

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,

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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

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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

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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

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1 [non-A, non-B] hepatitis carrier status in blood
 2 donors cannot at present be justified."
 3 Now, those Lancet letters then came to be
 4 considered at a meeting at BPLL0007202. This is
 5 a meeting of the Advisory Committee on the National
 6 Blood Transfusion Service, 17 June, it's 1987,
 7 although the date doesn't appear at the top, chaired
 8 by Dr Harris of the DHSS and we'll see that Dr Cash
 9 was a participating member of the group.
 10 If we turn please to page 4, we can see the
 11 discussion. Here it's headed "ALT testing for
 12 transfusion associated hepatitis", paragraph 30:
 13 "The Chairman asked whether the Committee agreed
 14 with The Lancet article concluding surface tests for
 15 hepatitis could not be justified."
 16 Then we see Dr Cash's view being expressed:
 17 "Dr Cash said that Scottish Directors were
 18 proposing to establish such tests in view of impending
 19 product liability legislation in 1988; there was also
 20 clear indication that the private sector would test
 21 and they did not wish to fall behind."
 22 There's then a reference in paragraph 32 to
 23 Dr Smithies saying there was a research proposal -- so
 24 still only at the proposal stage -- and the third
 25 paragraph -- sorry, the third sentence of paragraph 32

1 companies, were using ALT testing or surrogate testing
 2 in relation to their products.
 3 If we then go to PRSE0001444, we can see
 4 a further letter to The Lancet, this time co-authored
 5 by Professor Cash. The date is 4 July 1987 and we can
 6 pick it up halfway down the page, the right-hand
 7 column -- actually if we look at the bottom half of
 8 the page, please, Soumik, the heading of the letter is
 9 "Testing blood donors for Non-A, Non-B Hepatitis:
 10 Irrational perhaps, but inescapable". A somewhat
 11 attention-grabbing headline.
 12 Then there is reference to some of the earlier
 13 letters in The Lancet. If I pick it up about
 14 two-thirds of the way down that first paragraph, the
 15 letter continues:
 16 "No large study to answer this critical question
 17 has yet been presented, and we agree that the size of
 18 the benefit to be gained from surrogate testing cannot
 19 be accurately established without such a study.
 20 However, the time for this study has already passed.
 21 Starting now will give us an answer in 3-4 years --
 22 and that is probably 3 to 4 years too late. The
 23 introduction of surrogate marker testing for [non-A,
 24 non-B hepatitis] is now virtually inescapable, for
 25 three reasons:

1 records what was presumably the DHSS view:
 2 "There was insufficient evidence of [non-A,
 3 non-B] after the HIV deferral of donors had been
 4 introduced. It was therefore now even less cost
 5 effective."
 6 Then we can see Dr Gunson saying that:
 7 "[The] introduction would be premature, causing
 8 an unjustified loss to panels.
 9 "Dr Forrester gave an assurance that there would
 10 be no decision until research had been carried out.
 11 "The Chairman summarised the views. If testing
 12 was introduced it should be national; he noted the
 13 research on baseline data would be carried out; the
 14 position would be monitored here and abroad."
 15 So no recommendation from this committee to
 16 introduce testing, but you will have seen the
 17 reference, if we just go back up to paragraph 31, to
 18 Dr Cash's views.
 19 There are two themes there expressed and,
 20 because time doesn't permit me to go to all the
 21 documents or all of Professor Cash evidence to the
 22 Penrose Inquiry, I can say those are two themes that
 23 reappear in the contemporaneous material: his concern
 24 about the impending product liability legislation and
 25 his concern that the private sector, pharmaceutical

1 "(1) In 1988 European legislation on strict
 2 product liability comes into force in the UK. If harm
 3 should come to the recipient of a therapeutic product,
 4 the producer will be held liable unless he can
 5 demonstrate that he used all known methods and
 6 information to avoid the risk. Under these rules
 7 a patient who contracted [non-A, non-B hepatitis] via
 8 transfusion of blood or a blood product would have
 9 a claim against the supplier if it was shown to come
 10 from a donor who had not been tested for both
 11 raised ALT and anti-HBc."
 12 We know, of course, that is precisely what came
 13 to pass.
 14 "(2) Although we all hope that pooled plasma
 15 fractions will soon be made safe by heating or other
 16 antiviral treatment, these processes remain to be
 17 validated in large-scale trials. Meantime, even if
 18 surrogate marker screened would only modestly reduce
 19 the level of infectivity in these products, many would
 20 argue ..."
 21 Sorry, we're just below the table, Soumik, on
 22 the left-hand side:
 23 "... many would argue that some improvement is
 24 better than none.
 25 "(3) The UK transfusion services, although the

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

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

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

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

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

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

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

1 meeting.

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

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

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

25 "The SNBTS Directors do not wish, and currently

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

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

5 Point 2:

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

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

14 "3. We have no doubt that an important forum
 15 for the continued debate is indeed the BTS/NIBSC
 16 group(s) and the current [non-A, non-B] debate (which
 17 began some 2 years ago here) and the confused central
 18 management attitudes to the Medicines Act and Product
 19 Liability had much to do with driving me to seek the
 20 establishment of this joint enterprise.

21 "4. I really don't believe you should view the
 22 Lancet letter as any more than part of a debate which
 23 was initiated in this journal's columns by our friends
 24 colleagues at Edgware. It can also be viewed as yet
 25 another attempt to persuade central management (DHSS)

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

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

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

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

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

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

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1 request was declined."

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

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

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

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

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

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

12 Then it continues:

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

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

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

25 "DHSS have expressed their concern and dismay at

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

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

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

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

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

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

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

4 If we then pick matters up at PRSE0001159, we
5 have a further SHHD internal memo, this is dated
6 17 December 1987, it is from Dr Forrester, entitled
7 "Screening of blood donations for non-A, non-B
8 hepatitis", and it records that:

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

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

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

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1 them. They can have SNBTS products, apparently
2 gratis, made from untested donations. Or they can
3 have commercial products, at the cost of their Health
4 Boards, made from partially tested donations:
5 partially, because ALT screening is only one of the
6 two tests proposed together to reduce transmission of
7 non-A, non-B hepatitis.

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

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

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

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

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

3 However, there were some further communications
4 between Professor Cash and Dr Gunson on the issue of
5 testing. I'm not going to go through them now but I'm
6 just going to give you, sir, the relevant references.
7 So there's a letter from Professor Cash to Dr Gunson,
8 12 January 1990, reference there for the transcript is
9 NHBT0000027_011, and the particular concern being
10 expressed by Professor Cash was that, within England
11 and Wales, Regional Transfusion Centres were going to
12 start using routine ALT testing of plasmapheresis
13 donations.

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

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

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1 surrogate testing.

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

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

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

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

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1 "(a) to assess the prevalence of post
 2 transfusion [non-A, non-B] in the UK,
 3 "(b) to evaluate surrogate markers for the
 4 disease,
 5 "(c) to investigate the natural progression and
 6 seriousness of the disease, and
 7 "(d) to produce a library of 'known' infected
 8 sera with which to evaluate any future assays which
 9 became available?"
 10 Then Professor Cash's answer is:
 11 "Yes to all ... questions."
 12 So his view is such a large scale prospective
 13 study should have been carried out. Then he poses,
 14 himself, two further questions:
 15 "... there would be advantage in seeking the
 16 answers to two further questions: (a) Why did
 17 Dr McClelland's 1981 proposal fall? (b) Did the
 18 disbanding of the MRC Blood Transfusion Research
 19 Committee have anything to do with this?"
 20 I took you yesterday, sir, to the statement in
 21 which he had expressed his dismay at disbanding of
 22 that committee.
 23 Then if we go to the next page, question (2) is:
 24 "If such a study had been carried out, to what
 25 extent is it likely to have met the objective set out

1 in (1) above? (b) To what extent would such a study
 2 have provided more information upon which to base
 3 a decision on whether surrogate testing should be
 4 introduced?
 5 "ANSWERS: (a) I see no reason why a properly
 6 resourced and supported UK group could not have
 7 achieved parity of performance with the US TTV study
 8 grouped.
 9 "(b) I'm not sure what is meant by more
 10 information. If DHSS had signalled that it was
 11 prepared to consider surrogate testing then the
 12 definition of more information would have been donor
 13 and patient data derived from a UK population. That
 14 said, I always felt that the size of the proposed
 15 study (600 patients) may have been rather small to
 16 achieve all the objectives described above, notably
 17 (c)."
 18 Then I don't think I need to trouble you with
 19 the next question. If we go over the page, top of the
 20 page, Professor Cash is asked:
 21 "In the second half of the 1980s, (a) Did SHHD
 22 medical officers place sufficient weight on the likely
 23 prevalence and seriousness of post-transfusion [non-A,
 24 non-B hepatitis]. (b) To what extent did their views
 25 in that regard influence their opinion on whether

