document, please, is [SGH0028027]. This is simply an extract of minutes of a directors' meeting on 27 September 1988, which I don't, I am afraid, have the full minutes of this meeting. This now, of course, post-dates the Chiron news release in May 1988 of their test and discovery, and we can see under "ALT Technology" in the third paragraph:

"The NIBSC/UK BTS working party were recommending that ALT testing of blood donations should begin in England and Wales."

I think I may have put that to Dr McClelland who I think said he didn't know what that referred to. Are you able to help us with what this recommendation related to?

A. No, I can't, sir, to be honest. I don't think I was there at the time, but you will recall just a few minutes ago in my letter to Iain Fraser, I draw his attention to the fact that the whole of this debate -- not the whole but some of this debate was now being considered by an independent group that was masterminded by NIBSC. I think you already know I have a great

respect and time for the NIBSC, the whole aspect.

So I wasn't there and I don't know how it arose. To be honest, it came as a surprise to me. I have probably just forgotten -- seeing it there that the NIBSC -- they were a pretty conservative bunch.

Phil Minor who is a name that appears frequently, he was the director of the biology section of the NIBSC and it came as a great surprise that they reached a point where they said, "We think you should introduce ALT," because they are very close to government. Jeremy Metters was lurking around in NIBSC on many occasions. I used to bump into him.

Q. And also presumably, the NIBSC would have a majority of scientists working there so it would perhaps seem odd if a scientist would recommend ALT testing if the scientific data from the UK wasn't really there to support it.

A. I find it fascinating.

Q. I'm not sure --

A. I can't help, I am afraid.

Q. I'm not sure we can add to what's set out in the minutes there.

A. I can't help.

Q. Then, please, further down the next paragraph we see a reference to:

"It was confirmed that Scotland was awaiting reaction to the request for funds and the PES bid for 89/90."

In the next paragraph, too:

"Specific antibody testing ..."

The purpose of this is me taking you to the minute. We see a few lines down reference to the Ortho test:

"The test was not imminent and the data presented had been inconclusive ... It was agreed not to plan any medium term policy on the successful introduction of Chiron technology and ALT would remain the test of choice meantime."

So at least as at September 1988, the focus was still on ALT.

A. Yes.

Q. We know that at that stage the scientific details of the Chiron discovery had not yet been published.

A. Sure. Thank you.

Q. Thank you. Finally, to complete this part of the Scottish chronology, could we go, please, to [SNB0027350]? Again a minutes of a directors' meeting on 13 September 1988. Could we go to page 4, please?

A. I note Rosalind Skinner is an SHHD doctor.

Q. Yes. And page 4, please. You see the top of the page:

"Donation testing for NANB."

Could we go down to the fifth paragraph, which I think may be in bold type:

"JDC confirmed that Scottish directors would not commence surrogate testing until the Department of Health and SHHD supported and funded the project, which would be a task for the national advisory body ... to consider."

I think the reference to "national advisory body" is probably what became known as the "Advisory Committee on Transfusion-transmitted Diseases", because if we go back two pages, please, to 7351, under "Discussion (b)", "AIDS", the second last paragraph on the page states:

"After discussion it was agreed that UK Blood Transfusion Services should establish a group to advise the departments of health on policies."

So I think that's probably a reference to what became known as the "Advisory Committee --"

A. I have almost lost touch with the confusing number of committees. I do apologise. I'm sure that's right. I don't know.

Q. Back please to page 4, 7353, when you, professor, stated or confirmed at this meeting that:

"Scottish directors would not commence surrogate testing until the Department of Health and SHHD supported and funded the project."

Had that been your position at the outset or was that you adopting a new position?

A. No, I mean, it's a fundamental truism that we couldn't have done it anyway because of the funding situation. And that applied to Hepatitis C and so on and so forth. So it is true we were engaged in a public debate saying, "We think we should do that, we think we should do that". Whether we did it or not would be totally dependent on an instruction from the Scottish Office.

Q. Yes. So is it just funding or is it in addition needing approval or instruction from the SHHD?

A. Well, "funding" means approval, sir.

Q. I see.

A. And there were many situations in relation to our PES submissions on other topics. I would be rightly hauled into the department to discuss them with the medics there and so on and the non-medics as well. So there was an iterative process going on over the years about bits that we had put in and explaining to them why we needed it and so on and so forth. So funding -- and I vaguely remember seeing Mr Macniven's statement here. He was fairly senior up in terms of the approval of something. Then he put it into the treasury people. So it was all one and the same thing as far as we were concerned.

Q. I understand and hypothetically speaking, if the SNBTS had received funding for something which, for whatever reason, wasn't required, so there was then spare funds for the SNBTS, do you consider you could have used those funds for a different purpose, ie for surrogate testing, or would you have considered you would have to go back to the SHHD for approval?

A. I don't think I could answer this question but I can tell you very clearly that there was a long period of time -- I don't know when it changed -- in relation to funding that we were -- we put in our PES and down from on high came, "Yes, you have got four pence to do that," and this was clearly ring-fenced and the CSA -- so we had to account for this money being used for the consideration that the department have said, "Yes, you can do that".

Similarly, at some point in the 80s -- I can't honestly remember -- that changed and the allocations were lump allocations to the CSA, and if you go into your archives, you will see there is fairly buzzy correspondence between myself and my old friend Jim Donald, because I took the view that the department were giving us the money and the CSA were pinching it to do other things, the ambulance service or whatever. So the whole business of budget control and funding control

is an interesting area, sir, which -- that's as much as I can tell you now -- I would need -- if you wish to get into much more detail --

Q. I understand.

A. But all these years certainly, I would think up to 88, they were ring-fenced and if we didn't spend it, it went back, or we had to ask permission to use it for other things.

Q. I think Mr Macniven's evidence, when he was in post, was that there were lump sum allocations, albeit exceptionally some particular items may be ring-fenced, but it may just be --

A. I think there were lump sums in terms of well -- for instance, they might say, "You are buying that many blood bags each year. You have been doing this for yonks. The price has gone up by whatever it is, so there you are." But when it comes to what we used to call "new developments", like surrogate testing and so on, like HCV, that was very strictly controlled.

Q. But presumably the question is just that hypothetical because the sums required to start surrogate testing, they wouldn't be found elsewhere. They would so significant that they would have to be really specifically provided for.

A. Yes.

Q. Thank you. For completeness, we should perhaps pick up the reference to "product liability" and "product licensing". The minutes state:

"JDC had repeated at the last meeting the need for a clear policy statement and intention of priority from the SHHD. Mr Panton, who undertook to investigate this situation at the SHHD, hoped to make a definitive statement next time."

I suppose what's not clear from the minute, professor, is whether this relates to the Consumer Protection Act which was already in force by this time -- it came into force in March 1988. This meeting is December 1988 -- and/or it related to the European Community directives in respect of the licensing of blood products. So that's simply unclear from the face of the minutes, I think.

A. I think so. It was probably both, sir, I would think.

Q. I understand. Thank you.

That finishes the set of directors' minutes. We should, I think, look at one or two of the PES funding applications just to see when funding for surrogate testing was sought. Could we start, please, with a 1982 document, which is [SGH0018873]? We can see, professor, the title "SNBTS forecast development estimates 1984 to 1986". Go to the bottom of the page. We can see,

bottom left-hand corner, "February 1982" and bottom right-hand corner "JDC/CSA-82/1".

Do you know, professor, what was the purpose of this document and to whom it was sent? It doesn't seem to be a formal PES but can you help us with its purpose?

A. Yes, I hope so, sir. Sitting very ineffectively, as far as we were concerned, above us was the CSA Blood Transfusion Service subcommittee, and on this committee were two SHHD folk. So it was well represented in members of the management committee of the CSA. And I felt it would be helpful as an aside -- in my view it was a complete waste of my time, but I thought it would be helpful if there was a background note that those interested on the BTS subcommittee could read in relation to many things, and in your database you will find me producing briefing notes on all sorts of things, self-sufficiency and what not.

And this is in relation to the PES, background information in terms of the operational stuff. I would send this document, sir, to the secretary at that time, 1982, John Mutch. And John Mutch would ensure that (a) his senior colleagues in the CSA had a good look at it and had an opportunity if they wished, to come back to me. More importantly he would see that copies got into the Scottish Office. That's to Graham Scott in

particular and the undersecretary at the time, 1982, would be John Walker. They got a quick advance look at it as well. And then, when the papers came out -- the subcommittee -- every member had a copy.

So that was what this was all about. It's about background briefing in relation to anything, and this happened to be forecast development estimates.

Q. So am I right in thinking, professor, this document is really advance notice or warning of likely expenditure or issues in the future, rather than a present application for funding?

A. I can't say. Almost certainly it's a briefing note and we tried to produce each year a briefing note for --

Q. I understand. Can we go to page 6, please? It's 8878. We will see a reference to hepatitis. In paragraph (d) we see:

"New hepatitis testing developments."

I take it, professor, you would have drafted this document.

A. I regret I'm responsible.

Q. "It is anticipated that technical developments --"

A. I should say, that said, it was discussed by the directors. I mean, they had to say, "Yes, okay, carry on, Cash". I was responsible for that.

Q. Thank you. And you stated --

A. Sorry --

Q. "It is anticipated that technical developments will have reached a point within the next five years that the introduction of the testing of all donations for non-A non-B Hepatitis markers or associated markers will be mandatory."

When you say "markers" or "associated markers", is that a reference to a direct test or perhaps a surrogate test or allowing for both?

A. Yes, indeed. Brian McClelland and Ruthven will have told you that they had Dow and Bob Hopkins busy looking for secret markers. So this was always a possibility --

Q. You go on to state -- and it's underlined:

"The BTS subcommittee may wish to note this probable development."

Which is again perhaps consistent with it being a briefing paper.

A. Yes.

Q. We can see what is said there for ourselves, and I think you estimate the cost of such testing as being in the region of £150,000 per annum. You also say:

"The recent published studies would indicate that a figure of £300,000 is likely to be more realistic (two further tests on each donation)."

So obviously in 1982 you were certainly alive to the

possibility of --

A. Just watch this space really.

Q. Yes, I understand.

We can then go to what I think is the first PES, where a formal bid for funding for surrogate testing is actually made. It's in 1986. It's [SNB0112637]. If we see this is the SNBTS PES 1986 programme narrative, bottom right-hand corner "JDC/CSA/5/86/1", and someone has handwritten on "1/5/86". Do you know, professor, when this document is likely to have been drafted?

A. That handwriting is me.

Q. Is it likely to have been drafted --

A. Almost certainly that date, rather than when it finally reached the CSA. I can see now Elizabeth Porterfield, my PA, typing it. It must have been -- that "1/5/86", I suspect is the time at which she typed it up.

Q. Yes. I think we know that PES 1986 would relate to funding sought for the next year for April 87?

A. That's correct, sir.

Q. So the document is likely to have been drafted in 1986?

A. I'm certain of that, sir, yes.

Q. I'm grateful. If we can go to what is said on surrogate testing, please, at page 2640, we can see table 1.

We can see table 1 we can see a column of items and columns for various years, 86/87 and then 87/88 and then

88/89, and then 89/90. And under item 5(g), we see "Non-A non-B Hepatitis testing", and the sum of £810,000 being sought in the year 87/88. And then the year 88/89, £836,000 being sought, and we can see some discussion of such testing, please, at page 2649. Under 4, "Additional donation microbial screening". Under (b) "NANB", you stated:

"Despite the absence of specific tests to detect donations which transmit non-A non-B Hepatitis, there is increasing evidence that both in Europe and North America formal moves will be made, within the next 12-18 months, to introduce surrogate testing of all donations."

I think that, as it turned out, was absolutely right, at least as far as the USA was concerned.

A. Yes.

Q. You go on to state:

"Current studies in the States have costed this exercise at $7 per donation. For the SNBTS this would be approximately £1.5 million per annum (using current exchange rates). There would be additional capital monies required and the US costings do not include a significant revenue cost for subsequent counselling of donors. Provision has been made for this development to commence in 1987-88 (part year)."

I couldn't reconcile the figures, professor, in stating that:

"For the SNBTS this would be approximately £1.5 million per annum."

And then the actual figures being 810,000 and £836,000.

A. I am afraid it's such a long time ago -- perhaps I should say that it was well-known in the SNBTS that I had virtually no mathematical facilities whatsoever and -- it's my responsibility but a wonderful guy called John Francis was our finance director and he spent a lot of his time -- he was well-known to all the directors and their teams -- and so he generated -- I mean, that table looks very impressive. I can tell you I would have great difficulty in understanding half of it because John produced the data.

Q. I speculate --

A. If this becomes an issue, then he is still alive and well and I'm sure he will explain.

Q. He is just waiting for our call?

A. Yes. Poor old John, yes.

Q. I speculate it's possible the £1.5 million may have been a reference to dollars. I suppose this may have been back in the happy days when we used to get $2 to the pound. I'm not sure.

A. It does say using current exchange rates. There were bits of these briefings that other people wrote and I was so relieved that they did it but I take responsibility.

Q. Thank you. The next document, please, is the 1987 PES, which is [SNB0113743]. We can see that's what it is from the front page, and in the bottom right-hand corner again your initials on it and I think then drafted in 1987. Perhaps June 1987?

A. Yes.

Q. Yes. And if we can go, please, to page 7, which is 3750.

THE CHAIRMAN: Just before you leave it, where it says "CSA6" on the first page and then "87/1", is that the first CSA paper of June dated in June 1987 or is there some other explanation for this?

A. No, I think it's a date, sir, ie 1 June. What's worrying me is I didn't type this, Elizabeth did it, was it 6 January 1987?

THE CHAIRMAN: No, I think that --

A. Yes.

THE CHAIRMAN: It was June 1987. The only issue is whether it's the first document of a series or whether it's the actual date.

A. It is the date.

Q. You think it's June?
A. I'm pretty certain about that. That could be checked, Elizabeth is alive and well.
THE CHAIRMAN: Because that would have fitted with the last PES as well.
MR MACKENZIE: Yes. Thank you.
Could we go, please, to page 3750? Table 1, with a similar layout. Item 5(f) we see "Non-A non-B Hepatitis testing". Under 88/89 the sum of 300,000 sought, and 89/90 105,000 sought.
Firstly, professor, again it's hard to reconcile that the previous year about £800,000 was sought and now it's £300,000.
A. Yes. Again, I must refer you to dear old John. I have a suspicion that what this is about is that when we got allocated whatever, that would be a recurring sum. When we came the next year, we were asking the question, did we simply want to recur that or did we want to top it up in some way, and I suspect these are a series of top-ups that were added on to the original figure.
Q. I see.
A. And I do wonder if it was 800 -- yes. That's all I can honestly suggest.
Q. So there may be accounting reasons which aren't obvious to you, for some of these --

A. That's right.
Q. -- differences?
A. I mean, just seeing it, why do you need less than you did last year? These are not fixed. These are recurring -- when you get into the game of surrogate testing or HCV, you are on a recurring -- you have got to keep going. So I suspect these are top-ups.
THE CHAIRMAN: I don't know how far you want to go, Mr Mackenzie, but the first item is the revenue baseline, which appears to carry forward from the year before an aggregate figure, which is then inflation-linked and then one has a series of other items. I just do not know whether it's worth looking at it to compare.
MR MACKENZIE: I don't think we have to, sir, but it may be enough for me to know that perhaps one shouldn't look at a single PES in isolation. One may have to refer to the previous years and so on.
A. Certainly if you are looking -- you are looking in the wrong direction if you are looking at me.
Q. Thank you, professor. We should also look at page 12, which is 3755. We are back here to words, professor, which I certainly find easier than figures. We see:
"NANB surrogate donation testing."
This is now a PES drafted after the directors'

recommendation of 3 March 1987 to introduce surrogate testing. And we can see what's stated:

"The SNBTS directors have now decided that in the light of the advent of new product liability laws in 1988 and an emerging unchecked private sector blood collection services, it would be prudent to plan to commence this programme in the financial year 1988/89. The costing are estimates only and it is proposed that we plan to ensure the financial burden covers two financial years but begin in July 1988 (the date new product liability legislation will be introduced)."

Pausing, professor, the reference to "an emerging unchecked private sector blood collection service" or "services", what relevance did that have to the issue of surrogate testing?

A. You may recall that in one of the documents I produced I drew your attention to the fact that I was commissioned by the Northeast Thames Regional Health Authority to have a look at their blood transfusion services and when I got down there -- that was into London -- and when I got down there, I found myself in some huge -- which at those times I was not used to -- huge private hospitals, looking at their blood stuff. And in the discussions I had with very pleasant people who were running these shows, it became very clear to

them -- and that was probably one of the reasons I was down in this study -- that they were not being delivered enough blood from the local transfusion service -- it happened to be Marcela Contreras' centre -- enough for what they wanted for the workload they had, and it became very clear that they were thinking very hard about setting up their own blood transfusion service, their own donors and so on, that they paid and so on and so forth.

It became very clear that this wasn't just a sort of -- they had been in touch with senior politicians and so on and so forth, and I became quite concerned about this and there came a moment, a year or so later, when a good doctor in Gloucester, I think it was, announced he was going to -- he had had enough of all these people, he was going to set up his own blood transfusion service because they were not getting enough blood.

And I tell you, there is a whole section in the archives that you have -- probably not in the court book -- in the archives -- of me expressing great concern about this to the Scottish Office and so on and so forth, and asking the Scottish Office, would ministers in Scotland declare -- over their dead body would private blood transfusion services be developed. And I said this because partly in my discussions in

London the boys were saying, "Well, from a marketing point of view, we will get there because we will just introduce ALT testing".

So these people were in a position in the United Kingdom, if they were let loose, in an economy that thrived in market principles -- they in fact would -- they could add tests as they wished -- we saw this in the States -- whether it was needed or not, it was a marketing advantage.

Q. I understand --

A. So that's what it's all about.

Q. We had seen reference previously to there being -- pressure may have been put on the SNBTS to introduce surrogate testing because the manufacturers of blood products --

A. And the Haemophilia Directors were beginning --

Q. And this is really a similar position but in respect of blood components?

A. These were people producing red cells, platelets, and so on.

Q. I understand.

A. They never got off the ground.

Q. Professor, I think I'm right in thinking that this paragraph really comprises the SNBTS's formal submission following the recommendation of 3 March 1987,

essentially to SHHD, in support of surrogate testing. I don't want to be too critical, professor -- I appreciate the difficulty you had in the lack of data from the UK because of the lack of prospective study; it was perhaps quite hard to make the case in a way one would have wished if the data was there -- but can I suggest this to you, that, even with the lack of UK data on the prevalence of non-A non-B post-transfusion and whether there was a correlation in the UK between surrogate markers and donors and post-transfusion hepatitis recipients -- even against that background of a lack of data, with the benefit of hindsight, could the case have been made perhaps a bit more strongly by the SNBTS, perhaps by listing a number of factors, including at least the apparent correlation in the USA from their studies -- listing the potential seriousness of NANBH, perhaps suggesting that surrogate testing at least offers the potential of increasing the safety of blood and, perhaps most importantly, perhaps stressing that if a prospective study of recipients was not to be carried out, then ministers should really err on the side of patient safety and introduce such testing, or do you think that --

A. Actually I think we have had this conversation before, you and I. I think I will repeat that now, looking

back, we certainly could have done probably a better job. If you ask the question, "Why do you think you didn't?" It's not only a question of not having the data, you have to ask who stopped us getting the data? We have had problems here with the word "deliberately" or "knowingly" before but there is absolutely no doubt whatsoever that the people to whom we would be putting this case that you are suggesting we should, were the very people that in fact had prevented us from doing what we thought we should do so that we could make this balance sensible. We could make it all together, this balance sensible decision.

Looking back, I suspect that I really felt that to some extent all we could do was simply flag it, signal it. You could argue that McClelland in his submissions, which all went to the Department of Health, were fully well-known in the Scottish Office -- his detailed submissions for a prospective study. You could argue that Harold Gunson -- we didn't agree with all the data.

I said this to you before, the other day. Harold Gunson's paper, excellent paper -- I don't agree with all the numbers -- excellent paper in which he made an effort to look at the clinical impact which he thought might be happening in the United Kingdom, the department had all these.

So maybe that was the reason why I, sitting in my position, developing PES estimates, didn't go into detail. Do I regret it? If you pursue me, yes, I'm sure I do, but I can think of good reasons why I felt that this one -- and later we will see in Hepatitis C, there was a period of time when we felt we were just bashing at a door that was shut.

