Thursday, 11 November 2021

(10.00 am)

SIR BRIAN LANGSTAFF: Before we start, can I say that today being 11 November, for the benefit of not only those who are here but also those who may be watching online and may be concerned to observe the silence at 11.00, for those who wish to do so we will take a break this morning, Ms Richards, at or about 10.50 and take our morning break then, rather than later, just so that you know.

Presentation by Counsel to the Inquiry on Professor John Cash

MS RICHARDS: Thank you, sir.

So the two topics I'm going to be focusing on this morning, by reference to Professor Cash and his own decisions and actions are the questions of surrogate testing for non-A, non-B hepatitis (so testing of blood donations for non-A, non-B) and then the introduction of delay in introduction of testing of blood for hepatitis C.

So dealing first with surrogate testing, we can perhaps, most usefully, pick the picture up in relation to Professor Cash at PRSE0002641. This is an SNBTS Directors' meeting, 25 June 1986, with Professor Cash in the chair and, if we go to page 5,

we will see about a third of the way down the page the heading "Surrogate testing for [non-A, non-B]" and this is what the minutes of the director's meeting record:

"There was increasing evidence that the USA and several European countries were introducing anti-HBc and/or ALT testing of blood donors in an effort to minimise the risks of [non-A, non-B] transmission through blood and blood products. Dr Cash believed that the SNBTS would some come under pressure from clinicians to introduce testing.

"A limited study involving follow up of donors with abnormal liver function tests was about to take place in Edinburgh and Dr Urbaniak had been in touch with a gastroenterologist in Aberdeen who had expressed an interest in investigating post transfusion [non-A, non-B] infection, but he had not yet received a response.

"Dr Fraser had advised Dr Cash that he (Dr Fraser) and Dr Marcela Contreras (Edgware Transfusion Centre) were keen to set up a small group to explore the feasibility and practicability of this development and that it was their hope that Scottish RTC would contribute."

So that's the position discussed by the

directors with Professor Cash's involvement there described in June 1986.

If we then pick the picture up with some letters to The Lancet in 1987, NHBT0000025_010. I'm not going to go the through the detail of these letters but this is the first, April 1987. You will see the heading is "Surrogate Testing for Non-A, Non-B Hepatitis". The authors, if we go just a little further down the page, include Dr Contreras and Dr Barbara, so we will be able to look at this more directly through oral evidence in due course. But it was effectively expressing a degree of caution and if we look at the last two paragraphs of the letter -- so if we go further up, Soumik -- on the right-hand side, it says:

"Before we are forced to accept two screening tests of unproven benefit, which have high revenue implications, we need a national study to assess the incidence of raised ALT and anti-HBc in donors in different parts of the country. Also, and perhaps more importantly, a study is needed to assess the incidence of acute post-transfusion [non-A, non-B] hepatitis and to assess how many of those affected develop evidence of chronicity and serious clinical sequelae."

So that was the view being expressed by some in

April 1987. If we go to PRSE0002104, there were two further letters on this topic in The Lancet in June 1987. Again, I'm not going to go through them in detail. The first letter on the left-hand side, if we go just a little further down the page, we will see it was from Dow, Mitchell and Follett, so Scottish-based clinicians, and if we look at that last paragraph we can see again what was being suggested was a study:

"It would be prudent to do a UK study to assess the real incidence of acute post-transfusion [non-A, non-B] hepatitis and to assess the proportion of those chronically affected, before considering following the American surrogate testing policy."

Then the next letter, which, if we go down the page, is on the same topic, deals also with the doubts expressed by Dr Contreras and her colleagues and associates the author's views with that.

If we go over the page with that we can see who this letter is from, so Dr Gillon, Hussey, Howe, Beckett, Prescott. Dr Gillon there from the South East Scotland Blood Transfusion Service. If we just look at the top of that page, the conclusion of the letter was:

"We conclude that the introduction of ALT/anti-HBc screening tests as an indicator of

[non-A, non-B] hepatitis carrier status in blood donors cannot at present be justified."

Now, those Lancet letters then came to be considered at a meeting at BPLL0007202. This is a meeting of the Advisory Committee on the National Blood Transfusion Service, 17 June, it's 1987, although the date doesn't appear at the top, chaired by Dr Harris of the DHSS and we'll see that Dr Cash was a participating member of the group.

If we turn please to page 4, we can see the discussion. Here it's headed "ALT testing for transfusion associated hepatitis", paragraph 30:

"The Chairman asked whether the Committee agreed with The Lancet article concluding surface tests for hepatitis could not be justified."

Then we see Dr Cash's view being expressed:

"Dr Cash said that Scottish Directors were proposing to establish such tests in view of impending product liability legislation in 1988; there was also clear indication that the private sector would test and they did not wish to fall behind."

There's then a reference in paragraph 32 to Dr Smithies saying there was a research proposal -- so still only at the proposal stage -- and the third paragraph -- sorry, the third sentence of paragraph 32

records what was presumably the DHSS view:

"There was insufficient evidence of [non-A, non-B] after the HIV deferral of donors had been introduced. It was therefore now even less cost effective."

Then we can see Dr Gunson saying that:

"[The] introduction would be premature, causing an unjustified loss to panels.

"Dr Forrester gave an assurance that there would be no decision until research had been carried out.

"The Chairman summarised the views. If testing was introduced it should be national; he noted the research on baseline data would be carried out; the position would be monitored here and abroad."

So no recommendation from this committee to introduce testing, but you will have seen the reference, if we just go back up to paragraph 31, to Dr Cash's views.

There are two themes there expressed and, because time doesn't permit me to go to all the documents or all of Professor Cash evidence to the Penrose Inquiry, I can say those are two themes that reappear in the contemporaneous material: his concern about the impending product liability legislation and his concern that the private sector, pharmaceutical

companies, were using ALT testing or surrogate testing in relation to their products.

If we then go to PRSE0001444, we can see a further letter to The Lancet, this time co-authored by Professor Cash. The date is 4 July 1987 and we can pick it up halfway down the page, the right-hand column -- actually if we look at the bottom half of the page, please, Soumik, the heading of the letter is "Testing blood donors for Non-A, Non-B Hepatitis: Irrational perhaps, but inescapable". A somewhat attention-grabbing headline.

Then there is reference to some of the earlier letters in The Lancet. If I pick it up about two-thirds of the way down that first paragraph, the letter continues:

"No large study to answer this critical question has yet been presented, and we agree that the size of the benefit to be gained from surrogate testing cannot be accurately established without such a study. However, the time for this study has already passed. Starting now will give us an answer in 3-4 years -- and that is probably 3 to 4 years too late. The introduction of surrogate marker testing for [non-A, non-B hepatitis] is now virtually inescapable, for three reasons:

"(1) In 1988 European legislation on strict product liability comes into force in the UK. If harm should come to the recipient of a therapeutic product, the producer will be held liable unless he can demonstrate that he used all known methods and information to avoid the risk. Under these rules a patient who contracted [non-A, non-B hepatitis] via transfusion of blood or a blood product would have a claim against the supplier if it was shown to come from a donor who had not been tested for both raised ALT and anti-HBc."

We know, of course, that is precisely what came to pass.

"(2) Although we all hope that pooled plasma fractions will soon be made safe by heating or other antiviral treatment, these processes remain to be validated in large-scale trials. Meantime, even if surrogate marker screened would only modestly reduce the level of infectivity in these products, many would argue ..."

Sorry, we're just below the table, Soumik, on the left-hand side:

"... many would argue that some improvement is better than none.

"(3) The UK transfusion services, although the

major suppliers of blood and blood products in this country, cannot afford to ignore the wishes of consumers to be slide with 'non-A, non-B tested' products, even if it is believed that the real benefit in safety which is offered to the patient is marginal. Commercial suppliers will not be slow to point out that their products are made from tested plasma and must therefore be safer. Clinicians and patients can hardly be blamed for taking note of this message. And this argument may be applied equally to whole blood, red blood cells, platelets, and plasma. What better marketing ploy for a private blood bank than to emphasise that its donors are tested to exclude hepatitis using the standards applied in the United States, Germany and France? The local NHS blood supplier will have trouble shrugging off the accusations of providing a second-class product."

The letter continues. I'm not going to take time now going through the rest of it but, if we go to the top of the right-hand column, we can see the conclusion:

"Looking at these 3 factors -- producer's liability, competition and value for money -- we suggest that decision which has to be made is when rather than whether the UK transfusion services follow

the lead of the United States and other European countries in donor screening."

Then we can see there the authors of the letter: McClelland, Cash, Mitchell, Urbaniak, Brookes, Whitrow and Perry, and Professor Cash's name there.

This letter caused a degree of consternation amongst Regional Transfusion Directors elsewhere. If we go to PRSE0004482, this is a letter of 2 July 1987 from Dr Fraser, who was director of the Regional Transfusion Centre in Bristol, and it's addressed to Professor Cash. It thanks him for sending a copy of the letter that was due to appear in The Lancet, and then continues as following:

"I think that you will find that the Transfusion Directors in England and Wales will not be very pleased at reading this letter. I recollect that the topic was discussed briefly at the Scottish Transfusion Directors' meeting on 10 June last and it was agreed, I thought, that there was a need for synchrony with England and Wales. I have a feeling that the Scottish Directors had already made their minds up that they were going to suggest that surrogate testing for non-A, non-B Hepatitis would be carried out in the Scottish services and I think it is a pity that this was not actually mentioned at the RTD

meeting.

"Due mainly to your initiative and hopefully with some help from me, we have managed to set up a core group with NIBSC and the Blood Transfusion Services in the UK. I was assuming that this group would be able to advise on tests that might be required to be carried out on donor blood, at its various meetings, and I would have thought that the proposals that you and your colleagues have suggested in this letter should first have been discussed at this core group which is due to meet on 22nd July. I think you will find that there will be some adverse comments in the Lancet from the suggestions that you and your colleagues have made. We all managed to work together to introduced HIV antibody testing on the same date. I think it is only a shame that we have not been able to have the same type of discussion to agree whether or not to implement ALT and/or core antibody testing in the UK."

Professor Cash's response was dated 8 July -- and it's PRSE0001973 -- addressed to Dr Fraser.

It refers to a telephone conversation that they must have had and then he says this -- again, I won't go through every point but point 1:

"The SNBTS Directors do not wish, and currently

have no intention, of introducing [non-A, non-B] surrogate testing unilaterally."

So the Scottish directors weren't going to go it alone in Scotland essentially.

Point 2:

"Current views, which as you know were crystallised last March, are being expressed to support our Public Expenditure Survey (PES) submissions to SHHD for the next 5 years."

We will pick this up when we look at the Penrose evidence in the course of the morning, but a submission was being made, a PES submission for funding, in relation to this matter.

"3. We have no doubt that an important forum for the continued debate is indeed the BTS/NIBSC group(s) and the current [non-A, non-B] debate (which began some 2 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 colleagues at Edgware. It can also be viewed as yet another attempt to persuade central management (DHSS)

to give renewed thought to the way to the transfusion services interface with the Medicines Act and forthcoming legislation on product liability and perhaps even to ways for improving the co-ordinated management of the transfusion services on a UK basis."

The letter continues over the page but I don't I think need to go to more of it.

So you will see there Professor Cash's position was: we've set out our views because we want to stimulate a debate, one of the reasons, we don't propose to introduce surrogate testing unilaterally in Scotland, we are, however, putting in a bid for expenditure for funding to enable us to do work on this. Is essentially the position that was adopted.

We see a little more about the issue of the PES bid for funds at PRSE0004562.

This is an internal note within the SHHD. It's from Dr McIntyre and it's dated 21 July 1987, and you'll see the heading is "Surrogate testing for non A, non B hepatitis in Scottish blood donations". This wasn't sent to Professor Cash but it's discussing the issues to which the documents we've just looked at referred:

"Last year SNBTS applied in their PESC submission for funds to institute this testing. The

request was declined."

Then reference is made to The Lancet letter of June, which said, essentially, there needs to be a study, a UK-wide study, before we introduce the testing. Then reference to the Professor Cash and his colleagues' Lancet letter of 4 July and the note reads as follows:

"However in the Lancet ... Professor Cash and the SNBTS Regional Directors have set out a case for starting testing, claiming that it is inescapable and cost-effective. The purpose of this minute is not to discuss all the relevant issues, but to point out that SNBTS may institute testing without further discussion as a *fait accompli*. I understand that a renewed PESC item seeks funding for the coming year.

"In theory SNBTS should not be able to start without the necessary funds but in practice they may be able to start albeit in a limited fashion but nevertheless setting a precedent. If this had subsequently to be stopped for lack of money or on a decision that it was not cost effective adverse publicity is possible. The present PESC request is understood to be for £300K. The cost of testing is, according to the data in the Lancet letter, well in excess of £600K. Apparently spare resources already

effectively at the disposal of SNBTS could meet half the cost."

So, pausing there, the SHHD concern appears to have been that this letter indicated that SNBTS might unilaterally introduce surrogate testing and then it would be difficult to row back from that and it might result in adverse publicity for the Scottish Home and Health Department if it then refused to supply additional funding.

That is an inference you may wish to consider in relation to this letter.

Then it continues:

"Professor Cash has assured Dr Fraser of Bristol NBTS, in a letter dated 8 July, that he will not institute testing 'unilaterally'. We have however no assurance that he will not do so in the near future without specific funding and without necessarily reporting what he has done to CSA or SHHD."

So it appears that the Scottish Home and Health Department continued to be suspicious that there might indeed be a unilateral go-it-alone Scotland introduction by SNBTS.

Then we see what is said to be the response of the Department of Health:

"DHSS have expressed their concern and dismay at

the letter by Professor Cash and colleagues and have interpreted this as being SHHD policy; we have attempted to reassure them that it is not so. Their concern is that if we should commence testing unilaterally they will feel obliged to follow.

"Professor Cash and his colleagues have been given the opportunity to engage in a research programme to evaluate the need for this testing but have withdrawn as they feel 'the time for this study has already [passed]'."

There is then a letter at SBTS0000250_122, this is 1 September 1987, "To: Transfusion Directors". It's from Dr Perry copied to Professor Cash. I don't need to go through the full detail of it but if we just look towards the bottom of the page, at paragraph (b):

"We (SNBTS) are not ALT testing although it seems likely that such testing will be in place in the near future ..."

Then Dr Perry goes on to set out proposals to be ready for that if that eventuates.

There were then, towards the end of 1987, concerns expressed by Professor Cash again that commercial plasma fractionators were being permitted by the DHSS to note on product literature that donors

had been tested for ALT. I'm not going to go to the document but the reference, for the transcript and benefit of others, is PRSE0001194.

If we then pick matters up at PRSE0001159, we have a further SHHD internal memo, this is dated 17 December 1987, it is from Dr Forrester, entitled "Screening of blood donations for non-A, non-B hepatitis", and it records that:

"Professor Cash has pointed out to us ... that a commercial producer of blood products is being allowed by DHSS to include in their product insert a statement that that product is derived from donations which have been ALT tested. We have confirmed that Professor Cash is correct.

"For some time he has sought funds to screen all donations by both ALT testing and another test, as a way to exclude some donations likely to transmit non-A, non-B hepatitis. He has not received funds, for reasons previously explained, and so far as I know, no research is being mounted in Scotland or England into the cost and value of the screening.

"The recipients of SNBTS unscreened blood have no choice: they cannot get other blood. But the recipients of blood products do have a choice, usually no doubt made for them by the clinicians treating

them. They can have SNBTS products, apparently gratis, made from unscreened donations. Or they can have commercial products, at the cost of their Health Boards, made from partially screened donations: partially, because ALT screening is only one of the two tests proposed together to reduce transmission of non-A, non-B hepatitis.

"It is credible that the commercial products, derived from the donations of paid donors, are safer because of ALT testing than they would otherwise be. But it is not clear that a sensible clinician would prefer them to SNBTS products.

"The clinicians, however, stimulated perhaps by some of their patients, are likely to press us now to 'join the club', and SNBTS are sure to resume similar pressure."

So the position again internally within the SHHD appears to be a concern that this issue is being raised as a means of securing funding and it may be thought an unwillingness to provide the funding that would enable the testing to take place.

In his evidence to the Penrose Inquiry, Professor Cash recalled that, following the identification of hepatitis C in 1988/89, the controversy surrounding surrogate testing, as he put

it, gradually faded as attention turned to hepatitis C screening.

However, there were some further communications between Professor Cash and Dr Gunson on the issue of testing. I'm not going to go through them now but I'm just going to give you, sir, the relevant references. So there's a letter from Professor Cash to Dr Gunson, 12 January 1990, reference there for the transcript is NHBT0000027_011, and the particular concern being expressed by Professor Cash was that, within England and Wales, Regional Transfusion Centres were going to start using routine ALT testing of plasmapheresis donations.

There's a response from Dr Gunson, January 1990, at NHBT0000027_012, and a further letter back from Professor Cash, 30 January, PRSE0001347, and then from Dr Gunson again, 2 February, NHBT0000027_015.

Before turning then to the issue of hepatitis C screening, can we look at Professor Cash's two written statements to the Penrose Inquiry on this issue. The first in time is relatively uninformative but we'll go to it for the sake of completeness. It is PRSE0004065. You will see, sir, it is headed "C2 Witness Statement (Surrogate Testing)". C2 was the Penrose Inquiry's designation for the topic of

surrogate testing.

The statement starts on page 4 but the answers that are given by Professor Cash, and I don't mean this as a criticism, are relatively limited, perhaps because the material that he then had available to him in order to answer them was relatively limited. So I'm not going to go to the detail of any of his answers but you have there his first statement on this issue.

His second statement on this issue is rather more informative and it's at PRSE0003232. What's set out on this first page is not Professor Cash's own summary, this is the Penrose Inquiry's summary of what are said to be key relevant dates. I'm not going to go through the detail of it.

If we go over to the second page, you'll see, at the top of the page, the Penrose Inquiry's summary includes reference to some of the correspondence we've looked at. Then we have, further down the page, underlined, "Queries", and the question that is then posed to Professor Cash is:

"Should a large scale prospective study, as originally proposed by Dr McClelland in 1981 ... have been carried out in the UK in the early 1980s (or at some point thereafter) with the following aims:

"(a) to assess the prevalence of post transfusion [non-A, non-B] in the UK,

"(b) to evaluate surrogate markers for the disease,

"(c) to investigate the natural progression and seriousness of the disease, and

"(d) to produce a library of 'known' infected sera with which to evaluate any future assays which became available?"

Then Professor Cash's answer is:

"Yes to all ... questions."