1 surrogate testing of blood donors should be
 2 introduced?"
 3 Answer:
 4 "I am uncertain how to respond to this question
 5 as I have no recollection or record of discussing the
 6 topic with SHHD medical staff. That said, the
 7 internal SHHD documents supplied by the PI team would
 8 indicate fairly clearly that at least one Medical
 9 Officer believed that post transfusion [non-A, non-B]
 10 was uncommon and of little clinical consequence. He
 11 was not alone, but in my view efforts directed towards
 12 enhancing what was widely recognised as a very weak
 13 evidence base did not enjoy support of all UK
 14 Departments of Health, throughout the 1980s."
 15 Then if we look at the question at (5),
 16 Professor Cash was asked for his response to the
 17 following:
 18 "If surrogate testing of blood donors
 19 (ie testing for elevated ALT and/or anti-HBc) had been
 20 introduced in Scotland:
 21 "what percentage of donors are likely to have
 22 been deferred,
 23 "could a sufficient blood supply have been
 24 maintained, and
 25 "to what did extent are cases of

1 post-transfusion hepatitis C likely to have been
 2 prevented ..."
 3 If we go to the top of the next page we see
 4 Professor Cash's answers:
 5 "I have always believed that it would have been
 6 between 1-3%."
 7 That's the percentage of donors likely to have
 8 been deferred. His answer to the question "could
 9 a sufficient blood supply have been maintained" here
 10 is an unequivocal "Yes". Then he says, in response to
 11 the third question:
 12 "I believe I judged at the time that the benefit
 13 would have been significant, but the costs high and
 14 the impact on individual donors and on the robustness
 15 of our donor panels had, because we lacked relevant UK
 16 data, not been carefully considered."
 17 Then he adds a footnote with some observations.
 18 The first observation at (a) concerns the issue he
 19 raised in the contemporaneous communications about
 20 commercial plasma producers being allowed to include
 21 in their product literature references to surrogate
 22 testing. Then his second comment is as follows:
 23 "Documents which reveal that the position of the
 24 SNBTS Directors on surrogate testing, finally declared
 25 in July 1987 [that is presumably a reference to the

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

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

20 Can I turn then to the question of testing for
 21 hepatitis C. Again, we can pick this up, I think, in
 22 1988, if we look at PRSE0002365 -- sorry, PRSE0002363.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26

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

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

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

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

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

28

1 Paragraph 2 then refers to an anticipated
 2 meeting of the Dr Harris group, as it is referred to,
 3 on 17 October and an informal meeting due to take
 4 place at the Strand Palace Hotel on 23 August 1989, to
 5 look at preliminary UK data. Then you will see from
 6 paragraph 3 Professor Cash raising an issue about
 7 confirmation testing:
 8 "I pursued Mr Savage on confirmation testing
 9 which I believe is a crucial issue, both with regard
 10 to its absolute scientific/medical value but also
 11 a means whereby we can regain some initiative over
 12 Ortho."
 13 Then he sets out his understanding, which is
 14 that Ortho have an RIA confirmation test but it uses
 15 the same antigen as the screening test and Ortho
 16 currently do not wish or plan to market it.
 17 If we go over the page, Professor Cash continues
 18 that:
 19 "[He] indicated to Mr Savage that in my view
 20 this proposal was wholly unacceptable. We would
 21 wish/insist that the confirmation testing, which has
 22 a profound influence on the lives of many donors, was
 23 in our hands."
 24 He strongly advises Dr Harris' group to take up
 25 this issue in relation to confirmation testing.

1 There's then reference to in paragraph 4 to
 2 negotiations in relation to price.
 3 Paragraph 5 records that Mr Savage of Ortho had
 4 indicated that Denmark would start full testing on
 5 1 October. So that would have been 1 October 1989.
 6 Professor Cash then says:
 7 "Detailed questioning revealed that this
 8 statement was exceedingly speculative ..."
 9 Then paragraph 6:
 10 "Mr Savage believed that full tested in the USA
 11 would commence 'towards the end of the first quarter
 12 of 1990'.
 13 Then there's a footnote in which Professor Cash
 14 sets out in his advice as to how the UK should
 15 proceed:
 16 "(a) Let it be known to Ortho that a decision
 17 whether to introduce Chiron testing throughout the
 18 UK BTS will be made at the special meeting to be held
 19 on 17th October 1989.
 20 "(b) That after the meeting on 17th October,
 21 and presuming the inevitable that it will be agreed
 22 testing will be introduced -- but in a co-ordinated
 23 fashion, Ortho be advised that.
 24 "(i) A date for commencement will be considered
 25 when Ortho agree to make arrangements for confirmation

1 testing technology to be transferred to UK (NHS)
 2 laboratories;
 3 "(ii) That commencement will also be subject to
 4 the kit system getting an FDA licence.
 5 "(c) Subject to conditions (b) above being
 6 acceptable and delivered then I would suggest that the
 7 UK BTS plans to commence full testing on ..."
 8 Then this must be a date error, it says
 9 "1st June 1989". It must, I think, be a reference to
 10 1990.
 11 "... but significant funding is made available
 12 from 1st April 1990 for a two month run-up period
 13 (using stored sera) both at RTCs and confirmation
 14 laboratories."
 15 So those were Professor Cash's views as at
 16 August of 1989. Of course we know it's a little over
 17 two further years before the testing is, in fact,
 18 introduced.
 19 That Strand Palace Hotel meeting, the
 20 August 1989 meeting referred to in the letter, did
 21 take place as arranged. Professor Cash didn't attend
 22 but SNBTS, or Scottish representatives in the form of
 23 Dr Mitchell and Dr Follett, were there, and we have an
 24 account of the meeting in a letter dated
 25 25 August 1989 at PRSE0000815.

1 You will see it is addressed to Professor Cash.
 2 This is an account from Dr Mitchell:
 3 "At your request, Eddie Follett and I attended
 4 the meeting organised by Ortho Diagnostics in London
 5 ... The meeting was attended by Dr Harold Gunson,
 6 Dr Marcela Contreras and Dr John Barbara."
 7 There's then an account of the position said to
 8 have been set out by Mr Davis of Ortho. I'm not going
 9 to go through the detail of that.
 10 If we go over the page, it says in the second
 11 paragraph:
 12 "Mr Davis then moved to the real purpose of the
 13 meeting and asked a number of questions. I will
 14 itemise these and indicate the responses given by the
 15 persons who were present from the Blood Transfusion
 16 Service."
 17 So the first question:
 18 "1. Has any decision about blood testing been
 19 made? If not, how is it to be made and if any other
 20 information is required from Ortho ...
 21 "The answer was given that no decision had been
 22 made. That the decision would be subject to the
 23 advice of the National Advisory Committee on the
 24 Virological Safety of Blood. If the Advisory
 25 Committee were to make a recommendation, then this

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

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

8 The second question was:
9 "... 'What if a decision were to be made in
10 favour of doing the test? What would be the time and
11 events schedule? Would there be a simultaneous
12 announcement or a phasing ...?'"

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

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

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

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

25 "I indicated that, whilst I was willing to host

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

5 There was then a further discussion in relation
6 to that.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 **(10.52 am)**

11 **(A short break)**

12 **(11.33 am)**

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

18 **SIR BRIAN LANGSTAFF:** Thank you.