Q. Thank you, professor. I certainly understand your position that one shouldn't perhaps look at this paragraph in isolation. There is the wider context --

A. There is a whole --

Q. -- and other papers which were available.

A. That our good friends in the Scottish Office were well aware of.

Q. Thank you. And then the next PES, please, is 1988. It's [SNB0033078]. This is the last one I will look at. I think it's of interest for two reasons, firstly in respect of funding for screening but also in setting out problems with the blood supply at this time, which we will come on to look at in turn.

Firstly looking at funding, if we could, please, go to 3103, thank you. We can see under "Safety of blood donations", "Microbial donation testing". We can read the first sentence for ourselves and then the third sentence:

"Future candidates include NANB (surrogate testing is currently widely practised and Chiron Corporation have recently announced they are close to introducing a specific NANB test system to detect antibodies which will be marketed by Ortho Diagnostics) ..."

We should then look over the page, please, under paragraph (iv). We can read for ourselves what is said and you really make the point that:

"In the context of current and impending legislation, there is a need to consider whether the introduction of a new (specificity) donation screening test in the SNBTS is a policy matter outside the provenance of CSA policy."

The reference to a "policy matter outside the provenance of CSA policy", who would be responsible for such a policy matter?

A. The Scottish SHHD.

Q. I think one can understand the common sense of that. It would be a matter of national importance?

A. Absolutely. Not a problem, sir.

Q. Then we see again reference to some figures under 1989/89; we see "ALT screening of donations: £85,000."

Under 1990/91 we see "ALT screening of donations: £25,000". But in the item below "NANB screening of donations: £300,000."

That's a reference to the Chiron test, I suppose.

THE CHAIRMAN: The £25,000 is a negative figure.

MR MACKENZIE: I'm grateful, sir, thank you.

THE CHAIRMAN: This reflects the fact that there is a basic figure carried forward and these are adjustments. We can do a quick bit of arithmetic, Mr Mackenzie, even given the limitations --

A. I wouldn't dare.

MR MACKENZIE: The other point perhaps to note, if we look under the total for 89/90 of £118,000, I just ask that we bear that in mind when we come to look at another document.

That's the funding but this PES is also, I think, of interest for setting out concerns about blood supply at the time. So could we, please, go to page 3089? Of course, one of the difficulties with surrogate testing is that the service would have lost perhaps 3, 4, 5 per cent or whatever of donations.

A. Absolutely, sir.

Q. We see under this page headed "Blood collection programme":

"There has been a sustained decline in support of the SNBTS by the public since 1985. This has become more evident in the last 18 months."

There is a reference to a figure. And if we then

look at the total donor attendances for the years 78 to 88, we can see that from 86 onwards, the total donor attendances start to decrease. And then we can read for ourselves what's then set out. Over the page, please, again, we can read for ourselves at the top of the page, the paragraph culminating in the sentence:

"Self-sufficiency in plasma products cannot be met with this level of routine blood collection."

And the proposals for which funding is sought are set out, including appointment of a national recruitment and programme manager and a permanent TV/radio campaign. And the total sum sought is 221,000. So quite significant sums and then a separate but related matter is then:

"Escalation in clinical demand for blood products."

It's set out:

"There has been a significant and substantial increase in the clinical demand/use of SNBTS blood and blood products over the last decade. This escalation in demand is now considered to be out of control."

Various table and figures given. Go over the page, please, to see the proposal to address that. We can see under "Proposal":

"The establishment of an academic department of transfusion medicine, whose primary raison d'être is to

develop research directed towards defining the appropriate treatment of disease using blood and blood products."

Over the page again, please, the sum sought there is about 73,000. And in a final separate yet related item, "Supply/Self-sufficiency", it was stated:

"The major difficulties which have now emerged for Regional Transfusion Centres in meeting supply centre, primarily on the provision of platelet concentrates and supporting the fresh plasma needs of PFC."

We can see what else is said. Can we go then, please, on two pages? 3095 at the top states:

"The concern at the present time is that further significant increases in fresh plasma for PFC cannot be obtained from the existing blood donation input (which is falling in any event) because this option was fully explored in the period 1982-87. It seems certain then that the major contribution to any planned increases in plasma will be by a mixture of plasmapheresis and optimal additive solution."

We can go to page 3098 to see the proposals and the costings for that. We will see they are quite significant. We can see a third of the way down:

"The broad proposals are as follows ... "

Under the last one:

"Funding is initiated at RTCs to commence OAS and plasmapheresis programmes."

We can see in the figures given for the year 89/90 under "RTC plasma procurement", a sum stated of £400,000, which I assume would include the cost of their starting plasmapheresis. Would that be correct? You are nodding, professor.

A. Yes.

Q. Would that include purchasing new equipment and training staff in how to use it?

A. Yes, automated equipment but I suspect the biggest cost is OAS.

Q. What's OAS?

A. Sorry, optimal additive solutions.

Q. What's that in a sentence or two?

A. Instead of taking 200 mls of plasma from an ordinary donation, you take 300 mls. That's the whole lot. You now have something like a thick syrup that doesn't run into patients very quickly but what you do is you add the optimal additive solution, which is good for the red cells. It provides them food but crucially it lowers the viscosity. So in an acute shock patient you can run it in fast and we get 100 extra mls of plasma from that donation.

Q. We can see the total sum sought under that proposal for

89/90 is £650,000. So the funds sought for screening, certainly surrogate testing in that year, is really vying with these other quite considerable sums.

A. Oh, yes.

Q. We can leave that document, I think. This letter, I think, is also of some interest. Can we go, please, to [SNB0114790]. This is a letter of 25 July 1988 from yourself, professor, to Mr Donald at the CSA and it's headed "PES 1988: SNBTS priorities". The first paragraph states:

"In response to your recent communication of this topic, I have had a brief discussion with Duncan Macniven and we are agreed that it would be more helpful if I provided a prioritised list which conveyed my own opinions. The list is as follows:

"Priority A (self-sufficiency)."

I think we can see items 3 and 4 include "Supply/self-sufficiency", the sum of £470,000. I think that relates to items we have just looked at. Item 4 "Blood collection", £221,000. I think that relates to the permanent media campaign, the appointment of a blood collection manager, et cetera.

Under "priority B", going down a level, under 3, "Safety blood donations/microbiology". I think that would include the figure for ALT testing for 89/90

because we find again the figure of £118,000, which is a figure I asked us to bear in mind a few minutes ago.

If we go over the page there is also set out priority C, and perhaps from the point of view of the taxpayer, it's nice to see that the 50th anniversary celebrations are under priority C, which may be a bit unfair.

Over the page you set out:

"Perhaps it would be helpful to add that within the categories A, B and C, I have further prioritised the list with 1, 2, 3 et cetera."

Going back to page 1, please, not only is ALT testing at this stage under priority B, it's item 3 of 4 in this priority. And a question really, I think, comes to this professor: given the difficulties in blood collection in the second part of the 80s, would it really have been feasible to introduce surrogate testing in any of the years 1987, 1988, 1989, 1990?

A. I think that's an extremely good question and I find it a little difficult to give you a commonsensical response. What has not emerged -- I mentioned it before. What has not emerged in this Inquiry thus far, although I have mentioned it before, is that in 1987 we had a catastrophe that affected our blood collection programmes.

I think you saw in the graph it just went straight down and that catastrophe was engineered by the Scottish Office, poor chaps, in that I think I told you before they announced that the government was going to support the building of a very large private hospital on the Clydebank.

Now, one of the reasons I felt, after that initial decline since 1985, there -- was a man, a wonderful man -- we had awful troubles with him -- called Mr Brunton. The dear chap has now departed. He was a Scotsman journalist and he had a passionate view about the way the SNBTS -- we didn't know him otherwise but he kept writing articles -- was supplying blood to the evil private sector. And we got into all sorts of hassles with him and that is well documented in your archives, and when -- we had this from 83/4 from Mr Brunton and I was very twitchy about this -- there is a lot of documents -- and went and spoke to him and wrote to him and so on and so forth, but we couldn't move him and when it became apparent in 1987, the Clydebank hospital development, Mr Brunton went into fifth gear and we had -- Ruthven -- if you got Ruthven Mitchell back, they were reporting -- I don't know how accurate they were -- a 25 per cent drop, they thought, in the West of Scotland donor panel.

So severe was all this, and there is a lot of stuff in the archives, that I and Jim Donald went over to Clydebank one afternoon -- much to the anxiety of our friends in the Scottish Office, as you might imagine -- to see if we could talk them through all this and explain to them that, you know, we were in control and so on and so forth.

So when you say, you know, you had everything, all this, going on, this Clydebank thing hit us acutely. I won't go into the appalling situation in which I became aware of it just reading the Scotsman. We had not been briefed at all and it hit us -- so we had this acute effect and there is no doubt at the end of 1987, if you had asked me, "What about non-A non-B," I would have said, "Go away".

You are absolutely right, that's a fair point.

Q. Even though in March 1987 the directors had agreed surrogate testing should be introduced?

A. Yes, I think in March -- I think you will find the HCI thing was midsummer. In fact we were all on holiday, or a lot of people were on holiday when it was announced, but, yes, I mean, we were trundling on but we did not appreciate what was going to happen. So as I say, you are right, by the end of the year, I suspect we would have said, "Look, forget it in the meantime".

Q. We know that the March 1987 recommendation was to introduce surrogate testing in 1988. So looking at matters this way, if surrogate testing had been in place in 1988, 1989, 1990, is that likely to have had a knock-on effect in terms of the supply of blood to hospitals and supply of plasma to PFC?

A. It might. I mean, I think you all know that we were running on a high surplus of red cells in Scotland. From time to time there were troubles in the West. We eventually sorted this all out, and if you ask Jack Gillon, "What's your input now?" it's hugely down from what it was in our day and they are managing very fine.

In other words, I think better management of our resource -- you have already referred to my view that we were out of control in terms of the use. And Brian McClelland was later to -- I persuaded him to set up this thing, which he did for about 10 or 15 years, which had a major impact on the way we actually -- clinicians were using the red cells and so on. So I think you have got a good point and I suspect in 1988/89, we would have been struggling a little but having said that, we were making by then -- this is before David McIntosh arrived. We were making by then -- we got people like Ruthven and so on to come in

and we were passing data around to each centre giving stocks so that we could move stuff around.

Q. Thank you, professor.

Sir, that may be an appropriate place to take a break.

THE CHAIRMAN: Yes.

(10.31 am)

(Short break)

(10.44 am)

MR MACKENZIE: Thank you are, sir.

Professor, I finished looking at the documents I wished to take you to but I should now go to your statements. I can deal with them quite shortly because we have covered most of the ground. The first statement is [PEN0171741].

If we go through a few pages, we can see we asked you the same questions we asked the other witnesses. Could we go to page 6, please? I think it's the first substantive response, which is 1746. We asked:

"Why did the SNBTS first seek funding from SHHD in 1986 for the introduction of surrogate testing in 1987."

And you say that:

"As far as I can recall, during the preparation of the PES submission for 1986, I was requested (for the first time) to include a component which looked five

years ahead."

Who were you requested by?

A. I don't remember, sir, but almost certainly a chap called John Morrison, who was the CSA treasurer.

Q. I see. We can see a reference there again to consulting with European colleagues, and you told us a little about that yesterday, I think.

Then over the page, please, I think the other questions and answers we will just take as read because the answers are fairly short and as I say, we have explored matters in much more detail in your evidence.

Question 10 we asked:

"Why was surrogate testing of blood donors for NANBH not introduced in Scotland."

We can again read for ourselves your answer. I should perhaps say, when you say:

"Reference to Dr John Wallace ..."

And the question of requiring agreement of SHHD, I think that's a reference to events back in 1975, which we covered in topic C1, when Dr Wallace sought to continue using a more sensitive Hepatitis B surface antigen test. And people can go to the evidence in the C1 topic if they want to follow that up.

I think we should just then, professor, take the rest of your statement as read. We also then asked some

additional queries and you provided us with an additional statement, [PEN0171885]. There is a summary in various bullet points set out. I should for clarity, professor, say, of course, this summary is drafted by the Inquiry team, not by you.

A. Indeed.

Q. So people are aware of that.

A. Thank you, sir.

Q. I should also ask: do you think the summary is a reasonable one or do you think it contains any material errors or omissions?

A. No, without being too congratulatory, I had been knocked out frankly, throughout the whole of this inquiry, in terms of the quality of documents.

Q. Okay, thank you. Over the page we will see the supplementary questions. Query 1 related to:

"Should a large-scale prospective study have been carried out?"

Your position, we know, is yes. In your answer 2, we see what you say. I think in short, we have all the records we are going to get on the matter and we also requested a statement from Dr Moir on this point. I'll refer the chairman to that in the final wash-up at the end of this topic but in short Dr Moir can't help us.

Over the page, please, supplementary question 2.

The question we asked:

"If such a large scale prospective study had been carried out in the UK, to what extent is it likely to have met its objectives?"

And you stated:

"I see no reason why a properly resourced and supported UK group could not have achieved parity of performance with the US TTV study group."

I take it that remains your view?

A. Absolutely.

Q. And then you say in answer (b), you always felt that the size of the proposed study, 600 patients, may have been rather small to achieve all of the objectives. The reference to 600 patients, I think, comes from Dr McClelland's original proposed protocol?

A. Indeed.

Q. I suppose against that -- I think we heard from Professor Leikola yesterday that the Finnish study, I think, involved about 650 patients and it appeared to provide meaningful results but --

A. I think I would merely add -- I don't think it's important, sir -- that I think item (c) was a look at the long-term. So you needed a decent cohort of patients that had got it to see how serious it was and to be followed up over a long period of time. That's

all.

Q. Presumably the difficulty with item (c) --

A. The Finns didn't do that.

Q. With item (c):

"To investigate the natural progression and seriousness of the disease ... "

Given we now know that it may take over 20 or 30 years for cirrhosis, that probably wasn't an achievable objective for such a study, unless it was going to go on for 20 or 30 years, which seems unlikely.

A. I think Professor James would say you need a decent cohort to study.

Q. Okay. Question 3, the work of Drs Dow and Follett. We see your answer there and we have examined Dr Dow in some detail on this.

Over the page, please, in question 4, relating to SHHD medical officers. Again, we can see what you say in your answer.

Question 5, we asked the hypothetical question:

"If surrogate testing of blood donors ... had been introduced in Scotland, what percentage of donors are likely to have been deferred?"

You answered on the next page:

"I have always believed it would have been between 1 to 3 per cent."

We also asked:

"Could a sufficient blood supply have been maintained?"

You answered "yes" but I think that must be qualified by your evidence today?

A. Absolutely, yes.

Q. Question (c):

"To what extent are cases of post-transfusion Hepatitis C likely to have been prevented?"

And you stated:

"I believe I judged at the time that the benefit would have been significant but the costs high, and the impact on individual donors and on the robustness of our donor panels had, because we lacked relevant UK data, not been carefully considered."

So we are back to the question of the lack of UK data?

A. Yes.

Q. Thank you, professor.

You then go on in a footnote to refer to further matters, which I'm not going to go into in detail, save to say in respect of footnote (a), the relevant documents are 1 and 2, which you list over the page in your references, and we have in our inventory full court book numbers for them.

In short, under footnote (a) the question of ALT testing of plasma products and the Medicines Commission allowing commercial manufacturers to state their products had been so tested, I think it does seem to be, I think, accepted that it's unlikely that ALT testing would have materially increased the safety of the plasma products made from large pools of plasma. Do you agree with that?

A. Very large pools.

Q. Yes, Factor VIII/Factor IX.

A. I'm not sure about Scotland. It would have been very interesting. I think the other important point -- and it's on record in your files -- is that the clinicians, the Haemophilia directors, were beginning to say -- I used to get quite distressed by this -- "The reason we are buying commercial stuff," which I thought was very dangerous -- "is because you are not doing all the tests". It was just awful.

So there was not only pressure from the Haemophilia directors, there was an actual belief that that was the right thing to do and we would opt for a product that did that, and in the total context --

Q. I understand.

In respect of footnote (b), this concerns in short, proposals in England in 1990 and again in 1994, that

plasma going to BPL for the manufacture of blood products be surrogate tested, ALT tested. And again you have provided a list of references for this issue, and we have the signature court book references, but I'm not going to ask you any questions on this for four main reasons.

Firstly, it concerns events in England, rather than Scotland; secondly, I think it seems quite clear from the documents the proposals were made for commercial reasons, rather than to increase safety; thirdly, by this time in Scotland at least Factor VIII and IX products had been heat-treated to inactivate Hepatitis C. And lastly, it's unclear whether in fact the proposals were implemented in England.

So I can quite see, professor, why you mention it as part of the background but it does perhaps seem to be just that: background. So I'm not going to take up time at the hearings in going over it in detail. Thank you.

That's that statement, thank you.

There is another short statement I would like to go to, please. It's [PEN0172767]. We will see this statement is headed "Resignation as Consultant Adviser to SHHD, 24 March 1986". The background to this, professor, is that the Inquiry team had noticed that you had resigned as consultant adviser to the SHHD and

I simply asked you why that was and in response you helpfully provided this statement, which I'm going to take as read, subject to asking you one question at the end and also subject to giving our reference numbers for your five references at the back.

Our reference numbers for reference 1, [PEN0172790], reference 2: [PEN0172789]; reference 3, [SNB0112544]; reference 4, [SNB0131559]; and reference 5: [LIT0010343].

The one question I'm going to ask you is this, professor, and with reference to this other document. Could we go, please, to your job description as national medical director, which is [SGH0012619]. We can see that this document is headed "Blood Transfusion Service -- National Medical Director. Job Description."

At the bottom of the page we will see the date is April 1977. Item 5, one of your duties:

"He will advise the SHHD on national policy questions affecting the development of the BTS."

And the question is simply this, professor: was your resignation as consultant adviser to the SHHD consistent with item 5 in your job description?

A. I think that's a very good question.

All I can tell you is that having been appointed national medical director, I was asked to go and see

Graham Scott, who formally invited me to become their consultant adviser, and the Scottish Office -- I know, DHSS, they have got lots of consultant advisers in various specialities and if I said yes, said Graham, I would have the handsome reward of £275 a year.

So I have always been under the impression -- and I think that's right -- that of course my item 5 as national medical director -- I spent a lot of time advising and cajoling and so on, but the consultant -- but my understanding was a consultant adviser to the departments of health, you are supposed to sit back, not be defending the national medical director -- to sit back and respond to questions in relation to the broadest international blood transfusion and so on. And it was that role that I ultimately felt I should leave because of what was about to happen.

Q. Yes. If the SHHD had sought your advice on transfusion matters after your resignation as consultant adviser, would you have given that advice freely?

A. Absolutely. My resignation on the second occasion was really, I felt, morally obliged. Because I was about to, I thought -- it took longer than I thought -- I was about to seriously criticise the Department of Health in London and I thought this would be a severe embarrassment to my mates in the Scottish Office and

I felt that I should get out of the way. You know, it would not be appropriate for me. But on the other hand at any time -- and they did. And in fact, Hamish Hamill in 1990 asked me to come back and advise them. You have got documents to confirm that. So there was no problem.

Q. I suppose, professor, on one view, the better question may be the other way around: was item 5 of your job description consistent with you being consultant adviser to the SHHD, in that there may be occasions when, as national medical director you felt you had to speak out against the government or whatever, which may then place you, as it did, in a difficult position?

A. Yes, extremely difficult, I can assure you.

Q. I understand.

Finally, professor, there are two letters I would like to briefly take you to and put one question to you. Can we go, please, to [SNB0059240]. I think you have seen this letter again relatively recently, professor?

A. Oh, yes.

Q. A letter from yourself to Mr Hugh Morison of 21 August 1986. I don't need to take you through it because you have seen it, I think. Then also for completeness, the response, [SNB0132880]. Which is a letter by Dr MacDonald, 8 October 1986 to yourself.

Really my question is this, professor, that, while

one can quite understand that this correspondence may be part of the background to the topics under consideration by the Inquiry, on the face of it, this correspondence does not appear to be of central importance to topic C2, surrogate testing, because firstly, the main trigger for the letter appears to have been the Sandoz incident, which is not a matter of direct relevance to the Inquiry and secondly, and while this is ultimately a matter for the chairman, it does appear from the C2 documents and oral evidence that surrogate testing was not supported within SHHD because they were not persuaded that there was a good case on the merits, rather than SHHD's position having been decided on issues of personnel, personalities, or relationships?