So his view is such a large scale prospective study should have been carried out. Then he poses, himself, two further questions:

"... there would be advantage in seeking the answers to two further questions: (a) Why did Dr McClelland's 1981 proposal fall? (b) Did the disbanding of the MRC Blood Transfusion Research Committee have anything to do with this?"

I took you yesterday, sir, to the statement in which he had expressed his dismay at disbanding of that committee.

Then if we go to the next page, question (2) is:

"If such a study had been carried out, to what extent is it likely to have met the objective set out

in (1) above? (b) To what extent would such a study have provided more information upon which to base a decision on whether surrogate testing should be introduced?

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

"(b) I'm not sure what is meant by more information. If DHSS had signalled that it was prepared to consider surrogate testing then the definition of more information would have been donor and patient data derived from a UK population. That said, I always felt that the size of the proposed study (600 patients) may have been rather small to achieve all the objectives described above, notably (c)."

Then I don't think I need to trouble you with the next question. If we go over the page, top of the page, Professor Cash is asked:

"In the second half of the 1980s, (a) Did SHHD medical officers place sufficient weight on the likely prevalence and seriousness of post-transfusion [non-A, non-B hepatitis]. (b) To what extent did their views in that regard influence their opinion on whether

surrogate testing of blood donors should be introduced?"

Answer:

"I am uncertain how to respond to this question as I have no recollection or record of discussing the topic with SHHD medical staff. That said, the internal SHHD documents supplied by the PI team would indicate fairly clearly that at least one Medical Officer believed that post transfusion [non-A, non-B] was uncommon and of little clinical consequence. He was not alone, but in my view efforts directed towards enhancing what was widely recognised as a very weak evidence base did not enjoy support of all UK Departments of Health, throughout the 1980s."

Then if we look at the question at (5), Professor Cash was asked for his response to the following:

"If surrogate testing of blood donors (ie testing for elevated ALT and/or anti-HBc) had been introduced in Scotland:

"what percentage of donors are likely to have been deferred,

"could a sufficient blood supply have been maintained, and

"to what did extent are cases of

post-transfusion hepatitis C likely to have been prevented ..."

If we go to the top of the next page we see Professor Cash's answers:

"I have always believed that it would have been between 1-3%."

That's the percentage of donors likely to have been deferred. His answer to the question "could a sufficient blood supply have been maintained" here is an unequivocal "Yes". Then he says, in response to the third question:

"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."

Then he adds a footnote with some observations. The first observation at (a) concerns the issue he raised in the contemporaneous communications about commercial plasma producers being allowed to include in their product literature references to surrogate testing. Then his second comment is as follows:

"Documents which reveal that the position of the SNBTS Directors on surrogate testing, finally declared in July 1987 [that is presumably a reference to the

Lancet article], whilst at the time subject to much English (and SHHD) ridicule, was, less than 3 years later, espoused by DHSS, CBLA and some former vociferous NBTS Directors. Of interest is that SHHD claimed it had not been briefed by DHSS on much of this radical change in policy. Thus former expressions of righteous indignation and strident calls from SHHD for research before change (which was never supported), rapidly gave way, as predicted by SNBTS Directors, to the inevitable pressures of the market place. Even more remarkable is the evidence that the introduction of large scales surrogate testing in England and Wales was commenced after the introduction of HCV donation screening -- again for market reasons."

So those were his written statements. I'll come at the end of the presentation to a handful of references for the very lengthy transcripts of oral evidence in the Penrose Inquiry.

Can I turn then to the question of testing for hepatitis C. Again, we can pick this up, I think, in 1988, if we look at PRSE0002365 -- sorry, PRSE0002363.

This is a letter Professor Cash wrote to Ortho in July 1988, asking about whether Ortho was marketing the recently announced development of a kit to detect

non-A, non-B antibody, and he asked if there was some idea of the current time schedule to the point of full marketing in the UK for full donation testing.

The response he had at PRSE0002112 from Mr Follett of Ortho was effectively to say, in that first paragraph:

"[We] do have an agreement ... to develop and market the product but I do not know precisely when this product will be available. The best information I have been able to obtain is that the product may be available towards the end of 1989."

There's then a discussion, if we move to May 1989, in the Advisory Committee on Transfusion Transmitted Diseases meeting of 14 May, NHBT0000088_001. You'll see that those present included Professor Cash. If we go to the bottom of page 3, we'll pick up the heading "Non-A, Non-B Hepatitis", and there's reference to there being an oral report by Dr Barbara, that's Dr John Barbara:

"... on progress with anti-HCV testing of donors in England and Wales: ALT/anti-HBc study."

Then if we go over the page, the second item is headed "Anti-HCV testing of donations from Scotland":

"Professor Cash reported that the SNBTS would be interested in taking part in evaluative trials of the

Ortho Pharmaceutical Company's Chiron test and said he would be grateful if Dr Gunson would contact him about this matter."

Then it was explained that the West of Scotland Centre had a bank of frozen donor samples already tested for ALT. So there was an expression of interest in taking part in the evaluative trials of the test kit and, if we look -- I don't need to put it up on screen but Professor Cash wrote in July 1989 to Ortho asking for some testing kits which would enable SNBTS to undertake 5,000 tests, essentially on an evaluative or trial basis.

We can then pick that up at NHBT0000076_003. This is Dr Gunson to Professor Cash on 26 July 1989. He says:

"I am pleased that you are carrying out 5000 tests for anti-HCV. John Barbara has now almost completed the tests on the 9000 from England and when the results are to hand I will send them to you.

"I am having some difficulties with Ortho who are wanting to know when (not if) we are going to introduce routine testing and how many tests we wish to order."

Then there's a reference to a meeting in Rome in September:

"The intention of the meeting is to review the European experience with the test.

"My view is that 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 introduced the test unilaterally."

So two points emerging from that last paragraph: first, a desire, it might be said, to be cautious and not take any decisions in advance of understanding the European experience; and, secondly, a desire that neither Scotland nor England and Wales go it alone but that they collaborate.

NHBT0000188_016 is a letter from Professor Cash, August 1989, 4 August, to Dr McIntyre at the Scottish Home and Health Department following a meeting he had had with Ortho. He says at paragraph 1, this is Professor Cash speaking:

"I advised Mr Savage [that's the Ortho representative] that the decision to introduce this testing would be made on a UK basis and that a key group in the decision-making process would be the group originally chaired by Dr E Harris (DOH). I therefore declined to discuss start dates, ordering policies, et."

Paragraph 2 then refers to an anticipated meeting of the Dr Harris group, as it is referred to, on 17 October and an informal meeting due to take place at the Strand Palace Hotel on 23 August 1989, to look at preliminary UK data. Then you will see from paragraph 3 Professor Cash raising an issue about confirmation testing:

"I pursued Mr Savage on confirmation testing which I believe is a crucial issue, both with regard to its absolute scientific/medical value but also a means whereby we can regain some initiative over Ortho."

Then he sets out his understanding, which is that Ortho have an RIA confirmation test but it uses the same antigen as the screening test and Ortho currently do not wish or plan to market it.

If we go over the page, Professor Cash continues that:

"[He] indicated to Mr Savage that in my view this proposal was wholly unacceptable. We would wish/insist that the confirmation testing, which has a profound influence on the lives of many donors, was in our hands."

He strongly advises Dr Harris' group to take up this issue in relation to confirmation testing.

There's then reference to in paragraph 4 to negotiations in relation to price.

Paragraph 5 records that Mr Savage of Ortho had indicated that Denmark would start full testing on 1 October. So that would have been 1 October 1989.

Professor Cash then says:

"Detailed questioning revealed that this statement was exceedingly speculative ..."

Then paragraph 6:

"Mr Savage believed that full tested in the USA would commence 'towards the end of the first quarter of 1990'."

Then there's a footnote in which Professor Cash sets out in his advice as to how the UK should proceed:

"(a) Let it be known to Ortho that a decision whether to introduce Chiron testing throughout the UK BTS will be made at the special meeting to be held on 17th October 1989.

"(b) That after the meeting on 17th October, and presuming the inevitable that it will be agreed testing will be introduced -- but in a co-ordinated fashion, Ortho be advised that.

"(i) A date for commencement will be considered when Ortho agree to make arrangements for confirmation

testing technology to be transferred to UK (NHS) laboratories;

"(ii) That commencement will also be subject to the kit system getting an FDA licence.

"(c) Subject to conditions (b) above being acceptable and delivered then I would suggest that the UK BTS plans to commence full testing on ..."

Then this must be a date error, it says "1st June 1989". It must, I think, be a reference to 1990.

"... but significant funding is made available from 1st April 1990 for a two month run-up period (using stored sera) both at RTCs and confirmation laboratories."

So those were Professor Cash's views as at August of 1989. Of course we know it's a little over two further years before the testing is, in fact, introduced.

That Strand Palace Hotel meeting, the August 1989 meeting referred to in the letter, did take place as arranged. Professor Cash didn't attend but SNBTS, or Scottish representatives in the form off Dr Mitchell and Dr Follett, were there, and we have an account of the meeting in a letter dated 25 August 1989 at PRSE0000815.

You will see it is addressed to Professor Cash. This is an account from Dr Mitchell:

"At your request, Eddie Follett and I attended the meeting organised by Ortho Diagnostics in London ... The meeting was attended by Dr Harold Gunson, Dr Marcela Contreras and Dr John Barbara."

There's then an account of the position said to have been set out by Mr Davis of Ortho. I'm not going to go through the detail of that.

If we go over the page, it says in the second paragraph:

"Mr Davis then moved to the real purpose of the meeting and asked a number of questions. I will itemise these and indicate the responses given by the persons who were present from the Blood Transfusion Service."

So the first question:

"1. Has any decision about blood testing been made? If not, how is it to be made and if any other information is required from Ortho ...

"The answer was given that no decision had been made. That the decision would be subject to the advice of the National Advisory Committee on the Virological Safety of Blood. If the Advisory Committee were to make a recommendation, then this

would go to Ministers in England and Scotland for a final decision. It was made clear by us that no decision was possible before the October 17 meeting which was to follow the Rome meeting ..."

So that was what was being set out as the anticipated decision-making process: advice from the ACVSB and then a decision by Ministers.

The second question was:

"... 'What if a decision were to be made in favour of doing the test? What would be the time and events schedule? Would there be a simultaneous announcement or a phasing ...?'"

The answer, and again I won't go through the whole of it, was:

"We explained that if such a decision were to be made, then the UK would move in unity and that there would be a simultaneous announcement as happened with the HIV antibody testing."

Then there is an explanation as to the preparations that would need to be made, arrangements for counselling of donors, staffing and other matters.

If we go to the top of the next page, we can see Dr Mitchell referring to the position in Scotland. He says:

"I indicated that, whilst I was willing to host

a meeting in the Glasgow Centre, there was little likelihood that the Scottish Transfusion Directors would wish to have any kits in the foreseeable future until a decision was made."

There was then a further discussion in relation to that.

Then if we go to the bottom half of that page, again, I'm not going to go through the detail but there was a discussion, amongst other things, about the need for a confirmatory test and it's said:

"It was emphasised Ortho needed to have a confirmatory test and they indicated that this would be available in time for the Rome meeting."

There's then a discussion about the position in the States. The FDA hadn't yet given approval but the expectation was that that would happen early in 1990.

If we just pick it up in the last six lines of that page:

"We were surprised at this [that was what was the information about the position in the US] and why Britain was being asked to rush ahead of the United States since, in the past, we had tended to be somewhat behind the USA decisions."

Then over the page there's then a discussion about the training needs and backup programmes that

would be required. There was a presentation -- this is paragraph 5 -- by Dr Barbara and Dr Mitchell -- sorry, if we go to paragraph 5, Soumik -- about some studies and some figures.

Then if we go to the final page -- no, I'm sorry, Soumik, it's the page before that. My apologies. That's the agenda. So this is the conclusion of that:

"It was made abundantly clear that we could not pre-empt the decision of the Advisory Committee [that's the Advisory Committee on the Virological Safety of Blood], that we were not representing the Advisory Committee and we were certainly not representing the various Departments of Health."

Then there were further discussions and, if we go to the final paragraph, we can see Dr Mitchell saying this:

"In view of the comments in The Guardian, which I am sure you will have seen, and the press interviews with Dr Harold Gunson, I have written to you in some detail concerning the contents of the meeting that was held in London. I wish to stress that no decision was made that no Department of Health was committed to any decision in advance of the recommendations of the Advisory Committee which will make its own decision

following the Rome meeting and taking account of all the scientific evidence which is being made available."

Then he says he passed that on to Dr McClelland and Dr McIntyre.

Sir, I think that account probably brings us to the right point at which to take our first break.

SIR BRIAN LANGSTAFF: Yes, we'll do that now. We will come back at 11.25. 11.25.

(10.52 am)

(A short break)

(11.33 am)

MS RICHARDS: Sir, my apologies for the delay. There is a further document on surrogate testing I wanted to just put up on screen, and we're just making those arrangements, but I'll slot that in as and when the document is available.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: So, continuing then with the narrative in relation to Professor Cash and the introduction -- or the delay in introduction -- of hepatitis C screening.

We'd looked at Dr Mitchell's account of the meeting with Ortho at the Strand Palace Hotel in August 1989.

Also in August 1989 there's a letter from

Dr Cash and others published in The Lancet.

It's at NHBT0083819.

26 August 1989, the first letter on the left-hand side is authored by Dr Contreras and Dr Barbara and I can ask them about that. The second letter which begins towards the bottom of the page reads as follows:

"Whilst we share the views of your [August 5] editorial on the importance of the new detection systems for [hepatitis C] antibodies, especially in the context of screening blood donations, we take issue with the last point made by Professor Kühnl and colleagues in the correspondence section ... of the same issue."

Then the letter goes on to deal with this issue of confirmatory testing, which we've seen was a matter of concern and some importance to Professor Cash:

"The apparent absence of a confirmatory test will cause serious problems for blood transfusion services, which are likely to bear the brunt of sensitive donor counselling. A repeatably reactive ELISA test is suggestive but not definitive evidence for antibody. We accept that the existing difficulty (use of the same antigen) is scientifically less than satisfactory, but it is better than nothing. Ortho

Diagnostic Systems should make available, as a matter of urgency, appropriate reagents and/or tests so that even when an identical antigen is used, assay systems that are fundamentally different from the marketed ELISA screening tests can be used for confirmation testing. Of no less importance for blood donors, as you have indicated in your editorial, is the need for Ortho and/or Chiron to deposit the sequence of the viral genome in the GenBank database. These matters are so important that they should be taken up by the Government health departments. In view of the impending European legislation on blood transfusion, European governments are especially well placed to coordinate such actions."

So we see that emphasis there on confirmation testing being expressed by Professor Cash, along with Drs McClelland, Urbaniak, Brookes and Follett.

There were further communications between Professor Cash and Ortho about the issue of confirmation testing. I'm not going to go to all of them but I'll give a couple of references for the transcript. So NHBT0027482 was Professor Cash's letter of 3 October 1989 to Ortho, again asking in relation to the tests and asking for supplies to be made available for reagent purposes.

Then if we look at NHBT0000188_123, we can see the next development was Ortho writing to Professor Cash on 27 November 1989, saying:

"I am pleased to be able to inform you that the Export Permit for the Ortho HCV antibody ELISA test has been approved by the US Food and Drug Administration.

"This means that we can now supply product labelled for 'In vitro diagnostic use' instead of 'Research use only'."

There was then a further letter, I'm not going to go to it, but from Ortho to Professor Cash about the confirmation testing. The reference for your note, sir, and for the benefit of anyone who wants to look at it, is NHBT0000188_122. Then Professor Cash wrote again on the issue of confirmatory testing to Ortho, again no need to put it up on screen but at NHBT0000188_127.

If we could next have up, please, SBTS0000155_102. So this was a letter from Dr Ludlam to Professor Cash, 5 December 1989, in relation to the introduction of routine anti-HCV screening of blood donors and Dr Ludlam set out this perspective, picking it up in the second line of the letter:

"I realise that the present antibody test is not

ideal and that confirmatory tests as well as a more 'sensitive' antibody test would be advantageous. The present test may well not identify all [non-A, non-B] infectious units and furthermore there may be false positive results."

So setting out there, essentially, what the reasons were for hesitancy. Then Dr Ludlam says:

"On balance, however, it seems to me that a case can be made for using the present anti-HCV assay to screen all donations and discarding all positive units.

"I appreciate some of the drawbacks of introducing a screening test for 'infectious' donations of blood but I wonder whether we should not be considering the recipients. I am mindful of the debate about, and enormous effort that went in to, the setting up of anti-HTLVIII screening in 1985. I well remember the view being put forward in early 1985 that anti-HTLVIII testing should be introduced and that positive units should be discarded (without informing the donor). If this policy had been adopted, one possible outcome would have been fewer transfusion cases of HTLVIII infection in recipients of a low number of products eg red cells. It could be argued that we are in a similar position now with anti-HCV

testing. You will be as familiar as I am with the long term complications of [non-A, non-B] hepatitis I fear that if there is delay in the introduction of anti-HCV testing we will be exposing patients to preventable viral infection.

"I do appreciate that the decision to introduce an imperfect test is difficult but on balance I would encourage SNBTS to do so at an early date.

"You may have many cogent arguments against what I am suggesting and if so I should be most interested to learn of them."

So that was Dr Ludlam, December 1989, and, of course, we know that it's nearly two years after that that the testing is introduced in most of England and Wales, Scotland and Northern Ireland.

There's a further perspective at PRSE0001562. This is Dr Boulton to Professor Cash, 21 February 1990, and we will be able to ask Dr Boulton himself about this. If we pick it up in the second paragraph:

"Could I just add that in spite of obvious difficulties with the current Ortho Elisa assay (susceptibility to 'stickiness', unreliability of predictive value with heat-treated samples, etc) I have developed a very strong feeling that the

screening of donors for HCV antibodies should be introduced at the earliest possible opportunity. This is 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. Furthermore there are apparently five known cases of HCC due to PTH. The reason, therefore, from my ..."

Sorry, I should say, I am assuming a PTH is obviously post-transfusion hepatitis. I am assuming HCC is being used there to refer to hepatocellular carcinoma.

"The reason, therefore, [for] my proposing this view is actually one based on future litigation. I am pretty convinced that the NBTS and SNBTS will find legal action taken against them in about 10 years' time from persons who have sustained post transfusion hepatitis as a result of receiving HCV antibody containing blood which was presumably infectious for HCV at the time."

So a perspective there from Dr Boulton who had been indeed working in the field of haematology more generally, before taking up a position within SNBTS.