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

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

25 Also in August 1989 there's a letter from

1 Dr Cash and others published in The Lancet.
2 It's at NHBT0083819.
3 26 August 1989, the first letter on the
4 left-hand side is authored by Dr Contreras and
5 Dr Barbara and I can ask them about that. The second
6 letter which begins towards the bottom of the page
7 reads as follows:

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

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

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

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

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

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

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

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

25 "I realise that the present antibody test is not

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

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

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

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

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

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

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

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1 testing. You will be as familiar as I am with the
 2 long term complications of [non-A, non-B] hepatitis
 3 I fear that if there is delay in the introduction of
 4 anti-HCV testing we will be exposing patients to
 5 preventable viral infection.
 6 "I do appreciate that the decision to introduce
 7 an imperfect test is difficult but on balance I would
 8 encourage SNBTS to do so at an early date.
 9 "You may have many cogent arguments against what
 10 I am suggesting and if so I should be most interested
 11 to learn of them."
 12 So that was Dr Ludlam, December 1989, and, of
 13 course, we know that it's nearly two years after that
 14 that the testing is introduced in most of England and
 15 Wales, Scotland and Northern Ireland.
 16 There's a further perspective at PRSE0001562.
 17 This is Dr Boulton to Professor Cash,
 18 21 February 1990, and we will be able to ask
 19 Dr Boulton himself about this. If we pick it up in
 20 the second paragraph:
 21 "Could I just add that in spite of obvious
 22 difficulties with the current Ortho Elisa assay
 23 (susceptibility to 'stickiness', unreliability of
 24 predictive value with heat-treated samples, etc)
 25 I have developed a very strong feeling that the

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1 screening of donors for HCV antibodies should be
 2 introduced at the earliest possible opportunity. This
 3 is not because of the 'science', but because there
 4 appears to be little doubt that people have contracted
 5 HCV as a result of transfusions which they would not
 6 have received had those transfusions been screened for
 7 HCV antibody. Furthermore there are apparently five
 8 known cases of HCC due to PTH. The reason, therefore,
 9 from my ..."
 10 Sorry, I should say, I am assuming a PTH is
 11 obviously post-transfusion hepatitis. I am assuming
 12 HCC is being used there to refer to hepatocellular
 13 carcinoma.
 14 "The reason, therefore, [for] my proposing this
 15 view is actually one based on future litigation. I am
 16 pretty convinced that the NBTs and SNBTS will find
 17 legal action taken against them in about 10 years'
 18 time from persons who have sustained post transfusion
 19 hepatitis as a result of receiving HCV antibody
 20 containing blood which was presumably infectious for
 21 HCV at the time."
 22 So a perspective there from Dr Boulton who had
 23 been indeed working in the field of haematology more
 24 generally, before taking up a position within SNBTS.
 25 In terms of events in the course, then, of 1990,

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1 we'll be picking that up with other witnesses in due
 2 course over the coming weeks and months.
 3 In relation to Professor Cash himself, I'm going
 4 to pick the picture up next in 1991.
 5 NHBT0000076_006.
 6 This is Dr Gunson writing to Regional
 7 Transfusion Directors in England and Wales on
 8 22 January 1991 but copied to Professor Cash. We see
 9 that from the bottom of the letter.
 10 This is an announcement of the Department of
 11 Health's position:
 12 "1. The Department of Health have agreed that
 13 routine testing of all blood donations for anti-HCV
 14 can be put into operation.
 15 "2. I have been asked to try and ensure that
 16 testing starts simultaneously in [regional transfusion
 17 centres] in England and Wales and that it is
 18 co-ordinated with commencement of testing in
 19 Scotland."
 20 Then there's a request to the Regional
 21 Transfusion Directors to let Dr Gunson know what they
 22 consider to be the earliest date they could commence
 23 testing.
 24 Paragraph 4 refers to the need still to conclude
 25 the financial arrangements to cover both routine

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1 screening and supplementary tests.
 2 Paragraph 5 refers to proposals for a protocol
 3 for the carrying out of the tests, which is still to
 4 be discussed within the Department of Health.
 5 Then 6 says:
 6 "I will inform Ortho and Abbot that routine
 7 screening for anti-HCV has been approved and that we
 8 will inform them of the starting date in due course."
 9 If we then turn to NHBT0000073_033 we will see
 10 Professor Cash's response to Dr Gunson's memo. So
 11 this is dated 24 January:
 12 "Many thanks for your memo of 22nd January.
 13 "I have liaised with SNBTS RTDs and we are
 14 unanimous in advising, with the greatest respect but
 15 in the strongest possible terms, that anti-HCV
 16 donation testing should not be commenced in the UK BTS
 17 until after the Gulf conflict is over or at least
 18 until such time as we are confident our blood
 19 collection and microbiology testing teams can cope
 20 with what will be quite substantial changes and
 21 increased workloads.
 22 "Just at the moment there are a lot of exhausted
 23 staff in our RTCs and I would judge that when the
 24 troops go in, our current frenetic activity will be
 25 sustained.

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

8 Over the page:

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

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

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

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1 that an immediate start was entirely impractical.

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

6 "Thinking ahead to the end of June 1991 and
7 checking over previous correspondence I think we need
8 to do one more thing in the not too distant future.

9 I refer to defining what 'start date' will mean --
10 it's a re-run of the HIV-1 programme.

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

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

24 Over the page:

25 "Sorry to pester but I suspect you will have to

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

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

7 That's NHBT0000073_063, please, Soumik.

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

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

15 "The starting date and its definition.

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

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

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

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

17 "4.14. It was agreed that testing of blood and
18 plasma donations would commence on a specified date.
19 There would not be retrospective tests carried out on
20 donations collected prior to that date."

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

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

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

9 "You will want to know that our NBTS colleagues
10 are struggling, on a number of accounts, to meet
11 1st July deadline, as previously discussed and
12 I thought agreed. We believe the fundamental problem
13 is one of financial resourcing.

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

18 "Harold Gunson would advise DOH that the
19 1st July start date should be delayed until such time
20 as an evaluation of the new generation of HCV
21 screening tests had been completed. If this is
22 accepted it could push a start date to September."

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

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1 "The definition of a start date now proposed
2 will be exactly as stated -- the date when routine HCV
3 donation testing will commence. NBTS colleagues do
4 not wish to accept the original proposal ... that the
5 definition of a start date would be that on that date
6 all RTC products issued would have been HCV tested."

7 Top of the next page:

8 "More anon when things are clearer!"

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

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

18 Then you will see what Dr Gunson sets out:

19 "You will recall that in my letter to you of
20 15th February I suggested that 1st July 1991 might be
21 an appropriate date to commence anti-HCV screening of
22 blood donations.

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

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

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

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

18 Over the page it says:

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

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

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

25 "Dear Harold

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

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

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

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

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

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1 of the wording in that respect. I can double-check
 2 but I don't remember that coming up as an issue in the
 3 oral evidence. But I may be wrong. Professor Cash
 4 gave evidence to the Penrose Inquiry on, I think,
 5 ten separate occasions --
 6 **SIR BRIAN LANGSTAFF:** Yes.
 7 **MS RICHARDS:** -- and his evidence on this particular -- on
 8 the issue of HCV testing -- surrogate testing and then
 9 anti-HCV screening I think spread over three different
 10 occasions, separated by a number of days or weeks. So
 11 I may need to double-check that.
 12 **SIR BRIAN LANGSTAFF:** While I'm raising issues, just one
 13 further question. It's really going back to
 14 PRSE0002763, and this is where Professor Cash queries
 15 what "starting" means, "start date", and he is
 16 referring there to "plasma already in bond and waiting
 17 uplift", and presumably other products, RTC products,
 18 those in associated hospital blood banks.
 19 So he's raising the possibility that after --
 20 if, as we've seen, it is likely that on 1 September
 21 what was happening was testing of all new supplies,
 22 the supplies currently in the system might very well
 23 have been infected because they hadn't been tested.
 24 **MS RICHARDS:** Yes.
 25 **SIR BRIAN LANGSTAFF:** That has repercussions -- if it's

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1 Northern Region will be negative for Hepatitis C
 2 antibody.
 3 "My personal view is that not to test now that
 4 we have the ability to test would be indefensible
 5 under the current Product Liability Legislation.
 6 I appreciate that individual Directors may take
 7 a different view on the potential liability under the
 8 Consumer Protection Act, but the fact that this Centre
 9 is testing should not materially alter that judgment.
 10 "I would be interested to know if any Centre is
 11 currently carrying out any additional tests such as
 12 Hepatitis B core testing or ALT testing and if so,
 13 what criteria are being used to select donors/samples
 14 for testing."
 15 Now I'm not going to explore to any extent the
 16 decision taken by Dr Lloyd. As I say, that will be
 17 for future hearings. I draw attention to it because
 18 it's the response from Professor Cash that's relevant
 19 for today's purposes.
 20 In what you may think are characteristically
 21 powerful terms, Professor Cash wrote to Dr Lloyd on
 22 7 May 1991, NHBT0000074_019.
 23 He says this:
 24 "I received your copy letter to the UK BTS
 25 Directors ... with quite profound dismay, which