Do you have any response to that suggestion, professor?

A. Yes, I am happy to go with it but as you well know, if you look carefully at John Forrester's contributions to the surrogate testing debate, I think it has to be said -- briefed the -- his colleagues pretty heavily against the SNBTS and specifically at one point myself. But I don't -- the notion that that had any material effect on the decisions that were made, I disregard and I don't think it's very important.

Q. Thank you, professor.

THE CHAIRMAN: Mr Mackenzie and Ms Dunlop, how do we move at this stage? Should I ask the other parties?

MR MACKENZIE: I think it may be better for the other parties to ask questions on C2, I think.

THE CHAIRMAN: We will deal with it as two quite distinct chapters.

MR MACKENZIE: I think so.

MR DI ROLLO: Mr Dawson on C2.

THE CHAIRMAN: Mr Dawson?

Questions by MR DAWSON

MR DAWSON: Thank you, sir.

Professor Cash, I would like to ask you first of all some questions about the 3 March recommendation, and Mr Mackenzie has taken you through the documents relating to that but I would like to focus on the reasons why that recommendation was made at that time.

Would it be correct to say, by way of background, that the SNBTS position throughout the first half of the 1980s and really into 1986 had been to support the concept of a large prospective, local study?

A. Absolutely right, sir.

Q. And in 1987 in March, that there was a change in the attitude from that position?

A. I think -- I could answer that both ways, sir, honestly. I could say, no, there was no change but the world had

gone past us in the night and we would have strongly supported in 1987 a study. But we felt it was too late.

Q. Was it not the fact at that stage that, given what had happened at WPTAH in November 1986 and the fact that they had recommends a study which focused on donors only, that you knew full well in early 1987 that your previous ambition was never going to be realised?

A. Absolutely.

Q. Okay, thank you.

Would I be correct in saying -- I think you have confirmed this already but I just want to be absolutely sure -- that the person who was leading on this issue in SNBTS was Brian McClelland?

A. Very much so.

Q. I would just like to take you to some of the evidence --

A. Perhaps I should for accuracy --

Q. Of course.

A. I think at a stage, and you have already heard it, Brian began to slip a lot of the responsibility to Jack Gillon, and in fact the seminal meeting in which they said, "Yes, we will do this trial," that you have referred to, Brian was there. In the minutes it says Jack was looking after his interests but over the long period it was Brian.

Q. I think in your evidence, earlier in the week, you said

that you were perhaps not as familiar with this whole area as Dr McClelland and that you very much left it to him to get on with. Is that right?

A. Yes, that is right. When I say -- I mean, I need to be careful but if you had asked me some of the detailed figures of the incidence of the American publications, I would have been rushing off to the library, whereas Brian had them in his head. But I was extremely interested in what was going on.

Furthermore, Harold Gunson, who I interrelated with, I think you will have guessed, quite a lot, was passionately interested in this area and I picked up a lot of stuff from Harold as well. But it's true, I did not have the expertise that Brian had by any means.

Q. I would like to just take you to some brief passages from Dr McClelland's evidence in relation to this topic. This is certainly my understanding of his position as regards why it was in March 1987 the decision was made that the recommendation should be put forward. Could I just get up on the screen some of these passages. It's the transcript for 15 November 2011.

That's Day 63, sir.

I'm looking first of all at page 143. It's right down at the bottom of that page and this is a passage where Mr MacKenzie was asking Dr McClelland some

questions about this very topic, why it was that the recommendation was made, and he was looking specifically at The Lancet letter slightly later in the year, and he was asked the question:

"At this time in July 1987 ... "

Which is when the Lancet letter was published:

"... to what extent was patient safety a factor in your consideration?"

To which he answered:

"It was the factor in my consideration."

If I could just take you to another passage, which is slightly earlier in the transcript, on page 141. We see there at line 13 -- again this is Mr Mackenzie asking some questions, he said:

"Question: What was the main or the determining factor or factors which led you to recommend that surrogate testing should be introduced?

"Answer: Well, I felt there was -- even in the absence of a proper -- you know, a definitive prospect of randomised controlled study to provide a real answer, that there was sufficient evidence -- the evidence which had convinced the Blood Products Advisory Committee of the FDA, that surrogate testing needed to be introduced and led to the decision in the United States was, while not complete and not definitive, very, very difficult to

ignore, and I had no conviction that the epidemiological situation, the sort of prevalence, the amount of Hepatitis C -- or non-A non-B Hepatitis infection in the UK was really that much less than it was in America, in 1986, because, you know, commercial paid donors had stopped. They had introduced similar changes in donor selection in relation to AIDS that we had, and I felt if, in the light of, you know, those two major changes, the United States felt it had to introduce this testing, we were in a very, very poor position to not follow suit in the UK, unless we had convincing evidence that it really genuinely wasn't a problem."

I would just like to take to you a third passage, which is a little bit further on, on page 147. This is a passage in the same body of evidence when Mr Mackenzie is trying to elicit Dr McClelland's understanding, and he says in relation to some questioning about UK studies that were available at this time:

"As I recall, the only studies that looked at surrogate testing and concluded that it didn't have any effect, if you look carefully at them actually, the number of patients enrolled was very small and probably not sufficient to draw any conclusions from at all as a statistical basis."

I would like to take you to one other passage on

a different day, but so far we have Dr McClelland saying patient safety was the consideration, that he had become convinced by this stage that certain weight could be placed on the American data and the American position and that he was not dissuaded from that view by the UK studies. Are you following this so far?

A. Just, I think, sir.

Q. Could I just move you on to what seemed to me to be the last of the main props, I think, to Dr McClelland's position. For that I need to go to the transcript for the next day, which is 16 November, Day 64. I'm looking at page 116 of the transcript.

This was a passage in which I was asking some questions of Dr McClelland about something he had said the day before and he was talking about the material that had been produced by Harold Gunson at the working party group meeting in November.

A. The big paper.

Q. I think you have already referred to it yourself, professor.

A. I think I understand that.

Q. I asked him:

"I think in your evidence yesterday you said that this document in particular was one which had been persuasive as regards the development of your thinking

towards recommending introducing surrogate testing. In particular I think you said that the numbers that were being used in this document had been influential. Is that correct?

"Answer: That is correct, yes."

If one looks over the page at 117, I asked for a bit more explanation as to why that was. In summary he says at line 20:

"I think seeing those numbers, as it were in cold blood, probably was a factor in my trying to push it on a bit more."

So it seems to me from Dr McClelland's evidence, these are perhaps the four main planks of his argument as to why he had changed his view about surrogate testing.

I'm not so much interested in looking in detail at the data but I'm quite interested in exploring with you why it was that the judgment was exercised by the directors at that time to make the recommendation.

I hope you follow these reasons, professor, because I would like to know whether, as far as you are concerned, these were the reasons why the SNBTS directors made the recommendation in March 1987?

A. I can't honestly remember but my gut feeling would be no. What I would be interested in would be to have my

old friend Brian sitting next to me instead of looking at the transcript of something you have said in the very recent past.

Can you enlarge upon that for me because when you say he had changed his view, one of the problems I have with a lot of this stuff -- not Brian or myself -- is that you start seeing stuff in this Inquiry and you begin to say, "Oh, I didn't know that happened," and so on, and you can begin to drift and change your view from what it might have been years and years and years ago.

And I'm not suggesting that has happened here but he is now saying he has changed his view. I certainly have to tell you I was not aware of that at the time. And what changed that produced the decision was Brian suddenly appearing with a letter that -- a draft letter that we subsequently published saying, "Look, it's too late". I do not recall -- I must be absolutely honest with you, I do not recall Brian saying, "We need to introduce it". He was saying, "It's too late to do a study", apart from the fact the study on the table was not worth the paper it was written on. Even if you -- he was saying to us, "Even if at this stage we do a prospective study, it will be too late", because he took the view it would take three to four years before we had an answer. And we all felt, "Oh, crumbs. If

that is correct Brian -- and you are the expert -- we know from what's happening in Europe and what had happened in the States, the whole world is moving on."

Q. What I'm just trying to get from you, Professor Cash, at this point, for whatever reason, be it because it's too late or be it because it's not going to be funded, the prospective study is not going to happen. Is that right?

A. That's correct.

Q. Against that background and with that consideration put out of your mind, the recommendation was made in March 1987. What I want to know is: was it made for these reasons?

A. I'm honestly repeating myself and I think the notion that never, ever would a proper study -- in other words -- be conducted. I don't think that was in our mind.

The study on the table at that point we regarded as not being helpful at all. And Brian had reached a point, I think, of weariness, in which the notion of pursuing yet again -- I have to say, this view was shared by Harold Gunson -- he was very unhappy himself about this. The view that we should try again to get a proper prospective study, the view was that it was a waste of time and I think -- I'm thinking about what

discussions -- I think the major reason was --
I think -- the time -- it's too late.

Q. But surely in answering the question about patient safety, which was the first page I took you to, Dr McClelland was asked, "Was patient safety a factor in your consideration", and he said:

"It was the factor."

A. I wouldn't dispute that. And without being too colourful, and at times I have great difficulty with this, if, for instance, the word got out that we were shedding donors, large numbers of donors, into oblivion and a very serious matter where there was no confirmatory testing, families were struggling -- you have heard all this before. If in fact this began to -- and the word got out -- a number of occasions in the Inquiry the worry was: would the donor panel hold up if the word got out we were fingering people in this way?

The dominant beneficiaries of the blood we were supplying were people that were not getting -- so if you are talking about patients, there is a vast -- thousands of them out there that if the donor panel had collapsed and we were not -- I'm not exaggerating these things to be honest -- they would be in serious trouble. So the notion that it was all about the patients that actually got the non-A non-B was only part -- certainly mine and

I'm certain Brian's -- concern about patients.

Q. Obviously there are considerations with donors which were no doubt part of --

A. I'm not talking about just donors. I'm talking about the impact of what that might have on the collection of blood in the years ahead.

Q. No doubt --

A. If we had gathered the prospective studies and we got the figures, just like I was saying the other day with aspirin, with oral anticoagulants, we would have sat there and said, "Whatever the figure, can we afford in fact to do this? Are we content?" And I'm sure what we would have done, if we got into that position, ie we had the patient data, we would have sent people like Jack over to the States, because they will have been at it for some time, to talk in very great detail about the impact it may or may not have had on our donor panel and on theirs.

Q. Perhaps if I just get to the proposition I wish to make and see if you agree with me or not. Do you agree with me that the recommendation was made due to the fact that you had reached the view on the available evidence, which was not the ideal or the complete evidence that might be available, because you didn't have the study, that matters had reached a point where you were

satisfied as a group that such a measure would have a material benefit on preventing post-transfusion non-A non-B Hepatitis in patients?

THE CHAIRMAN: Just a minute, I'm not sure that I follow what such a measure is.

MR DAWSON: Such a measure as the introduction of surrogate testing, sir. Sorry.

THE CHAIRMAN: Do you follow it, professor?

A. I do.

MR DAWSON: I could perhaps break it down.

THE CHAIRMAN: I think you have to be careful at this point. I have already heard Professor Cash's views, which I may be inclined to accept. So if you are now putting propositions that are different, I would rather you did it in a way that he can respond to.

MR DAWSON: Absolutely.

To look at the evidence that you had at this time, the position, as I think we have clarified, is that there was no prospective study; there wasn't one on the horizon. So the reality is that although that might have been ideal to have that evidence, you didn't have it. Is that right?

A. That's correct.

Q. And you did have, however, some other evidence, which might not be ideal because it was from abroad, and

obviously there is an emphasis on the importance of local evidence in this matter. But as you said yourself, you had some information coming from your European colleagues and also there was the American information that Dr McClelland appeared to be relying on to a certain extent. Is that right?

A. I'm not sure to what extent he was relying on it.

Q. Yes, but that information was available?

A. It was in the public domain, very much so.

Q. Do you think that that information was material in you reaching the decision to make the recommendation as a group?

THE CHAIRMAN: That's the recommendation in March 1987 specifically?

MR DAWSON: Yes.

A. I think we were persuaded with the notion if you looked at the American data, there were very substantial variations in the figures in terms of -- that were geographically related.

The notion that this could all be put down, as I think you have rightly said, to paid donors, is nonsense. Nevertheless, it appeared there were big, big differences. Those of us who knew New York Blood Centre quite well, you could imagine that, compared to the leafy glades of Wisconsin and so on.

And the real question, I think, in our minds was to what extent should we move to accept this American data, when in actual fact, if we did our study ourselves, we were much closer to Wisconsin or Helsinki where Jussi Leikola came from. And if that was so, would that influence the UK decision to go or not go? And -- I mean, I think it's in that context that we instinctively backed off in March and said, "We really must continue to pursue the notion of a study". But later Brian came up and said, "It's not on, we are too late".

Q. When you say "later", was that by the July?

A. Yes, by July.

Q. By July, okay.

A. I'm sorry if I'm not being very clear.

Q. No, it's very difficult to understand.

A. You are really picking some really very interesting nuances that my memory is struggling to stay with.

Q. I think you have pointed out, and I think this is quite plain, that, for various reasons, the American data was not ideal, for reasons you have pointed out, and also that it was not necessarily immediately applicable to Scotland. Far from it.

So we have established that the data was not ideal for your purposes. But at this stage, had you made the

decision that, though it's not ideal, given the fact that we were not going to get ideal data, it is sufficient for us to make a recommendation that surrogate testing --

A. I honestly don't think we would have. I honestly don't. But I really don't think we would have at that stage because I think we -- on the one hand there were these great anxieties about all blood supply and on the other hand we hadn't the faintest idea really as to the impact of what we were doing on the patients.

I mean, let me explain. I said the other day those people an aspirin or oral anticoagulants, it is known, the numbers are out; it is known, you know, the extent of the risks involved and individual doctors then have to make a judgment as to whether, when they see their patient, they are going to put them on these various drugs. We really didn't have that data -- I'm repeating myself. And I think instinctively this may be about the medical profession. I do not know. Instinctively, I don't think we would have been inclined to say, "Well, let's just accept the Americans". The fact of the matter -- I don't know whether it is Wisconsin -- if we had taken that column and said, "Let's look at that on the table", I think a lot of people would have said it's not worth a candle.

Q. Was the recommendation made because the directors thought that the implementation of surrogate testing would be materially beneficial for patients?
A. I can't remember but I have already said my own view was the introduction of surrogate testing would have had some benefit, right?
Q. Some benefit?
A. Yes.
Q. Do we get to the stage of material benefit?
A. No, no -- "material" means you know the numbers, for me anyway. But the notion that it would have had some benefit, I certainly don't dispute at all. I would accept that completely. The real question is: what do we mean by "material"? What is the real odds-on bet here that's worth putting your money on when you know -- you have already got a pretty good -- not very good -- handle on the cost. I'm not talking about money.
Q. So just to be clear, the position is that you thought -- or as a group you thought it would have some benefit but you were not in a position to be able to quantify what benefit it would have?
A. Absolutely right. I'm sorry it has taken this long.
Q. Not at all.

Can I just move on from that area, which is the reason why the decision was made, or the recommendation

was made, to the issue which we have covered to some extent, which is to do with the communication at that stage with SHHD. I think you have already accepted in your evidence that the communication to SHHD of the reasons why you were making the recommendation was not ideal. Is that fair?

A. Yes, I think so, sir, yes.

Q. And do you also accept that you did not communicate clearly to SHHD the reasons why you thought that the study being proposed by the working party was, in your words, "a mistake"?

A. I can't answer that. I can't honestly remember. Certainly I had some fierce conversations with poor old Harold Gunson who chaired the committee. So he knew very well --

Q. I'm obviously talking about the communication of your views about the study, which you had obviously discussed with Dr Gunson, to SHHD?

A. I appreciate that but it was my experience that anything I said to Harold was in the SHHD within half an hour. I'm exaggerating but I don't think that was a serious problem. If you say, is there any documented evidence that I actually stepped in and communicated on this with SHHD, to the best of my knowledge the answer is no.

Q. There is certain documentation, which I don't want to go

into in detail, which suggests that throughout 1987 there were people within SHHD who were very much focused on signing up to the study, and it doesn't really seem from that documentation that they had as sophisticated an understanding of the shortcomings of the study as you have articulated already. Do you think it was your responsibility to communicate to them your views on the shortcomings of that proposal?

A. Yes. I can't remember now in our directors' -- you would need to look, to be honest, at the directors' meetings, which John Forrester attended, along with one of his administrative colleagues, the point at which we discussed all this but, yes, I would accept your point and I'm absolutely sure in my mind that John Forrester was pretty clear as to my views on this. But, I mean, I would leave it to John to respond to that.

Q. Right. If you didn't clearly set out the reasons why you were making the recommendation, and you didn't clearly explain why the study was a mistake, why do you think that Dr Forrester understood clearly what the position was?

A. Because he had attended our directors' meetings and listened to the debates going on to and fro.

You could well argue that one of the -- it was a weakness that they were sitting in with us but

I purposely arranged this years and years -- in the early 80s, when I started, that SHHD colleagues joining us in the directors' meeting so that they were briefed and indeed could engage in the discussion if they so wished.

Q. I could turn it round the other way in fairness to you, Professor Cash. Did they ever come to you and say, "We are not too sure why it is you are making this recommendation. Could you explain it a little more clearly, please?"

A. Yes, I think that's a fair point but I wouldn't wish to pursue it.

Q. When Dr MacDonald, who you will recall was the chief medical officer at this time, gave some evidence on this topic, he suggested that the working relationship between SHHD and SNBTS at this time was a little difficult. This was in a late 1986, into the first half of 1987. Would you agree with that?

A. Completely.

Q. Do you think that the difficulties in the working relationship had an impact upon the effectiveness of the communication between SNBTS and SHHD on this issue?

A. Yes, it is probable, but I mean, I think wherever you get communication problems on all the issues, there is a potential for difficulty. But I wouldn't particularly

single out this one. I wouldn't, anyway. I realise you are pursuing this particular ...

Q. Could I just ask you about a couple of the comments that you have made in your evidence on this topic already? Really just for the purpose of clarification.

Could I have a look, please, at the transcript for 29 November, which is Day 70 of the evidence at page 169.

This is a passage again where you are being asked about your views at various different times. In particular, I think, Mr Mackenzie was asking you here about the position at the end of 1986, and he was examining this issue of how there had been perhaps a change from 1986 into the beginning of 1987, and you said at line 8:

"So I would have -- even if it had cost -- I wouldn't have been happy with just going ahead and doing it. We eventually decided that we were going to be forced into this. The market was going and we had no control whatsoever. But that came later."

Just to be clear, you are talking about late 1986 at this stage and you are making reference to some later period. What I want to just be clear on is what you meant when you say that eventually you were going to be forced into this. Of course, you are talking about the

introduction of surrogate testing there. By whom would you have been forced into it?

A. Well, I discussed with you this morning the potential development of private blood banks and blood collection agencies, one. Two, if you asked Dr -- Dame Professor Marcela Contreras what she was doing in 1994, which astonished me, talking about the introduction of ALT testing because they wanted to sell intravenous immunoglobulin into Europe. When I saw it, I couldn't believe what I was reading. So pressures were put on some old friends of ours -- these old friends having vociferously opposed our thoughts that we were going to be driven by market forces in that direction -- there they were a few years later actually going down that track.

So when you say we would be forced, I don't think anybody is beating us on the head. There would be an inexorable drift, my concern was -- in 1994, if these things were implemented. But some of my good friends and colleagues were actually talking about exposing a lot of donors to potential -- being rejected, and anxieties and worries. Why? So they could sell the products that these donors were giving voluntarily. I found that quite difficult.

So there were potential pressures and I think we

were just alluding to this. That's all, sir.

Q. As I understand it, the pressures you mentioned there really are two. One was the potential private blood banks.

A. Who were going to up the ante.

Q. I follow that. And the other one was the suggestion being made from Professor Contreras.

It's interesting, I think, is it not, that those two things were things that were happening in England at this time. Were they realistic pressures on you in Scotland?