In terms of events in the course, then, of 1990,

we'll be picking that up with other witnesses in due course over the coming weeks and months.

In relation to Professor Cash himself, I'm going to pick the picture up next in 1991.

NHBT0000076_006.

This is Dr Gunson writing to Regional Transfusion Directors in England and Wales on 22 January 1991 but copied to Professor Cash. We see that from the bottom of the letter.

This is an announcement of the Department of Health's position:

"1. The Department of Health have agreed that routine testing of all blood donations for anti-HCV can be put into operation.

"2. I have been asked to try and ensure that testing starts simultaneously in [regional transfusion centres] in England and Wales and that it is co-ordinated with commencement of testing in Scotland."

Then there's a request to the Regional Transfusion Directors to let Dr Gunson know what they consider to be the earliest date they could commence testing.

Paragraph 4 refers to the need still to conclude the financial arrangements to cover both routine

screening and supplementary tests.

Paragraph 5 refers to proposals for a protocol for the carrying out of the tests, which is still to be discussed within the Department of Health.

Then 6 says:

"I will inform Ortho and Abbot that routine screening for anti-HCV has been approved and that we will inform them of the starting date in due course."

If we then turn to NHBT0000073_033 we will see Professor Cash's response to Dr Gunson's memo. So this is dated 24 January:

"Many thanks for your memo of 22nd January.

"I have liaised with SNBTS RTDs and we are unanimous in advising, with the greatest respect but in the strongest possible terms, that anti-HCV donation testing should not be commenced in the UK BTS until after the Gulf conflict is over or at least until such time as we are confident our blood collection and microbiology testing teams can cope with what will be quite substantial changes and increased workloads.

"Just at the moment there are a lot of exhausted staff in our RTCs and I would judge that when the troops go in, our current frenetic activity will be sustained.

"We would be most grateful if you would see Ministers are appropriately advised. We would wish you to emphasise that we do not intend to be obstructive in any way but believe this increased load (HCV donation tests) in the present circumstances could lead to GMP [good manufacturing practice] failures in existing overstretched programmes."

Over the page:

"We remain firmly committed to starting on the same day as our NBTS colleagues and if pressed by Ministers I would suggest, in the circumstances, a May/June date should be considered. However, I would much prefer to wait another month and then respond to your letter."

So you will see what appears to be a fairly unequivocal communication from Professor Cash that it should not be introduced until later in the course of 1991, and the reason that's given is essentially the workload and the need to be in a position to deal with the screening programme having regard to additional burdens anticipated in relation to the impact of the Gulf War.

Dr Gunson replied on 28 January 1991 -- I'm not proposing to go to that letter; the reference, for the transcript, is PRSE0004144 -- and Dr Gunson agreed

that an immediate start was entirely impractical.

There's then a further letter from Professor Cash at PRSE0002763, 15 February 1991, and this is in relation to the discussion of a start date for the programme. It says:

"Thinking ahead to the end of June 1991 and checking over previous correspondence I think we need to do one more thing in the not too distant future. I refer to defining what 'start date' will mean -- it's a re-run of the HIV-1 programme.

"Whatever the 'start date' will be, do we mean that by 9 am on that day all RTC products and those in associated hospital blood banks will be HCV (screen) negative? The definition of RTC products will, of course, be those not from BPL or PFC. If we adopt this definition, then clearly testing will have to commence well in advance of the 'start date'.

"Next we will have need, as on previous occasions, to obtain a policy decision with regard to plasma already in bond at both fractionation centres and awaiting uplift (at RTCs) for the fractionation centres. If a decision is made to test aliquots from these donations, the task is doable but formidable."

Over the page:

"Sorry to pester but I suspect you will have to

pursue Dr Metters' Committee on these topics. Once again we would very much like the SNBTS to stay in line with NBTS/BPL."

There is then a discussion of the start date at the meeting of the Advisory Committee on Transfusion Transmitted Diseases on 25 March 1991.

That's NHBT0000073_063, please, Soumik.

We'll see it was a meeting chaired by Dr Gunson. Professor Cash was present, along with Drs Contreras, Craske, Follett, Mitchell, Wagstaff and Professor Tedder.

If we go to the second page, paragraph 4 is headed "Introduction of anti-HCV tests into NBTS and SNBTS":

"The starting date and its definition.

"The proposed starting date of 1 July [so that's what's recorded as being the proposed date] presented difficulties since it was considered essential that the second generation test from both Ortho and Abbott should be evaluated prior to the commencement of routine tests. Ortho tests were being evaluated by Dr Barbara at North London RTC and he had, to-date, only received pre-production batches of the tests. It was known that there was procedural differences between the pre-production and production batches.

These test kits should be available within 10 days to 2 weeks. The situation with Abbott was uncertain since they had not yet given an official date for launching their second generation test.

"The preliminary results obtained by Dr Barbara on the test kits from three manufacturers were reviewed and it was agreed that further testing at all three RTCs was essential. It was agreed that Newcastle RTC would provide samples from their donors in the study for Dr Barbara and Glasgow RTC would do the same once Abbott had provided 2nd generation test kits since this would avoid thawing the samples more than once.

"The [Chair] was asked to contact Abbott and from the information he received recommend a starting date for the commencement of tests."

"4.14. It was agreed that testing of blood and plasma donations would commence on a specified date. There would not be retrospective tests carried out on donations collected prior to that date."

There's then a discussion about confirmatory testing over the page but I'm not proposing to go through that. So you will see there, by this point in time, there was a proposed starting date of 1 July but a question mark being raised in relation to that

proposed start date because of what was said to be the need to evaluate the new second generation tests that had been produced.

If we look next at SCGV0000163_053, and we go to the next page, this is a letter from Professor Cash to Mr David McIntosh in SNBTS, dated 27 March 1991, and it refers to the meeting, the minutes of which we have just looked at, and says this:

"You will want to know that our NBTS colleagues are struggling, on a number of accounts, to meet 1st July deadline, as previously discussed and I thought agreed. We believe the fundamental problem is one of financial resourcing.

"At a meeting of the UK BTS Advisory Committee on Transfusion Transmitted Diseases in Manchester on Monday last [so that's the meeting we just looked at], the following was agreed:

"Harold Gunson would advise DOH that the 1st July start date should be delayed until such time as an evaluation of the new generation of HCV screening tests had been completed. If this is accepted it could push a start date to September."

Then what is recorded is Dr Mitchell and Professor Cash both supporting that proposal, and then (b):

"The definition of a start date now proposed will be exactly as stated -- the date when routine HCV donation testing will commence. NBTS 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."

Top of the next page:

"More anon when things are clearer!"

That was Professor Cash's communication to Mr McIntosh of his understanding of the decision that had been taken and the putting back of the start date.

There's then a communication from Dr Gunson NHBT0000073_065. This is a letter which, as is plain, is intended to send to all Regional Transfusion Directors in England and Wales, dated 3 April 1991. It's copied to Professor Cash. We don't need to look at it but that is apparent from the second page.

Then you will see what Dr Gunson sets out:

"You will recall that in my letter to you of 15th February I suggested that 1st July 1991 might be an appropriate date to commence anti-HCV screening of blood donations.

"You may be aware that since the three-centre trial of anti-HCV tests was completed, Ortho and Abbott have produced second generation test kits which

have additional antigens to the C-100 of the test we have evaluated. There may also be other companies supplying anti-HCV tests.

"The Department of Health has agreed that there should be a 'second-round' comparative evaluation of the anti-HCV test kits at the Newcastle, North London and Glasgow RTCs, together with appropriate confirmatory testing. It has not yet been possible to commence the evaluation using production batches of the second generation tests referred to above and one of these will not be available until later this month.

"It is undoubtedly in our interest that this evaluation takes place. However, to complete this study and become operational by 1st July 1991 is too tight a schedule. It is difficult to state precisely a revised date, but I think we should aim to commence routine screening for anti-HCV by 1st September 1991."

Over the page it says:

"I thought you should have this information as soon as possible."

Then we can see the list of those to whom the letter is copied, including Professor Cash.

Then Professor Cash's response to that is at NHBT0000191_133. This is 5 April:

"Dear Harold

"Thank you for your letter of 3 April on this topic. My colleagues would wish you to know that this most recent development leading to a start date in September 1991 has the SNBTS Directors' fullest support."

Now, it's right that I should point out that, in his evidence to the Penrose Inquiry, and we'll look at some bits and pieces of that but time doesn't permit an exhaustive trawl through it, Professor Cash expressed a degree of unhappiness about the putting back of a date from 1 July 1991. He described what he said had been some difficult and distressing telephone conversations over a particular weekend with Dr Gunson.

It was explored with him during his oral testimony that the contemporaneous correspondence didn't necessarily reflect that and I'll give you some reference, sir, in due course, to some of the passages in his Penrose evidence.

SIR BRIAN LANGSTAFF: I think this does says "my colleagues would wish you to know", was there any discussion about whether, in practice, that meant "my colleagues and I"?

MS RICHARDS: I can't recall, I'm afraid. Or, rather, I don't recall there being any particular discussion

of the wording in that respect. I can double-check but I don't remember that coming up as an issue in the oral evidence. But I may be wrong. Professor Cash gave evidence to the Penrose Inquiry on, I think, ten separate occasions --

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: -- and his evidence on this particular -- on the issue of HCV testing -- surrogate testing and then anti-HCV screening I think spread over three different occasions, separated by a number of days or weeks. So I may need to double-check that.

SIR BRIAN LANGSTAFF: While I'm raising issues, just one further question. It's really going back to PRSE0002763, and this is where Professor Cash queries what "starting" means, "start date", and he is referring there to "plasma already in bond and waiting uplift", and presumably other products, RTC products, those in associated hospital blood banks.

So he's raising the possibility that after -- if, as we've seen, it is likely that on 1 September what was happening was testing of all new supplies, the supplies currently in the system might very well have been infected because they hadn't been tested.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: That has repercussions -- if it's

right it may have repercussions for the accuracy of the start date adopted for Skipton.

MS RICHARDS: It might indeed, sir, yes, absolutely.

SIR BRIAN LANGSTAFF: Although no-one, of course, would have had that in contemplation at this stage, but yes, thank you.

MS RICHARDS: Now, what then happened in May of 1991 is that the director of the Newcastle regional transfusion centre decided not to await the universal start date for the autumn of 1991, and he explains his position at NHBT0000074_014.

This is a communication from Dr Lloyd, director of the Regional Transfusion Centre in Newcastle, from whom we hope the Inquiry will be hearing.

It's 2 May 1991, directed to all directors of transfusion services, copied to, amongst others -- well, copied to Dr Gunson and Professor Cash.

It says this:

"As you know there was a date of 1st July set for Hepatitis C Antibody testing. Fairly recently this was changed with a provisional date set for September 1991.

"In view of the fact that we were already set up for testing, I have decided to keep to the July date. By 1st July, all units of blood for transfusion in the

Northern Region will be negative for Hepatitis C antibody.

"My personal view is that not to test now that we have the ability to test would be indefensible under the current Product Liability Legislation. I appreciate that individual Directors may take a different view on the potential liability under the Consumer Protection Act, but the fact that this Centre is testing should not materially alter that judgment.

"I would be interested to know if any Centre is currently carrying out any additional tests such as Hepatitis B core testing or ALT testing and if so, what criteria are being used to select donors/samples for testing."

Now I'm not going to explore to any extent the decision taken by Dr Lloyd. As I say, that will be for future hearings. I draw attention to it because it's the response from Professor Cash that's relevant for today's purposes.

In what you may think are characteristically powerful terms, Professor Cash wrote to Dr Lloyd on 7 May 1991, NHBT0000074_019.

He says this:

"I received your copy letter to the UK BTS Directors ... with quite profound dismay, which

I suspect will be shared by all my SNBTS colleagues.

"I cannot but conclude that this unilateral action is both disgraceful and mischievous. On a previous occasion I have expressed concern about NBTS management and have been taken to task when I used the word 'shambles'. Your action on HCV donation testing reveals, beyond doubt, that the NBTS is descending into a position now more accurately describe as chaos. It seems to be dog eat dog time, Huw, and I would suggest it is also time when you should remove the heading National Blood Transfusion Service from your headed notepaper and time for you and any of your staff who serve UK BTS and/or NBTS committees and working parties to be excluded."

Now it's right to say I think, and only fair to say, that when he gave his evidence to the Penrose Inquiry Professor Cash did express a degree of regret about the precise way in which he'd expressed his views in that letter.

The sentiment that this was an appropriate course to take was shared by a number of other Regional Transfusion Directors, who all wrote to Dr Lloyd, and those include Dr Contreras, Mr Martlew, Dr Boulton and Dr Entwistle, but we can ask them directly about that over the next few weeks.

Dr Lloyd responded to Professor Cash at NBBT0000192_031 in what you may think are quite dignified terms:

"Dear John ...

"Thank you for your colourful letter. Your views are graphically put, as I would have expected.

"I too have spent many hours looking at material relating to HIV litigation, but my conclusion is different to the one that you appear to be drawing. The situation now is quite different to that which existed when HIV 1 testing commenced, and I personally believe that to start HCV testing to the original schedule is the correct decision, even if it appears unpalatable to some.

"To suggest that my action was in your words 'mischievous', is to impart motives to this action which were not mine. If you wish to question motives, then perhaps you should be asking why a vague September start date has replaced with little explanation, a firm date in July."

Then, continuing with the position in relation to May of 1991, Professor Cash wrote to Dr Gunson on 8 May, NHBT0000074_024.

He referred to "the Newcastle saga". That's obviously a reference to Dr Lloyd's decision. Then he

set out a number of observations. He says in paragraph 1:

"It will, I suggest, be important that all participants (other than Newcastle) start at the same time."

Then he sets out a number of observations about the national large scale validation study which he was addressing, and suggesting that this should be in two phases. I'm not going to go through the detail of that.

If we go over the page he again sets out various recommendations as to which centres -- or centres using the different tests.

Then if we go to paragraph 5, in relation to the position in Scotland he says:

"Right now, it looks as though, when full screening begins, Edinburgh, Glasgow and Aberdeen will opt for Abbott. Thus, it would seem to me, that we should offer Glasgow only into this national (UK) study and the NBTS will have to find 2 Ortho Centres (because Newcastle have already opted for Abbott. I am sure Dundee and Inverness (using Ortho) would be happy to pitch in, but their donation collections are relatively small and this could be viewed as a disadvantage to Ortho."

Then he goes on to talk about the confirmatory testing associated with the study.

Also in May of 1991 Dr Gunson advised -- I don't propose to go it but I will just give you the reference -- NHBT0000192_024 -- that the Department of Health had reviewed the position in light of Dr Lloyd's decision to commence testing early and had concluded that the September date should remain and they were awaiting, amongst other matters, the second generation tests receiving FDA licences.

If we pick matters up still in May of 1991 with a further letter from Professor Cash to Dr Gunson at NHBT0000192_039, this raises some wider concerns.

So the first paragraph says:

"I can well understand that last week there's a time of preoccupation with the immediate tasks associated with damage limitation, following the unilateral actions of Newcastle RTC.

"On the first cold and wet Monday morning after that eventful week, I feel bound to raise with you and colleagues a matter of fundamental importance to the future of the UK [Blood Transfusion Service].

"It has always been the view in Scotland, both in the Scottish Office and throughout the SNBTS, that the introduction of additional microbiology donation

screening tests would be subject to Ministerial approval. Our understanding of this issue goes back many years to when SHHD directly intervened to stop one SNBTS centre unilaterally starting [hepatitis B surface antigen] donation testing. In recent times evidence that Ministers wished to acquire a firmer grip on this activity came with the establishment of the Advisory Committee on the Virological Safety of Blood. This development, in principle, was warmly welcomed in Scotland.

"In the past months we have witnessed two happenings in the NBTS which unequivocally indicate that our interpretation of the policy referred to above may be seriously flawed. I refer to the unilateral action of BPL demanding ALT donation testing and the most recent HCV episode in Newcastle. It is difficult not to conclude, particularly having witnessed the passivity of the [Department of Health] on both occasions, that Ministers no longer wish to be involved in this exercise and that their current intention is to leave such matters to respective Health Authorities. Should my conclusions be confirmed then I would wish to emphasise that I deplore this development. It will lead to chaos which will become evident in the courts. To the best

of my knowledge, this is a development in the management of blood transfusion services which is unique in Europe."

Then the next paragraph:

"You will recall that I proposed several years ago that there be established an authoritative ministerial advisory group which concerned itself with all policy issues relating to the safety of blood donations. I do believe this matter now requires urgent consideration. Such a group should not be restricted to virus transmission and must, above all, be authoritative.

"It is just possible that this issue, perhaps more than any other, can only be resolved satisfactorily UK by the establishment of a centrally managed [National Blood Transfusion Service], for authority is ultimately achieved by the allocation of funds. It is difficult not to conclude that we are rapidly reaching a situation where all the UKBTS Groups we have established, particularly those associated with BTS Guidelines, should be abandoned. It is every man for himself time and, against the background of the developments on harmonising quality in Europe, the recent episodes in the UK must surely be a matter for grave concern."

That was a more general observation on the organisation and structure of the National Blood Transfusion Service. Returning to the specific issue about hepatitis C donation testing and its introduction, Professor Cash authored a document at NHBT0000192_144.

This was 14 May 1991, addressed by Professor Cash to SNBTS board members, and you will see the subject is "HCV Donation Testing".

It refers to an article in the Sunday Times on 11 May, and then says this in the first main paragraph:

"Since early 1984, there has been growing concern throughout the UKBTS that microbiology donation screening kits should be appropriately evaluated before their large scale use is instituted. The primary concern, in this context, has been for the UK BTS to ensure, as much as is possible, that every effort has been made by kit manufacturers to maximise both sensitivity and specificity."

Then he refers to the need for the task to evaluate which kits might give rise to false negatives or false positives.

If we then go further down -- sorry, if we go over the page, picking it up in the second paragraph,

he says:

"The standard set by the UK BTS in the [HIV] exercise have been extended to the HCV kits. The SNBTS has contributed substantially to this exercise. The results have been interesting (and a little worrying)."

Then he goes on to give detail of that and also to refer to the outcomes in relation to confirmatory testing.

Then if we pick it up in that fourth paragraph:

"As the UK BTS validating team was in the process of advising Ministers and RTCs that both these kits could be used and that UK BTS should commence full scale screening on 1st July 1991, the kit manufacturers announced their intention to withdraw their kits and replace them with second generation kits. These new kits were claimed by the manufacturers to be an improvement over those tested by the UK BTS validation team, but no satisfactory data was available to confirm this at this time and it was noted that the FDA had not yet approved their use ... It was concluded that an evaluation of these second generation kits should be undertaken as a matter of urgency and a scheduled start time (for full RTC screening) was estimated to be

1st September 1991."