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1 right it may have repercussions for the accuracy of
 2 the start date adopted for Skipton.
 3 **MS RICHARDS:** It might indeed, sir, yes, absolutely.
 4 **SIR BRIAN LANGSTAFF:** Although no-one, of course, would
 5 have had that in contemplation at this stage, but yes,
 6 thank you.
 7 **MS RICHARDS:** Now, what then happened in May of 1991 is
 8 that the director of the Newcastle regional
 9 transfusion centre decided not to await the universal
 10 start date for the autumn of 1991, and he explains his
 11 position at NHBT0000074_014.
 12 This is a communication from Dr Lloyd, director
 13 of the Regional Transfusion Centre in Newcastle, from
 14 whom we hope the Inquiry will be hearing.
 15 It's 2 May 1991, directed to all directors of
 16 transfusion services, copied to, amongst others --
 17 well, copied to Dr Gunson and Professor Cash.
 18 It says this:
 19 "As you know there was a date of 1st July set
 20 for Hepatitis C Antibody testing. Fairly recently
 21 this was changed with a provisional date set for
 22 September 1991.
 23 "In view of the fact that we were already set up
 24 for testing, I have decided to keep to the July date.
 25 By 1st July, all units of blood for transfusion in the

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1 I suspect will be shared by all my SNBTS colleagues.
 2 "I cannot but conclude that this unilateral
 3 action is both disgraceful and mischievous. On
 4 a previous occasion I have expressed concern about
 5 NBTS management and have been taken to task when
 6 I used the word 'shambles'. Your action on HCV
 7 donation testing reveals, beyond doubt, that the NBTS
 8 is descending into a position now more accurately
 9 describe as chaos. It seems to be dog eat dog time,
 10 Huw, and I would suggest it is also time when you
 11 should remove the heading National Blood Transfusion
 12 Service from your headed notepaper and time for you
 13 and any of your staff who serve UK BTS and/or NBTS
 14 committees and working parties to be excluded."
 15 Now it's right to say I think, and only fair to
 16 say, that when he gave his evidence to the Penrose
 17 Inquiry Professor Cash did express a degree of regret
 18 about the precise way in which he'd expressed his
 19 views in that letter.
 20 The sentiment that this was an appropriate
 21 course to take was shared by a number of other
 22 Regional Transfusion Directors, who all wrote to
 23 Dr Lloyd, and those include Dr Contreras, Mr Martlew,
 24 Dr Boulton and Dr Entwistle, but we can ask them
 25 directly about that over the next few weeks.

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1 Dr Lloyd responded to Professor Cash at
 2 NBBT0000192_031 in what you may think are quite
 3 dignified terms:
 4 "Dear John ...
 5 "Thank you for your colourful letter. Your
 6 views are graphically put, as I would have expected.
 7 "I too have spent many hours looking at material
 8 relating to HIV litigation, but my conclusion is
 9 different to the one that you appear to be drawing.
 10 The situation now is quite different to that which
 11 existed when HIV 1 testing commenced, and I personally
 12 believe that to start HCV testing to the original
 13 schedule is the correct decision, even if it appears
 14 unpalatable to some.
 15 "To suggest that my action was in your words
 16 'mischievous', is to impart motives to this action
 17 which were not mine. If you wish to question motives,
 18 then perhaps you should be asking why a vague
 19 September start date has replaced with little
 20 explanation, a firm date in July."
 21 Then, continuing with the position in relation
 22 to May of 1991, Professor Cash wrote to Dr Gunson on
 23 8 May, NHBT0000074_024.
 24 He referred to "the Newcastle saga". That's
 25 obviously a reference to Dr Lloyd's decision. Then he

1 Then he goes on to talk about the confirmatory
 2 testing associated with the study.
 3 Also in May of 1991 Dr Gunson advised -- I don't
 4 propose to go it but I will just give you the
 5 reference -- NHBT0000192_024 -- that the Department of
 6 Health had reviewed the position in light of
 7 Dr Lloyd's decision to commence testing early and had
 8 concluded that the September date should remain and
 9 they were awaiting, amongst other matters, the second
 10 generation tests receiving FDA licences.
 11 If we pick matters up still in May of 1991 with
 12 a further letter from Professor Cash to Dr Gunson at
 13 NHBT0000192_039, this raises some wider concerns.
 14 So the first paragraph says:
 15 "I can well understand that last week there's
 16 a time of preoccupation with the immediate tasks
 17 associated with damage limitation, following the
 18 unilateral actions of Newcastle RTC.
 19 "On the first cold and wet Monday morning after
 20 that eventful week, I feel bound to raise with you and
 21 colleagues a matter of fundamental importance to the
 22 future of the UK [Blood Transfusion Service].
 23 "It has always been the view in Scotland, both
 24 in the Scottish Office and throughout the SNBTS, that
 25 the introduction of additional microbiology donation

1 set out a number of observations. He says in
 2 paragraph 1:
 3 "It will, I suggest, be important that all
 4 participants (other than Newcastle) start at the same
 5 time."
 6 Then he sets out a number of observations about
 7 the national large scale validation study which he was
 8 addressing, and suggesting that this should be in two
 9 phases. I'm not going to go through the detail of
 10 that.
 11 If we go over the page he again sets out various
 12 recommendations as to which centres -- or centres
 13 using the different tests.
 14 Then if we go to paragraph 5, in relation to the
 15 position in Scotland he says:
 16 "Right now, it looks as though, when full
 17 screening begins, Edinburgh, Glasgow and Aberdeen will
 18 opt for Abbott. Thus, it would seem to me, that we
 19 should offer Glasgow only into this national (UK)
 20 study and the NBTS will have to find 2 Ortho Centres
 21 (because Newcastle have already opted for Abbott.
 22 I am sure Dundee and Inverness (using Ortho) would be
 23 happy to pitch in, but their donation collections are
 24 relatively small and this could be viewed as
 25 a disadvantage to Ortho."

1 screening tests would be subject to Ministerial
 2 approval. Our understanding of this issue goes back
 3 many years to when SHHD directly intervened to stop
 4 one SNBTS centre unilaterally starting [hepatitis B
 5 surface antigen] donation testing. In recent times
 6 evidence that Ministers wished to acquire a firmer
 7 grip on this activity came with the establishment of
 8 the Advisory Committee on the Virological Safety of
 9 Blood. This development, in principle, was warmly
 10 welcomed in Scotland.
 11 "In the past months we have witnessed two
 12 happenings in the NBTS which unequivocally indicate
 13 that our interpretation of the policy referred to
 14 above may be seriously flawed. I refer to the
 15 unilateral action of BPL demanding ALT donation
 16 testing and the most recent HCV episode in Newcastle.
 17 It is difficult not to conclude, particularly having
 18 witnessed the passivity of the [Department of Health]
 19 on both occasions, that Ministers no longer wish to be
 20 involved in this exercise and that their current
 21 intention is to leave such matters to respective
 22 Health Authorities. Should my conclusions be
 23 confirmed then I would wish to emphasise that
 24 I deplore this development. It will lead to chaos
 25 which will become evident in the courts. To the best

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

4 Then the next paragraph:

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

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

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

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

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

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

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

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

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1 he says:

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

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

10 Then if we pick it up in that fourth paragraph:

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

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1 1st September 1991."

2 Then he sets out conclusions, saying:

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

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

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

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

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

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

19 Then skipping a sentence:

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

25 Then the document concludes over the page but

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

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

10 There was then a further meeting of the Advisory
11 Committee on Transfusion Transmitted Diseases on
12 10 June 1991. I'm not going to go to it. The
13 reference, for the transcript, is NHBT0000044_003.
14 There was a discussion there of a number of matters,
15 including how to handle donations and donors found to
16 be hepatitis C positive.

17 If we then look at PRSE0001183, it's a further
18 letter from Dr Lloyd to Professor Cash. This is dated
19 4 July. It says:

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

24 Then Dr Lloyd sets out his broader concern:

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

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

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

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

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

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

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

18 "2. Why was anti-HCV testing delayed until
19 1st September 1991?"