A. Oh, I don't know. I really don't -- I honestly don't know and I don't wish to be cynical or speak out of turn, but when we saw what went on in 1987 with the Clydebank hospital, in the context of profit and government interest in markets, you know, it rocked us, to be honest. Not that they shouldn't do that but when the Scottish Office mates of ours claimed that they had consulted carefully -- when this man Brunton moved into the fifth gear, our Scottish Office colleagues publicly went on the record to the media to say, "We have already discussed this in great detail with our colleagues in BTS and they are fully supportive". They had done no such thing.

So politics and all sorts of things. Public sector

organisations are inevitably -- and rightly -- very dependent on these movements. And I think to predict that they won't ever happen, and to say, "That was England. It couldn't happen in Scotland," I don't believe a word of it.

Q. So in any event, they were influencing your thinking?

A. No question.

Q. I accept that.

Could I just again go to a passage that I just wanted to get some clarification on. This is a passage in the same transcript, Day 70, but at page 175. Perhaps we should actually just have the end of page 174 first.

You will remember this passage no doubt, Professor Cash. This is when you were talking about the meeting that you had had at the beginning of 1987, I think, and you had talked with your various European colleagues, the Vox Sanguinis meeting.

A. Yes.

Q. They had been saying to you, and you quote at the bottom:

"It's all happening."

Over the next page you say:

"So in that period you have asked what changed me, I began to get the jitters that once again in the UK we

had gone to sleep, we were off the ball, and I felt that I had a duty as national director to advise my colleagues that we should get in an application for money in the event -- knowing that in the event of the Department of Health saying, "Yes, okay, go," at least the budget was there to get down to the detailed difficulties of doing it."

So you mention there that after this conversation or discussion you had with your European colleagues, you had the feeling that, "Once again in the UK we had gone to sleep". Who did you mean by "we"?

A. Me, Brian, Harold Gunson, the corporate whatevers. It had just, you know -- I felt, I think, at the time -- it's difficult to remember. It just seems to have gone off the ball, a bit off the agenda. And I think Brian McClelland would say that he just getting nowhere and he was getting very little support. Yes.

Q. Okay. Thank you very much, Professor Cash.

Thank you, sir. I have no further questions.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: I have no questions, sir.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: Mr Sheldon will cover this topic, sir.

THE CHAIRMAN: Mr Sheldon.

Questions by MR SHELDON

MR SHELDON: Professor, we have heard quite a bit about the directors' meeting of 3 March 1987, as a result of which the directors recommended the introduction of surrogate testing. I think we understand there was a discussion at that meeting about surrogate testing and that some directors were against that proposal or that move. Is that correct?

A. If you are referring to what I think you are referring to, when Brian McClelland produced this proposal -- am I correct? Is that the meeting?

Q. Sorry, perhaps it would help just to go to the minutes of it. Bear with me. It's [SGH0016653]. If we move forward, please, to the item about non-A non-B testing -- sorry, I don't have a page number for that, I am afraid.

A. I think this is the meeting when Brian McClelland proposed -- put his paper, his letter up. That was the letter that we fiddled with a little and then everybody signed and it went off, and it was published in July.

Q. Ultimately published in The Lancet in July, yes.

A. I'm content to talk on that basis.

Q. I think we understood that albeit that the ultimate decision was unanimous, there were some directors who were uneasy about the idea of surrogate testing.

A. I said yesterday, I think, that all of us, certainly

including myself, but all of us were very uncomfortable with finding our position -- and we were not in that letter recommending the introduction; we were saying, "It's too late. We are going to be forced into doing it." But none of us wanted to go down that track and I think it is quite important that I make that very plain, sir.

Q. Yes. I'm sorry, we have now moved on from the relevant passage, but I think we can see from page 1 that Dr Forrester was there from SHHD; is that right?

A. Yes, if it's on the minute.

Q. Can we just see page 1 briefly again? So we see Dr Forrester is the SHHD representative?

A. Yes, indeed. John is there.

Q. So he presumably would be aware from the discussions of the unease that was felt about that?

A. Yes.

Q. And we ultimately have the recommendation. We have The Lancet letter. Could you look, please, at [SNB0113846], please? I think we have looked at this before. I don't think we need to detain ourselves very long on it but this is your letter to Dr Fraser at the Bristol BTS, really, I think responding to a concern about the SNBTS recommendation. You say, point 1:

"The SNBTS directors do not wish ... [to introduce

NANB surrogate testing unilaterally].

"2. Current views ... crystallised last March, are being expressed to support our PES bid."

Three, that this is part, I suppose, of a continued debate about the Medicines Act and product liability, and indeed that The Lancet letter is no more than part of a debate initiated by our friends and colleagues at Edgware and can be viewed as yet another attempt to persuade central management at the DHSS to give renewed thought to the way that transfusion services interface with the Medicines Act.

So you give a number of reasons perhaps there why the recommendation was made, and can we look, please, now at [SGF0012085]? If we look to the foot of this, that appears to be a memo, I think, from Dr McIntyre, 21 July 1987, to Mr Macniven, dealing with the question of surrogate testing. Do we see about a third of the way down with a little "x" beside it, there is a note in The Lancet for 4 July:

"Professor Cash and the SNBTS regional directors set out a case for starting testing, claiming that it's inescapable and cost-effective."

Then if we look further down the letter, we see, I think, two paragraphs further on:

"Professor Cash has assured Dr Fraser of Bristol

NBTS, in a letter dated 8 July, that he will not institute testing unilaterally."

Reading short to the next paragraph, we see:

"DHSS have expressed their concern and dismay at the letter by Professor Cash ... and have interpreted this as being SHHD policy. We have attempted to reassure them that is not so."

Does it appear from this memo at any rate that Dr McIntyre had seen your letter to Dr Fraser, or at least been informed of its content?

A. I don't know the answer to that. All I know is that John Forrester would have had a copy of the draft and it would have been into McIntyre by lunchtime. That's all I can be sure of, sir.

Q. Yes. So would it be fair to say that really in terms of the recommendation to introduce surrogate testing, the need for surrogate testing, SHHD at this time were getting what might be described as "mixed messages" from SNBTS?

A. No, not at all. And I think you keep -- all of you keep saying we recommended it. We just simply said, "It's inevitable. It's going to happen. We are going to be caught here and we need to plan for that eventuality."

I can't -- I've already said to you, sir, if I may say, we did not -- we were all very unhappy about this.

We were not saying, "This is excellent, let's go for it". We were saying, "We are caught". But all this inactivity that we have had since 1980, we still in 1986/87 do not know where we are, and we thought -- I'm repeating myself. The whole thing -- please, we did not recommend that we started it. We simply said, "The writing is on the wall, we think, as best we can judge".

Q. Right. Moving on then to a slightly different topic, I think you perhaps suggested that the reason why studies didn't go ahead really was because you were prevented from doing studies, you didn't get funding to do studies by the SHHD/Department of Health.

I just wonder if that's right, professor. Perhaps we can look briefly at what Dr McClelland said about that matter. It's Dr McClelland's evidence Day 63. At pages 85 to 86, I think. Can we go on to the next page, please? And down, please.

I'm sorry, I may have the wrong reference.

I think perhaps if I can simply summarise what Dr McClelland said about this on Day 63. He said that really, if the members of the Hepatitis working party had put their shoulders behind a proposal for a large scale prospective study, then something would have happened?

A. Which working party are you referring to?

Q. The UK Working Party On Hepatitis.
A. Right.
Q. Do you accept that characterisation of matters?
A. I honestly -- he is speculating that if the working party had said X, that funding would be made available and that's, I have to say, a complete speculation.
Q. All right.
A. You then have to look very carefully at who was on the working party, and when I tell you that two of them were civil servants, Smithies -- Alison and John Forrester. Another two were Harry Zuckerman, who for ten years had steadfastly and very consistently opposed the investment of money in this exercise; and the other, I think, was Howard. There was no English director apart from Harold Gunson. I could well imagine the department people saying, "This is not --" if they had said, "We strongly recommend it," I think the department could well have said, "This doesn't really represent the people who have major concerns about safety of blood". So you are asking me to speculate, and if you want me to, I would say that if that working party had recommended strongly a prospective study, it wouldn't still have been funded.
Q. All right. So you would disagree with Dr McClelland in that respect?

A. Yes.
Q. All right. I'm just thinking that taking that a little bit further, would you accept that as the smaller department, SHHD might look to DHSS to fund what would have been a pretty expensive study?
A. Absolutely right, sir. I should, however, mention that great discussions had been going on. £8 million a year for surrogate testing. I think that's a figure that was bandied around. You needed about £1 million a year, maximum, to do this proper study. I thought, if you had set up the study and told the clinicians out there that, "We are really doing this very seriously," over a period of three or four years, you would have spent 3 or £4 million, come up with some serious data compared to introducing it at £8 million, I think it would have been very economic indeed. And I don't understand why that was not seen. I really don't.
Q. I think the final area that I would like to ask you a little about is your comment about -- and I think I have to ask you little about this -- Dr Forrester, who you said at one point had been briefing against SNBTS. I really just wonder if that's a comment that you would stand by and if so, really what you mean by that or if you have any particular examples in mind.
A. Yes, I can. I don't want to get -- I'm reluctant to get

into personalities. If you look at the information that has been brilliantly gathered together by the team here, you will come to a point -- I'm sure you will recall this -- in which Dr Forrester, in briefing -- I think it was Archie McIntyre -- is describing the work of Brian Dow and his -- the Glasgow studies, and he actually says -- I don't want to take -- time has gone by -- that the results of the Dow study were not welcomed by Professor Cash.

Q. All right.

A. As though Professor Cash is gunning away here to introduce surrogate testing and Dow and Eddie Follett have said, "It's a complete waste of money," that somehow I was unhappy with this. Aside from the fact that I didn't happen to think the Glasgow studies, as a scientist, were as helpful as they might have been, that's completely set aside. The notion that I actually was belting to get surrogate testing introduced is a nonsense. You have to ask -- I don't think you have to, but in the context of the question you have asked: why did John say that?

Q. All right. We may have to try to find that particular memo, professor. I'm not sure I'm aware of that particular reference.

A. I've got it marked in my book.

Q. Can we look, briefly at a different memo. This is [SGH0028137].

This is a memo from Dr Forrester, I think dated 1 December 1986, reporting on the UK Working Party on Transfusion-associated Hepatitis, and I think we have looked at this briefly already with you, professor. Just looking at the second page, if we may, we had looked at this final paragraph:

"The position explicitly reached at the meeting is to recommend research of no great significance or scientific interest."

I think in essence, when you appeared here on Tuesday, professor, you really agreed with that?

A. Yes.

Q. And --

A. John, who is on the committee, he was the committee -- a member of the committee who produced a project that he says is of no great scientific interest.

Q. Well, if we can just look on the first page, please. So this is a report of the working party. Do you say that Dr Forrester would have had an influence, a decisive say, if you like, on what this committee, this DHSS committee, was doing?

A. I wasn't there, sir.

Q. All right.

A. I really don't know. You need to ask Brian McClelland.
Q. All right.
A. If you look at the list, as I have got, you will see that of the six members that attended, Dr Alison Smithies, DHSS, John Forrester, SHHD are listed as members, not as observers. I don't know whether that's a typo or not, sir.
Q. All right. If we just look briefly at this first page --
THE CHAIRMAN: Are you going to go into it in some detail?
MR SHELDON: I think not, not if I can avoid it.
THE CHAIRMAN: Because we are breaking the morning up in rather a different way, it's 11.50. I count on you to exercise your judgment.
MR SHELDON: Perhaps I can simply ask Professor Cash now whether this memo shows any signs of briefing against SNBTS, and leave the professor to look at the memo over the break and we can come back to that.
THE CHAIRMAN: Yes. Perhaps you might see if you can give further information about the memo that you do remember yourself.
Right. We will have a break now.
(11.53 am)
(Short break)
(12.05 pm)

THE CHAIRMAN: Yes, Mr Sheldon.
MR SHELDON: Thank you, sir.
Before the break, professor, we were looking at this memo, 1 December 1986, and it was really just to put to you the question whether this shows any sign of briefing against SNBTS in the sense of demonstrating antipathy, hostility towards SNBTS in any way.
A. You asked me to look at the paper you supplied, sir.
Q. Yes.
A. I have done that. The answer is none.
Q. All right.
A. Would you like me to refer you to the paper I was referring to?
Q. I think it might be helpful.
THE CHAIRMAN: I think you should do that.
MR SHELDON: Just to have a look at that.
A. [SGH0028141]. This is a memo from Dr Forrester to Dr Scott.
Q. Yes.
A. Copied to Murray and McIntyre. I'm looking at the third point in this memo:
"Dr Cash is pressing for the English BTS to seek a start of this ..."
That's surrogate testing:
"... apparently on the grounds that the UK are

lagging behind 'other parts of the world'. The initial -- and very prudent -- response is likely to be a call for research."

I agree with that:

"Some has already been done last year in Scotland ..."

This is Brian Dow and Follett:

"... but turned out discouraging for Dr Cash's purposes."

I'll leave to you --

Q. How do you say that's briefing against SNBTS or against you, Dr Cash?

A. Well, what we knew was that the department was opposed to this and Dr Forrester is signalling that I am for it, and as a consequence of which I had no interest in the Dow/Follett study. Forgive me but I regard that as briefing against me.

Q. All right. So you took this as a sign that Dr Forrester was in some way against you?

A. I didn't take it too personally, I have already said. This was an incident. If you want evidence in the C2 topic of a certain unhappiness, I'm simply saying here is an example. Given a lot of time, I think I might be able to find some more but this, I think, is the biggest one that I'm aware of.

THE CHAIRMAN: I don't want you to go too far and you know, it's for me, Mr Sheldon, to decide whether this is a disparaging comment or not.

MR SHELDON: Indeed, sir. I'm content to leave it there, sir.

Those are all my questions. Thank you.

MR MACKENZIE: I have no further questions, sir.

Ms Dunlop will now conduct the C4 examination.

THE CHAIRMAN: Very well.

Questions by MS DUNLOP

MS DUNLOP: Hello again, Professor Cash.

A. Hello.

Q. As would be expected, we have a statement from you relating to this topic as well, topic C4. The number of that statement is [PEN0172094]. Could we have it on the screens please? There it is.

We are really starting with news of the Chiron breakthrough here, professor.

A. Yes.

Q. And we made some progress, after we published the preliminary report, in matching up some of the documents. The first paragraph refers to our having obtained the correspondence which demonstrates you firing off some letters at the beginning of July. You wrote to Chiron, you wrote to Ortho in the United States

and you wrote to, let's call them "British Ortho", in High Wycombe. And the response that you had from Ortho, the British Ortho, which we are not going to go to but it is [SNB00083586], I thought was slightly deflating.

You had written saying, "When can we get our hands on some testing kits, please?" And Mr Follett, no relation I have been told?

A. No.

Q. Mr Follett wrote back and said that they had a lot of work to do still and that it was likely to be towards the end of 1989 before the kits would be available.

I wanted just to look at a document, [SNB0024411], which is one of several announcements of the Chiron breakthrough, and we can see the same sort of information being communicated, we have already seen in, I think, it's Science and Nature and so on. This is Blood Bank Week.

I was going to ask you if this was your underlining, which is not quite as impossible to answer as it sounds. Do you see that in the top right-hand corner, item 3e(iv) of 14.6 -- this is going to be 1988. I can take you to a minutes of a directors' meeting on that date. 14 June 1988, that's [SNB00027333].

Maybe we will just keep the Blood Bank Week open. Look at the directors' meeting, 14 June 1988,

[SNB0027333].

As so often in the Inquiry, professor, I think I know what happened and that can be very dangerous but it looks to me as though you decided this was something that should be discussed at the directors' meeting. If we look at the minutes, if we look at page 2, we can see the start of item 3, which was "Matters Arising", from the minutes of the previous meeting, no doubt, and then page 4, section e "Donation Testing" and then on to the next page, we can see item (iv), it's a perfect match with the little typed note at the top of the Blood Bank Week extract. So do you think it was your underlining?

A. Almost certainly, yes. I would think so.

Q. Yes.

A. And I should say that the Blood Bank Week is not the most prestigious journal in the world and I have a serious submission that my mates didn't get it, that I had chased this up through other American channels. Yes, it looks awfully like my pen and everything else, yes.

Q. Right.

A. Guilty.

Q. It may not have been the most prestigious journal but it does have something very well worth knowing in it, presumably, which is the last paragraph?

A. Yes.

Q. When it says:

"The Times ..."

It's presumably meaning the New York Times?

A. I presume so, yes.

Q. So the New York Times is quoting Harvey Alter as having said that:

"The identification of the non-A non-B Hepatitis protein is what we have been looking for for ten years. One has to be sceptical but the data I have seen looks very good."

A. And he is heavy weight.

Q. Yes, so that was a very worthwhile endorsement for the publication to include.

A. Indeed.

Q. I'm sorry, we rather prematurely left the minutes. Can we just look back and see that page 5 of [SNB0027333]?

THE CHAIRMAN: Could we just get the date of the blood bank into the notes, please?

MS DUNLOP: Yes. I'm told it's on the next page, in fact there is a date there. Thank you. 13 May 1988. So very much the same sort of time as the other publications that we have already looked at with this announcement.

Right, so back to the minutes:

"... the statement in a recent issue of Blood Bank Week that Ortho would soon market an ELISA test for NANB antibody. JDC would contact Ortho Diagnostic Systems to enquire about the availability of the test in the UK."

There you are in the right-hand column, which we know is the initials of the person to take some action.

A. Yes.

Q. So that explains to us the background to those letters. I think it takes us into the next part of your statement, so if we could return to the statement, please. Actually, no, I'm sorry, I want to go back to the minutes again. Can you keep the statement, obviously just go back to those minutes?

Can we go to page 3? Right. I also wanted to highlight the penultimate paragraph on page 3 because this is taking us into the next part of your statement and it introduces us neatly to the two groups issue, if I can call it that:

"There was a need for microbiological operational advice specific to blood transfusion services and it was important this should be uniform throughout the UK. EAGA could offer advice only as to policy, having no infrastructure to execute policy. JDC would discuss the possibilities with Dr Wagstaff."

I was interested, professor, in that reference to

the difference between policy and operations. I think we understand that but the implication of this seems to be that you were envisaging a group which did both. Is that right?

A. I can't honestly remember, to be absolutely honest with you, but it makes a lot of sense, doesn't it? I mean, that would be an excellent proposition. But we know -- and eventually knew very clearly -- that that was not what DHSS had in mind.

Q. So it would have been a UK-wide group that would have been responsible both for the formulation of policy and for issuing instruction to implement that policy?

A. Well, yes, but the instructions come via ministers and so on, in terms of ... but, yes, the dream originally was to have a group which was heavily represented with people from transfusion centres who actually knew the game in terms of donation testing, both the technology and the science, and would include virologists, would include departmental people.

But, yes, that said, I did not have any problem with the notion of the two, providing the one -- that's the advisory group on the viral safety of blood -- was open and transparent and had effective representation on it in terms of the science, as it related to donation screening.

So I wouldn't see this splitting of two in any way sinister from our dream of one. If we could have got it to work, you might argue that having two, if they really worked closely together and there was transparency and everybody knew what was going on, would actually be a more effective use of resources.

Q. Right. So whether one group or two groups, the operational dimension would be decided upon by a UK-wide body, which would then report to the respective ministers as to the practical steps that required to be taken and the ministers would then issue appropriate instructions?

A. Yes.

Q. Is that the sort of vision you are describing?

A. Yes, that was the original vision.

The key to this -- and poor old Harold Gunson got very -- I hate to use word -- the "shambles" that developed with HIV and that we were determined that that wouldn't happen again, and indeed Jeremy Metters and his colleagues moved to do something about that.

Q. Right. We will come to HIV in just a moment, professor, but that vision that's articulated there, of possibly having the one body that could do both, doesn't ever seem actually to have been got up and running with either of the groups that was formed.

If we look at [SNB0061923], this is the terms of reference for the Transfusion-transmitted Diseases Committee, and we can see that that's really quite policy-focused. As first formulated at the start of 1989, it's quite policy-focused. You keep up with our transcripts, I know, so you perhaps --

A. I try.

Q. You are perhaps aware of some of the information, some of the documentation from that period, that is the second half of 1988 and the early part of 1989, which might suggest that there was a bit of an accidental quality to the establishment of the two groups.

When we look at the directors' meeting for 13 December 1988, it does look as though you and Dr Gunson were saying that a group needed to be formed because nothing was coming from government.