Then he sets out conclusions, saying:

"If we extend these UK observations to Scotland then each year we can predict (without HCV donation testing) the following:

"There will be approximately 170 donations ... infected with HCV and placed at issue ..."

Then he goes on to give further details in relation to that. Top of the next page, he then sets out various figures, and fourth paragraph down says:

"... in simple terms, we would have approximately 1,900 donors to deal with who we believed were false positives."

It goes on then to talk about costs and then, in the last paragraph, says this:

"It would seem prudent and responsible to pursue the idea of full evaluation of the second generation (HCV) test kits."

Then skipping a sentence:

"Beyond this, representations are being made, in the light of the developments in Newcastle RTC, as to whether, in future, the SNBTS is bound to a UK BTS approach with regard to donation testing, against a background of Ministerial involvement."

Then the document concludes over the page but

I don't need to trouble you with that. So it would appear from this document that Professor Cash was effectively agreeing with the need for there to be this further evaluation of the second generation kits, for the reasons which he there set out.

There were some further communications between Gunson and Cash in relation to the suggestion of the need for a ministerial advisory group but I'm not proposing to trouble you with that.

There was then a further meeting of the Advisory Committee on Transfusion Transmitted Diseases on 10 June 1991. I'm not going to go to it. The reference, for the transcript, is NHBT0000044_003. There was a discussion there of a number of matters, including how to handle donations and donors found to be hepatitis C positive.

If we then look at PRSE0001183, it's a further letter from Dr Lloyd to Professor Cash. This is dated 4 July. It says:

"I was pleased to see you at the recent meeting in York and thank you for 'burying the hatchet'. May I respond by apologising for any problems that I have caused you by starting testing this April."

Then Dr Lloyd sets out his broader concern:

"On a wider theme, I'm concerning that the UK

seems to be dragging its feet over testing I appreciate that many questions are not answered and for some Transfusion Centres, their organisation will find it difficult to introduce another test. By waiting until everyone's problems etc are sorted out, we run the risk of accepting the lowest common denominator. I somehow doubt that you would be happy to accept the lowest common denominator approach. The attitude of UK Transfusion Centres has often not been very positive and when we look at the plasma procurement situation (South of the border) over the years, it presents a very dismal picture. A little more fire and enthusiasm for Transfusion is required and a little less local protectionist activity and negative thinking."

There were then various communications -- again we've set them out in our written presentation, I don't think I need to go to them -- in relation to some of the detailed working out of the introduction of the hepatitis C screening. So there's a letter from Professor Cash in July to SNBTS directors and communications between Professor Cash and Dr Gunson in August in relation to the position regarding confirmatory testing. But I'm not going to trouble you with looking at those now.

There are, however, just two documents further to look at on the issue of hepatitis screening. The first is NHBT0000077_061. It's a letter from Professor Cash to Dr Gunson, 8 August 1991, headed "[Post-transfusion hepatitis] (HCV): Future Litigations", so anticipating that there may be litigation in the future, arising out of the delay in introducing hepatitis C screening, and he says this:

"I do believe it is important that consideration is given to the formulation of an agreed statement of the UK BTS professional position with regard to HCV donation testing.

"It seems to me that the key elements which need to be addressed, in the context of a defence position in subsequent litigations, are as follows:

"1. Why didn't UK BTS introduce surrogate (ALT/Anti-HBc) testing?

"2. Why was anti-HCV testing delayed until 1st September 1991?"

Those obviously are the two key questions. He doesn't give his answer in this letter but simply says:

"Perhaps we might wish to give this a run round at the next ACTTD meeting [that's the Advisory Committee on the Transfusion Transmitted Diseases].

On the other hand, you may feel this would be the most appropriate forum."

I think there's a "not" missing from that letter.

Then over the page, he continues:

"You will see from the enclosed (which I'm sure you've seen) [and that's a reference to an article in the Independent 'Patients may sue over hepatitis C in blood'] the cause for my concern and why I feel this matter is of some urgency. You promised to send me a set of Dr Metters' Committee Minutes: they haven't yet arrived."

We can see that the enclosure is the extract from The Independent newspaper.

So the other document I wanted to ask you to look at, sir, on this issue is Professor Cash's Penrose Inquiry witness statement on this topic of screening for hepatitis C. It's at PRSE0002529. We looked at some of Professor Cash's observations about the advisory committees, which he sets out on the first two pages of this statement, yesterday. I'm not going to go back to that.

If we go to the third page, if I pick it up on the bottom half of the page, there's what might be described as a general set of observations from

Professor Cash. He says this:

"To the best of my recollection we sought to avoid the difficulties we had in 1985, with the introduction of HIV donation screening. Whilst we anticipated that once again SHHD would insist on the primary of DHSS, with respect to the timing of the introduction of HCV donation screening in the UK, we believed in 1989 that the SNBTS should generate significant independent data as soon as possible which could be used as a lever for timely central action."

Then, if we go over the page, he was asked some questions about the decisions of the Advisory Committee on the Virological Safety of Blood, of which he was not a member, and his answer at (b) is:

"I was not privy to the business of ACVSB. But I was advised ..."

He doesn't say in this by whom, I can't recall without checking if it's clarified in his oral evidence or not:

"... I was 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 thereafter deferred until April 1990. Efforts to obtain the reasons for this deferral were not successful. That said, it is of interest that in

August 1989 the need for introducing another donation screening test had not yet been considered by SHHD."

Then if we look at the next page, top of page 5 there's reference to communications between Professor Cash and Dr Gunson -- some, not all, of which, I've shown you in the course of the morning, sir -- and we see the top of the page there's a reference to a letter in which Professor Cash refers, as at August 1989, to it being only a matter of time before the new testing programme would be commenced.

The question that is posed then by the Penrose Inquiry is:

"At this point, was he [ie Professor Cash] envisaging a shorter time period than in fact eventuated?

"Answer: Yes, I anticipated the SNBTS/WBTS Ortho kit assessment would reveal that we had a kit which would allow us to make a start, on the basis that specificity would be acceptable and sensitivity would be better than no screening."

Then if we look towards the bottom of this page, just above the last few lines, there's a question posed about the interrelationship between the respective health departments. So the question is:

"... were the health departments for Scotland,

England/Wales and Northern Ireland working jointly on the decision or was it an issue on which Scotland would follow whatever decision was taken in England? Was the formal position that the decision for Scotland would be taken in Scotland, independently from the decision for England?

"Answer: From the several conversations I had with Dr McIntyre [that's the medical officer within SHHD] I never had any doubt that although the decision for Scotland would finally be taken in Scotland, the SHHD operation 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; an aspect of management which I assumed ensured that the release of funds permitting the purchase of kits for donation screening by SNBTS RTCs was actually in the hands of the CSA's Finance Director who was to await instructions from SHHD."

Then if we look at the bottom half of the page you'll see, sir, from the text that's not in bold print, so the Penrose Inquiry's summary, refers to the Ortho Rome symposium in September 1989, refers to, then, a meeting of the -- or various meetings of the

ACVSB, and indeed refers to the judgment of Mr Justice Burton in the National Blood Authority proceedings.

Then the question is posed as to whether anyone has any comments or recollections of events at this time, and this was Professor Cash's comments:

"My recollections are that this was the beginning of a period of much unhappiness and frustration. It began with the pressure I put on Dr Gunson to reveal why the ACVSB secretariat had deferred considering the existing HCV kit valuation data (generated in 1989) until April 1990.

"When the deferred ACVSB meeting finally took place on the 23 April 1990 I discovered (after a briefing from Dr Perry) that both he and Dr Gunson had argued in committee that there was already sufficient data for ACVSB to recommend to Ministers the introduction of a first generation HCV donation screening as soon as possible. (This was a view I shared). I was advised that Drs Gunson and Perry's views were rejected and instead the committee agreed to mount its own HCV kit evaluation exercise. I recall that Dr Gunson was distressed at this turn of events and repeatedly emphasised to me that the ACVSB was in the hands of DHSS officials and the academic

virologists and that his role as DHSS adviser was being openly challenged.

"More unhappiness was to emerge for Dr Gunson and myself when the ACVSB came to examine the data generated from its evaluation of the first generation HCV kits when DHSS insisted that yet another evaluation should take place -- of second generation kits -- before routine testing would be authorised."

I draw attention to that because some of the correspondence we've looked at would suggest that in terms at least of his written formal communications at the time -- we can't obviously know about what conversations were taking place behind the scenes or between him and Dr Gunson, but the communications we've looked at would suggest Professor Cash in agreement with this evaluation of the second generation tests. So it's one of a number of I think what might be said tensions in relation to Professor Cash's evidence.

There are a number of further questions. I'm not going to go through the detail of all of them. If we go over the page, to page 8, Penrose Inquiry question 21 is:

"Why ... was it necessary to tie introduction of the test in the UK to approval by the FDA?"

This was Professor Cash's response:

"Rightly or wrongly I recall the FDA licensing process was regarded as important. There was a general view that the scientific processes of assessment of these diagnostic kits by the FDA were more rigorous and independent of political/commercial influences than in many countries, including the UK. That said, I recall that some were less certain that the issuing of FDA licences was entirely independent of political (US) pressures. No kit licensing arrangements existed in the UK."

Then if we turn next to page 11, please, we get, on this page, to the issue of the deferral of the start date in the course of 1991.

So question 33 suggests that there was difficulty in moving the issue forward in the early part of 1991, and this was Professor Cash's response:

"To the best of my recollection it was at the ACVSB meeting of the 25 February 1991 that the decision, made in November 1990 to start routine donation screening in July 1991, was reversed -- though I am not aware of any documents which confirm this and I recall I was later advised by Dr Gunson that he did not attend this meeting. But there is a document dated 21 February (4 days before the ACVSB

meeting) which seems to indicate that DHSS had already determined, without consultation with ACVSB, that there would be yet another kit evaluation -- the second generation study. I was later advised (23 March 1991) that SHHD had previously been consulted and had agreed to this second DHSS inspired and unnecessary delay. Dr Gunson advised NBTS Directors and others of this position on 3 April 1991."

So you will see in this statement Professor Cash expressing a degree of disagreement with what was taking place and suggesting that this was at the instigation of the Department of Health and that it was unnecessary.

Again, you will no doubt wish to consider what he was saying in his formal communications at the time. Some of these are issues that he was pressed on during his oral evidence to the Penrose Inquiry. It's also right to note that we are likely to have the benefit of being able to examine this in more detail by reference to witnesses from the Department of Health or witnesses involved in the ACVSB decision-making, and we will be seeking to unpick the Departmental decision-making process in later hearings.

Then if we go towards the bottom half of the page, you will see the last few lines refer to what Professor Cash described as:

"Some very distressing conversations with Dr Gunson over the week end before the ACTTD meeting of the 25 March 1991 left me in no doubt that, despite his letter of the 22 January to NBTS Directors signalling the commencement of forward planning for a full HCV donation screening start day, this had been reversed by DHSS in early February 1991 against Dr Gunson's wishes and without consultation with him or other members of ACVSB. Dr Gunson also insisted that SHHD had been party to this decision and that both Departments of Health were extremely anxious that there would be no difficulties at the 25 March ACTTD meeting. There was no reason at all why we could not have introduced screening using the first generation kits."

Two questions arise in relation to that. The first is: is that right as a matter of fact? That will be one of the many issues, sir, that you may need to consider when you consider why it took until the autumn of 1991 for screening to be introduced. So there is the general issue as to whether that's the case. But the second, specific to

Professor Cash, was: was that the view that was being express by him at the time?

SIR BRIAN LANGSTAFF: When he wrote that unusual correspondence to Dr Lloyd, expressing his view of Dr Lloyd's breaking ranks, he didn't say, "I happen to agree with your logic about introducing tests but you really nonetheless have to bow to the majority". He didn't put it that way, did he?

MS RICHARDS: He didn't, no. It's right to say that in his Penrose Inquiry oral evidence Professor Cash did talk on a number of occasions about the importance of there being a unified UK-wide position and a unified UK start date, and he continued to adhere to that.

But you're absolutely right. He did not convey to Dr Lloyd nor, I think, to anyone else in the -- nor to Dr Gunson, I should say, in the correspondence we've seen, a view that there was no reason why screening couldn't be introduced using the first generation kit.

So it's open to you, sir, in due course, and having heard much more evidence and received submissions, to conclude that that sentence is correct, but it begs the question of whether that was what was being said by Professor Cash at the time and,

if it was not, why not?

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Of course you are not going to have the ability to hear further from Professor Cash on that issue.

SIR BRIAN LANGSTAFF: Or Professor Gunson.

MS RICHARDS: Or Dr Gunson, no.

Then, you will see, he then says:

"Until sight of this witness statement request, I was not aware that Scottish Ministers had not been briefed about the start date until 24 July 1991. I suggest this is a matter of great significance and believe may give some support to Dr Gunson's claim that SHHD officials had been party to the contrived further delay, which had been conceived and implemented by DHSS officials."

Again, that is an issue upon which he was questioned during his oral evidence as to some of the ways in which he characterised the DHSS's role.

Then he continues:

"I recall that Dr Mitchell advised me that the ACVSB was aware of the existence of second generation tests at its November 1990 meeting, but had agreed that an evaluation of these kits could be fitted in after the commencement of full screening using the

first generation test. It follows that for some reason there was a significant change in policy and that the ACVSB was not consulted. Certainly the notion that the second generation kits could have readily been evaluated soon after the introduction of routine HCV donation screening enjoyed the support of the SNBTS. Thus earlier Ministerial approval would also have enjoyed our support.

"The position adopted by the Director of the Newcastle RTC [so Dr Lloyd] in April/May 1991 proved to be very revealing. Among other things I recall it had much to do with the proposition made to the SNBTS Board in June 1991 that the SNBTS should emulate Newcastle, disregard the positions of SHHD and CSA and establish full HCV donation screening ASAP. As I recall it was a hotly contested debate, but the proposal was defeated. Some of us who opposed it viewed it as one, which if approved, could have triggered a descent into chaos and hence my reference to a potential 'disaster' ... In my view, the disaster would have been the operational fragmentation of the UK BTS, but closer to home the SNBTS. The impact of a fragmented UK BTS to the quality of care of UK patients would have been considerable."

So there Professor Cash is articulating the

position consistent with documents we have seen at the time that there should be a universal co-ordinated approach and not individual areas taking their own course.

So that's the written statement in relation to hepatitis C screening. There's then -- in relation to surrogate testing, there was one document which I should have taken you to, sir, and didn't.

This goes back to 1986 on the question of surrogate testing. It's PRSE0002109 and it was a letter from Professor Cash to Dr Fraser in Bristol, "NANB: Surrogate Testing". It says this:

"I have a feeling that as the drums are beating louder and louder in other parts of the world on this topic the Brits remain fast asleep. I may be wrong but I would like to better briefed on this matter."

Then he refers to raising the issue at an SNBTS Directors' meeting some months ago:

"... and we agreed that you would explore the idea of setting up a UK prospective trial. I recall you saying to me that you pursued this at the NBTS Directors' Meeting (I'm afraid I wasn't there) and it went down like the proverbial lead balloon!

"I'm bound to conclude that I feel we cannot leave the matter as it is and would value your

comments on the suggestion that we (you and I) get down in the near future to plan a 'consensus meeting' designed to look at the issues associated with NANB donation testing. I believe we should invite people from abroad -- Harvey Alter, for instance. The purpose of the meeting; to which all UK BTS directors would be invited, would be to see whether we can reach conclusions which would enable us to make some clear operational decision and that these would be transmitted to the various Departments of Health."

In any event I refer to this, sir, because it's that concept of the drums beating louder and louder in other parts of the world while the Britons remain fast asleep, which is a powerful expression of Professor Cash's views on that issue.

Sir, the final issue in our written presentation is the issue of Professor Cash's involvement in the look-back exercise. Our time is, to some extent, constrained and what I'm going to do before I deal briefly with that, if I may, is just give you and others the various references to Professor Cash's Penrose evidence.

I have touched on some of the written statements but so as to avoid the need, in due course, for everybody to go through the exercise the Inquiry team

has gone through of gathering them altogether, I hope it will assist recognised legal representatives if I just give the references to all the written statements, and then I will give the references to the oral transcripts. I don't think we have probably got time sensibly to go through the oral transcripts but I can indicate where people will be able to find them.

So there were a large number of written statements from Professor Cash on different topics, and they are as follows in terms of references:

PRSE0000491, that's cash on Z8, the Z8 product and clinical trials.

There's PRSE0000529, statement about the PFC.

There's PRSE0000651, also a statement about Z8.

PRSE0001273 is Professor Cash's statement about the look-back exercise.

PRSE0001411 is concerned with ALT testing.

Some of these are very short supplemental statements some are much more detailed and lengthy statements.

There's PRSE0002529, that's hepatitis screening and we've just been looking at that statement.

PRSE0002836 is on the topic of viral inactivation, so the heat treatment by the PFC.

PRSE0003232 is about -- well, it's relevant to

questions of surrogate testing, essentially.

PRSE0003395 is HIV/AIDS.

PRSE0003463 is a further statement in relation to the PFC.

PRSE0004020 is a statement from Professor Cash, amongst other things, in relation to a statement from Mr David McIntosh.

PRSE000465, statement about surrogate testing.

PRSE0004252 is an updated statement about HIV/AIDS.

PRSE0004484 is about donor selection and prison blood collection.

Also on the topic of donors, PRSE0004558.

There is also a very short supplemental statement on a tiny topic, I can't remember off the top of my head what it was, but it is SBTS0002559.

So those are the written statements. I hope that's all of them. If I've missed any I will ensure that that information is corrected.

Professor Cash gave evidence on a number of different occasions. Taking them -- so oral evidence. Taking them in chronological order:

He gave evidence to the Penrose Inquiry on 23 April 2011, PRSE0006010, and that evidence was about high-risk donors, prison blood collection and

collection from donors with a history of jaundice.

Then PRSE0006043 is Professor Cash's evidence on 8 September 2011, and that topic -- that was topic B3 -- I'm going to have to remind myself what topic B3 was now. I think that's viral inactivation. In any event, there's the transcript.

Then there's his oral evidence on 27 September 2011, PRSE0006048. That's in relation to HIV/AIDS.