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

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

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

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

5 Then over the page, he continues:

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

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

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

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

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1 Professor Cash. He says this:
 2 "To the best of my recollection we sought to
 3 avoid the difficulties we had in 1985, with the
 4 introduction of HIV donation screening. Whilst we
 5 anticipated that once again SHHD would insist on the
 6 primary of DHSS, with respect to the timing of the
 7 introduction of HCV donation screening in the UK, we
 8 believed in 1989 that the SNBTS should generate
 9 significant independent data as soon as possible which
 10 could be used as a lever for timely central action."
 11 Then, if we go over the page, he was asked some
 12 questions about the decisions of the Advisory
 13 Committee on the Virological Safety of Blood, of which
 14 he was not a member, and his answer at (b) is:
 15 "I was not privy to the business of ACVSB. But
 16 I was advised ..."
 17 He doesn't say in this by whom, I can't recall
 18 without checking if it's clarified in his oral
 19 evidence or not:
 20 "... I was advised that DHSS did not move to
 21 promote HCV kit assessment until January 1990 and that
 22 the anticipated deliberations on this topic by ACVSB
 23 were thereafter deferred until April 1990. Efforts to
 24 obtain the reasons for this deferral were not
 25 successful. That said, it is of interest that in

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1 England/Wales and Northern Ireland working jointly on
 2 the decision or was it an issue on which Scotland
 3 would follow whatever decision was taken in England?
 4 Was the formal position that the decision for Scotland
 5 would be taken in Scotland, independently from the
 6 decision for England?
 7 "Answer: From the several conversations I had
 8 with Dr McIntyre [that's the medical officer within
 9 SHHD] I never had any doubt that although the decision
 10 for Scotland would finally be taken in Scotland, the
 11 SHHD operation policy on this issue was to defer
 12 totally to the primacy of DHSS, and that Scottish
 13 Ministers would fall in line with their London based
 14 colleagues. I was further advised that this position
 15 had been conveyed to the CSA; an aspect of management
 16 which I assumed ensured that the release of funds
 17 permitting the purchase of kits for donation screening
 18 by SNBTS RTCs was actually in the hands of the CSA's
 19 Finance Director who was to await instructions from
 20 SHHD."
 21 Then if we look at the bottom half of the page
 22 you'll see, sir, from the text that's not in bold
 23 print, so the Penrose Inquiry's summary, refers to the
 24 Ortho Rome symposium in September 1989, refers to,
 25 then, a meeting of the -- or various meetings of the

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1 August 1989 the need for introducing another donation
 2 screening test had not yet been considered by SHHD."
 3 Then if we look at the next page, top of page 5
 4 there's reference to communications between Professor
 5 Cash and Dr Gunson -- some, not all, of which, I've
 6 shown you in the course of the morning, sir -- and we
 7 see the top of the page there's a reference to
 8 a letter in which Professor Cash refers, as at
 9 August 1989, to it being only a matter of time before
 10 the new testing programme would be commenced.
 11 The question that is posed then by the Penrose
 12 Inquiry is:
 13 "At this point, was he [ie Professor Cash]
 14 envisaging a shorter time period than in fact
 15 eventuated?
 16 "Answer: Yes, I anticipated the SNBTS/WBTS
 17 Ortho kit assessment would reveal that we had a kit
 18 which would allow us to make a start, on the basis
 19 that specificity would be acceptable and sensitivity
 20 would be better than no screening."
 21 Then if we look towards the bottom of this page,
 22 just above the last few lines, there's a question
 23 posed about the interrelationship between the
 24 respective health departments. So the question is:
 25 "... were the health departments for Scotland,

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1 ACVSB, and indeed refers to the judgment of
 2 Mr Justice Burton in the National Blood Authority
 3 proceedings.
 4 Then the question is posed as to whether anyone
 5 has any comments or recollections of events at this
 6 time, and this was Professor Cash's comments:
 7 "My recollections are that this was the
 8 beginning of a period of much unhappiness and
 9 frustration. It began with the pressure I put on
 10 Dr Gunson to reveal why the ACVSB secretariat had
 11 deferred considering the existing HCV kit valuation
 12 data (generated in 1989) until April 1990.
 13 "When the deferred ACVSB meeting finally took
 14 place on the 23 April 1990 I discovered (after
 15 a briefing from Dr Perry) that both he and Dr Gunson
 16 had argued in committee that there was already
 17 sufficient data for ACVSB to recommend to Ministers
 18 the introduction of a first generation HCV donation
 19 screening as soon as possible. (This was a view
 20 I shared). I was advised that Drs Gunson and Perry's
 21 views were rejected and instead the committee agreed
 22 to mount its own HCV kit evaluation exercise.
 23 I recall that Dr Gunson was distressed at this turn of
 24 events and repeatedly emphasised to me that the ACVSB
 25 was in the hands of DHSS officials and the academic

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1 virologists and that his role as DHSS adviser was
 2 being openly challenged.
 3 "More unhappiness was to emerge for Dr Gunson
 4 and myself when the ACVSB came to examine the data
 5 generated from its evaluation of the first generation
 6 HCV kits when DHSS insisted that yet another
 7 evaluation should take place -- of second generation
 8 kits -- before routine testing would be authorised."
 9 I draw attention to that because some of the
 10 correspondence we've looked at would suggest that in
 11 terms at least of his written formal communications at
 12 the time -- we can't obviously know about what
 13 conversations were taking place behind the scenes or
 14 between him and Dr Gunson, but the communications
 15 we've looked at would suggest Professor Cash in
 16 agreement with this evaluation of the second
 17 generation tests. So it's one of a number of I think
 18 what might be said tensions in relation to
 19 Professor Cash's evidence.
 20 There are a number of further questions. I'm
 21 not going to go through the detail of all of them. If
 22 we go over the page, to page 8, Penrose Inquiry
 23 question 21 is:
 24 "Why ... was it necessary to tie introduction of
 25 the test in the UK to approval by the FDA?"

1 This was Professor Cash's response:
 2 "Rightly or wrongly I recall the FDA licensing
 3 process was regarded as important. There was
 4 a general view that the scientific processes of
 5 assessment of these diagnostic kits by the FDA were
 6 more rigorous and independent of political/commercial
 7 influences than in many countries, including the UK.
 8 That said, I recall that some were less certain that
 9 the issuing of FDA licences was entirely independent
 10 of political (US) pressures. No kit licensing
 11 arrangements existed in the UK."
 12 Then if we turn next to page 11, please, we get,
 13 on this page, to the issue of the deferral of the
 14 start date in the course of 1991.
 15 So question 33 suggests that there was
 16 difficulty in moving the issue forward in the early
 17 part of 1991, and this was Professor Cash's response:
 18 "To the best of my recollection it was at the
 19 ACVSB meeting of the 25 February 1991 that the
 20 decision, made in November 1990 to start routine
 21 donation screening in July 1991, was reversed --
 22 though I am not aware of any documents which confirm
 23 this and I recall I was later advised by Dr Gunson
 24 that he did not attend this meeting. But there is
 25 a document dated 21 February (4 days before the ACVSB

1 meeting) which seems to indicate that DHSS had already
 2 determined, without consultation with ACVSB, that
 3 there would be yet another kit evaluation -- the
 4 second generation study. I was later advised
 5 (23 March 1991) that SHHD had previously been
 6 consulted and had agreed to this second DHSS inspired
 7 and unnecessary delay. Dr Gunson advised NBTS
 8 Directors and others of this position on
 9 3 April 1991."
 10 So you will see in this statement Professor Cash
 11 expressing a degree of disagreement with what was
 12 taking place and suggesting that this was at the
 13 instigation of the Department of Health and that it
 14 was unnecessary.
 15 Again, you will no doubt wish to consider what
 16 he was saying in his formal communications at the
 17 time. Some of these are issues that he was pressed on
 18 during his oral evidence to the Penrose Inquiry. It's
 19 also right to note that we are likely to have the
 20 benefit of being able to examine this in more detail
 21 by reference to witnesses from the Department of
 22 Health or witnesses involved in the ACVSB
 23 decision-making, and we will be seeking to unpick the
 24 Departmental decision-making process in later
 25 hearings.