A. I think that's right. It's difficult to remember but there was also, I remember vividly, very great concern that the Metters committee, as it eventually was called, had many of the deficiencies, aside from the secrecy -- had many of the deficiencies, of the problems, that we had with the small group that advised DHSS for HIV. And both Harold Gunson and I were concerned about this. Harold particularly, because Harold, as I think I have said in some statement, felt very vulnerable on that

Metters committee to the praying mantises, he said, of the virologists, the academic virologists. I wasn't on it so I couldn't see it.

And Harold felt very concerned that there needed to be -- and I totally agreed with him -- a broader church, an involvement of people who were really in the game, that they could advise Harold in some way such that he -- and I think I have said it in my statement -- could take it up to the Metters committee. I think it started off as the Ed Harris committee.

Q. It did.

A. Yes.

Q. There are a number of references, professor, to the virologists on ACTTD?

A. Yes.

Q. And you were on that?

A. Yes, I was.

Q. I just wondered, so that we are clear, who were the virologists on ACTTD?

A. I would need some notice but I think Phil Minor, Richard and Philip Mortimer.

Q. On the ACTTD?

A. Yes, I was going to go on --

Q. We will have a look at the minutes of ACTTD in a moment.

A. That's the non-BTS virologists. I mean, John Barbara

eventually came on. He was an excellent addition. Eddie Follett, as I recall, came on as well.

Q. It struck me, professor, that at least from the membership at its inception, the only two who would qualify for the description "virologist" on that committee would be Dr Mortimer and Dr Follett.

A. Thank you. I'm mixing up, no doubt, for what may have happened later, I can't remember, but I think you would find my old friend Richard Tedder sneaked in eventually. I know this because we had some --

Q. I think all I wanted to establish was am I correct that you would see both of these individuals as virologists?

A. Yes, absolutely.

Q. Right. But you would draw a distinction in whatever epithet you would apply to them, you would see them as transfusion virologists, rather than academic virologists?

A. Not Phil. I mean, he was PHLS. He is an outstanding laboratory diagnostic, hugely important to the hospital services, as a reference centre. But Phil wasn't experienced in large-scale screening, as, for instance, John Barbara was, who came from North London.

Q. North London, yes.

A. Eddie Follett was in a sense identical to Phil because he came from a regional virus reference laboratory,

Ruchill. If you asked the Scots, who then would be their best person to have the knowledge in terms of donor screening, aside from Ruthven -- and I think we often forget that Ruthven Mitchell was a superb laboratory guy and understood and had an great empathy for the work, but he had working for him a man called Mr Archie Barr.

Q. Yes.

A. Who was, to be honest, a legend in this field.

Q. Right.

A. He was a technician, an MLSO, very senior.

Q. Right. Can we go back to Professor Cash's statement, please, and I did note the mention you make of HIV. It seems to me, however, Professor, that there are some important differences between this story -- that is the introduction of screening for Hepatitis C -- and the screening aspects of HIV. The first is that there was no will we, won't we phase with HIV screening, it was really taken as a given from the start that screening had to be introduced. Would you agree with that?

A. Yes, and that because it was triggered by EAGA.

Q. Right.

A. That's absolutely right. Which was the CMO that chaired EAGA. I should just say this, and I'll tell you because I was on EAGA, politically Mrs T and cabinet were

extremely anxious about HIV, and rightly so, and so there was no question of "Shall we or shall we not?" You are absolutely right. That's one of the differences.

Q. Yes. The other is that you mention a lack of urgency but it is perhaps worth reminding ourselves that test kits began to become available for use around about April 1985 and screening was introduced in October 1985, so it does look to have been a reasonably expeditious process.

A. I think in my statement -- I don't know -- is it B? -- Whatever it is, I think the performance with HIV was creditable but there was -- there were some problems. I'm just looking at this moment at a document that you referred me to at about half past four in the B4, of that big clinical study, and there were some real problems there.

Q. I think we established --

A. But compared to HIV -- HCV, in the context of urgency and focus, different as chalk and cheese. I agree with that.

Q. Yes. Right.

Thinking about ACVSB, can we look, please, at [SGH0031265]? Just to remind ourselves that this is the minute from Dr Harris, the then DCMO, dated

14 July 1988, which kicked off the thinking that led to the establishment of the VSB committee. It does seem that this was happening around the time when people were anticipating that something big was about to happen with non-A non-B Hepatitis, and we have looked at the directors' minutes from 14 June, so all around about the same time, that this is perceived as being on the horizon. There has been a Chiron announcement, the endorsement from Harvey Alter.

A. Yes.

Q. And the other thing to note is that it does seem to have sprung, in some sense or another, from EAGA, that there possibly had been discussion at EAGA and recognition that EAGA would not be the appropriate body.

A. Indeed. That was very specifically -- that's AIDS.

Q. Yes, absolutely. And we have looked at this document before and there are some interesting features of it, including the reference on the second page under the discussion of the CBLA to the wish that they had to market products and intermediates overseas, which seems interesting; they obviously saw themselves as having a market beyond England and Wales.

And in fact at the very end, we can see the reference -- and we have looked at this before -- about non-A non-B, and in fact on to the final page, that

Dr Harris is hoping to bring the group together shortly.

So when in your statement you say that:

"ACVSB had been conceived by DHSS officials partly in response to criticisms ..."

You had made:

"... of the way officials had managed the HIV/BTS interface."

I take it you will accept that a number of things came together in the summer of 1988?

A. I'm merely quoting what Harold wrote to me and said, "You have contributed --" but no more than that -- "your moaning had some sort of impact, so stop moaning now," as it were.

Q. Yes.

A. I think Brian McClelland, I saw in the transcript, lays claim to discussions with Harold to the -- but I'm sure that's right. I doubt whether my moaning had much effect.

Q. Another point you make in the answer to question 2 concerns the secrecy that surrounded the deliberations of ACVSB.

A. Absolutely. Yes, an absolute disaster.

Q. I just wanted to follow that strand with you. If we look at [SNB0024517]. This is a directors' meeting held at the headquarters of SNBTS on 29 September 1989, and

if we look at the top of page 2, we can see that the VSB committee was discussed as an issue and we are told that it is to be in order for Dr Perry and Dr Mitchell -- members of that committee -- to report its discussions and recommendations to their fellow directors.

Ms Corrie is to obtain this assurance in writing from Mr Panton and to say she hoped the transfusion directors could have copies of the minutes.

As you would expect, there is a bit of to-ing and fro-ing, which we are not going to look at, but the end of the story seems to be [SNB0024627].

Going to page 2, please. This is the directors' meeting 13 February 1990, so the to-ing and fro-ing has taken from September until the following February, and we have the final answer:

"It is to be in order for Dr Perry and Dr Mitchell to report the discussions and findings of the committee to fellow directors but the minutes could not be copied. They could, however, be passed around and discussed at directors' meetings informally. Dr Gunson confirmed that the same position applied in the NBTS."

In light of that, professor, is it fair to refer to a strict code of secrecy?

A. I think you would have to ask what happened then. I can tell you I had a pretty tough time with Archie McIntyre

on one occasion and he made it very clear to me that he sat on the committee and that he would advise me, when he believed there were things that I should be told. But the notion of us influencing the agenda, like us having a chat and saying, "Could we get this discussed on the agenda," was unacceptable and I think Bob Perry -- I need to -- I mean -- I'm absolutely certain that both Robert Perry and Ruthven Mitchell found themselves in a very, very difficult position and -- I mean, David McIntosh, just used to blow -- and rightly so -- blow his top up about this.

So we were not having minutes handed round, we were not being regularly briefed and I think they would say they were being regularly briefed by the chairman of that committee not to say things.

Q. So are you saying that this didn't happen? Are you saying that Dr Perry and Dr Mitchell didn't show you the minutes?

A. No, we have got evidence that on rare occasions it did happen and we will be talking about HCV donation testing and Bob leaking to me that he and Harold Gunson had attempted at the committee and failed at a particular point. And when I raised this with Harold months later -- it was in March 1991, when we had these awful phone calls -- he had grave objection that Bob Perry had

broken the confidentiality and spoken to me. He didn't know that this had taken place and we got all very upset with each other.

So, yes, I would say that in my experience -- and certainly I know David McIntosh -- we, as managers of the SNBTS, were not properly briefed at all.

Q. Right. That sounds a bit of a guddle, professor, because if the formal position was that Dr Perry and Dr Mitchell were allowed to report the discussions to fellow directors and Dr Gunson is confirming that the same position applied in the NBTS, why did Dr Gunson get steamed us because that had happened?

A. Very good question. I need to look at the date of this. How long had the committee been in action?

Q. This is February 1990. So it had been meeting for ten months.

A. I think we will come to this later. In the 1991 debacle with the HCV donation testing, we did not know precisely what was going on. We will come to that.

Q. Okay. It's just that you say in your statement that you had no mechanism by which you could have an input on the construction of the agenda, submit briefing papers or have access to meeting minutes.

A. I know what you are saying.

Q. You understand the point I'm making?

A. I appreciate that but I have to tell you that my memory -- and I'm sure Bob Perry would confirm -- whatever is there didn't, for some reason or other, happen.

Q. Right, and of course you could write to the secretariat at any point --

A. There are some records which I wrote to the chairman saying, "I wonder whether you could consider --" I think actually the surrogate testing, the C2 topic -- "I wonder whether you would be prepared to consider that."

I recall very vividly on that occasion not getting a reply and then seeing, not until a few weeks ago in this Inquiry, that in fact it was discussed.

Q. Can we turn to the next page, please? You say that:

"The ACTTD was the brainchild of Dr Gunson."

Would it be fair to say though it was the brainchild of Dr Gunson and you? You are reported at the minutes of the directors' meeting --

A. Yes, probably, yes.

Q. Yes.

A. But again, just as DHSS gave the lead to SHHD, Harold considered himself the senior partner. And in terms of population, he was dead right and -- yes, I'm sure I was involved because we discussed his worries about

the Metters committee. So, yes -- but Harold -- that committee was the property of Harold.

Q. The ACTTD?

A. Yes.

Q. Right. Just so that we have the sequence of events accurate, we will just have a look at these minutes from December 1988, [SNB0027350] at page 2. This is a directors' meeting which was also attended by Dr Gunson.

A. Yes.

Q. It's actually headed up "AIDS" but I think it goes more widely than AIDS, and this is the basis for my suggestion that at least at that time you all thought nothing was happening. That's how it reads:

"Dr Pickles of the Department of Health had indicated some nine months ago that the department would take an initiative but this had not happened and meanwhile certain problems needed to be addressed."

So there was a discussion, and then:

"It was agreed that UK Blood Transfusion Services should establish a group to advise the departments of health on policies. It was noted that the matter was urgent."

In fact there is a reference to HTLV-I:

"HG agreed to liaise with Dr Pickles as soon as

possible."

So I just wanted, I think, perhaps to correct an impression that ACTTD was formed in response to ACVSB. It seems to have been formed when there was a perception of a vacuum?

A. Yes, this is all coming under the documents you are showing me, AIDS. And I have to say my best memory -- and one needs to look at the first meeting minutes of ACTTD -- I have no doubt you have got -- my best memory is that in fact the Advisory Committee on Transfusion-transmitted Diseases was established after the establishment of the Metters committee, as we called it, just after, and was in response to that but you may say, "You are wrong, your memory is wrong," and that wouldn't be the first time.

Q. Well, it's a long time ago but that's not quite how it reads; it does read as though the initiative for the TTD committee comes from this sort of sentiment, that nothing is happening and a group is needed and needed urgently. And really that group is formed very efficiently because it's having its first meeting two months later, in February 1989.

A. I think in advance --

Q. Yes, meanwhile the group mooted by Dr Harris in July 1988 is being put together and there were

various minutes and memoranda which no doubt at the time you weren't aware of and then letters inviting various people to serve, but it doesn't have its first meeting until April 1989.

A. I wouldn't wish to make a major -- but Harold knew what was going on with the Harris committee and in terms of the nature of it, in terms of the professional interests -- and I have always assumed that that's how we got into discussions in which the TTD was -- but you may say that's not quite right. I wouldn't wish to argue, to be honest.

Q. Fine. Just to go back to your statement then, please, this is one of the references to the different kinds of virologists. If we look at line 4, you say:

"Dr Gunson wished to encourage the ACVSB academic virologists to dialogue with the UK BTS virologists."

That's why I was asking you that earlier. I was just wondering who you had in mind but I think we have really covered that.

Can we just look at the minutes of the first meeting of the TTD committee? That's [SNB0061975]. You are right that in that gap between December 1988 and 24 February 1989 Dr Gunson appears to have acquired some more information because he says that:

"The Department of Health were in the process of

forming a group but its brief would be wider than blood transfusion medicine, embracing transplantation and other aspects of disease transmission."

So not so much a policy/operational distinction but a distinction being drawn because the remit of one group is to be very broad and the remit of the other is to be more narrow. That's how that reads.

A. Yes, I think -- I mean, it's interesting you see it in these terms. For me the Harris committee reported to ministers and the Advisory Committee On Transfusion-transmitted Diseases -- and this became a very hot contentious issue -- actually reported to Harold Gunson.

Q. Right.

A. And later an event happened which was very unfortunate, in which a newly appointed chairman of the TTD committee believed strongly that it should be reporting and advising the Metters committee or the Harris committee and that was put down.

Q. Right. Certainly --

A. So it was a bit messy. I think I refer in my statement there were tensions that developed.

Q. Yes.

A. Because Harold had written the remit of the -- the remit of his committee and I don't think that would have been

fully agreed by Ed Harris.

Q. Right.

A. These things can happen.

Q. Yes. Certainly we can see there an ambition for this committee, that it would be providing advice to the departments of health. That's at the end of paragraph 2.

A. Absolutely. That was the ambition.

Q. Yes, but certainly by the meeting of ACVSB in April 1990 that was being adjusted so that ACTTD were really tucking in behind ACVSB.

A. Very much -- yes, "We will consult you when we wish. We do not wish/require any of your papers, thank you very much, we will control --

Q. Subordinate in fact?

A. Very much.

Q. The other thing that's interesting about this is paragraph 4:

"It was also agreed that, whilst decisions of the committee would be subject to consultation with regional transfusion directors, any dissent would require good reasons."

Whose proposal was that?

A. I have no idea. I like that stuff.

Q. Slightly Stalinesque.

A. Isn't it? It couldn't have possibly been mine.
Q. Let's move on. Can we go back to the statement, please? We asked you about how the membership was determined and you have answered that. I think we are slightly better informed now, so that our question about Dr Perry, whether he was nominated by SHHD, in fact he was approached directly by the Department of Health, so I think we were wrong about that.

Then you said that you proposed Dr Mitchell for the TTD committee and you have explained your grounds for doing so.

Right --

A. I think it's in this context that Stan Urbaniak's name appears.
Q. It does, yes. I wasn't going to return to that but if you have some information on that.
A. Just to say he was not well and we all thought, "Stan, relax." And Ruthven stepped into the breach.
Q. It would have been a very long journey for him at a practical level, if he had to travel --
A. I don't think that would have worried Stan.
Q. It wouldn't?
A. Oh, no.
Q. Okay. Can we turn on to the next page, please? We asked a little bit about the early minutes of ACVSB and,

unsurprisingly, you said, since you weren't a member, you are not able to deal with these questions.

Question 6. You proceeded with your intention to arrange testing of the Ortho assay. In fact Ortho beat their own prediction; they had their kits out before the end of 1989, as you know.

A. Yes.

Q. And there was an English evaluation begun and also a Scottish study. We asked if the Scottish study, which we have looked at before -- and we don't need to go to it again, I don't think, but the reference is [SNB0061596], and that's a report from October 1989. We asked if that was the equivalent of the English study and you thought it was, but it is fair to record that the Scottish one actually had nine different objectives? So it was quite a wide-ranging study?

A. Yes. I'm clear on that now. It was a separate study that we -- we did not know, to be honest, that Harold was at it. We were jumping the gun, you see. If you go back to HIV, you will, I'm sure, remember that Archie McIntyre banned the involvement of Ruthven's team with HIV kits. It was to all be done centrally controlled.

We, unbeknown to Archibald or anybody else, set up -- and this time with HCV -- that we would do a quick

look at some kits or whatever kit we could get hold of, and our obsession -- and it relates to surrogate testing. Our obsession was not actually at the time will it pick up all the positives, our obsession was are we going to have a huge background noise so we will lose a lot of donors and cause a lot of problems, because when we started, the prospect of a confirmatory test was bleak. So we did our own thing and when I phoned Harold he said, "Yes, and we have been doing our own thing," and the stuff sort of gelled.

Q. Right. Looking at your answer (b), which is on the screen now, you tell us that, in initiating this work, you were seeking to avoid the difficulties you had had in 1985.

A. Yes, that's what I have just been saying.

Q. That comment that you anticipated that once again SHHD would insist on the primacy of the DHSS, does that refer to the incident you have just mentioned, Dr McIntyre saying that he didn't want --

A. Yes, with HIV -- I'm sure you remember --

Q. I do remember.

A. -- I went thundering into him saying, "We are thinking of doing a kit test for HIV; we think we can get hold of some stuff," and so on and so forth, and Archibald poured water over this pretty heavily and it was then it

became very clear, for the first time for me, that these matters, they had devolved to DHSS.

Q. Right. It's just that it did seem that in your answer you are going slightly further than saying that it was just that exchange about who was going to be looking at kits because you say that you anticipated that:

" ... SHHD would insist on the primacy of DHSS with respect to the timing of introduction of HCV donation screening."

Obviously, we are going to come back to this but are you saying that you thought that you would be dictated to by SHHD about when screening would be introduced for Hepatitis C?

A. I don't think -- I mean, the answer to that is yes, I have always thought that and still do, but I don't think that was heavy -- I mean, the thing that concerned me was that in the assessment, the evaluation -- at this time, when we moved into the evaluation of kits, before we even think about timing of starts, the Scots had a place in the team, the UK team, that was being involved.

If you look at HIV, that did not take place, and that was not by accident. All I'm saying -- there is no doubt about that. All I'm saying is that we wanted to use this as a lever to get Ruthven and his team, that

were quite outstanding by international standards, into any UK game that was being played, which we were certain would be run by DHSS. And that's how it transpired.

Q. All right.

A. And we were successful with this one.

Q. Can we look at the next question? I don't think that we really need to explore this with you because we seem to have had our answer, which is that the samples of special interest were included in the study that I have just mentioned; that is the study involving Dr Dow and others, which was first reported in October 1989.

A. Brian Dow had a lot of very good samples for study.

Q. Right. Can we go to the next page then, please? Here we are in July 1989 and we referred to a view expressed by Dr Mortimer that the Ortho tests were reliable. We asked about whether there was a prevailing sense of the timescale within which testing might be introduced and we asked about the possibility of ACVSB commissioning its own evaluation of the tests.

You talk about communings in the summer of 1989, and I think we should look at some of this information. Can we look firstly, please, at [SNB0061580]? This is you, on 3 August 1989, writing to your fellow directors on the subject of NANB testing, and I think this bears out your observation, or your recollection, that you were,

as a group of directors, believing that donation screening could be commenced between April and June 1990 because you have this comment that, although you had no idea when you would start:

" ... I'd back the horse with 'some time after April 1990' on its nose."

One of the salient points you make is that:

"The decision to commence testing will be a UK one and will be made by the UK departments of health."

But then you say in paragraph 2:

"The start date ... will, as with HIV-1, also be a matter for central government decision, with, of course, appropriate consultation with the UK BTS directors."

And then some more practical considerations are addressed in paragraphs 3 and 4. Then, if we look on to the next page, please, you say you have started a battle with Ortho on confirmation testing, and we can see from a number of different items of documentation from around this time that that was a concern of yours and others from very early on.

In your statement you make reference to a letter from the following day, which -- sorry, this is not on my list, but SNB0043897. Sorry, that's the wrong document. That comes later. I think this is one of

your briefing notes, which you refer to -- I may have the wrong one -- you refer to as one of your own references in your statement.

Yes, I'm sorry, to look at it now would be to take it out of order. Can we put the briefing note back for the moment and go back to the statement, please? I'm confusing myself thoroughly here. You are referring to this to vouch your recollection that in October 1989 you advised SHHD that the SNBTS directors believed donation screening could be commenced between April and June.

So, yes, sorry, we should look at it.