He then gave evidence on 27 October 2011 PRSE0006057 and that, I think, was in relation to topic C3. It was again concerned, I think, with the position in relation to PFC, as I recall, but I can double-check that.

Then he gave evidence on 16 November 2011 PRSE0006064. That's on the question of surrogate testing.

He gave evidence on 29 November 2011, PRSE0006070. That's a continuation of his evidence on surrogate testing and then a commencement of his evidence on hepatitis C testing. He goes there into rather more detail about what he describes as the distressing conversations he had with Dr Gunson, in particular, about the deferral of the start date for HCV testing. So there is quite a lot that may be

worth considering in his oral evidence there.

Then, 1 December 2011, is, I think, a continuation of the evidence on that topic PRSE0006072.

Then he gave evidence on 11 January 2012, PRSE0006082. That's still on the issue of hepatitis C testing.

Then I think his final oral evidence is on 17 January 2012, PRSE0006085, and that was in relation to the hepatitis C look-back.

I'm not going to take you now, I think, sir, on reflection, to extracts from his oral testimony because it is very difficult to follow without simultaneously looking at all of the documents that are being referred to during the oral examination and, otherwise, I would be at risk of plucking individual bits of his answers out of context without looking at what are hundreds and hundreds of pages of oral testimony. No doubt, in due course, those who wish to make submissions about decision-making on these issues will be assisted by looking at the evidence that Professor Cash gave to Penrose.

Can I then come finally, and by reference to the contemporaneous documentations, to Professor Cash's involvement in the look-back exercise. He told the

Penrose Inquiry he wasn't directly involved in the carrying out of the look-back exercise but the documentation suggests he certainly had some involvement in the decision-making as regards whether and, if so, when and how it should be set up.

If we start with -- I think it's PRSE0001133, this is Professor Cash writing to his colleagues within SNBTS on 9 July 1990, "HCV: look-back programme":

"As promised, I have discussed this topic with Harold Gunson.

"We both agreed the following:

"It would not, after we start anti-HCV donation screening, be appropriate to introduce a systematic look-back programme on previous recipients -- as was done for HIV-1.

"It would be appropriate, in the period before routine anti-HCV donation screening commences, to examine the anti-HCV status of donors who have been implicated in a case of reported PTH."

There's what's said to be the agreement between Professor Cash and Dr Gunson in mid-1990, of course over a year before the hepatitis C screening was finally introduced. What we don't get from this letter is an understanding of what the reasoning was

in relation to either of those positions.

If we then look at NHBT0000073_007, this is a letter, October 1990, Professor Cash to Dr Gunson. It's primarily concerned with the issue of donor counselling and a report from Jack Gillon, but if we go over the top of the next page, we can see the issue of look-back. He says:

"... I would much appreciate your thoughts on the issue of 'look-back'. You will have noted that our team have indicated the need for a policy statement and in their view 'look-back' should be attempted."

There were then discussions or -- sorry, there was then a letter from Dr Gunson saying this will be considered by the Advisory Committee on Transfusion Transmitted Diseases in January 1991. The reference for that, I'm not proposing to go to it, is NHBT0000073_028.

If, however, we look at -- sorry, just give me a moment.

PRSE0001573. We can see Professor Cash writing to Dr Metters, Deputy CMO, in November 1990:

"In anticipation of the commencement of HCV blood donation testing throughout the UK in the foreseeable future, the Scottish National Blood

Transfusion Service Directors have asked me to write to you with a request that a policy of 'look back' is considered by the ... Advisory Committee on the Virus Safety of Blood."

Then if we turn to PRSE0003568. We're now in February 1991. This is an internal SNBTS meeting, a meeting of its medical and scientific committee chaired by Professor Cash, and we will be able, I think, to pick some of these issues up with oral witnesses.

But if we turn to page 4 there's a heading towards the top of the page about "Donor Counselling: HCV Donation Testing", and then the next paragraph reads:

"In the light of national events ..."

That is, I suspect, a reference to the fact that the testing programme had not yet commenced.

"... it was agreed that no 'Look Back' should be introduced at present."

It's then -- I think we then have to look to 1993 for the issue to be raised again by Professor Cash himself, at PRSE0003928.

So this is now two years after the introduction of the hepatitis C screening, or a little over two years after, and Professor Cash wrote to Dr Gunson in

these terms:

"HCV confirmed positive donors: look back.

"At a recent RCPE Symposium on HCV a distinguished speaker indicated that efforts ought to be made by the transfusion services, in the first instance, to track patients who had received blood and blood components. He argued that some of these patients could benefit substantially from some modern therapeutic manoeuvre and that we had a duty to ensure this option was made available.

"This view was discussed at a recent meeting of the SNBTS Medical and Scientific Committee and while it received support colleagues stepped back from introducing a look-back policy until such times as further (UK) deliberations had taken place.

"It occurred to me that it might be appropriate for the item to be researched for, and discussed by, MSBT."

That's the Advisory Committee on the Microbiological Safety of Blood and Tissue, I think. Sorry, the acronyms become a little confusing.

Then if we look at PRSE0003685, this is a discussion, now in May of 1994, of the SNBTS Medical and Scientific Committee chaired by Professor Cash. We can pick up the position in relation to look-back

at the bottom of page 5. Where it said:

"This very complex and extremely important issue was discussed at length. The Committee unanimously agreed that on finding a 'known' (or regular) donor who was now anti-HCV pos, the SNBTS should ..."

Then there are a number of proposed steps set out. First is:

"i. Retest previous archive samples to exclude 'missed' sero conversion ...

"ii. For donations issued to hospital blood banks, other RTCs, etc, the SNBTS will provide ..."

Certain information to the clinician.

(iii) sets out the proposal in relation to donations issued to known patients by SNBTS blood banks and then:

"iv. It was agreed that the procedure to be followed would be based on that outlined in the forthcoming publication on the subject in Transfusion Medicine ..."

Then:

"v. From an SHHD perspective, AK [and that is Dr Aileen Keel] expressed a view that the SHHD may not have a locus in this matter and that the SNBTS should make a decision on lookback for HCV that was based on their professional judgment. However, before SNBTS

took any action, AK asked to be given the opportunity to discuss the issues with SHHD colleagues to seek their views and asked that the SNBTS take no formal action until she had subsequently contacted JDC."

That's Professor Cash.

"vi. Once AK had communicated the SHHD position to JDC and provided SHHD were in agreement that the SNBTS should implement this policy, JDC would write to D [McClelland] to provide details of the SNBTS policy, thereby allowing a decision to be taken on a starting date for the process. [Professor Cash] also would formally advise NBA, NIBTS, SACTTI and MSBT of the SNBTS policy."

We are definitely in acronym soup by now.

"vii. If SHHD agreed that SNBTS should develop and implement a lookback policy for HCV, [Dr Keel] subsequently would communicate this to [the Department of Health].

So that's the discussion which took place there, and again we'll be able to unpick some of the decision-making here with later witnesses.

There's a reference at NHBT0095526_0026 to there being pressure to promote a look-back policy.

Do you need that reference again, Soumik? NHBT0095526 --

SIR BRIAN LANGSTAFF: It may be the underscore might be 026.

MS RICHARDS: Yes, it may be.

Thank you, Soumik.

So it's a letter -- this is, in fact, from Dr Ala to a doctor at the liver unit of the Queen Elizabeth Hospital in Birmingham, but it's about hepatitis C look-back, and you will see --

SIR BRIAN LANGSTAFF: For those who want to follow this, Dr Ala was in charge of the transfusion at the Regional Transfusion Centre in the West Midlands, was he?

MS RICHARDS: Yes and he was writing here in his capacity as chair of the Advisory Committee on Transfusion Transmitted Infection, and he says:

"... I have been under some pressure to promote a 'look-back' policy for all those patients who received blood products from donors we subsequently found to be anti-HCV positive when screening was introduced to the BTS.

"The advocates of this policy (mainly the Scottish National [Blood Transfusion Service]) argue that ..."

Then we can see the reasoning that's being set out there:

"Interferon alone, or in combination with Ribavirin will arrest progression of liver disease and disappearance of viral RNA in a large proportion of patients (over 60%)."

Just pausing there, and again we'll see this as we look at look-back issues in more detail with witnesses or by way of further presentations, but one of the themes was "Is there any point in doing a look-back if there's no treatment that we can give to patients?" There may be a number of obvious answers to that, or perhaps some less obvious answers to that, but, in any event, what's being said here was this now a treatment and therefore, a greater obligation to trace people who may have been infected with.

So we see that from the second point.

"We have a moral duty to counsel these individuals with an eye to making this potentially effective treatment available to them.

"Even though sexual transmission is reportedly low with HCV, we should, nevertheless, provide cautionary advice because the situation is not yet clear."

Top of the next page:

"We risk public and media opprobrium for being

either negligent or secretive."

There are then set out the potential reasons for not undertaking such a policy. So the reasons for undertaking it were those being put forward, it is said, mainly by the Scottish Directors. The contrary reasons given here:

"It will create crate unnecessary anxiety.

"Little will be gained for the effort and expense involved.

"Long-term results of [interferon]/ribavirin therapy are not yet available ...

"We will generate the very adverse media publicity we would seek to avoid."

Then the letter continues to say that:

"... I have convened an *ad hoc* meeting in Birmingham [5 August 1994], to discuss this issue and attempt to reach some policy decision. This will not be easy, and I know Professor Cash and Professor Tedder do favour doing a 'look-back' while several others are agnostic."

That's what is being recorded as being Professor Cash's position by that time.

There was a paper produced by Professor Cash for -- I think it is for that meeting. No, it may be for a later meeting. I think it is produced arising

out of that meeting, sorry. PRSE0001236. So it's HCV look-back, Professor Cash. If we go over the page, you'll see it's headed "Recommendations of the Standing Advisory Committee on Transfusion Transmitted Infection to the MSBT Concerning the Merits of Adopting an HCV 'Look-Back' Policy", and then it refers to the meeting on 5 August, to which Dr Ala had made reference:

"An *ad hoc* assembly of experts met on 5th August 1994 to discuss the feasibility of initiating a 'look-back' policy to identify, test, counsel and, if necessary, refer surviving past recipients of blood components from donors later found to be anti-HCV seropositive after [testing] was introduced in September 1991."

I won't go through the detail of the report. If we just go to page 4 and look at the summary, it says:

"The SACTTI [that is the Standing Advisory Committee on Transfusion Transmitted Infection] feels there is a serious case for considering a look-back policy for HCV. To do otherwise, when a look-back programme for HIV already exists, suggests double standards. The wider implications of such a policy will need further consideration and the SACTTI recommends that the Hepatitis Advisory Group and the

MSBT consider the matter further as soon as possible."

There are further discussions both within Scotland and nationally but I think we'll probably pick those up more usefully with later witnesses. In early 1995 Professor Cash wrote to Dr Metters with some suggestions about the look-back, which, by this stage, had been agreed in principle. I won't go to that letter but the reference for the transcript is NHBT0005835.

Perhaps the final document just to look at on this issue is STHB0000687.

So this is October 1995. It's a meeting of the SNBTS Medical and Scientific Committee. So this is a point in time at which the look-back, the national look-back exercise has been decided upon.

If we go to page 4 -- I'm not proposing to go through the detail, but there's a heading "HCV Lookback" and an "Update of the SNBTS Position".

Perhaps the only sub-paragraph that I should highlight for present purposes is sub-paragraph (iv):

"With respect to recipients of blood components pre HCV testing, the MSC agreed:

"- that testing of available donor archive samples would be neither cost effective nor appropriate.

"- that an offer to test anyone who had received blood components or products prior to HCV screening was likely to be the most effective option.

"- that this (latter option) should not be pursued until the present HCV lookback exercise was substantively complete.

"- that the sample connection and testing process should be provided by the Blood Transfusion Services."

So that's an update of the internal position whilst the look-back exercise nationally was ongoing. That, I think, effectively concluded Professor Cash's involvement directly with the issue.

So, sir, I'm almost on time. That's the presentation in relation to Professor Cash. You will appreciate, and I hope those listening will appreciate, there is a vast amount of material generated by Professor Cash, directed to Professor Cash or into which he was copied and an even wider volume of material in relation to the decisions and actions of SNBTS more generally. So this is an introduction and overview, rather than an exhaustive exercise. But I hope it assists in identifying a number of themes that will then be picked up with oral witnesses over the coming weeks.

SIR BRIAN LANGSTAFF: Yes. Well, thank you. That's been very helpful.

We will take a break now then until 2.05, when I expect we will hear from Ms Scott, will we --

MS RICHARDS: We will hear from Ms Scott.

SIR BRIAN LANGSTAFF: -- and she will be telling us about Dr Gunson?

MS RICHARDS: Exactly, yes.

(1.04 pm)

(Luncheon Adjournment)

(2.05 pm)

SIR BRIAN LANGSTAFF: Yes.

Presentation by Counsel to the Inquiry on Dr Harold Gunson

MS SCOTT: This afternoon and into tomorrow we're going to be hearing about the work, actions and views of Dr Harold Gunson.

In the same way that Ms Richards made clear with Professor Cash, Dr Gunson was a key figure in the English Blood Service and there are many thousands of documents that one could look at to explore what he thought about things, what he did, and he was involved for very many years. So, inevitably, the documents that we've drawn attention to, both in the written presentation and over the next day or so in the oral

presentation, are selective.

I hope that by going to some of the documents we'll get an idea of what his views were about some of the key issues that we're going to be exploring in the coming hearings and what action he took and what part he took in some of the key decisions that were taken over the relevant period.

I'm going to start by looking at his CV, which is NHBT0000025_002, and it's page 16 of that document. We can see there his name and, if we go over to the following page and pick it up at the bottom of that page, we can see, beginning in 1953, Resident Clinical Pathologist, and then a number of appointments in Canada, returning in 1959 to take up a role as a Senior Hospital Medical Officer in a Regional Transfusion Centre in Manchester.

He then became the consultant in charge of the transfusion centre in Lancaster from 1964 to 1975 and, while in that post, became an honorary consultant to the Lancaster District of Lancashire Area Health Authority.

Then from September 1975 to March 1980, he became the director of the Oxford Regional Transfusion Service and, from April 1980 to October 1988, he was the director of the North Western Regional Blood

Transfusion Service, which was based in Manchester.

Then if we go up to the top of the page, we can see that he then, from there, moved in October 1988 to become the National Director of the National Directorate of the NBTS and we heard on Tuesday the circumstances in which that post was created.

Then in April 1993 he was appointed the first Medical Director of the National Blood Authority until his retirement in July 1994. Then we can see from July 1994 until the time that that document was written he, although being retired, actually held a post as a part-time consultant to the National Blood Authority. My current understanding is that, primarily, his role during that period was in response to litigation but it may be there is more information that will bring a different complexion to that period of his working life.

So those are the roles that he undertook. Just picking up, importantly, under present appointment, the penultimate entry there, October 1981 to July 1994, we can see that, overlapping with many of his posts and in particular his directorship of Manchester and his role in the National Directorate and the NBA, he was appointed the Consultant Adviser on Blood Transfusion to the Chief Medical Officer at

the Department of Health and Social Security and then, of course, when it became the Department of Health.

I'm just going to look at a couple of documents which gives us some insight into how he viewed that particular role. The first one is CBLA0001498.

We can see that that's a letter written on 16 November 1981, so shortly after he had been appointed Consultant Adviser, it's headed on the Manchester National Blood Transfusion Service paper, "Dear colleague", and if we go to the second page we can see it's from Dr Gunson. Then if we go back, please, to the first page, it's the third paragraph down:

"As you are aware, the post of Consultant Adviser is a personal on and the advice proffered is, therefore, personal also. However, it would be foolish for advice to the DHSS to be out of line with general views on a particular topic. In this regard I intend to keep in touch with Bill Wagstaff and the Chairmen of Divisions, but also hope to keep myself informed of matters and problems in the various regions which could have national importance. I hope you will feel that you can discuss these with me, or write and let me know about them. Also, I would appreciate agendas and minutes from the various

working parties. If you wish me to attend any meeting of a working party where you think the discussion will be helpful, I will endeavour to do so; the same applies to the meetings of the Western and Eastern Divisions."

I will come on in a moment to look at some of the working groups and committees that Dr Gunson attended.

So we can see there the role is a personal one but he is going to keep himself very much up-to-date with what others are thinking and what decisions and actions are being taken.

Then the second document which throws some light on this is NHBT0018339. Now, this, we can see, is a minute of a "Regional Transfusion Directors' Meeting" on 7 October 1981, and we can see, about halfway down the list of those who are present, Dr Gunson's name and we can see, at the bottom, that that meeting is chaired by Dr Wagstaff, who we saw mentioned in the previous document.

If we then go over the page, please, to page 7 we can see at item 11 "Consultant Adviser to DHSS":

"In view of Dr Tovey's retirement, Dr Gunson has been asked to fulfil this role."

Then skipping down to two thirds of the way down

that paragraph, what he does there is he describes the different administrative arrangements there are going to be, namely that he is going to discharge his role from Manchester not from London, because he is going to continue in his role as director of the Manchester centre. I'll pick it up, it says:

"Where statements had to be made on behalf of the DHSS this would be done by DHSS and not by the consultant adviser to the DHSS. Dr Gunson expressed his willingness to attend any meetings of working parties or regional groups at which his contribution would be useful ..."

So echoing what he says in his later letter but, importantly, he says this:

"... he saw his role as reflecting the views of the RTDs and NBTS at large and communicating these to the DHSS where appropriate."

So a slightly different complexion there to the role. In that later letter he says it's a personal one, and "I'll be expressing my personal views", but here he seems to be suggesting that he may be rather more of a representative voice of RTDs to the DHSS.

Then I'll just take you to a document, NHBT0000086_009, again which gives us a bit of information about the role.

This is a training session given by Dr Gunson to lawyers in the HIV litigation. Dr Gunson was engaged as the blood transfusion expert for the defendants, both the health authorities and Central Government, in that piece of litigation.

If we could pick it up at page 11, at the top of that he says:

"The purpose of the Consultant Adviser is to provide advice of a personal nature to the CMO or nominated officers at DHSS as distinct from collective advice from the Speciality as a whole."

Then explains why he had a rather different arrangement to the previous two holders of the post, who were Sir William Maycock and Dr Tovey.

Then the next paragraph he says:

"Events were to prove that my advice was required on many occasions during the next few years since within one year the relationship between AIDS and the transfusion of blood and its products was proven. It must be recognised that my advice on these matters was on personal basis; responses from The Service to matters concerning HIV infection amongst other topics were elicited from the Chairman of the RTD Committee."