1 Then if we go towards the bottom half of the
 2 page, you will see the last few lines refer to what
 3 Professor Cash described as:
 4 "Some very distressing conversations with
 5 Dr Gunson over the week end before the ACTTD meeting
 6 of the 25 March 1991 left me in no doubt that, despite
 7 his letter of the 22 January to NBTS Directors
 8 signalling the commencement of forward planning for
 9 a full HCV donation screening start day, this had been
 10 reversed by DHSS in early February 1991 against
 11 Dr Gunson's wishes and without consultation with him
 12 or other members of ACVSB. Dr Gunson also insisted
 13 that SHHD had been party to this decision and that
 14 both Departments of Health were extremely anxious that
 15 there would be no difficulties at the 25 March ACTTD
 16 meeting. There was no reason at all why we could not
 17 have introduced screening using the first generation
 18 kits."
 19 Two questions arise in relation to that. The
 20 first is: is that right as a matter of fact? That
 21 will be one of the many issues, sir, that you may need
 22 to consider when you consider why it took
 23 until the autumn of 1991 for screening to be
 24 introduced. So there is the general issue as to
 25 whether that's the case. But the second, specific to

1 Professor Cash, was: was that the view that was being
2 express by him at the time?
3 **SIR BRIAN LANGSTAFF:** When he wrote that unusual
4 correspondence to Dr Lloyd, expressing his view of
5 Dr Lloyd's breaking ranks, he didn't say, "I happen to
6 agree with your logic about introducing tests but you
7 really nonetheless have to bow to the majority". He
8 didn't put it that way, did he?
9 **MS RICHARDS:** He didn't, no. It's right to say that in
10 his Penrose Inquiry oral evidence Professor Cash did
11 talk on a number of occasions about the importance of
12 there being a unified UK-wide position and
13 a unified UK start date, and he continued to adhere to
14 that.
15 But you're absolutely right. He did not convey
16 to Dr Lloyd nor, I think, to anyone else in the -- nor
17 to Dr Gunson, I should say, in the correspondence
18 we've seen, a view that there was no reason why
19 screening couldn't be introduced using the first
20 generation kit.
21 So it's open to you, sir, in due course, and
22 having heard much more evidence and received
23 submissions, to conclude that that sentence is
24 correct, but it begs the question of whether that was
25 what was being said by Professor Cash at the time and,

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1 if it was not, why not?
2 **SIR BRIAN LANGSTAFF:** Yes.
3 **MS RICHARDS:** Of course you are not going to have the
4 ability to hear further from Professor Cash on that
5 issue.
6 **SIR BRIAN LANGSTAFF:** Or Professor Gunson.
7 **MS RICHARDS:** Or Dr Gunson, no.
8 Then, you will see, he then says:
9 "Until sight of this witness statement request,
10 I was not aware that Scottish Ministers had not been
11 briefed about the start date until 24 July 1991.
12 I suggest this is a matter of great significance and
13 believe may give some support to Dr Gunson's claim
14 that SHHD officials had been party to the contrived
15 further delay, which had been conceived and
16 implemented by DHSS officials."
17 Again, that is an issue upon which he was
18 questioned during his oral evidence as to some of the
19 ways in which he characterised the DHSS's role.
20 Then he continues:
21 "I recall that Dr Mitchell advised me that the
22 ACVSB was aware of the existence of second generation
23 tests at its November 1990 meeting, but had agreed
24 that an evaluation of these kits could be fitted in
25 after the commencement of full screening using the

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1 first generation test. It follows that for some
2 reason there was a significant change in policy and
3 that the ACVSB was not consulted. Certainly the
4 notion that the second generation kits could have
5 readily been evaluated soon after the introduction of
6 routine HCV donation screening enjoyed the support of
7 the SNBTS. Thus earlier Ministerial approval would
8 also have enjoyed our support.
9 "The position adopted by the Director of the
10 Newcastle RTC [so Dr Lloyd] in April/May 1991 proved
11 to be very revealing. Among other things I recall it
12 had much to do with the proposition made to the SNBTS
13 Board in June 1991 that the SNBTS should emulate
14 Newcastle, disregard the positions of SHHD and CSA and
15 establish full HCV donation screening ASAP. As
16 I recall it was a hotly contested debate, but the
17 proposal was defeated. Some of us who opposed it
18 viewed it as one, which if approved, could have
19 triggered a descent into chaos and hence my reference
20 to a potential 'disaster' ... In my view, the
21 disaster would have been the operational fragmentation
22 of the UK BTS, but closer to home the SNBTS. The
23 impact of a fragmented UK BTS to the quality of care
24 of UK patients would have been considerable."
25 So there Professor Cash is articulating the

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1 position consistent with documents we have seen at the
2 time that there should be a universal co-ordinated
3 approach and not individual areas taking their own
4 course.
5 So that's the written statement in relation to
6 hepatitis C screening. There's then -- in relation to
7 surrogate testing, there was one document which
8 I should have taken you to, sir, and didn't.
9 This goes back to 1986 on the question of
10 surrogate testing. It's PRSE0002109 and it was
11 a letter from Professor Cash to Dr Fraser in Bristol,
12 "NANB: Surrogate Testing". It says this:
13 "I have a feeling that as the drums are beating
14 louder and louder in other parts of the world on this
15 topic the Brits remain fast asleep. I may be wrong
16 but I would like to better briefed on this matter."
17 Then he refers to raising the issue at an SNBTS
18 Directors' meeting some months ago:
19 "... and we agreed that you would explore the
20 idea of setting up a UK prospective trial. I recall
21 you saying to me that you pursued this at the NBTS
22 Directors' Meeting (I'm afraid I wasn't there) and it
23 went down like the proverbial lead balloon!
24 "I'm bound to conclude that I feel we cannot
25 leave the matter as it is and would value your

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

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

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

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

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1 questions of surrogate testing, essentially.
2 PRSE0003395 is HIV/AIDS.
3 PRSE0003463 is a further statement in relation
4 to the PFC.
5 PRSE0004020 is a statement from Professor Cash,
6 amongst other things, in relation to a statement from
7 Mr David McIntosh.
8 PRSE000465, statement about surrogate testing.
9 PRSE0004252 is an updated statement about
10 HIV/AIDS.

11 PRSE0004484 is about donor selection and prison
12 blood collection.

13 Also on the topic of donors, PRSE0004558.

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

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

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

23 He gave evidence to the Penrose Inquiry on
24 23 April 2011, PRSE0006010, and that evidence was
25 about high-risk donors, prison blood collection and

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

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

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

13 There's PRSE0000529, statement about the PFC.

14 There's PRSE0000651, also a statement about Z8.

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

17 PRSE0001411 is concerned with ALT testing.

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

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

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

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

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1 collection from donors with a history of jaundice.

2 Then PRSE0006043 is Professor Cash's evidence on
3 8 September 2011, and that topic -- that was topic
4 B3 -- I'm going to have to remind myself what topic B3
5 was now. I think that's viral inactivation. In any
6 event, there's the transcript.

7 Then there's his oral evidence on
8 27 September 2011, PRSE0006048. That's in relation to
9 HIV/AIDS.

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

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

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

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1 worth considering in his oral evidence there.
 2 Then, 1 December 2011, is, I think,
 3 a continuation of the evidence on that topic
 4 PRSE0006072.
 5 Then he gave evidence on 11 January 2012,
 6 PRSE0006082. That's still on the issue of hepatitis C
 7 testing.
 8 Then I think his final oral evidence is on
 9 17 January 2012, PRSE0006085, and that was in relation
 10 to the hepatitis C look-back.
 11 I'm not going to take you now, I think, sir, on
 12 reflection, to extracts from his oral testimony
 13 because it is very difficult to follow without
 14 simultaneously looking at all of the documents that
 15 are being referred to during the oral examination and,
 16 otherwise, I would be at risk of plucking individual
 17 bits of his answers out of context without looking at
 18 what are hundreds and hundreds of pages of oral
 19 testimony. No doubt, in due course, those who wish to
 20 make submissions about decision-making on these issues
 21 will be assisted by looking at the evidence that
 22 Professor Cash gave to Penrose.
 23 Can I then come finally, and by reference to the
 24 contemporaneous documentations, to Professor Cash's
 25 involvement in the look-back exercise. He told the