A. Yes, that's right.

Q. I wanted to give you the opportunity of referring to your own reference. That's the document we just had, [SNB0043897]. This is actually one of these briefing notes for the Common Services Agency. You discussed the general concept with Mr Mackenzie earlier this morning and this is quite a full note for the members of the Blood Transfusion Service subcommittee. It's actually November 1989. But you give them quite a lot of background.

A. I think they found all this too full.

Q. I'm sorry --

A. They found much of this too full.

Q. Too full? Right. Can we go on to the next page,

please? There we are. "Post-transfusion viral hepatitis". Explanation of Hepatitis B and non-A non-B and then a complicated scientific breakthrough you explain as being something that has happened with the aid of chimpanzees and genetic engineering:

"The position has changed dramatically. Ortho has announced its intention to make test kits in the last three months. They have distributed the first kits for evaluation and WBTS [West of Scotland Blood Transfusion Service] is evaluating the test."

Then on to the next page, please. A bit more explanation of some of the science. Then go down through it and then on to the next page, please.

Interesting to note that again you are pointing out -- and this is number 8 -- the difficulty of there being no confirmatory test and then your prediction there is to be a meeting in London on November 11. I think in fact it was November 6th, not a material difference. You were expecting that advice for the minister would be formulated at that meeting and it seemed probable that the advice would be positive and that the UK blood transfusion service would introduce routine HCV donation screening in mid-1990.

So I understood, when I looked at this, professor, that you were referring to it to illustrate that in 1989

that was your expectation about timescale.

Can we go back then, please, to the statement? We are at 2097. You say that you were advised that DHSS did not move to promote HCV kit assessment until January 1990 and that the anticipated deliberations on this topic by ACVSB were deferred until April 1990.

I think, for the record, professor, we should note that that meeting, ACVSB on 6 November 1989, did decide on a pilot study and that that was carried out and was before the committee in January 1990. So it's perhaps not quite as your recollection has it --

A. I think I'm recalling a conversation with Harold, which may be quite wrong. I apologise. But there was some deferral because I remember hounding poor old Harold about this.

Q. Certainly --

A. I don't want to make an issue of it.

Q. Certainly from the minutes of these meetings -- and these are important meetings -- November 1989, January 1990, April 1990 and July 1990, all meetings of ACVSB -- one can detect the members of the committee approaching the possibility of taking a decision in principle and then perhaps receding slightly from it.

So in a general sense I think we understand what you

mean by perhaps deferral but I don't think they were deferring discussion of kit evaluation.

The other point that has been made to us, which I think you would accept as fair, was that a number of members of the ACVSB were either themselves involved in separate evaluations or knew about other evaluations, so there might have been an element of duplication --

A. Yes.

Q. Yes -- if ACVSB had begun at that point commissioning more widespread studies?

A. My concern was that much earlier than this we were advising the CSA that we had enough data in Scotland to make this thing -- this was on. As I recall -- and I think you have mentioned it -- Philip Mortimer said, "Hey, I think this kit's a runner," and against that background I think he said that, you know, soon after or around when we made our comments, and my impression was, and still is, until you sought me out that, it really was quite some months and months before the Metters committee said, "Right, we are going to have a proper study here." There was a -- there seemed to me -- and what was very clear to us was until the Metters committee had done whatever they wished to do, we were going nowhere in terms of a decision about testing and so on and so forth.

Q. Right.
A. And I think maybe my assumption that there was some delay may be wrong but I do remember hounding Dr Gunson about. You know, "Why aren't they getting ahead and then, if they want to assess it, why aren't they going on and getting on with it?"
Q. Sir, I think that would be a good point at which to pause.
(1.06 pm)
(The short adjournment)
(2.00 pm)
MS DUNLOP: Thank you, sir.
Could we go back to Professor Cash's statement, please? That's [PEN0172094], and we are now at 2097. Thank you.
Professor, before lunch we looked at the genesis of the two different committees and we looked at some of the early evaluations of the Ortho kits that were taking place, and we are really still in 1989. I wanted to look next at what appear to be some early indications of how the decision was going to be reached. So trying, if we can, to look at what the understanding was of those who were involved as to who was making the decision and how.
If we look at paragraph 9, we mention a letter you

sent, dated 28 July 1989, and that mentions the decision-making process. I think we will just have a look at that to orientate ourselves. It's [SNB0082603].

You are writing to Dr McIntyre saying that the major concern at that time was:

"The considerable marketing pressure being exerted on us by Ortho Limited to introduce full routine Chiron NANB donation screening."

You are putting on record the position following a telephone conversation you had had with Dr McIntyre in the preceding week.

You go on to say in your letter that:

"The decision to commence routine donation testing using the Ortho (Chiron) test throughout the SNBTS would be made by SHHD and that it would not be appropriate at this time for senior SNBTS managers to liaise with Ortho Limited with respect to arranging supplies of tests for routine donation testing. Such discussions should not take place until instructions are received from SHHD."

And you are asking him to confirm this position.

If we go back to the statement, we hazarded a guess that this letter might almost be reflecting that you wanted something from SHHD that you could show to Ortho to relieve the pressure that they were putting on you.

You say that the answer to that is no. I just want to look at the next two questions before I ask you for your response, because really they all belong together.

In question 10 we mention Dr McIntyre's reply and we say that:

"Dr McIntyre's reply suggests that the principle of introducing a further test had not yet been determined."

We also refer to Dr McIntyre mentioning that any new test would be introduced simultaneously throughout the UK.

Then in question 11 we referred to correspondence between you and Dr Gunson about the timing of screening and the desirability of Scotland and England moving together on the matter. More correspondence. And again, asking about your understanding at that time of the timescale involved.

Can we look then at Dr McIntyre's reply. That's [SGH0028026]. So Dr McIntyre is replying to you, referring to the existence of the ACVSB and saying that:

"If it is considered desirable to introduce a further routine screening test for blood donors, I understand that this will be done simultaneously throughout the UK, as was done in the case of the current HIV test."

And that letter is being copied to Dr Metters.

We switch now to your understanding and your position. Can we look at [SNB0061574]? This is around the same time. Dr Gunson is writing to you by a letter dated 26 July 1989. He is pleased to hear that you are doing a study, saying that he is having some difficulties with Ortho who are wanting to know when, not if, they are going to introduce routine testing and how many tests they wish to order, referring to the meeting in Rome and in fact saying:

"My view is we should not move until we know what our European colleagues are doing. For the UK it is important that the SNBTS and the NBTS act in close collaboration since I can foresee difficulties if one of us introduces the test unilaterally."

You replied promptly to that letter. So that's [SNB0082606]. 28 July 1989. You thank him for his letter and mention that in fact you are not doing 5,000 donations, you are doing 3,000, and mention the interesting samples. Dr Mitchell was going to Rome instead of you, and you say:

"We will not move unilaterally unless instructed to do so by SHHD, thus close collaboration seems certain. A wonderful idea if we could act in union with other European countries but doubt we have that corporate level of understanding and trust."

Then you tell him that you have taken a very hard line with Ortho.

I wanted to suggest to you, professor, that the whole tone of this correspondence is that the two of you were going to be working together on the introduction of screening and that was what you wanted?

A. Absolutely.

Q. Right. So you were perfectly happy with that, indeed you saw that as the best course?

A. Yes, absolutely.

Q. Right. Good. Can we move back then to the statement? Question 12. I don't think we need to spend a lot of time looking at that. Dr Mitchell refers to figures and we asked if they were from the ongoing work of Dr Dow and others, and the answer to that is yes.

Then question 13. We asked about the decision-making process again. You said you never had any doubt that:

"... although the decision for Scotland would finally be taken in Scotland, the SHHD operational policy on this issue was to defer totally to the primacy of DHSS and that Scottish ministers would fall in line with their London-based colleagues. I was further advised that this position had been conveyed to the CSA."

But really everybody, whether at the policy level, if you are thinking of the elected politicians, and at the operational level, yourself and Dr Gunson, everyone was speaking of moving together. So it wasn't really that a position was being foisted upon you with which you didn't agree, it was what you wanted as well?

A. No, no -- well, can I just say that the way Harold Gunson and I would be working together with our teams would be in the evaluation of the kits.

Q. Right.

A. I was never sure, to be absolutely honest -- I was absolutely sure about myself, that I had no locus whatsoever in terms of the timing, dates that were going to be decided, put to ministers and so on.

So the working -- us closely working to the -- we would have been delighted to have been sat down together and said, "Let's work out a time that suits us both", and so on, but the truth of the matter is that was very much -- I was not allowed to be involved with that. But the evaluation of kits with my right-hand man, Archie Barr and Ruthven Mitchell, we were very much involved, working with Harold.

Q. Well, I think it goes a little bit beyond that, doesn't it, because as a matter of principle there is going to be a decision taken at some point on what the date is to

be?

A. Yes.

Q. It doesn't matter what that date might end up being but it is being communicated to you that the date will be the same for Scotland and for England and Wales and Northern Ireland.

A. Indeed.

Q. At this point you have no problem with that because that's what you think is right, too.

A. I have no problem with the principle as long as we get on and produce the science from which a decision can be made.

Q. Right. So if we are taking a snapshot of the position in the summer of 1989, you are signed up to the idea of simultaneous introduction?

A. Yes, no question about that, rightly or wrongly.

Q. Okay. Moving on to question 14, we note that this refers to confirmatory testing and we know that you and others had a letter in The Lancet in 1989 making the point about how important it was to have a satisfactory confirmatory test, and we understand that.

Then on to question 15, which is about Rome, you say that you remember this as the beginning of a period of much unhappiness and frustration. You were putting pressure on Dr Gunson to reveal why the ACVSB

secretariat had deferred considering the existing kit evaluation data until April 1990.

We have, to some extent, already covered this, Professor Cash, but I don't think there is any sign from the minutes that they deferred considering data on kit evaluation from their January meeting to their April meeting. If you want to look at the minutes, we can do that.

A. I'm happy to take --

Q. You are happy to take --

A. Oh, yes.

Q. Right. Then you say that you discovered, after the meeting of ACVSB, which actually I think was 24 April 1990, that both Dr Perry and Dr Gunson had argued in favour of a recommendation there and then in principle to introduce screening, and you say you shared that view. But Dr Gunson and Dr Perry's views had been rejected and instead the committee agreed to mount its own HCV kit evaluation exercise.

I think by this point actually, professor, what we are talking about is Ortho against Abbott, so the fact that there was an Abbott kit coming on the scene?

A. I think so but it was the first generation.

Q. Yes.

A. That's the key thing, I think.

Q. Yes, but it was seen as important --
A. And it was a big one, it was thousands.
Q. In 1990 it was seen as important that there would be an assessment of Ortho against Abbott.

Then can we look on to the next page, just for the record, what was envisaged at the April meeting was a really, very large study and then, given the change of circumstances in two important respects between April and July, that comparative study was toned down or reduced in scale.

We are now looking at 16 and you say that you are deferring to Dr Mitchell and Dr Dow on this matter but we were asking about the events -- and this is going back a little bit -- in September 1989, where there had been the evaluation by Dr Dow and his colleagues.

I just wanted to have a quick look again at these minutes. We have looked at them already but on a slightly different point. Can we look at [SNB0024517]?

Can we go to page 3, please? Just to note again that the directors, yourselves as a collective body, are recording the same understanding that I have been rehearsing with you and you have agreed, a common understanding that any routine testing would be on a UK basis, on a date to be determined by the Department of

Health, following the advice of ACVSB; which would be meeting next on 5 November. I think it's actually 6 November. It doesn't matter.

Then the directors go on to record points with which we are familiar, crucial importance of a satisfactory confirmatory test, implications for donor management, and various financial points and then some practical issues as well.

Can we go back then to the statement and to 17? Taking the narrative on a bit, Ortho pressing ahead with their confirmatory test. We asked a bit about the defining characteristics of a satisfactory confirmatory test. I don't think we need to revisit that. I think we have a rough understanding of the difference between a confirmatory test, properly so-called, and a supplementary test?

A. A supplementary test, yes.

Q. Then 18. These letters, which we have looked at before, [SNB0061560] is the letter to you of 27 November saying that Ortho now have an export permit and then 1561, also from Ortho but this time Ortho in the USA, talking about the prototype RIBA tests.

Then some further questions. Again, you are deferring to Dr Follett and Dr Dow about the different techniques involved in confirmatory testing.

Then 20, the final report of the SNBTS evaluation was produced and we have covered what "dev kit" means. Then 21 on the next page, please. Repeated references at meetings to the need for the Ortho test kit to be approved by the FDA for use in screening in the United States.

We asked why it was necessary to tie introduction of the test in the UK to approval by the FDA. And you said that you remember this being regarded as important, as a general view that the scientific processes of assessment of these diagnostics kits by the FDA were more rigorous and independent of political/commercial influences than in many countries, including the UK.

I thought it would be interesting to remind ourselves of the relevance of this factor in the assessment of HIV kits. Could we just do that by looking back at [DHF0027101]. This is a minute by Dr Alison Smithies dated 21 January 1985. She says in the second paragraph:

"We also discussed whether or not any reference should be made to tests not being accepted in the UK unless they had FDA approval and decided that such stipulation might not act in Wellcome's best interests in the short term. FDA approval was, in any case, one of the factors to be considered in any evaluation."

So not something that I think we are really in a position to probe but just to note that FDA approval perhaps didn't have quite such a dominant role in the HIV story?

A. Well, particularly when Wellcome were in the game, and the odds are on Wellcome might not be quickly licensed. That was not in Her Majesty's Government's interests.

Q. Anyway, we have reminded ourselves of that slight difference. Perhaps we can go back to the statement again, please, at page 2101. And we are coming close to the hornet's nest.

A. Yes.

Q. You presumably know that we have a little bit more of an understanding of this now?

A. My heart sank and I thought that was me but I have now discovered, thank goodness, it wasn't. I don't know what it's all about. Still.

Q. I'm sorry if the question implied that in any way you were responsible for a hornet's nest. That wasn't the intention.

A. I thought you would say, "That's a typical Cash statement".

Q. We understand that on this occasion it was Dr Mitchell, who, however unwittingly, had brought back this hornet's nest from the United States and it was a set of

guidelines prepared by the American Association of Blood Banks, the American Red Cross and the Council of Community Blood Banks and dated 8 February 1990, and it related to forward planning for the introduction of screening in the United States?

A. Right, thank you.

Q. The statement was sent to the Department of Health by SHHD and that, I think, was where the hornet's nest was stirred up.

A. I can imagine.

Q. And the comment was made by someone called Pam Reenay from the Department of Health. Our speculation is that the hornet's nest was that it brought into very sharp focus the likelihood of the United States introducing screening in early course, and therefore being possibly slightly at odds with what was happening in the United Kingdom.

We have also been looking, Professor Cash, at another event in February 1990, which was a symposium actually organised by Ortho and occurring in London, also on 8 February, I think, 1990, and we know that a number of very leading figures in the area came and spoke at that symposium and they were speaking about Hepatitis C and in particular about the testing kits.

We have come across a letter that you received from

Dr Boulton, who was one of those who attended the symposium and I thought it would be good for us just to have another look at it. We looked at it yesterday. It's [SNB0141644]. Have you seen this again recently?

A. No, I haven't.

Q. Just to let you have a look at it.

A. Oh, I remember, yes.

Q. Yes.

A. Yes, I'm remembering it.

Q. Right. So he is saying --

A. "Get on with it".

Q. In a nutshell, he is saying the test isn't perfect but he feels very strongly that the screening of donors should be introduced at the earliest possible opportunity, not because of the "science", but because there appears to be little doubt that people have contracted HCV as a result of transfusions, which they would not have received had those transfusions been screened for HCV antibody.

Put like that, it sounds quite simple. You would presumably have agreed with Dr Boulton's view?

A. Yes, and that was where I was after the very first Glasgow study that we did on our own, that we were passionately concerned, as I said, overwhelmingly, with the specificity, and to our delight and surprise --

because there was great worries about this -- it was fantastic and it didn't get much better than that over the years. We recognised that with the Ortho, there may be an odd missing one in terms of a positive control, but something -- the view I took something was better than nothing at that stage. And I think this is what Frank is doing later.

Q. Yes so --

A. This chase for the Holy Grail of a perfect test kit, it's an illusion.

Q. So he is reporting to you on 21 February.

A. Yes.

Q. I wondered if you could remember what, if anything, you did with this report. There is a five page report of the symposium that goes with it, I should say.

A. I can't honestly remember, unless it appears, you are going to tell me, in a minute.

Q. Sorry, I don't have any rabbits in the hat on that.

A. Very disappointing. I honestly don't know, I can't remember, sorry.

Q. So the answer may be that you just regarded it as being in harmony with your own views --

A. More fuel to beat poor old Harold, who was the only person I could actually beat over the head in this particular context because he sat on the Harris/Metters

committee.

Q. Yes. Right. Please can we go back to the statement? We referred to some other events in the spring of 1990, including the April 1990 meeting and Dr Perry and Dr Gunson feeling that a decision should have been taken at that point, and we have obviously asked Dr Perry about that.

Then Dr Young, looking for a paper for the Common Services Agency. 25, on the next page, please, that is dealt with. Dr McIntyre's response. And then 26. This is a letter we have looked at already too and we don't really need to look at it again, but because in the interval between the meeting of ACVSB on 24 April and Dr Metters' letter, two things have happened, the FDA have approved the test for routine use in the United States and the confirmatory tests are out, the decision is being taken to advance the next meeting, so it is being brought forward to 2 July.

It's perhaps in that regard slightly surprising that a clear decision wasn't taken on 2 July. But just to look at your answer, I wondered about this comment you make that the deputy CMO advised Dr Perry in June 1990 that the time had come for ACSVB to consider not when to start HCV screening but rather whether it needed to be done at all.

Actually I'm not sure that I have followed that reference, Professor Cash.

A. I was going to say, I hope that reference is correct and that's the right interpretation. Earlier we had had Archie McIntyre saying -- going on about all this, "John, we are not actually sure we are going to introduce any test at the moment". And I have obviously at some point picked up that in many respects the letter -- the DCMO letter to Perry in some respects backs up what Archibald is saying.

Q. So what you meaning to refer to at that point is the letter from the DCMO to Dr Perry?

A. Yes, indeed.

Q. I wonder if we could have a look at that, [SNB0020245].

A. Maybe it's a misquote.

Q. I was just a bit puzzled by your answer, Professor Cash, and if you could explain it to us, I think that would be helpful.

Do you think there is something in this letter that suggests that the committee might be asked whether screening needed to be done at all?

A. It wasn't that the committee -- well, yes, in the sense that -- I have interpreted something somewhere -- and I may be quite wrong -- that DHSS are not yet of a mind that a new test is needed.

PROFESSOR JAMES: Line 2, paragraph 3.
A. Thank you.
MS DUNLOP: Is it not possible that what Dr Metters is meaning is that decision time is here in terms of actually making the positive decision in principle to recommend the introduction of screening? I don't think he is really canvassing as a realistic option that the UK may decide not to do any screening at all.
A. I interpreted it as meaning what you first said, that they were saying, "Look, we need to consider now then the introduction of testing". That's -- that was my interpretation. I just felt, if that's the interpretation, it's very late in the day for us to reach that decision. That's all.
Q. Yes, I think there is not much of a difference between us, professor, it's just that you have read more into the letter that I have.
A. That's highly probable.
Q. I read it in a slightly different manner. I had understood it as meaning only that, "No decision in principle having been taken yet, now may be the time when we have to take the decision in principle"?
A. Yes.
Q. But you have seen in this some sort of canvassing of the option of deciding not to do it at all? Do you still

think that was a realistic --

A. That may be a bit hard. I was using it in a sense to give support to Archie McIntyre's comment much earlier:

"Stop running before you can walk, John. We haven't yet made a decision that that's where we are going. That's not necessarily the direction we are going."

That really is all.

Q. Yes. I think if we read the progression of the minutes from November 1989, there does seem to be a direction of travel, and it is that at some point a decision in principle to recommend the introduction of screening is going to have to be taken and the only debate is whether it can be decided yet, if you like.

A. It's just when he said, "We need to consider whether donations should be screened for Hepatitis C", I just felt, "Blimey," at that time, after we have been at it "This seems very odd". That's all. I wouldn't wish to --

Q. All right.

THE CHAIRMAN: Does the annex help, Ms Dunlop?

MS DUNLOP: The annex is the list of questions. I'm very happy to look at that.