SIR BRIAN LANGSTAFF: Just stopping there for a moment, he

began his role in October 1981?
MS SCOTT: Yes.
SIR BRIAN LANGSTAFF: So when he says "within one year the relationship between AIDS and the transfusion of blood and its products was proven", he's talking about before October '82?
MS SCOTT: He is, and, sir, we'll come on to look at some of the documentation and how he says -- on later reflection, at what point he says that he was convinced that HIV or AIDS was caused by blood transfusions.
SIR BRIAN LANGSTAFF: Yes.
MS SCOTT: We will get on to that tomorrow.

So moving on then to the committees and working groups that Dr Gunson participated in and I should say, although there are a lot -- I am going to mention a lot of them, this is not an exhaustive selection. There are other working groups, committees and so on that he participated in.

So, as a Regional Transfusion Director, as one would expect he was a regular attender at Regional Transfusion Director meetings, and the Regional Transfusion Directors had various working groups and committees and he was chair of the Regional Transfusion Directors committee, called the UK AIDS

Working Group. The Inquiry, as I understand it, has only found minutes of one meeting of that group to date but investigations continue.

He also attended the regional meetings of consultants of the Blood Transfusion Service and, sir, you may recall on Tuesday we heard that Dr Tovey had instituted a system where there were three supra-regional group meetings and Dr Gunson again, as one would expect as a director, attended the relevant one for him, which for Manchester was the northern.

He also attended meetings when they occurred between Regional Transfusion Directors and Haemophilia Centre Directors, and we have a number of examples of meetings of that nature.

He was a member of the Advisory Committee on the National Blood Transfusion Service, from its inception in December 1980 and, again, we heard about how that was created and circumstances that that was created, on Tuesday and we looked, on Tuesday, at the terms of reference of that group, which for reference, is CBLA0001207, and it was to advise the DHSS and the Welsh Office on the co-ordination of the development and work of Regional Transfusion Centres and Central Blood Laboratories in England and Wales, and the English and Welsh Blood Transfusion Service with those

of Scotland and Northern Ireland.

He chaired two of its subcommittees, the working party to advise on plasma supplies for self-sufficiency in blood products, in February 1983, and also the working group on AIDS. The names of some of these committees and working groups are quite a mouthful.

Once the National Directorate was formed in 1988 and the Advisory Committee was abolished, as we heard on Tuesday, he became -- the National Management Committee of the NBTS was formed, in December 1988 it had its first meeting, and he was, as you would expect as National Director, a member of that committee. We looked at their terms of reference on Tuesday.

He was a member of the UK Working Party on Transfusion Associated Hepatitis from its inaugural meeting in September 1982, and the terms of reference for that can be found -- and we don't need to turn this up -- CBLA0001625, and I can read those out because they are short.

So the terms of reference for that group were to promote the investigation of the epidemiology of transfusion associated hepatitis to promote research and to make recommendations to the director of the UK Transfusion Service regarding procedures and screening

for its prevention.

Between 1982 and 1988 he was a member of the Central Blood Laboratory Authority. He was chair of some of their subcommittees, such as the central committee for research and development in blood transfusion, he was chair of that subcommittee from June 1983. He was chair of their working group on AIDS from October 1983, and the terms of reference for that group -- again, we don't need to go to this -- can be found at CBLA0001754, and that document says that it was set up to consider the problem of AIDS in relation to the transfusion of blood and blood products.

That was a committee on which Professor Bloom sat and we can see, from the minutes of the document of the first meeting, that I've just given the document reference for, that Professor Bloom was asked to be the link between the CBLA working group on AIDS and the Medical Research Council committee on AIDS because he sat on both of those committees.

Now Dr Gunson resigned from the CBLA when he took up his role as national director to avoid any conflict should the CBLA policy materially differ from the aims of the National Blood Transfusion Service.

He was a member of the National Blood

Transfusion Service and CBLA Liaison Committee from January 1989. He was a member of the NIBSC, the National Institute for Biological Standards and Control, and the UK Blood Transfusion Service Liaison Group, which first met in March 1987.

The purpose of that committee is set out at NHBT0108865_010. We don't need to go to that now. In essence, it was a committee set up to formulate scientific guidelines for the standardisation and safety of blood and blood products, and subsequently became, as I understand it, the Standing Advisory Committee on Transfusion Transmitted Infections or SACTTI. He attended a couple of SACTTI meetings before his retirement.

He was also a member of the SNBTS NBTS -- so the Scottish National Blood Transfusion Service and the National Blood Transfusion Service -- Liaison Committee, as Ms Richards made clear yesterday, and the chairmanship of that committee alternated, as I understand it, every meeting between Scotland and England, and when it was England's turn he was chair. They had their first meeting in January 1989.

He was also a member, as you heard yesterday, sir, on the Advisory Committee on the Virological Safety of Blood, or ACVSB, from 1988 to 1994.

If we can just look at the terms of reference to that committee, because I don't think we went to those yesterday, it's PRSE0003956.

So we can see there "Advisory Committee on the Virological Safety of Blood", and if we go to page 4 of that document, you can see it's:

"To advise to the Health Departments of the UK of measures to ensure the virological safety of blood, whilst maintaining adequate supplies of appropriate quality for both immediate use and for plasma processing."

He was also chair of the UK Advisory Committee on Transfusion Transmitted Disease, ACTTD, and we heard yesterday that Professor Cash, in his Penrose evidence, described that the existence of that committee as Dr Gunson's brainchild.

That committee was formed in February 1989. The terms of reference are worth looking at. It's NHBT0027680.

If we go, please, to page 3 of that document, we've got there:

"Draft

"Terms of Reference

"1. To consider the epidemiological, clinical and laboratory aspects of disease which may be

transmitted by the transfusion of blood and blood products.

"2. To determine the appropriate policy which should be implemented by the UK Blood Transfusion Services for the control of transfusion transmitted disease.

"3. To advise the Departments of Health accordingly."

If we go back to page 2, we can see the membership includes both Professor Cash, Dr Contreras, Dr Gunson, Dr Wagstaff, Dr Mortimer, Dr Mitchell, and so on.

Dr Gunson, in his statement for the HCV litigation, which we find at NHBT0000026_009 addressed the relationship between those two committees, so the relationship between the Advisory Committee on the Virological Safety of Blood and the UK Advisory Committee on Transfusion Transmitted Disease.

So we can see that's the header of his witness statement for the *Re A and Others* HCV (hepatitis C) litigation.

If we turn, please, to page 29 at paragraph 73, he says this:

"The ACVSB was a powerful committee. As was noted at the outset ... it was appreciated that it

would be covering many of the same issues as the ACTTD. The relationship between the two Committees was formally addressed at the meeting of the ACVSB on 24th April 1990, where the Chairman proposed that it would be the responsibility of the ACVSB to advise Ministers on the virological safety of blood, while the ACTTD would consider the operational implications of policy, advise the Department on non-viral threats to blood and contribute to the advice on viral safety through input to the ACVSB. I confirmed that I shared this view not the respective roles of the two Committees and did not believe that it involved any conflict.

"It was accordingly the ACVSB which was the leading Committee in formulating policy with regard to introduction of HCV testing. Of course neither the Committee nor I, as explained in Section A, had any direct authority to impose decisions on the Regions, which retained operational responsibility for the RTCs. It was my role, once policy had been determined within the Committee, and where necessary approved by Ministers, to communicate the decision to the RTDs and to make every effort to ensure their co-operation."

He was also a member of some of the Medical Research Council committees. He was a member of the

Blood Transfusion Research Committee Working Party on Post-Transfusion Hepatitis, which had its first meeting in February 1980, and the terms of reference are set out, we don't need to go to this, in MRCO0000029_003 and they were to promote research and to assess the nature and size of the problem of post-transfusion hepatitis in the UK, with particular reference to changes in transfusion practices.

He was also a member of the Medical Research Council's Working Party on AIDS subcommittee on epidemiological studies. He was a member of the Expert Advisory Group on AIDS from 1985 to 1993. Ms Richards took you yesterday to the terms of reference of that group.

He was also a member of the Expert Advisory Group on AIDS (the EAGA) screening test subgroup which had its first meeting in February 1985. The terms of reference to that can be found at DHSC0000425, we don't need to go to that, but the terms of reference were to advise EAGA on the introduction of an antibody test to the AIDS virus. He was also a member of the EAGA subgroup on AIDS counselling.

He was a member of certainly one Department of Health and Social Security committee, being chair of the DHSS Plasma Supply and Blood Products Working

Group Medical Subcommittee, which had its first meeting in April 1988. We can see in the terms of reference, which we don't need to go to -- well, we don't need to go but can be found at DHSC0002017 and, in that document, it says that the Medical Subcommittee needed to consider the problem of yields and how much plasma would be required for the fractionation of Factor VIII and Factor IX.

He was also the UK representative on the Council of Europe Committee of Experts on Blood Transfusion and Immuno-Haematology. They met annually. It was a forum for exchange between European blood services and we have evidence of Dr Gunson both preparing reports for those meetings, setting out what the practice was in the UK, and reporting back from those meetings, as to what the practice was in other European countries.

He acted as Expert Adviser to the Committee on the Safety of Medicines Subcommittee on Biological Products on the issue of AIDS and, as I said at the beginning, there are other committees and working groups on which he sat, which I haven't listed.

But one can see the breadth and width of his participation in the committees, and also the fact that there were so very many committees and working

groups meeting and making decisions over this period.

We know from the oral evidence that Dr Gunson gave in the hepatitis C litigation, *A and others*, that he was a regular reader of The Lancet, the BMJ, the New England Journal of Medicine and Vox Sanguinis, as well as the two American blood journals, Transfusion and Blood. What he said in his oral evidence for *Re A* was at Manchester -- at the Manchester centre they had a comprehensive library.

I'm going to now look at a document, one of the few documents I think that we've got from his time in Oxford. DHSC0100006_130.

Just to remind you, sir, and everyone that's listening, that Dr Gunson was the director of Oxford between 1975 and March 1980. This is a very poor copy and it's not entirely clear what the date of this document was, but if we go to the end, the last page, we can see it's got Dr Gunson's name on it, and at the bottom, last paragraph there, it says:

"Details of required expenditure are given in Appendix II. Costs are detailed as those applicable in a full financial year and those revenue costs which will be incurred in 1976/7."

So the inference from that is that this is a document that was prepared in either probably 1975

or possibly early 1976.

SIR BRIAN LANGSTAFF: Yes, it might be in the course of '76 to '77. But it's within that two-year period anyway.

MS SCOTT: Indeed.

So if we can go back to the first page --

SIR BRIAN LANGSTAFF: Sorry, just come back. Just above section 6.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: "Assuming that the ... building work is completed by November 1976 then the earliest time that the proposals can be implemented is 1st January 1977 ..."

So this is plainly written before November '76.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: One would have thought that, given that there is an assumption relating to building work, it would be some time before November '76.

MS SCOTT: Quite.

So if we go back to page 1, this is a report that Dr Gunson has produced addressing the need to increase the quantities of plasma collected for fractionation without impacting upon the supply for blood for transfusion in hospital.

So if we look at that first paragraph, it gives

us some information about what was happening at the Oxford Regional Transfusion Service at the time:

"At present, the Oxford Regional Transfusion Service supplies some 5,000 litres of plasma annually to the Oxford Haemophilia Centre. This is achieved by separating the plasma from approximately 22,000 donations. Expansion plans are in hand to increase the volume plasma supplied for fractionation to 6,500 litres per year. Although this represents an increase of only 22 per cent it will necessitate the handling of 36,000 donations annually since it is proposed to reduce the volume of plasma removed from each donation to 180ml, instead of the 210-220ml removed at present. The proposal to further increase the volume of plasma for fractionation to 10,000 litres per year will involve the separation of plasma from 55,000 donations. This represents an increase of 53 per cent above our committed expansion and an increase of 150 per cent above our present separation."

Then if we can go down to the section 1, halfway down, "Availability of Donors", he makes the point there that:

"The present region serviced by the Oxford BTS does not conform to the Oxford RHA boundaries."

Sir, that's a theme that we will see in many of the documents that when -- as we heard on Tuesday, the Regional Transfusion Centres were formed first with their areas, and then the regional health authorities took them over, and the two boundaries didn't always coincide precisely.

If we turn over the page, we can see halfway down that page (i) and (ii), we can see:

"Increasing blood collection up to 19,000 donations per year will result directly in an increase in the clerical work associated with donor call-up and records."

Then we have Dr Gunson setting out what the impact of that will be, dependent on whether or not computerisation can be brought into the equation, and it can be inferred from that, perhaps, sir, that he was a fan of or keen on computerisation of the Transfusion Service.

Then we go down to (c) "Blood collection", and we learn from that that, at present in Oxford, there are mobile blood collection teams which carry out 18 donor collections each week and the proposed increase will require an additional three and, in some weeks, four donor clinics.

Then if we go over the page to page 3, at the

bottom of page 3 is a section 3 "Disposal of additional units of blood", it says there:

"The Regional Transfusion Service has a reasonable balance, at present, with respect to blood collection and issues to hospitals. The collection of an additional 15,000 to 19,000 will affect this balance adversely and it is important that it is put to effective clinical use."

Pausing there, sir, that is, again, one of the issues that we will see returned to, that once you increase the plasma for fractionation, what do you do with the balance of the blood, the red cells, and that's what Dr Gunson here is grappling with.

"Out of the various possibilities the one that I recommend to the Regional Health Authority is that the Oxford [Blood Transfusion Service] assumes responsibility for the service of those hospitals in the East Berkshire [Area Health Authority], at present receiving their supplies of blood and blood products from the [North West] Thames [Blood Transfusion Service]. This line of action has several advantages", and he then sets those out and we don't need to go to that.

So we can see there -- here this an example of Dr Gunson working out how he can improve and increase

his plasma supply for fractionation while making use of the balance of the blood, if I can put it that way, by taking over supply to other hospitals. I wanted, sir, to draw your attention to a paragraph that we find on page 4, just above where it says "Section 4 Laboratory Offices":

"I note that the hospitals in East Berkshire AHA (in particular, Wexham) receive a considerable supply of cryoprecipitate. This presumably arises from the unavailability of AHF concentrate in the [North West] Thames region. I hope that consideration will be given to their receiving a supply of concentrate should these proposals be accepted."

So one of the themes or issues that the Inquiry will be looking at in the coming hearings is the extent to which, if at all, Regional Transfusion Centres had a hand in or an influence over the products that clinicians were using, and here Dr Gunson appears to be expressing a view about what might be an appropriate product, albeit in very general terms.

On that theme, if we can return -- if we can look, please, at NHBT0000086_009, which is the document we looked at earlier, it's the HIV litigation education course, and we go to page 11 of that

document, we can see -- which I now can't find.
(Pause)
Sorry, it is page 15, that's why. So he's talking here about the functions of the work of the NBTS and he says, at that second paragraph:
"Another core function of RTCs is to provide clinical advice to hospitals in all matters relating to transfusion medicine."
So, sir, precisely what that means is something that the Inquiry will be considering. It's not clear but that's something that can be picked up with witnesses in oral hearings.
Sir, I'm going to now turn to look at a document or two from Dr Gunson's time in Manchester, and just reminding ourselves that that's April 1980 to October 1988. I'm going to turn, first of all, to NHBT0020196.
This is, as I understand it, a statement from Dr Gunson in the HIV litigation.
So if we turn, please, to page 29, we can see at the bottom it's signed -- well, I can tell you that's Dr Gunson's signature, and dated, it looks like, 11 January 1989, but there are references in the statement to June; so it may be that that is -- that says June. It's not very clear.

So if we then go back to page 1 of that document, he has quite a lot of information about what it was like on the ground at the Manchester centre. So he says in that second paragraph, himself way down:
"Another function in Manchester, but not in Oxford [so there is a difference in practice between the two], was the purchase of commercial materials within the RTC budget for the treatment of [haemophiliac] patients. It was my responsibility, in conjunction with the Directors of the Haemophilia Service, to negotiate the provision of the commercial factor VIII concentrates to supplement supplies from within the NHS. The Regional Team of Officers who subsequently became the Regional Management Team, allocated a specific budget for this purpose to the Blood Transfusion Service, which was finally approved by the RHA [going over the page]. From this we purchased supplies to fulfil the diverging gap between NHS supplies and demand. In general, the Regional Health Authority allocated sufficient finance, and I am not aware of under treatment for the lack of Factor VIII supplies, although some non-urgent surgical procedures were deferred.
"Demand certainly increased over this period. However, the [north-west] region, in general, used

less Factor VIII per patient per year than other regions."
Sir, you will have heard some evidence from the haemophilia centre perspective on this and you will need to balance this evidence against that.
"The [north-west] Regional Supplies Department were involved with the negotiations with the companies. From 1982/83 the regional standing financial instructions demanded that for contracts over £100,000, tenders had to be sought. The Regional Supplies Department devolved its duties to several District Supplies Departments. The tendering procedures for commercial Factor VIII concentrates were carried out by the Supplies Department ..."
Then we can skip down to the next paragraph. It explains that before orders were placed meetings were held with the Haemophilia Centre Directors and the ordering process occurred approximately -- and then if we go over the page:
"The ordering process occurred approximately once a year ... [and] because of increased usage, it was necessary to supplement Supplies of commercial Factor VIII in December/January."
Then he goes on to say that:
"Dr Wensley [who was the Haemophilia Centre

Director] was very much involved in the purchase of Factor VIII and was the person responsible for the distribution of both commercial and NHS products from the RTC. Dr Lee, then Consultant-in-Charge at the Lancaster Centre, managed the supplies of Factor VIII allocated to that Centre and Dr Evans those supplied to the Manchester Children's Hospital.
Then if we go over to page 11 and 12, he gives us an insight into how the yearly need for products was calculated in the North West region. It's at the bottom there:
"Within the [North West] region, we worked on a year to year basis with the local knowledge of consultants in the Regional Haemophilia Service. This was based on the number of corrective surgical operations needed in the following year, together with the number of patients able to pursue a home treatment regime, with an added percentage added for emergencies. Home treatment involves extra supplies of Factor VIII in that a haemophiliac would inject Factor VIII at the commencement of a bleed without waiting to see if the bleed was serious enough for him to attend hospital for treatment.
"The regional centres were all given plasma targets agreed by the Directors and the Director of

the [BPL] and generally from 1978 these were in proportion to the region's population."

Then he says:

"In order to monitor the targets we received monthly statements of the amount of plasma sent to the BPL had the quantities of products returned."

Then he goes on to say, in addition to this:

"... the DHSS statistical department at Blackpool received quarterly reports on a range of blood and plasma collection data from all RTCs and the results collated for all regions were returned."