1 Penrose Inquiry he wasn't directly involved in the
 2 carrying out of the look-back exercise but the
 3 documentation suggests he certainly had some
 4 involvement in the decision-making as regards whether
 5 and, if so, when and how it should be set up.
 6 If we start with -- I think it's PRSE0001133,
 7 this is Professor Cash writing to his colleagues
 8 within SNBTS on 9 July 1990, "HCV: look-back
 9 programme":
 10 "As promised, I have discussed this topic with
 11 Harold Gunson.
 12 "We both agreed the following:
 13 "It would not, after we start anti-HCV donation
 14 screening, be appropriate to introduce a systematic
 15 look-back programme on previous recipients -- as was
 16 done for HIV-1.
 17 "It would be appropriate, in the period before
 18 routine anti-HCV donation screening commences, to
 19 examine the anti-HCV status of donors who have been
 20 implicated in a case of reported PTH."
 21 There's what's said to be the agreement between
 22 Professor Cash and Dr Gunson in mid-1990, of course
 23 over a year before the hepatitis C screening was
 24 finally introduced. What we don't get from this
 25 letter is an understanding of what the reasoning was

1 in relation to either of those positions.
 2 If we then look at NHBT0000073_007, this is
 3 a letter, October 1990, Professor Cash to Dr Gunson.
 4 It's primarily concerned with the issue of donor
 5 counselling and a report from Jack Gillon, but if we
 6 go over the top of the next page, we can see the issue
 7 of look-back. He says:
 8 "... I would much appreciate your thoughts on
 9 the issue of 'look-back'. You will have noted that
 10 our team have indicated the need for a policy
 11 statement and in their view 'look-back' should be
 12 attempted."
 13 There were then discussions or -- sorry, there
 14 was then a letter from Dr Gunson saying this will be
 15 considered by the Advisory Committee on Transfusion
 16 Transmitted Diseases in January 1991. The reference
 17 for that, I'm not proposing to go to it, is
 18 NHBT0000073_028.
 19 If, however, we look at -- sorry, just give me
 20 a moment.
 21 PRSE0001573. We can see Professor Cash writing
 22 to Dr Metters, Deputy CMO, in November 1990:
 23 "In anticipation of the commencement of HCV
 24 blood donation testing throughout the UK in the
 25 foreseeable future, the Scottish National Blood

1 Transfusion Service Directors have asked me to write
 2 to you with a request that a policy of 'look back' is
 3 considered by the ... Advisory Committee on the Virus
 4 Safety of Blood."
 5 Then if we turn to PRSE0003568. We're now in
 6 February 1991. This is an internal SNBTS meeting,
 7 a meeting of its medical and scientific committee
 8 chaired by Professor Cash, and we will be able,
 9 I think, to pick some of these issues up with oral
 10 witnesses.
 11 But if we turn to page 4 there's a heading
 12 towards the top of the page about
 13 "Donor Counselling: HCV Donation Testing", and then
 14 the next paragraph reads:
 15 "In the light of national events ..."
 16 That is, I suspect, a reference to the fact that
 17 the testing programme had not yet commenced.
 18 "... it was agreed that no 'Look Back' should be
 19 introduced at present."
 20 It's then -- I think we then have to look
 21 to 1993 for the issue to be raised again by
 22 Professor Cash himself, at PRSE0003928.
 23 So this is now two years after the introduction
 24 of the hepatitis C screening, or a little over two
 25 years after, and Professor Cash wrote to Dr Gunson in

1 these terms:
 2 "HCV confirmed positive donors: look back.
 3 "At a recent RCPE Symposium on HCV a
 4 distinguished speaker indicated that efforts ought to
 5 be made by the transfusion services, in the first
 6 instance, to track patients who had received blood and
 7 blood components. He argued that some of these
 8 patients could benefit substantially from some modern
 9 therapeutic manoeuvre and that we had a duty to ensure
 10 this option was made available.
 11 "This view was discussed at a recent meeting of
 12 the SNBTS Medical and Scientific Committee and while
 13 it received support colleagues stepped back from
 14 introducing a look-back policy until such times as
 15 further (UK) deliberations had taken place.
 16 "It occurred to me that it might be appropriate
 17 for the item to be researched for, and discussed by,
 18 MSBT."
 19 That's the Advisory Committee on the
 20 Microbiological Safety of Blood and Tissue, I think.
 21 Sorry, the acronyms become a little confusing.
 22 Then if we look at PRSE0003685, this is
 23 a discussion, now in May of 1994, of the SNBTS Medical
 24 and Scientific Committee chaired by Professor Cash.
 25 We can pick up the position in relation to look-back

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1 took any action, AK asked to be given the opportunity
 2 to discuss the issues with SHHD colleagues to seek
 3 their views and asked that the SNBTS take no formal
 4 action until she had subsequently contacted JDC."
 5 That's Professor Cash.
 6 "vi. Once AK had communicated the SHHD position
 7 to JDC and provided SHHD were in agreement that the
 8 SNBTS should implement this policy, JDC would write to
 9 D [McClelland] to provide details of the SNBTS policy,
 10 thereby allowing a decision to be taken on a starting
 11 date for the process. [Professor Cash] also would
 12 formally advise NBA, NIBTS, SACTTI and MSBT of the
 13 SNBTS policy."
 14 We are definitely in acronym soup by now.
 15 "vii. If SHHD agreed that SNBTS should develop
 16 and implement a lookback policy for HCV, [Dr Keel]
 17 subsequently would communicate this to [the Department
 18 of Health].
 19 So that's the discussion which took place there,
 20 and again we'll be able to unpick some of the
 21 decision-making here with later witnesses.
 22 There's a reference at NHBT0095526_0026 to there
 23 being pressure to promote a look-back policy.
 24 Do you need that reference again, Soumik?
 25 NHBT0095526 --

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1 at the bottom of page 5. Where it said:
 2 "This very complex and extremely important issue
 3 was discussed at length. The Committee unanimously
 4 agreed that on finding a 'known' (or regular) donor
 5 who was now anti-HCV pos, the SNBTS should ..."
 6 Then there are a number of proposed steps set
 7 out. First is:
 8 "i. Retest previous archive samples to exclude
 9 'missed' sero conversion ...
 10 "ii. For donations issued to hospital blood
 11 banks, other RTCs, etc, the SNBTS will provide ..."
 12 Certain information to the clinician.
 13 (iii) sets out the proposal in relation to
 14 donations issued to known patients by SNBTS blood
 15 banks and then:
 16 "iv. It was agreed that the procedure to be
 17 followed would be based on that outlined in the
 18 forthcoming publication on the subject in Transfusion
 19 Medicine ..."
 20 Then:
 21 "v. From an SHHD perspective, AK [and that is
 22 Dr Aileen Keel] expressed a view that the SHHD may not
 23 have a locus in this matter and that the SNBTS should
 24 make a decision on lookback for HCV that was based on
 25 their professional judgment. However, before SNBTS

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1 **SIR BRIAN LANGSTAFF:** It may be the underscore might be
 2 026.
 3 **MS RICHARDS:** Yes, it may be.
 4 Thank you, Soumik.
 5 So it's a letter -- this is, in fact, from
 6 Dr Ala to a doctor at the liver unit of the Queen
 7 Elizabeth Hospital in Birmingham, but it's about
 8 hepatitis C look-back, and you will see --
 9 **SIR BRIAN LANGSTAFF:** For those who want to follow this,
 10 Dr Ala was in charge of the transfusion at the
 11 Regional Transfusion Centre in the West Midlands, was
 12 he?
 13 **MS RICHARDS:** Yes and he was writing here in his capacity
 14 as chair of the Advisory Committee on Transfusion
 15 Transmitted Infection, and he says:
 16 "... I have been under some pressure to promote
 17 a 'look-back' policy for all those patients who
 18 received blood products from donors we subsequently
 19 found to be anti-HCV positive when screening was
 20 introduced to the BTS.
 21 "The advocates of this policy (mainly the
 22 Scottish National [Blood Transfusion Service]) argue
 23 that ..."
 24 Then we can see the reasoning that's being set
 25 out there:

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1 "Interferon alone, or in combination with
2 Ribavirin will arrest progression of liver disease and
3 disappearance of viral RNA in a large proportion of
4 patients (over 60%)."
5 Just pausing there, and again we'll see this as
6 we look at look-back issues in more detail with
7 witnesses or by way of further presentations, but one
8 of the themes was "Is there any point in doing
9 a look-back if there's no treatment that we can give
10 to patients?" There may be a number of obvious
11 answers to that, or perhaps some less obvious answers
12 to that, but, in any event, what's being said here was
13 this now a treatment and therefore, a greater
14 obligation to trace people who may have been infected
15 with.
16 So we see that from the second point.
17 "We have a moral duty to counsel these
18 individuals with an eye to making this potentially
19 effective treatment available to them.
20 "Even though sexual transmission is reportedly
21 low with HCV, we should, nevertheless, provide
22 cautionary advice because the situation is not yet
23 clear."
24 Top of the next page:
25 "We risk public and media opprobrium for being