THE CHAIRMAN: It goes beyond whether or not we should have testing. I think that's the only point that I'm interested in.

MS DUNLOP: I can't remember if it's in this version of the letter or if it has a separate number. Is there another page after this? Yes, there we are, thank you.

[SNB0020247]

It's actually quite a detailed list of questions that are going to be considered at the meeting.

A. You know, it was just item 4:

"If testing were to be introduced ..."

Let me say that's very rhetorical.

MS DUNLOP: Well, yes.

THE CHAIRMAN: Maybe what a very pernickety civil servant would actually set out.

A. Absolutely, sir.

MS DUNLOP: Just to finish looking at the annex, I don't know who but someone in the Department of Health has put together this list of questions which are presumably to shape the discussion at the meeting.

A. I'm sure that's right.

Q. If we look, I think there is another page, isn't there or is that it? Yes, there is. Here we are. There is not much between us, professor, you are probably reading more into the use of the conditional than I am. Perhaps it's a civil servant being very careful to recognise that no decision in principle has been taken.

A. Yes, and I'm naturally paranoid.

Q. Oh, right. If we just look back at the letter, so the first page of this. Yes, the other point to note is, of course, that the previous meeting, the 24 April 1990, has decided that there is going to be this large study, whether it was to be up to 50,000 or up 100,000 samples isn't very clear but on any view quite a large study, and the letter is saying that there probably isn't time for that. So the issue is urgent?

A. That's encouraging, yes.

Q. Yes.

A. Events are moving fast.

Q. So it's not really that the climate is, "We may be able to decide not to do this at all"?

A. No, no.

Q. The climate is: "We probably have to decide to do it."

A. There were things in the papers which says, "If we have to do this, X, Y and Z", and I thought -- I'm repeating myself, I apologise.

Q. Fine. I think we have reached a common understanding. I hope so. Let's look back at the statement. Some further questions which I think are not really directly matters for you.

27, 28, on to the next page. Then 29:

"The ACVSB meeting of 2 July did recommend that screening be introduced but not before the results of a

comparative study of Ortho and Abbott was completed."

We asked about this comparative study and I think the point that seems to strike a number of those who have commented is that it would be possible to introduce screening straight away and, as long as you had some centres using Ortho kits and some centres using Abbott kits, you were going to get the same sort of data on how well they performed in relation to each other.

A. Yes, yes. I say that hesitatingly because I don't know about today but right until I left in 1997, the different kits, you get these circles in which there is good overlap but there are some outriders. In other words, if you are a donor in Glasgow and you give your blood in Edinburgh, you may find that Glasgow says you are positive -- this is screen positive -- and Edinburgh says "Rubbish", because they are using different tests. This was a chronic problem which, as I recall, at some point exercised us very greatly.

Q. But you actually cast your vote in favour of the proposition that we put, that the decision was taken in principle but implementation was deferred. We suggested that that was actually rather a waste of time because the conclusion of the study was that any one centre could use either of the two kits.

A. Sure.

Q. So as it turned out, not a lot of progress was made.
A. That's correct.
Q. Not everywhere agrees that the time was wasted.

In question 30 we asked whether Dr McIntyre sent an internal memo after the meeting of 2 July as appears to have been his practice because there are matching reports of VSB meetings on other occasions, but we don't seem to have one for this meeting and we can't really take the matter much further, other than to say that the Scottish Government have advised us that no memo of this description remains on the branch file. So whether it ever existed, we don't know.

Then 31, onwards. We are coming on to events towards the end of 1990. So the meeting on 21 November 1990, deciding that screening should be introduced as soon as practicable and Dr Gunson saying then that a six-month period to set up testing would be excessive.

We actually obtained that mention of the 1 April 1991 being the realistic start date not from the minutes but from Dr McIntyre's report of the meeting. So actually not in the formal minutes.

A. Interesting.
Q. And can we just read on through 31 and 32 before we come to your input. This is a question about the submission

going to the Scottish Health Minister and we know that the submission didn't go until 24 July 1991.

Can we look, please, at [SNB0053696]? This is just to start this chapter of the story. Dr Mitchell obviously thought that the meeting in November 1990 was sufficiently important that he had to write to you and say what had happened?

A. He did and it's an example of where he did, you know, he did communicate, it wasn't secret, absolutely right.

Q. For current purposes it's important for us to note paragraph 3(a), that the decision, which had been made, was:

"... to introduce testing for anti-HCV using either the Ortho or the Abbott test, depending on local circumstances and experience of individual RTCs. The exact date of introduction would be at the earliest practical moment but it was reiterated that the UK would proceed in unity."

Then I think the letter deals with more practical matters. But just to complete the examination of it, we can turn on to the next page, please.

A. I think the important thing there is the penultimate paragraph.

Q. Yes.

A. Hugely important.

Q. Yes. The second generation test coming from Ortho and one anticipated from Abbott.

That comment about the UK proceeding in unity, I haven't been able to find anything in the minutes of the ACVSB meeting of November 1990 that discusses the position of Scotland at all. So I take it from what Dr Mitchell is saying in his letter that there must have been some discussion about all the different parts of the United Kingdom moving together but it doesn't seem to be clearly minuted.

A. No.

Q. Anyway. Can we go back to the statement, please? At this point I think it would be helpful for us to go through the succeeding months by looking at our extended narrative. It saves us looking at too many documents. So could we have that in front of us, please? It's [PEN0172165].

This does take us from November 1990 to the point where screening is introduced. So what we hope are the significant events and the significant documents are highlighted in it.

I do want to look at the first letter. [SNB0052555]. This is the letter that you sent to the other directors on 27 November 1990. This all fits together, Professor Cash. Obviously you have had this

letter from Dr Mitchell.

A. Yes.

Q. And you are sharing the information with everybody else?

A. I hope so.

Q. "We are a wee bit nearer to D-Day and we both believe it would be to our corporate advantage to take a further step forward along the planning route."

I just wondered whether you could expand for us that term "corporate advantage".

A. In the context of sticking together?

Q. I just wondered what you were meaning when you were using it there.

A. I think no more, to be honest, than I was very anxious that we all, as a team, stayed as a team. That's all at that stage.

Q. Right. And that underlining in the second paragraph?

A. What?

Q. The underlining of "simultaneous start date". That must be your underlining?

A. Yes, I would think so, or my typist's, Elizabeth.

Q. So you would usually tell the typist you wanted something underlined?

A. These were the days when I wrote everything out longhand, and bless her ...

Q. Really? You wrote it out longhand?

A. Yes, yes.
Q. I was imagining you with a Dictaphone?
A. You can imagine if I did that, she would produce ten pages for me just to say "good morning".
Q. Fine. Right.

So you are talking about a simultaneous start date and we can deduce from the underlining of that that to you that was extremely important?

A. Yes, and I sensed it was important to everybody.
Q. Right. So this is a UK simultaneous start date?
A. Yes.
Q. Right. And they were actually asking for some concrete information. You are asking at the end of November 1990, so within a matter of days after the meeting of ACVSB, what's the earliest start date each centre could manage and also some practical matters about which kit they would all choose and so on.

Back to the narrative then, please. We do know that for Edinburgh and Southeast Scotland, the reply that came said that they could start on 25 February.

Can we move on through this narrative, please, and on to the following page?

This note of discussions at a meeting of the NBTS/SNBTS liaison committee records a number of points. Importantly, the first is a concern on the part of

Dr Gunson that the Department of Health has still not decided on a start date. Is that a start date for England and Wales or a start date for the whole UK?

A. No, I think they were -- as I understood it, just as I had gone out to our team and said, you know, "If the wind is behind you, when do you think you could start," so we can get a consensus as to where we were as a team. I think Harold had done something pretty similar and then I think he suddenly released -- and this became a huge problem -- that it wasn't as easy south of the border, because in Scotland there were going to be top sliced money made available from the Scottish Office for us to get on and do it, whereas in England it was going to be left for regional health authorities to fund, and already -- and I think Harold told me this -- this became a bitter, long, entrenched battle apparently. The RHAs were saying, "We will but give us the money first," just as they were doing in Scotland, and there was a sticking point and it became a very big issue indeed.

Q. You see, you say, Professor Cash, that you had written to your fellow directors and asked, "How quickly could you manage?" and you think Harold had done something similar. The thing is he hadn't, at least not as far as we can tell, because he doesn't send a memo to the

directors of England and Wales until 22 January. So that's slightly puzzling.

I think what we are having difficulty in following is whose decision it was to fix the date? Was the date going to be stated from the health departments and then you would all try to achieve it or were you going to suggest a date to the government departments and they were going to endorse it? How was it to happen?

A. My understanding was that I would have been letting Harold know that I had consulted the team up here and that was the best we could do in terms of -- when I say "start date", there is actually some correspondence about that. When would you be in a position that everything on your shelf was dinky dory and tested. To get to that position -- and I always understood that was the key thing. To get to that position, different centres may have to actually start at slightly different times. I think that was acceptable.

So we were in a position and we were trying to find out, you know, (a) if we just said "Go for it", what dates would come out from the Scottish boys and we would pass this on to London or via -- to London via Gunson, copied into the Scottish Office.

My understanding -- and I may be quite wrong -- that the dates would emerge from the Metters committee --

that was unquestionably my understanding.

Q. Hang on. You said something there which I want to pick up.

A. Yes.

Q. I understand the point that I think you are making in paragraph 3 in this note. We are in 9.248. Just at the top. That you asked for a more definitive operational description for a start date. So I think what I understand that to mean is what do you mean by "start date"?

A. Absolutely right. I think I just said that.

Q. Does it mean the day you unwrap the first kit from the box?

A. Yes.

Q. Or does it mean the date on which you say everything we have has been tested for HCV antibody?

A. That's correct.

Q. Right. And you seem to suggest in the answer you just gave that you were comfortable with different centres opening their kits on different dates and beginning their testing on different dates.

A. If they said to me that in Inverness, "Because of our particular circumstances, to reach 30 January or whatever, to get everything on the shelf, we have looked carefully at this and we will have to start then --" if

Edinburgh said, "We can do it," and there is something slightly different -- I mean, we are talking about slight differences but it is recognising that different centres have got different logistic problems and some of the problems are very different -- were very different indeed. So that's all.

I'm not talking about, which we will come to later, the sort of Newcastle exercise, where you are months and months and months in advance of any date that has been given.

Q. So are you saying that what mattered to you was the date -- what can we call it? The inventory date, which is --

A. That to me -- yes. I don't know -- and I was saying to Harold, "What does the Department of Health think about this?" But, yes, my desire, rightly or wrongly, is for a minister to be able to say that on 30 January or whatever it was, every unit that's sitting on the shelf and waiting for patients in the UK has been tested.

Q. So your goal was that that should be the same around the whole of the United Kingdom?

A. That that date -- yes, if it was a runner, that would be kind of nice.

Q. And you were relaxed about different centres opening up their packs of kits --

A. Yes, as long as it was -- yes.
Q. -- and starting testing on different dates.
A. Yes.
Q. And that's how you felt at the time?
A. Yes.
Q. Right. It does seem from this meeting that you were a little unclear actually about what was meant by "start date". So rather than having an understanding that what you were all aiming for was a common inventory date, you were further back than that and you were asking, "What do we mean by 'start date'?"
A. Yes, I was. I was going back to Harold and saying, "We have talked about start dates. What could we actually mean? Do you mean on the shelf or do you mean that's when centres start testing?"
Q. I accept that you were asking that question but what I haven't noticed is any communication from you at the time saying, "It doesn't matter when different centres start testing as long as we all have our inventory tested by a certain date".
A. Yes, I'm sorry I haven't got a bit of paper that convinces you. I apologise. And I'm just -- but you have specifically asked me would I be worried if Edinburgh started on Wednesday and Inverness started on Friday of that week? No, I wouldn't. If you said what

about Edinburgh starting three months in advance of Inverness, I would have been very worried.

Q. There isn't surely very much room for manoeuvre, is there, because is it not the red cells that have the shortest shelf life? So there is only ever going to be quite a short difference. I mean, if people are going to start --

A. That is absolutely correct.

Q. -- testing the red cells, those dates have to all be very close --

A. But if you discovered it was three months, then there is something wrong.

Q. Right. But you are communicating that you had a flexibility in your view which would accommodate different start dates, in the sense of the commencement of testing?

A. Yes, slight differences.

Q. Slight differences in terms of commencement?

A. I think you would find Brian will say that the average shelf life of red cells in Edinburgh was much shorter than that in Glasgow because of the high rate that was coming in. In other words, they could discard much earlier.

Q. Right. Okay. Let's move on through 1991.

We are going down through 249, 250 and then we see

the reference to Mr Tucker's memorandum. Mr Tucker records that in a conversation with Mr Canavan of the Department of Health, he has suggested it might be better to set a target of 1 April as the earliest possible date but leave it to blood transfusion centres to come in line thereafter, since to delay for the slowest could mean a long wait.

That was common sense, was it not?

A. Yes.

Q. Right. What would have been wrong with saying, "The target date is 1 April", and just hoping that as many centres as possible would be ready and knowing that the setting of the target would make people hurry up?

A. I don't think -- you are catching me -- I don't think anything is wrong.

Q. Right.

A. The notion of sitting on and delaying for the slowest is something that I wasn't comfortable with, and if there were clearly very slow centres -- if the data came back saying we couldn't start until wherever, and it was very slow indeed, important questions need to arise. And I would be content -- we wouldn't need to ask them in Scotland because I'm quite certain this wouldn't have arisen.

Q. Well, Mr Tucker, in a broad sense, was right in

predicting that to delay for the slowest could mean a long wait because as it turned out, some centres took longer to get themselves organised and get ready than others, and I emphasise I'm not meaning any criticism because for some centres there were different issues that had to be resolved. But waiting until those issues, some of them quite major, were resolved, did mean a long wait or at least a longer wait, did it not?

A. Yes, if you are thinking in the context of second generation and so on.

Q. No, actually I'm thinking of waiting for the English centres to get their finances sorted out.

A. Yes, absolutely.

Q. Right.

A. Absolutely and that, as I have said earlier -- it became a major issue, one on which I briefed David McIntosh.

Q. You see, Mr Tucker is not, I think, in this comment in favour of waiting for the slowest. He sees that as a disadvantage. If you wait for the English centres to get their funding sorted out, that could mean a long wait and he sees that as a disadvantage.

A. So do I. I mean, I don't think -- the real question is what did Mr Tucker do about it.

Q. You think it was for Mr Tucker to take active steps? What do you think he should have done?

A. What do I think he should have done? He should have called a meeting and said, "We have reason to believe there are some significant problems south of the border." David McIntosh would have briefed him, because I briefed him, that "Yes, we have reason to believe, from Harold Gunson, that the overriding problem is funding and it's a complex problem that we are not familiar with and it's a battle between the Treasury and regional health authority finance officers", and the question then arises -- I mean, this will take us soon into David McIntosh's statement. The question then arises: are we going to sit then and us be delayed because there is an administrative fiscal problem and it's not technical, and so on and so forth. And I would have argued at that time, "No, we shouldn't be delayed. Tell the chaps to sort themselves out." And Harold knows this and he became very anxious. He knew of my view there and he became very anxious about it. Which we will come to later.

Q. So who would have been at the meeting Mr Tucker should have called?

A. I think the first thing -- who should have been at the meeting?

Q. Yes.

A. The undersecretary, his ultimate boss.

Q. That's Mr Forsyth?
A. No, no, no.
Q. Sorry, the Civil Service undersecretary?
A. Yes.
Q. Right.
A. I'm not sure. I think at that time it may have been Hamish Hamill. It may have been Hugh Morison, but the ultimate boss. Ultimately the CMO. The decision for us in Scotland -- as I think the CMO in his statements and oral hearings -- to go it alone, if the English can't keep up or whatever, was a big one. And so in my view it wouldn't have been a meeting that Mr Tucker had called; he would have been advising his senior medical and administrative colleagues to call a meeting.
Q. Are you saying that that step should have been taken in January 1991 or are you saying that --
A. For me it was March.
Q. Okay, well, less --
A. That's what I briefed David McIntosh on.
Q. Right. So you are not saying then that Mr Tucker, having recorded this train of thought in January 1991, was under some obligation there and then to arrange for a meeting to be called --
A. No, I'm not --
Q. -- to address the start date.

A. I'm not even saying he has an obligation. All I'm saying is that -- to get out if that is a real factor -- that he is in fact saying that we may be running into problems with the slowest in England. Somebody needs to say, "Hang on a minute," in principle, "What is the problem in England?"

We had ascertained in evidence from Harold Gunson that we knew it, and I sought to persuade David to go in and talk to colleagues in the department because this in fact was very important. And for me that arose -- for me personally, the real, honest, open acceptance of this by Harold to me was this awful telephone episode we had in March.

Q. Okay. I think we are getting ahead of ourselves. Let's stick to the chronological approach.

A. But I couldn't speak with any great authority about Mr Tucker. He may have known something that I didn't know.

THE CHAIRMAN: Are we having a break?

MS DUNLOP: We will be having a break. I think I'm not aiming to go much past four, so we might as well have it about half way, which is now. Thank you.

THE CHAIRMAN: Very well.

(3.05 pm)

(Short break)

(3.25 pm)

MS DUNLOP: Right, Professor Cash, we were looking at paragraphs 9.250 onwards just before the break, and if we look at 251, we see what seems to be the equivalent of your letter of 27 November 1990. So you had written to your fellow directors asking when they could be ready and this, on 22 January 1991, is Dr Gunson going to his fellow directors asking the same question.

He is saying testing is to start simultaneously and is to be co-ordinated with Scotland, and asking to be advised of the earliest date. I hadn't planned to look at this but I think in view of what you just said, we should have a quick look at it. [SGF0012029], please.

Really paragraph 2:

"I have been asked to try and ensure that testing starts simultaneously in RTCs in England and Wales and that it is co-ordinated with commencement of testing in Scotland."

Looked at now, there could be a bit of a nuance there, couldn't there? Simultaneously with England and Wales and co-ordinated with Scotland.

A. I find after 30 years-odd, nitpicking over words I find not very inspirational to be honest.

Q. I completely agree with you. That's why we are just glancing at this to note that people didn't talk in

great detail about what they meant by "testing". The correspondence from this time talks about "testing" and that seems to me to mean opening up your box of kits and starting testing of blood donations you have collected --

A. I completely agree with you.

Q. Okay. Can we go back to the narrative, please? We are at 9.251. That's that memo we have just looked at and then there is a passage in italics, which we have added in because we hadn't, I think, fully appreciated the significance of the Gulf conflict or I think, as it's now called, "The First Gulf War".

A. Yes.

Q. We do know that that was absolutely contemporary, so in fact the aerial bombardment to expel the Iraqi forces had begun on 17 January, so it must have been very much in the news and obviously in your minds at that time?

A. What is not known is that 90 per cent of the blood that was made available for British troops came from Scotland.

Q. Right. You are correct. We don't know that. And it certainly is mentioned in several different items of correspondence from this period, that it was obviously understandably a major concern.

In fact you are writing to Dr Gunson and saying:

"We remain firmly committed to starting on the same day as our NBTS colleagues."

So as far as you were concerned, as national medical director of SNBTS, it was to be simultaneous for Scotland as well?

A. Sure.

Q. So perhaps an innovation on Dr Gunson's comment about simultaneous for England and Wales, co-ordinated with Scotland, as far as you were concerned simultaneous with England and Wales as well -- and no doubt Northern Ireland as well.

Can we move on, please. Dr Gunson replied to your letter on 28 January. Dr Gunson, I'm sure not really meaning that he has no sense of urgency. He is perhaps just trying to communicate to you a reassurance that he wasn't trying to suggest you should start within days. And mentioning the need to sort out financial provision in England and Wales.

So he seems to be saying -- I think quite apart from any Gulf War problems -- that centres in England and Wales wouldn't be in a position to start anyway because the finances hadn't yet been sorted out. Right.

So we move through February, nothing particularly significant, I think, and nothing I want to look at, until 15 February. So if we can move on to

paragraph 9.254, you are writing to Dr Gunson on 15 February and again saying that you would very much like the SNBTS to stay in line with NBTS/BPL, and this time this is in relation to a definition of "start date". So you would like a common understanding of what "start date "means.