The Inquiry has been looking in -- trying to find this cohort of documents and investigations are still ongoing.

Then if we go over to page 13, the last paragraph there:

"Although the use of cryoprecipitate" --

In fact, perhaps we read the paragraph above, actually:

"From 1974, RTCs removed part of the plasma from donations of whole blood shortly after its collection and this was used, in addition to general clinical requirements, for the preparation of cryoprecipitate and for issue to BPL for fractionation into products. Nationally and also in the [North West] region, the

number of donations from which plasma was removed increased in numbers. In the latter part of 1983 a nutrient solution became available so that it could be placed on the red cells after removal of all the plasma from the donation. This allowed a 50% increase of plasma to be obtained from each donation."

We will see reference to that as one of the tools in the charge for self-sufficiency.

He goes on:

"Although the use of cryoprecipitate declined nationally between 1975 and 1985, the usage in the [North West] region remained high, as a result of the policies adopted by the Regional Haemophilia Service. Cryoprecipitate competed with plasma sent for fractionation so that the latter targets were not achieved. However, Factor VIII from cryoprecipitates was used to treat haemophilia patients and this supplemented the supplies of NHS and commercial Factor VIII concentrate. Details of the production of cryoprecipitate and plasma for fractionation are available at the RTC ..."

He goes to say:

"... although for some years the RTC supplied Lancaster with cryoprecipitate."

Then he goes on to set out the changes to the

centre itself between 1982 and 1984, when they moved into a new building, and then in 1985 to 1986, funding was provided for a plasmapheresis centre and a smaller one in Lancaster. We will see reference to that in some of the documents we look at later.

Sir, I'm just going to look also at, DHSC0002195_044.

This is a document note of a meeting that took place in September 1979, so shortly before Dr Gunson moved from Oxford to Manchester. It's a "Note of [a] meeting of an *ad hoc* group of Regional Transfusion Directors", and we can see on the attendee list it's attended by Dr Gunson.

The reason I draw your attention to it, sir, is because it shows some insight into what certainly this group of people were discussing about choice of product in September 1979. We pick it up at the second paragraph:

"It was reported that there was not universal acceptance by Directors of the proposition that blood products should be distributed by BPL proportionally to plasma supplied, but with some safeguards for Regions with special problems, eg Regions which treated Haemophiliacs from other Regions, it was felt that a distribution scheme on this basis would prove

generally acceptable."

So we saw Dr Gunson earlier saying that the targets were set on the basis of population, and then here we see there being discussion about the blood products you receive back being pro rata effectively for the plasma that you provided, with some exceptions, for example for the area that served Lord Treloar's College, for example.

Then if we miss out the next paragraph it goes on:

"A tendency to revert to cryoprecipitate was discernible in some regions due, in part, to lack of money to buy commercial concentrate or to collect more plasma for fractionation at BPL. It was agreed that this was yet another example of the way in which the use of blood products and the development of blood product production was being distorted by the availability of products which were apparently 'free'.

"Dr Tovey said that the NBTS was at a stage where it must be decided whether the service went forward as a truly national service, properly co-ordinated, or as a number of regional services each going their own way."

It's noted Dr Lane put forward his views in a paper.

Dr Bird then expresses a strong view:

"... that the NBTS should generate its own revenue."

Then Dr Lane draws attention to the fact that:

"... supplies of fresh frozen plasma were beginning to tail off in many regions. It was agreed that this was not the result of any shortage of donors but was generally due to shortage of money needed to maintain the level of plasma supplies."

Notes that:

"Regional Health Authorities were not sympathetic to requests by Directors for money to finance plasma collection if they are not to receive a proportional part of the finished factor VIII or PPF in return."

So we can see there a suggestion that the use of cryoprecipitate is, at least in some regions, thought to be high because of a lack of money for either buying commercial product or an ability to provide plasma to BPL in order to receive products back.

I'm just going to draw your attention, sir, to some of the comments -- or not comments, some of the evidence, rather, that Dr Gunson gave in the hepatitis litigation which paints his view of the general picture facing the Blood Transfusion Service

while -- I presume -- it's a little bit clearer what period he is talking about, but I presume while he was working there, working full time, but it's a little bit unclear.

If we can go, first of all, please to NHBT0000143 and page 79 of that. So we can see that's Thursday, 19 October 2000, so that's the date on which Dr Gunson was giving evidence. He was giving evidence, I think, for about five and a half days in all. This was the first day of his evidence and if we turn to page 79, if we go to line 3917, which is about a third of the way down, so "Q" is the barrister asking the question. He is being examined-in-chief at this stage:

"Something which does not appear in your statement, but is perhaps useful for the court to have -- it has been given already informally by my learned friend -- can we have in very round figures at the relevant times how many donations per year were made in England and Wales, or collected?"

It is little bit unclear what the relevant times means. He says:

"In England and Wales it was roughly 2.5 million. The figures including Scotland was 3 million.

"Q. Sticking with England and Wales, if at any rate that is the figure you have, about how many donors does that represent?

"A. Something in the order or 1.5 to 1.6 million.

"Q. So on an average, an individual donor would give blood slightly less often than twice a year?"

He says:

"Many donors give blood twice a year, but there were some particularly commercial sites that we only visited once a year because you could not disrupt the work of the factory."

Then it goes on to question at 3939:

"Just to get an idea of sizes, about how many donations would be collected by the largest of the Centres?

"A. I think the largest Centre was undoubtedly South London, and they collected something at that time in the order of 250,000 donations a year."

The question:

"The smallest, I think --

"A. Something in the order of 80,000 to 100,000."

Then if we go over the page:

"Q. Just one other general question: what is

the broad turnover in the donor population? How many donors do you lose a year?

"A. From retirement, illness, donors moving from one venue to another, it is something in the order of 12 to 15 per cent per year.

"Q. People just getting busier and --

"A. And stopping, yes."

Then if we go, please, to NHBT0000146, it is at page 95, this is Dr Gunson giving evidence on 24 October 2000, and if we go to the bottom of that page, he is still being examined-in-chief, at this stage, by his counsel Mr Underhill:

"Q. What you say in paragraph 20 is that the blood supply within the service was a constant source of concern and during the period with which we are [go over the page] concerned here, you spent several hours most days ensuring that blood supply met demand throughout the country.

"Is that an exaggeration?

"A. No, it is not an exaggeration at all. I spent a long time, and so did many other members of the staff at the Directorate, trying to locate centres who could supply blood to other centres, where there was a shortage."

So we know here that he's talking about

post-creation of the National Directorate:

"The critical day, I have to tell you, in the week was Friday, when most of our time was spent on this activity, and it was made more difficult because even those centres who had a good stock of blood did not particularly want to give it away, in case they had emergencies they were unaware of come in during the weekend and they could find themselves then short, so it took a great deal of persuasion to obtain agreement to transfer blood from, say, Sheffield to London.

"Q. Yes.

"A. But the London centres all had difficulties, virtually, on a daily basis, particularly, I have to say, North London, where they have to supply a large number of teaching hospitals."

Then the last passage, sir, is NHBT0000148_001, and this is evidence given on Thursday, 26 October, you can see at the top there, and this is during cross-examination.

If we go to page 5, he gives some evidence about the supply in Manchester. If we go down to line 226 -- in fact, 221, we had better start at the question. Halfway through line 223:

"... just give us a feel for how you say the

problem of supply was between these years 1987 and 1991, that sort of period?

"A. Well, between 1987 and 1988 I was the director of the centre in Manchester and I was not the national director. Therefore I just ran a transfusion centre like my colleagues. We had considerable difficulties at certain times of the year, particularly during the school holidays and particularly around Christmas time, when we had a significant drop in donors, and it was always extraordinarily difficult then to catch up and there were several instances during that period, 1987/1988, that hospitals had to cancel routine surgery because there was insufficient blood available and this got into the press on a number of occasions."

Then he says:

"When I became the National Director, I established this system of having --"

Then there's a discussion about when that was and he says down at 243:

"I established a system whereby each transfusion centre sent me their stock levels for that day and any requests that they had for shortages of blood and we then, in the National Directorate, endeavoured to supply this blood from other centres and indeed from

Scotland as well.

"Q. Were you successful during that period?

"A. During that period we were extremely successful. There was not, I do not think, one critical report in the press during the whole of the periods until 1993."

Sir, then can we turn now to DHSC0002195_044. This is a document -- I think this is the document we just looked at.

SIR BRIAN LANGSTAFF: I think, yes, it is.

MS SCOTT: Forgive me. That's the document we just looked at. So let's not look at that again.

Can we look now at DHSC0002207_040.

Sir, this is -- I'm looking now at documents concerned with -- or parts of documents concerned with the drive towards self-sufficiency. This is a report -- or at the top of the page it calls itself a "Draft for discussion" of the -- for the Advisory Committee for the National Blood Transfusion Service Working Party to Advise on Plasma Supplies for Self-sufficiency in Blood Products in England and Wales", and can see, under "Membership of the Working Party", that includes Dr Gunson, and at the bottom of that page we can see that it is dated June 1981.

If we go over to page 2, and at paragraph 2.1 we

can see there that the "Requirement for Factor VIII" is set out. It says:

"Representatives of the Haemophilia Directors estimate that by the mid-1980s the annual requirement for FVIII will reach 100 M units for the United Kingdom. Forecasting beyond that time could not be accurate but it was considered that by the 1990s the need for FVIII could reach 150 M units per year."

It then goes on to set out some requirements for albumin.

Then at paragraph 3 it says:

"It was agreed that the estimates for plasma supply should be based upon that required to produce 100 M units. Although this total was estimated for the UK for the mid-1980s ... it was considered to be unnecessary to correct this for that required in Scotland or to consider a higher figure than this since estimates were vague for a longer period."

Then we go over the page to page 4, where there is a discussion about the type of Factor VIII preparation required. So what is that 100 million units going -- sorry, to page 3. I beg your pardon. Thank you.

How is that 100 million units going to be made

up? It says there:

"The Working Party has examined the various products available and considered the advantages and disadvantages of each, which are discussed in Appendix 1."

It's just worth going to have a look at what is said at appendix 1. It's page 9 of the report and it sets out the different kinds of products provided and produced at the RTCs:

"1. Fresh frozen plasma prepared at RTCs, and whilst it is a valuable source of coagulation factors it cannot play a part in the treatment of haemophilia A.

"2. Frozen cryoprecipitate is presented for clinical use in the transfer pack in which it is prepared. It is prepared in RTCs but it is difficult to have a national programme based on this product because:

"2.1 the high yield is not always attained in large-scale production ... lack of confidence in the FVIII content leads to over-ordering and waste.

"2.2 there is a significant incidence of adverse reactions due to the presence of residual plasma.

"2.3 the product is not convenient to store, transport and infuse particularly for home or

self-therapy.

"2.4 there are difficulties in ensuring adequate quality assurance and control."

Sir, you've heard similar evidence from a number of haemophilia clinicians.

"3. Freeze-dried cryoprecipitate:

"3.1 Small pool (8-12 donations) is produced in the Central Laboratories as the primary FVIII product in Finland, Switzerland and the Netherlands. The aim is to obtain a high yield and minimum donor exposure. However, all production methods involve multiple aseptic connections without terminal sterilising filtration of the product and spin-freezing of a relatively dilute solution of FVIII before drying introduces intractable problems of hygiene and thus maintenance of good manufacturing practice ... required in the UK will be very difficult.

"3.2 Large pool. Two approaches have been used.

"(a) In Belgium, about 1,000 cryoprecipitates, prepared at RTCs, are transported to the fractionation centre, pooled aseptically without sterilising filtration, the pool dispensed in 50-100 ml volumes, spin frozen and freeze-dried."

Then it sets out what the process is France of

large pool, again of about 1,000 donations. Then it says:

"Advantages over small pools are greater consistency of the product and are potentially more secure and a representative sample can be taken for quality control. However, a sterilising filtration is expensive in yield and 10% may be lost in rigorous quality control and the GMP problems are spin-freezing remain."

Then over the two pages, please, to page 11, we then get:

"intermediate purity concentrates ... begin with large-pool (500-5000 donations) cryoprecipitation of plasma ... plasma processed to give high potency ..."

Then:

"It has been estimated at BPL that approximately 27% of the initial [Factor VIII] activity is lost in this preparation which does not occur in freeze-drying large pool cryoprecipitate. Methods being examined to reduce those losses."

Then it goes to talk about high purity concentrate, further purification "expensive in yield".

There is a table that accompanies this appendix, which we find at page 10, which sets out on the

left-hand side the different products and, across the top, pool size yield, et cetera, advantages and disadvantages. The reason I want to draw your attention to this, sir, is because there is only one reference in this document and, in fact, from the whole appendix, when looking at the advantages and disadvantages of the different products, to infection via transmission, and we see that at "Freeze-dried [cryoprecipitate] (b) large pool", and if you go over to the disadvantages we see there "GMP problems", which we've just seen in the text "Larger pool for HB transmission", hepatitis B transmission, and then the hygiene problems, sterilisation, and so on. So that's what that appendix says.

So, if we then come back to page 3 of the document, where they are talking about types of Factor VIII preparation required, if we go halfway down:

"It was agreed that, although the above proportions of the various products were not fully agreed they served as a good basis for the determination of plasma needs."

They then set out that in total of the 100 million units of Factor VIII, they would have 10 million units of freeze-dried cryoprecipitate,

80 million of intermediate purity concentrate, and 10 of high purity. Then they set out what the different yields are for the different product: freeze-dried cryoprecipitate, 350 units per kilo, then that reduces down to 90 for the high purity.

Then at section 6 they discuss the amount of plasma that would be required in order to meet those targets and so, to get the 10 million units of freeze-dried cryoprecipitate, it involves 28,500 kilograms of plasma; for the intermediate purity concentrate 350,000 kilograms; and for the high purity 110,000; making a total of 488,500 kilos, which they round up at the bottom, for an annual aim of 500,000 kilograms of plasma.

Then, over the page, they set out the methods of obtaining that. First of all, looking at the yield of plasma from donations of whole blood, and they set out there that, during 1980, just over 2 million donations of whole blood were collected by the RTCs and they go on to say that it's difficult to forecast the need for red cells in the mid-1980s, but the working party consider a total of 2.2 million donations was a reasonable estimate, and so -- and they estimate that plasma from 51 per cent of the donations could be separated within 18 hours, with adequate facilities

and staff, which will realise some 200,000 kilograms of plasma for fractionation. So 200,000 out of the 500,000 from whole blood.

Then they go on to look at how to produce the balance of the 300,000 kilograms of fresh plasma. First of all, increase the collection of whole blood, and they say there that that would require 5.5 million donations annually, which would inevitably lead to waste and the working party do not consider this to be a viable proposition. So that's the waste of the balance of the red cells, and so on.

Then they go on to look at the introduction of plasmapheresis and set out the two different methods of plasmapheresis, manual and machine, and the advantages and disadvantages: manual is slower, machine is much faster and, at the bottom there:

"The Working Party recommends that the balance of 300,000 Kg fresh plasma is collected by plasmapheresis. This will require the establishment of Plasmapheresis Centres in the regions and the recruitment of donor panels to service them. Machine procedures were, in general, preferred but manual pheresis could be undertaken in certain circumstances.

Then the report concludes over the page at page 6, "Regional self-sufficiency":

"If it is assumed that the usage of Factor VIII concentrates will be pro-rata to population, the amounts of plasma to be collected by each region by plasmapheresis and the estimated number of plasmapheresis units is shown in Table 3. This assumes that 10,000 Kg (approximately) will be collected in an eight-bedded unit per year.

"However, it is known that the use of FVIII is not the same in each region which will lead to anomalies. Thus some regions would have to expend large sums to achieve self-sufficiency while others could achieve this state relatively easily. Until self-sufficiency is reached, every region has an incentive to produce as much fresh plasma as possible; thereafter there is no incentive unless surplus plasma can be offered elsewhere with suitable financial recompensation. Also, the situation may arise where an RTC cannot provide sufficient plasma due to lack of facilities which cannot easily be remedied. It is clear that further consideration must be given to this aspect."

Sir, I understand the reference there to every region having an incentive to produce as much fresh plasma as possible until self-sufficiency is reached to be a reference to regional self-sufficiency, not

national self-sufficiency.

Sir, I note the time. Is --

SIR BRIAN LANGSTAFF: Yes. Well, self-sufficiency across the board I think is what it could be meaning, couldn't it?

MS SCOTT: The incentive for the region to produce plasma is because they will get back pro rata what they give. Once they have made enough --

SIR BRIAN LANGSTAFF: I follow the point.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: It doesn't much matter because the view is the same that, unless and until there's enough produced in each region, that there won't be any incentive or there won't be an achievement of self-sufficiency across the board.

MS SCOTT: Yes. Sir, would now be a convenient time for a break?

SIR BRIAN LANGSTAFF: Yes, it would. So we will meet again then at 3.50.

(3.22 pm)

(A short break)

(3.50 pm)

MS SCOTT: Sir, the next document I want to take you to is DHSC0002211_030. It's a supplement to the report that we looked at before and my understanding is that it

was provided for a meeting that took place in September 1981, and just on -- if we go over to page 2, paragraph 1, since the last report that -- the Haemophilia Centre Directors have said that the quantity of cryoprecipitate had been over-estimated, and so they've reduced the amount of plasma required down to 435,000 kilos, which can be processed to provide 95 million international units of intermediate concentrate and 5 million international units of cryoprecipitate at current yield.

So that's the figure they are working from. I just wanted to draw your attention, sir, to page 4 of the report. Pages 2 and 3 set out how they get to the figures at the page 4. I don't think we need to go through the detail but "Summary and Conclusions", they set out in the report how much it will cost to produce the 435,000 units -- kilograms of plasma via the different processes that they looked at in the first report. Processing cost of doing it via whole blood, so your 200 kilograms of plasma from whole blood plus your 235 kilograms from whole blood, discarding the red cells, will cost you £28.1 million. So it seems that the discarding of the red cells is an expensive process.

Cost of producing a balance of 235,000 kilograms

by machine pheresis is 19.1 million and the cost of the producing it by manual pheresis is 17.3 million.

SIR BRIAN LANGSTAFF: The significant figures are really not the headline figures but they are the difference between.

MS SCOTT: Indeed.

SIR BRIAN LANGSTAFF: Getting out of the whole blood donations that's 20.6, machine pheresis is almost half that, 11.6, and less than half the original by manual pheresis, 9.8.