A. Yes.

Q. Can we move then through the next paragraphs and go next to 9.259 and we are now at the end of March.

A. Yes.

Q. This is you writing to Mr McIntosh and advising that the NBTS was struggling on a number of accounts to meet the 1 July deadline. You thought that that had previously been agreed and you believe that the fundamental problem was one of financial resources.

I think we should have a look at that letter, [SGF0012026]. What has now been agreed is that Dr Gunson is going to tell the Department of Health that the 1 July start date should be delayed until such time as evaluation of the new generation of tests has been completed.

And definition will be exactly as stated:

"The date when routine HCV donation testing will commence."

NBTS colleagues, your English colleagues, do not

wish to accept the original proposal that the definition of a "start date" would be that on that date, all RTC products issued would have been HCV-tested.

Then the next page, please. Copied to Dr McIntyre at SHHD. Can we go back to the first page, please? And in consequence of this being copied to SHHD, Mr Panton has written a note to Mr Hogg:

"This is worrying, please speak to Department of Health. We can't go to the minister until we know the start date."

So for whatever reason, people in SHHD thought that a submission couldn't be sent to the minister without a concrete start date in it.

A. Also, here is an example of a civil servant picking up there is a problem here. That's the funding one. We really need to look at this as a matter of urgency.

Q. Well. Certainly Mr Panton is concerned. We can see that. But you suggest in your statement that the delay -- that is the postponement from 1 July -- was something that was determined by DHSS and that SHHD were consulted and agreed to that DHSS-inspired and unnecessary delay.

I'm not sure that that can be right, Professor Cash, because it looks pretty clearly as though the receipt of this copy letter on 28 March was the first that SHHD

knew about it.

A. We haven't got to, because it's further back, this extraordinary series of phone messages I had, that immediately pre-dated the Advisory Committee on Transfusion-transmitted Diseases. It comes later. And I think that meeting was on 25 March. These were telephone conversations I had with Harold Gunson. We can go into them if you like but Harold sought my support for the phase 2, second generation kit thing and I initially rejected it. I can go into much more detail if you want.

The important point is in this debacle that Harold and I had and on which we fell out very, very badly, was a series of three phone calls. Harold kept insisting to me that SHHD are on side, and the side was the point -- he wanted me to come on side with -- and that is to agree to a second generation, which meant a delay and it meant certainly that 1 July had gone. And I am afraid there is no paperwork for this. What there is paperwork -- and I can explain it -- is that both Ruthven and I -- you see (a) there -- supported this proposal, and getting to that point was a very painful exercise.

Q. I think it's important, Professor Cash, that we don't conflate two different things.

A. Yes.

Q. One is a need to postpone the start date because the English centres weren't going to be ready. That's the first point. And the second is the desire to do an evaluation of second generation kits.

It may have been presented that there was a postponement so that an evaluation of second generation kits could take place but I think we should try and stick to the first, which is that there appears to have been a difficulty in England and Wales in achieving the 1 July start date because of funding problems.

A. And I am saying -- and this is very important in my mind -- the two are totally linked. And that's the problem. If you were a top civil servant in London and you discovered there were major problems here that were not going to be resolved -- that's the funding ones -- what on earth you could do to minimise the collateral damage, and we went through this with Harold in these phone calls. The obvious answer was why don't we delay then further and introduce the second generation test.

Already the same committee that ultimately did this -- they didn't actually, this was done by DHSS -- had said, "There is no need for a delay, we can actually fit in looking at second generation tests as we roll out

the phase 1 thing". I'm saying to you that the two are linked and I know this -- well, I don't know it, I was told this by Harold.

Q. Well, you are saying that the English centres weren't going to be ready for the 1 July and that there was to some extent use of a pretext?

A. Yes, a device, yes.

Q. Right. That device being that there needed to be an evaluation of the second generation kits?

A. Yet another big study, yes.

Q. Right. You say that you and Dr Mitchell had supported the pushing back of the start date to September but if it was solely about the evaluation of the second generation kits, why would it not have been possible just to start testing using the second generation kits and begin to assemble evidence on how they performed?

A. You mean start testing using generation 1 and then incorporate generation 2 in assessments?

Q. Well, whatever kits you could get. If it was still generation 1 --

A. Absolutely. This is what I said to Harold and indeed Ruthven, if you look at his letter, which we have seen in one of the paragraphs he said -- and I pointed it out to you -- very importantly he said, "By the way, Ortho are just about to launch a second generation kit and I

have reason to believe Abbott are not far behind". We have seen that. But he said, "There is no need to worry. The Advisory Committee on Viral Safety of Blood has said, 'We will fit the assessment in of the second generation kits that are now appearing once we have got the first generation in'," and they are absolutely right, that could have been done very readily.

I suspect that was done readily by half the world.

But, no, in the end no first generation, no nothing. We are going to go for a big other study on second generation. And I can only repeat what Harold made clear to me -- because I had a very tough time.

I refused to accept it originally. It was very painful. It got very personal between us. Harold insisted that this was a device to give the Department of Health more time, more space, to resolve these very difficult financial problems that they had, and secondly, he insisted -- this became very heated -- that SHHD knew all of this and -- this is not saying the date -- this is about the second generation evaluation, and the moment you sign up to that, July has gone.

Q. Well, in the first place the suggestion that SHHD knew what the plan was seems to be contradicted by this note that Mr Panton has written on.

A. That may be so, all I can say is that Archibald,

Archie McIntyre, was very close, through Advisory Committee on the Safety of Blood, to this whole scene, and I, in my mind, on this occasion assumed that Archibald was fully briefed on this. I do not know because I didn't phone him.

Q. That's the first point about the note on that letter appearing to record first intimation of postponement, but the second point is to try to find out what your position was. You are hearing of problems in England and Wales.

A. That's correct.

Q. These problems do not apply to Scotland.

A. That is correct.

Q. Are you saying, "Sorry to hear it, we must now go on and do what we think is right," or are you saying, "We will do all we can, we won't start because we know that would be awkward for you"?

A. No, I was saying -- and I was saying to David McIntosh, and I see he doesn't remember this. I was saying to David McIntosh -- I wrote to him saying there are financial problems and we discussed this. I said, "You have got to get into the department and -- into here -- and begin to say to them, 'Look, this is not of our making, we are all ready, we can go with generation 1, we don't need this'."

Q. So you were an advocate of what you later described as "going it alone"? You personally were advocating starting screening in Scotland and the English could sort out their own funding problems?

A. I was an advocate of doing what our masters, the Scottish Office people, said. They had made it very clear to us that we will do it on an all UK basis. I was very comfortable with that. But if we ran into situations in which -- we are not talking now about kit testing. We knew the kits were okay, we knew X, Y and Z, and we were into some internal English administrative problem, then at that point, I said to David, "I think you need to go and see -- ask the question, 'Do we need then to continue to hang in with the south of the border dates?'" and so on.

Q. Professor Cash, the thousands of documents in our database do not disclose you hanging back when there was a need to make contact with SHHD. In fact, quite the reverse; you were regularly and frequently yourself making contact with Dr McIntyre and others in SHHD. Why on earth would you have insisted that it was Mr McIntosh and not you who took that issue forward?

A. I can't answer that. I think the arrival of David, as general manager -- I just thought that -- I thought (a) he is a fresh face, doesn't have past problems with

colleagues in the Scottish Office but I -- I mean, I just made that decision and I thought David thought that was acceptable. In fact David was very keen to manage.

Q. Well, he is the general manager. But you are the national medical director, and surely this is about the safety of patients undergoing transfusion. Is it not in your patch?

A. Yes, I can't deny that but I mean, as things worked out, I was briefing David as to what was going on.

Q. You are asking the Inquiry to accept that you were firmly of the view that an approach needed to be made to SHHD to decouple the Scottish Transfusion Service --

A. To consider that.

Q. To consider decoupling the transfusion service in Scotland from the plans for England and Wales as far as HCV screening was concerned, you are asking us to accept that and yet it was Mr McIntosh you were expecting to take care of it?

A. To take us in -- I was -- I think in another statement I was very happy to go in with him as his expert medical adviser but to take it -- to get into the department, to get talking about it, yes, I was.

Q. Why did you not put anything on paper? I mean, we looked at your letter in the summer of 1989. You wrote

to Dr McIntyre, said you had had a phone conversation, and you thought it was important to put things in writing.

A. I agree.

Q. This is more important.

A. I wouldn't disagree.

Q. Why did you not put something in writing? So you didn't send a letter to Dr McIntyre?

A. No, no, I have no evidence of that.

Q. Right. Okay. Let's carry on with our examination of events in 1991.

Can we go back to the narrative, please? We are at 9.260. This is, I think, not directly relevant, this is the Contreras study. We will then go on to 3 April, which is 9.262. This letter we will look at. This is Dr Gunson's letter to his fellow directors in England and Wales, dated 3 April 1991, and this is [SNB0044883], if we could, please.

So Dr Gunson is writing to the English directors and saying that he had previously suggested 1 July might be an appropriate date to commence anti-HCV screening but that now there is a need to do an evaluation of second generation kits and that can't be finished by 1 July. It's all too difficult:

"It's difficult to state precisely a revised date

but I think we should aim to commence routine screening for anti-HCV by 1 September 1991."

Over the page, please. You are one of the recipients of a copy of this letter.

A. Yes.

Q. We see it actually also going to Dr Follett and Dr Mitchell.

Right. You replied and you replied quickly. You replied on 5 April. Can we go back to the narrative, please? Just to note in passing, that letter of 4 April, Dr Gunson is writing to the procurement directorate and saying that the timing of the study -- that is the comparison of Ortho and Abbott second generation kits -- has slipped because of the unavailability of test kits, and then you are replying on 5 April. Let's have a look at that, [SNB00063958].

You are telling Dr Gunson that:

"This most recent development leading to a start date in September 1991 has the SNBTS directors' fullest support."

In between 3 April and 5 April, had you canvassed your fellow directors?

A. I don't honestly know. I would doubt it but --

Q. I think we doubt it as well. So you probably wrote and recorded the support of your fellow directors without

specifically having asked them?
A. I think that's very probable.
Q. Right. And this is at a time when you say you had had difficult conversations with Dr Gunson and, what, to some extent had fallen out with him or is that putting it too highly?
A. No, it is not. We had fallen out badly.
Q. You had fallen out badly but you are extending to him the collective, fullest support of the SNBTS directors?
A. Yes.
Q. Why?
A. Because by the end of the falling out, we fell in again. It was over a weekend and I did, with some reluctance, what he begged me to do, and that was -- on the Monday, I think it was -- attend a meeting and not to object to the second generation study.
Q. So he had persuaded you against your will --
A. Yes.
Q. -- to go along with this plan to defer testing?
A. Absolutely right.
Q. Let's go back to the narrative, please? We then refer in 9.263 to communications in April, slightly more caution is being demonstrated in references to dates. It's now said simply that it's unlikely to be before 1 September. Then on to 15 April. Those in the

Scottish Home and Health Department are worrying about when they should be sending up their submission.

Can we then move on through April. I don't think there is anything I want to ask you about in the next couple of pages. Then we go to 30 April, which is just at the end of 9.268. It's this meeting that's interesting, Professor Cash. This is a meeting of the SNBTS/NBTS liaison committee and we are going to look at the minutes of that. [SNB0101108].

At this point it has become known that there are developments in Newcastle. Can we go on to page 2, please? "Anti-HCV testing commencement date":

"It had been suggested that a commencement date of 1 September 1991 UK-wide would be appropriate."

Then Dr Gunson is reporting that Newcastle Regional Transfusion Centre with Dr Hugh Lloyd in charge have commenced testing within the past week:

"No confirmatory testing was being undertaken and no information was available on donor counselling."

So Mr McIntosh is immediately telling SHHD about this development in Newcastle and Dr Gunson has already told the Department of Health:

"Dr Gunson hopes to establish multi-centre evaluation of second generation test kits with Newcastle as a participating centre. An SNBTS centre would

contribute to the evaluation."

I think that's the end of the discussion. Perhaps we should just check on the next page, if we could, please. Arrangements to be finalised between yourself and Dr Gunson, with Mr McIntosh kept informed.

Right, back to the narrative, please.

A. May I just interject?

Q. Yes.

A. It was David McIntosh, after those discussions, that insisted he would alert SHHD to the problem.

Q. I see that, yes.

These are vis a vis the Newcastle episode. Dr Lloyd actually sent a letter on 2 May to directors of transfusion services and I think we will get that on the next page. He says that because he was already set up for testing, he had decided to keep to the July date. His personal view was that not to test now would be indefensible under product liability legislation.

You and other transfusion directors wrote to Dr Lloyd expressing their opposition to Newcastle in inverted commas, "going it alone" and then we have a list of letters. The first one is from you, the second one is Dr Harrison. She was a London director, I think?

A. Yes.

Q. Dr Ala, Birmingham?
A. Yes.
Q. Dr Contreras, also London, North London. Then the last one is Dr Mitchell's. We have looked at Dr Mitchell's. It's quite a middle of the road sort of a letter.

I just wanted to ask you, the three letters that we have discovered, that is the Harrison, Ala and Contreras letters, they are all critical of Dr Lloyd. They are sent to him, expressing surprise and disappointment, to say the least, at what he has done. Why were they all copied to you?

A. I can't, for the life of me -- I don't know the answer to that.
Q. What was your profile that the writers of these letters from the English blood transfusion service all copied them to you? That's why we have them. They were all copied to you.
A. You asked what was my profile?
Q. Yes. You do not have a formal role in the English blood transfusion service.
A. Absolutely, none at all.
Q. Right. So why are they copying them to you?
A. No idea. We need to first check did I -- no, I have no idea, I have no idea. Did I copy my letter to Hugh -- which I now regret, those letters to Hugh -- to them?

Q. Well, I tell you what, it's nearly 4 o'clock and I think it would be quite a good place for us to stop just by closing down the particular Newcastle issue.
A. Yes.
Q. We have seen a couple of letters, Professor Cash, that first one, [SNB01187726] is expressed in strong language. There is no doubt about that. I just heard you say you regret those letters.
A. Yes, I do.
Q. Do you want to say what your view is of them now?
A. Well, I don't -- I still regret very much what Hugh did but I very much regret that I was so tough on him. I actually liked Hugh Lloyd and I will not go on in any great detail. I went to see him in Newcastle and had some good chats with him later. But my explanation, which is not an excuse, but my explanation is those telephone conversations I had with Harold Gunson -- it may have been the second, I think -- he gave me an absolute assurance that systems were in place, that the NBTS directors would keep in line because I had made it very clear to him that I was very worried about my colleagues up here, that they would accept this further delay. And he gave me assurance that they would hold the line and there was no problem.
And in any event, he made it absolutely clear to me

that if anybody got out of line at all or thought about it, DHSS would come down on them like a tonne of bricks. And there was a period of 24 hours/48 hours, when we all sat waiting with bated breath to see if that would happen, and hence a whole series of things developed.

And looking back -- and indeed, I regretted it at the time and looking back I felt that letter of mine was far too belligerent and frankly, if I was extremely critical of myself, I shouldn't have sent it, period, full stop.

Q. How quickly did you regret it?

A. Fairly soon. I have got a hunch that there was a moment when Hugh was going to be up in Edinburgh anyway, or something -- Hugh Lloyd -- and I wrote, I think quite a silly letter saying, "Why don't you just pop in and apologise to the guys?" I think that was just pathetic. I think that letter is around. And soon after then I realised. So it was fairly soon.

Q. Did it happen? Did he come and apologise?

A. No, he did not.

Q. We have been wondering that.

A. No, he did not.

Q. Right. I think --

A. There was a reason for that.

Q. Let's do things in order. What we haven't looked at are

a couple of letters in between. Dr Lloyd's letters to you, which is [SNB0045142]. You wrote to him on 7 May, he wrote back on 9 May. He did thank you for your letter:

"Your views are graphically put, as I would have expected."

A. Characteristically generous of him.

Q. He said that he personally believed that to start HCV testing to the original schedule is the correct decision, even if it appears unpalatable to some. Then he says that to suggest that his action was mischievous was to impart motives which were not his. And then, as you say, there was some further communication between the two of you.

The next letter is [SNB0045732]. By this time you have seen each other. Sorry, this is Dr Lloyd again, 4 July 1991. He has seen you at a meeting in York.

A. York.

Q. Yes. And a hatchet has been buried. He does apologise to you for any problems that he has caused by starting testing in April. He is then articulating concern about the UK dragging its feet. And funnily enough, expressing thinking not that different from Mr Tucker's.

He feels that a risk is being run of accepting the lowest common denominator. He doubts that you would be

happy to accept the lowest common denominator. Then he goes on to say that the letter that you had sent is being circulated widely, had given rise to concerns regarding the situation of many of his staff.

A. Perhaps in fairness to Hugh, I would also point out the sentence:

"The attitude of the UK transfusion centres to plasma procurement [that's self-sufficiency] south of the border over the years, presents a very dismal picture."

I have to say, it was absolutely right. He was pretty down and you know, I felt for him because I think he was a genuine guy.

Q. The regret that you felt at sending the original letter, you said you thought you regretted it quite quickly?

A. Yes, I did. I think it was quite quick but it was at York when I sat down with him and we talked.

Q. Did you start to feel he had done the right thing?

A. No, I didn't. I have to confess.

Q. So you felt he had done the wrong thing?

A. I felt I had done the wrong thing by writing to him in those terms.

Q. What about his actions? Did you remain of the view that he had done the wrong thing?

A. Yes, I remained -- and I think people are entitled to

their different opinions and he respected mine and, bless him, he says here, "I have taken no offence of your letter."

I'm very surprised. Yes, I felt at the time and still feel that breaking ranks like that was not a good thing to do.

Q. Why?

A. Why? Because I think it's very important, if you have a national service, in which donors, ordinary, good folk, are coming out and donating freely for the rest of the community, that those of us who run the show should see that we are running it all together in terms of -- as much as we can, but certainly safety.

And I have always felt in those terms and I don't think really I have changed.

Q. How does that fit with the distress you felt in your phone calls with Dr Gunson at the end of March, when you felt that the difficulties in England were taking the Scottish transfusion centres in a direction in which they shouldn't have to go? If you were all part of a corporate body --

A. Yes, but if in fact one discovered that there were sections of that corporate body, that going off in a completely different direction, through no fault of their own -- this was the fiscal system in which they

had to operate -- then the question arises: was there any overriding consideration that ought to be made? And I thought that's a fair approach.

Q. So the distinction, if I understand you correctly, between being willing to stick with Dr Gunson and his colleagues and not rock the boat by starting testing in Scotland, versus being critical of Dr Lloyd for starting testing in Newcastle, the distinction is that the former situation was through no fault of the English directors, whereas the latter situation, Dr Lloyd could and should have made a different decision? Is that the sort of distinction you are portraying?

A. Yes, I think so. I'm beginning to get rather confused but I think so.

Q. Right. Well, I think that we have your position.

The final letter, the letter that you sent to Dr Lloyd when you discovered he was going to be in Edinburgh, is [SNB0117806]. We have looked at this one before, but just to remind ourselves that it makes very strongly the point about teamwork, that you are all -- and I think by "all" we should understand the transfusion services of the United Kingdom -- one team and you found statements such as "accepting the lowest common denominator" to be deeply disconcerting:

"In our team we pick up the weakest and carry them

until such time as they have grown stronger."

So do you regret this letter?

A. Not so much.

Q. Right.

A. It's the "mischievous" -- I regret that very much.

Q. All right. You have told us he didn't accept the invitation to come for lunch and make a collective apology. We understand that. Do you stand by the views that are expressed in this letter?

A. That we should be operating in teams, you mean? And that we should -- if somebody stumbles, the rest of us should pick them up and keep going as a team? Yes.

Q. Right.

Sir we are going to have to continue, and plainly it's after 4 o'clock. I think particularly since this is the last sitting day of the week, it would be sensible to stop now. I don't have terribly much more to cover but plainly my colleagues in the front row will have some questions.

THE CHAIRMAN: Well, very well, we will do that.

Professor Cash, we are going to have another visit.

Is there a date when that's likely?

MS DUNLOP: We don't have a date, sir, yet. We have some options which we will be offering to Professor Cash.

THE CHAIRMAN: Yes, I think this area of evidence is clearly

of some general importance and we should try and get a date fixed and announced as far as we can.

MS DUNLOP: Yes, indeed.

(4.10 pm)

(The Inquiry adjourned until Tuesday, 6 December 2011 at 9.30 am)

I N D E X