MS SCOTT: Indeed. Then at the bottom of that page, it says:

"Apart from the ethical considerations of discarding red cells from whole donations and the difficulties that will be encountered in recruiting sufficient donors, this option would be prohibitively expensive. From the data analysed, manual pheresis seems to be the most economical way to achieve the required plasma volume. It is significant in this regard that commercial manufacturers of blood products use manual plasmapheresis to obtain their raw material."

Then if we go over to page 5, we can see what the committee are recommending at the bottom. It says there:

"The ADVISORY COMMITTEE is asked to approve the supplementary report to AC(81)11 and to seek Ministers' agreement with respect to consultation with RHAs with a view to determining the supply levels of plasma for the redeveloped BPL. The Advisory Committee is also asked to consider the future role of the Working Party with respect to discussions with RTDs on the supply of plasma and a consideration in detail of the plasma requirements for the preparation of specific immunoglobulins."

That seems to be the position in September 1981. We can see that when we trace the documents through that indeed the Advisory Committee did approve the supplementary report, we can see that and we don't need to go to it, DHSC001136 -- sorry, 0001136, and they did indeed agree to consultation with the Regional Health Authorities.

I'm going to take you now, sir, to a document in October 1983, so two years on. It's NHBT0001066_004. This is a document, it's entitled "Departmental Memorandum", so we can see it is from Dr Gunson to Dr Acheson, the CMO, dated 18 October 1983. So we can understand, I think, probably from the fact that it's a departmental memorandum, that this must be Dr Gunson, as Consultant Adviser to the CMO, providing

his views to the CMO.

It's entitled "Subject -- Speciality: Blood Transfusion; Five Years Back and Five Years Forward". So he sets out an introduction and he sets out some history at the beginning of that page, and then, at the second half of the page, in a paragraph:

"It would be useful to review the developments which have taken place in the use of these products.

"Red cell concentrates. Clinical acceptance of this product has been subjected to some controversy since in order to provide sufficient plasma for fractionation, the red cell concentrates have to be administered to certain patients suffering from blood loss."

Then picking up at the bottom of that page:

"The principle involved is to remove as much plasma from the donation as possible and replace part of this with a solution of saline, adenine, glucose and mannitol or sorbitol. The resultant red cells can be stored for up to 35 days and their administration is facilitated. This approach also has the benefit that from an individual donation of whole blood, 50 per cent more plasma can be obtained."

Then he goes on to talk about platelet concentrates and the -- he says:

"The use of an increasing pharmacopoeia of chemotherapeutic agents has resulted in patients suffering from leukaemia and certain other malignancies requiring supportive therapy for longer periods. One problem with this product is that it has had a self-life of only three days and with variable demand it has been difficult to either avoid wastage or meet demands. During the past two years new plastics have been developed which allow the storage period to be extended to five days. Whilst this will be a benefit, the increasing demand for this product is causing problems at present and alternative methods for the preparation of platelet concentrates will have to be considered, particularly with the increase in such procedures as bone marrow transplantation."

So, again, another sort of technical advance, which has made a difference to the blood service.

SIR BRIAN LANGSTAFF: By new plastics it means plastic bags, does it, to contain it?

MS SCOTT: That's my understanding. I may be corrected by another witness but that's my understanding.

Then:

"With regard to Factor VIII concentrate there has been an increasing production of this material at the Blood Products Laboratory from plasma collected

Regional Transfusion Centres during the past five years. At present approximately 40 per cent of the Factor VIII used it derived from this source; the remainder is purchased from commercial firms and their products are imported largely from the USA."

Then it mentions Factor IX concentrate and immunoglobulins and albumin. Then, at the bottom of that page, it comes on to disease transmission:

"Certain products have always carried the danger of transmission of hepatitis. With the introduction of sensitive screening tests on all donations, e.g. by radio-immune assay, the incidence of hepatitis B has been reduced, although not eliminated. The administration of the vaccine to high risk groups may also assist in this regard. However, the problem of non-A, non-B hepatitis remains and there is now the potential transmission of AIDS, about which I spoke at the last consultant Advisers' Meeting."

So it is clear that Dr Gunson has been keeping Dr Acheson -- or been providing advice to him about AIDS by October 1983.

Then can we go over the page then, please, to page 3 and we see what Dr Gunson says about the next five years:

"Whilst I think there will be several

developments occurring in the field of blood transfusion, some of which will be referred to below, I think the major advance that can be made is to achieve self-sufficiency in blood products for the UK."

Then he sets out the implications for the service of self-sufficiency, and then he goes on below (2):

"In order to achieve this goal, investment will be required, but it is important that advantages are taken of recent developments to minimise this."

So he speaks about the role of the additive solution in increasing plasma collection. He then talks at 2.2 about the use of plasmapheresis, which was what we see his committee -- what we saw his committees championing two years previously, in 1981:

"Although this is used in the Transfusion Service at present on a small scale, largely for donors whose plasma contains a high titre of specific antibodies, it is by view that in order to obtain sufficient plasma for self-sufficiency in fractionated products, without excessive blood collection and wastage of red cells, plasmapheresis will be needed."

Then he explains that that will be costly, in the next two paragraphs, and equipment will be

required. Then he goes on to say:

"It will be an advantage when all blood products can be derived from the UK donor population. Nevertheless, the transmission of non-A, non-B hepatitis, particularly from the products derived from pooled plasma will still be a problem in groups of patients, such as haemophiliacs, who receive these products regularly. I expect from the work which is now being carried out, that by the time five years has elapsed, a diagnostic test [will] be available."

SIR BRIAN LANGSTAFF: "... may be available."

MS SCOTT: "... may be available."

I beg your pardon, yes.

"However, in the meantime, we must examine ways in which in certain groups of patients exposure to the minimum number of donors can be effected. With respect to AIDS, it is too early to anticipate the effects in the UK, but it is important that every opportunity is taken to investigate possible ways in which the blood donor population can be screened."

Then he goes on to talk about on an organisational level. He says:

"On the organisational level, there has been a noticeable degree of collaboration between the Regional Transfusion Centres in recent years and there

are now an increasing number of functions which are nationally based rather than regionally."

He says:

"The supply of plasma, referred to above, is one ..."

Just pausing there, it's right that we've seen the supply of plasma being expressed as a national figure, but of course we still have regional funding and the difficulties that -- and I'm going to come on and look at some documents now which show it is difficulties that that gives rise to.

So if we can look then at CBLA0001800, which is a report to the CBLA by Dr Gunson, and we can see at bottom there it's dated January 1984, and he explains that he had a meeting in June 1983 with Regional Transfusion Directors to discuss plasma targets and the results were encouraging and that they thought at that time that they would be able to meet the targets and get financing.

Then he goes on in the second paragraph to explain that:

"During the latter part of 1983 ... informal comments from some RTDs gave cause for concern in that the targets which had been agreed as a planned programme were in jeopardy because of difficulties in

obtaining the necessary funds."

So he wrote to the RTDs in December 1983, and he goes on in the next paragraph to explain that only three of the RTDs are confident that their RHA will support the programme for increasing the plasma supply.

The remaining replies range between not hopeful or the necessary finance to an inability to predict the outcome of discussions with the RHA.

Then he sets out factors of significance:

"(1) Many RHAs are not willing to consider proposals on more than a year by year basis. Plans for the plasma supply require a programme based on a three to five year period.

"(2) Several regions are finding that with the current national plasma supply of 150,000 Kg per year, the demand for PPF is satisfied ..."

I'm not quite sure what that says:

"... apparently so, since in my view, insufficient time has passed with the increased supply of PPF to make a valid judgment."

I'm not quite sure what that says.

"... conclusion, however, has led to the view that the most economical way to achieve self-sufficiency is to purchase the additional

quantity [I think that says] of Factor VIII required."

I think that that last sentence is the key part to that paragraph 2, and:

"It is doubtful whether the quantity of plasma in 1984/5 will exceed that of the current year."

So that's the position and the concern that has arisen in January 1984, despite six months previously Regional Transfusion Centres being optimistic that they would be able to meet their targets.

If we can then turn to a report that Dr Gunson wrote in February 1984 arising out of this, and that's DHSC0001967.

We can see at the top:

"Plasma supply for self sufficiency in blood products.

"Analysis of options by HH Gunson.

"Supplement to report to CBLA ... [made] on 25th January, 1984."

If we go to the bottom of page 2, we can see that it's dated 13 February 1984.

Then if we go back to page 1, he says:

"My conclusions following a survey of RTCs was that it was unwise to assume at the present time that a sufficient quantity of plasma will be available for the successful operation of the new BPL."

So he gives considerations to the options which may be available.

So the first option is to:

"Pursue the present policies of encouraging RTDs to apply to their RHAs for finance for the increase in plasma supply with the assistance of Dr Lane and Mr Armour where this is appropriate."

He goes on to say in that next paragraph:

"This approach could be supplemented by additional advice from the DHSS."

But he concludes:

"... this has already been tried and although most RHAs agreed in principle, few have actually allocated finance for the purpose of the additional supply of plasma."

Then, second option:

"The CBLA scheduling assume managerial responsibility for the entire work of the RTCs."

He thinks this has "considerable merit" because it would lead to a true national service, with a greater degree of standardisation, but goes on to conclude at that second paragraph that:

"From a practical point of view ... the necessary administrative infrastructure could not be achieved by 1986 when the new BPL is due to be in full

production."

So he comes up with what might be described as a hybrid option at option 3, which is the option that he plumps for, which is that the CBLA should finance the collection of plasma in excess of that harvested by the ... (RTCs) in 1983/4. This would require funding for the collection of approximately 300,000 litres of plasma annually."

He describes it as a "promising option", and:

"Each RTC would be assessed with respect to its potential for producing plasma and the necessary financing agreed. Regional Health Authorities could purchase from the CBLA the products which they require ..."

Then he goes over the page to set out that he doesn't underestimate the difficulties that that would involve because:

"RTCs would be acting on an agency basis for the CBLA and there would have to be accountability for investment", and so on.

"A proportion of the plasma would have been paid for by the RHAs and the products derived from those would have to be supplied on a different basis from those derived from plasma financed by the CBLA."

Then the issue of clinical freedom, which may

result in the continuation of purchases of blood products from commercial firms.

That is a theme that we will see in some of the documents, undoubtedly as we go through the hearings, that the principle of clinical freedom raises a concern to the blood service because, while there may be BPL product available, clinicians may choose not to use it.

He says:

"Despite the problems I submit that this option is worthy of consideration ..."

Then at the bottom of that document he discounts the option of purchasing plasma from the United States to fill the gap left by the national supply.

So that is the position that Dr Gunson is advancing in February 1984. I think it might be a suitable time, sir, now, to play the -- we've got a couple of extracts from the World in Action documentary, entitled *Bad Blood*, which aired on 22 July 1985, in which Dr Gunson is asked some questions.

(Video played)

Sir, in the written presentation there it traces through a number of other documents, the story, if you like, of self-sufficiency in relation to Dr Gunson.

For reasons of time, I'm going to pick the story up, in broad terms, once he becomes the National Director in 1988, not by reference to any documents but we can see in the documentation, in the minutes of the meetings that he attends as National Director, indeed the first minute of a first meeting he attends as National Director, that, unsurprisingly, self-sufficiency is high on the agenda and the steps that he can take in his new role.

Of course, one of the key policy decisions that was made was in relation to cross-accounting, which was -- came in on 1 April 1989, whereby BPL bought plasma from the Regional Transfusion Centres and then Regional Transfusion Centres could charge hospitals for the products that they produced, and I'm just going to refer you to one document which shows that there is a difference in the way that was applied by different areas, and we can see that at NHBT0007355.

It's a minute of a meeting on 10 August 1989, NBTS, CBLA liaison committee and if we turn over to page 4 we can see at paragraph 5 that it's reported that:

"... differences between regions on whether or not product costs were passed on to District users was leading to confusion. Where costs were passed on to

Districts, commercial suppliers were sometimes being considered as alternatives to BPL. Dr Moore expressed the hope that following a meeting of Regional Transfusion *[sic]* representatives on 8th May, a common policy of Regions absorbing all cost and supplying 'free' product to districts would be adopted. In some cases however it was difficult for Regions to claw back from District budgets money previously allocated."

So that, I suspect, is an issue that we will be coming back to in forthcoming hearings.

I just want to pick up some correspondence from 1990, NHBT0015646 between Dr Gunson and Marcela -- Dr Contreras or Professor Contreras, 31 May 1990, "Dear Harold, National self-sufficiency in blood and blood derivatives", and she says there:

"I am writing on behalf of the Eastern Division of Consultants ... following [their] meeting on ... 24 May 1990."

She says:

"Members of the Division expressed their dissatisfaction about the lack of interest of the Department of Health in self-sufficiency. It was stated that it is not enough to say that 'ministers are committed to self-sufficiency' if this is not

backed by actions and financial support. We firmly believe that the time has come to reassess the situation regarding self-sufficiency. Members of the Division feel strongly that there is no reason why the plasma donated voluntarily by British donors should not go back to British patients. There are very good ethical and financial reasons for the encouragement of self-sufficiency. Why should we be paying twice for albumin and clotting factor concentrates? We are paying the commercial companies for imported products and at the same time are spending vast sums of money in apheresis and routine blood collection, as well as in the sophisticated running of BPL. Isn't it about time the Department made up its mind that the only way to succeed in self-sufficiency is by subsidising BPL?

"If we continue with current practices, we will be cutting our own throats. We already have the precedent of BPL competing with a Regional Transfusion Centre for the supply of products to a particular hospital, with BPL undercutting the 'NBTS discounted price'. We feel that it might be too late to turn the clock backwards. As core providers within the NHS, we feel that the NBTS should be excluded from charging.

"I have been asked to tell you that consultants in the Division are willing to go public on the issue

of self-sufficiency and are even prepared to stage a parliamentary lobby campaign. I would be grateful if could reply within the next two weeks."

The reply from Dr Gunson can be seen at NHBT0015645. It is dated 13 June 1990, and it says:

"If this matter were made public at the present time, in my view the scenario is likely to be as follows:

"The Department will reiterate that Ministers are in full support of self-sufficiency and illustrate this by citing the recent Executive letter ..."

For those that want to look at that it is DHSC0003978_009. We don't need to look at that now but that's the reference for it.

"They will point out also that financing has been provided for RTCs to collect the required quantity of plasma to provide sufficient products to achieve self-sufficiency. Moreover, they have told BPL to make every effort to ensure that their products are the preferred product for use in the NHS.

"It is true that when we asked for a financial supplement for either the cost of plasma or for BPL, the Department refused on the grounds that they were not convinced that this was necessary at the present time and evidence will be cited that the National

agreement is, in most instances, working well. Also, although it is early in the financial year, it will be pointed out that the supply of albumin to hospitals is above target.

"If one targets Factor VIII (or even albumin) as a product which is not being used in quantities which are available from BPL, the argument will be put forward that the DH cannot interfere with clinical freedom and since we are not a totalitarian state no person can be forced to use a particular product.

"If in the coming months it is apparent that there is an increasing stockpile of products at BPL and no action is being taken to ensure their distribution to hospitals for use, then I would agree that this should be brought to public attention. To do so now I think would be counter-productive and I hope that the members of the Eastern Division will agree with this conclusion."

So just before we finish, sir, just to draw out some of the themes in this piece of correspondence, it seems that Professor Contreras is raising concerns that the cross-accounting that, as I understand that -- the process of cross-accounting has effectively put Regional Transfusion Centres in direct competition with BPL for -- in terms of providing

products to hospitals, and she also raises the concern about that cost to Regional Transfusion Centres from effectively having to pay twice for product, once through the functions of the RTC by collecting blood through whole blood collections and plasmapheresis and, secondly, because they then don't get enough product back from BPL and have to buy in commercial products.

Dr Gunson seems to be raising a slightly different issue, and it's a little unclear to me how he gets to that from Professor Contreras' letter, but he seems to be raising an issue in relation to a stockpiling of product by BPL and that one of the reasons why -- perhaps why regions are not receiving the product that they need is because of stockpiling. So that is likely to be an issue that we will need to come back to in the forthcoming hearings.

SIR BRIAN LANGSTAFF: Does he say there is actually stockpiling taking place at the present?

MS SCOTT: No, he doesn't say that, but he seems to raise it himself. It seems to be something that he has raised himself as potentially a reason.

SIR BRIAN LANGSTAFF: He may be perhaps addressing the questions of the internal market which Dr Contreras raises, saying that the internal market means that one

supplier is compared to another on price by saying that, "Well, if it's the case that BPL products are not accepted, then obviously at the production levels which it's required it will build up a stockpile."

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Once it does that, then that should be brought to public attention. In other words, you're putting public pressure on the market to do what you want.

MS SCOTT: Yes. It's slightly -- I suppose the point I wanted to make is it's slightly odd to talk about it in those terms when Professor Contreras seems to be saying: we're having to buy commercial products because we're not getting the product that we want -- enough of the product that we want from BPL. In other words, there's a lack of product coming from BPL, which is forcing us to purchase commercial concentrate.

She uses the phrase -- she talks in terms of having to --

SIR BRIAN LANGSTAFF: Is she doing that or is she really complaining about the problems created by the internal market? That is, that there are suppliers competing with each other on price and BPL is not necessarily succeeding and yet they are supplying BPL with plasma?

MS SCOTT: I think she is doing both of those things, but she says in terms: why should we be paying twice?

SIR BRIAN LANGSTAFF: Twice. That is, paying the costs of plasma collection.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: And paying for some other product.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Then the answer given to that by Dr Gunson -- I'm not expressing any view upon the merits of these different points of view, just trying to identify what they are because, I agree with you, I don't think it's entirely clear. But it may be that what he is saying is: well, if we do raise this, as you're threatening to do by the consultants raising a public awareness, going to the press or whatever about it, these are the answers which I think the Department's going to give and, amongst other things, they will say, well, you can't tell the clinicians what product to use if they think there's something better that their patients should have.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: Or something different their patients should have.

MS SCOTT: Yes.

SIR BRIAN LANGSTAFF: So I think we can look at these at

leisure and work out perhaps what the dispute is really about, and perhaps evidence will help us, from Dr Contreras, I expect -- Professor Contreras now.

MS SCOTT: Yes.

So, sir, those are the last documents I wanted to draw your attention to in relation to self-sufficiency. Tomorrow I'm going to deal with the issues of testing for HIV and hepatitis C and then a handful of very short topics.

SIR BRIAN LANGSTAFF: Yes. Let's break now then and come back tomorrow at 10.00. 10.00. Thank you.

(4.26 pm)

(Adjourned until 10.00 am the following day)

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