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1 out of that meeting, sorry. PRSE0001236. So it's HCV
2 look-back, Professor Cash. If we go over the page,
3 you'll see it's headed "Recommendations of the
4 Standing Advisory Committee on Transfusion Transmitted
5 Infection to the MSBT Concerning the Merits of
6 Adopting an HCV 'Look-Back' Policy", and then it
7 refers to the meeting on 5 August, to which Dr Ala had
8 made reference:
9 "An *ad hoc* assembly of experts met on 5th August
10 1994 to discuss the feasibility of initiating
11 a 'look-back' policy to identify, test, counsel and,
12 if necessary, refer surviving past recipients of blood
13 components from donors later found to be anti-HCV
14 seropositive after [testing] was introduced in
15 September 1991."
16 I won't go through the detail of the report. If
17 we just go to page 4 and look at the summary, it says:
18 "The SACTTI [that is the Standing Advisory
19 Committee on Transfusion Transmitted Infection] feels
20 there is a serious case for considering a look-back
21 policy for HCV. To do otherwise, when a look-back
22 programme for HIV already exists, suggests double
23 standards. The wider implications of such a policy
24 will need further consideration and the SACTTI
25 recommends that the Hepatitis Advisory Group and the

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1 either negligent or secretive."
2 There are then set out the potential reasons for
3 not undertaking such a policy. So the reasons for
4 undertaking it were those being put forward, it is
5 said, mainly by the Scottish Directors. The contrary
6 reasons given here:
7 "It will create crate unnecessary anxiety.
8 "Little will be gained for the effort and
9 expense involved.
10 "Long-term results of [interferon]/ribavirin
11 therapy are not yet available ...
12 "We will generate the very adverse media
13 publicity we would seek to avoid."
14 Then the letter continues to say that:
15 "... I have convened an *ad hoc* meeting in
16 Birmingham [5 August 1994], to discuss this issue and
17 attempt to reach some policy decision. This will not
18 be easy, and I know Professor Cash and Professor
19 Tedder do favour doing a 'look-back' while several
20 others are agnostic."
21 That's what is being recorded as being Professor
22 Cash's position by that time.
23 There was a paper produced by Professor Cash
24 for -- I think it is for that meeting. No, it may be
25 for a later meeting. I think it is produced arising

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1 MSBT consider the matter further as soon as possible."
2 There are further discussions both within
3 Scotland and nationally but I think we'll probably
4 pick those up more usefully with later witnesses. In
5 early 1995 Professor Cash wrote to Dr Metters with
6 some suggestions about the look-back, which, by this
7 stage, had been agreed in principle. I won't go to
8 that letter but the reference for the transcript is
9 NHBT0005835.
10 Perhaps the final document just to look at on
11 this issue is STHB0000687.
12 So this is October 1995. It's a meeting of the
13 SNBTS Medical and Scientific Committee. So this is
14 a point in time at which the look-back, the national
15 look-back exercise has been decided upon.
16 If we go to page 4 -- I'm not proposing to go
17 through the detail, but there's a heading
18 "HCV Lookback" and an "Update of the SNBTS Position".
19 Perhaps the only sub-paragraph that I should
20 highlight for present purposes is sub-paragraph (iv):
21 "With respect to recipients of blood components
22 pre HCV testing, the MSC agreed:
23 "- that testing of available donor archive
24 samples would be neither cost effective nor
25 appropriate.

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

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

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

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

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

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1 presentation, are selective.

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

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

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

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

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

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

5 **MS RICHARDS:** We will hear from Ms Scott.

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

8 **MS RICHARDS:** Exactly, yes.

9 **(1.04 pm)**

(Luncheon Adjournment)

10 **(2.05 pm)**

11 **SIR BRIAN LANGSTAFF:** Yes.

**Presentation by Counsel to the Inquiry
on Dr Harold Gunson**

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

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

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1 Transfusion Service, which was based in Manchester.

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

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

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

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1 the Department of Health and Social Security and then,
 2 of course, when it became the Department of Health.
 3 I'm just going to look at a couple of documents
 4 which gives us some insight into how he viewed that
 5 particular role. The first one is CBLA0001498.
 6 We can see that that's a letter written on
 7 16 November 1981, so shortly after he had been
 8 appointed Consultant Adviser, it's headed on the
 9 Manchester National Blood Transfusion Service paper,
 10 "Dear colleague", and if we go to the second page we
 11 can see it's from Dr Gunson. Then if we go back,
 12 please, to the first page, it's the third paragraph
 13 down:
 14 "As you are aware, the post of Consultant
 15 Adviser is a personal one and the advice proffered is,
 16 therefore, personal also. However, it would be
 17 foolish for advice to the DHSS to be out of line with
 18 general views on a particular topic. In this regard
 19 I intend to keep in touch with Bill Wagstaff and the
 20 Chairmen of Divisions, but also hope to keep myself
 21 informed of matters and problems in the various
 22 regions which could have national importance. I hope
 23 you will feel that you can discuss these with me, or
 24 write and let me know about them. Also, I would
 25 appreciate agendas and minutes from the various

1 working parties. If you wish me to attend any meeting
 2 of a working party where you think the discussion will
 3 be helpful, I will endeavour to do so; the same
 4 applies to the meetings of the Western and Eastern
 5 Divisions."
 6 I will come on in a moment to look at some of
 7 the working groups and committees that Dr Gunson
 8 attended.
 9 So we can see there the role is a personal one
 10 but he is going to keep himself very much up-to-date
 11 with what others are thinking and what decisions and
 12 actions are being taken.
 13 Then the second document which throws some light
 14 on this is NHBT0018339. Now, this, we can see, is
 15 a minute of a "Regional Transfusion Directors'
 16 Meeting" on 7 October 1981, and we can see, about
 17 halfway down the list of those who are present,
 18 Dr Gunson's name and we can see, at the bottom, that
 19 that meeting is chaired by Dr Wagstaff, who we saw
 20 mentioned in the previous document.
 21 If we then go over the page, please, to page 7
 22 we can see at item 11 "Consultant Adviser to DHSS":
 23 "In view of Dr Tovey's retirement, Dr Gunson has
 24 been asked to fulfil this role."
 25 Then skipping down to two thirds of the way down

1 that paragraph, what he does there is he describes the
 2 different administrative arrangements there are going
 3 to be, namely that he is going to discharge his role
 4 from Manchester not from London, because he is going
 5 to continue in his role as director of the Manchester
 6 centre. I'll pick it up, it says:
 7 "Where statements had to be made on behalf of
 8 the DHSS this would be done by DHSS and not by the
 9 consultant adviser to the DHSS. Dr Gunson expressed
 10 his willingness to attend any meetings of working
 11 parties or regional groups at which his contribution
 12 would be useful ..."
 13 So echoing what he says in his later letter but,
 14 importantly, he says this:
 15 "... he saw his role as reflecting the views of
 16 the RTDs and NBTS at large and communicating these to
 17 the DHSS where appropriate."
 18 So a slightly different complexion there to the
 19 role. In that later letter he says it's a personal
 20 one, and "I'll be expressing my personal views", but
 21 here he seems to be suggesting that he may be rather
 22 more of a representative voice of RTDs to the DHSS.
 23 Then I'll just take you to a document,
 24 NHBT0000086_009, again which gives us a bit of
 25 information about the role.

1 This is a training session given by Dr Gunson to
 2 lawyers in the HIV litigation. Dr Gunson was engaged
 3 as the blood transfusion expert for the defendants,
 4 both the health authorities and Central Government, in
 5 that piece of litigation.
 6 If we could pick it up at page 11, at the top of
 7 that he says:
 8 "The purpose of the Consultant Adviser is to
 9 provide advice of a personal nature to the CMO or
 10 nominated officers at DHSS as distinct from collective
 11 advice from the Speciality as a whole."
 12 Then explains why he had a rather different
 13 arrangement to the previous two holders of the post,
 14 who were Sir William Maycock and Dr Tovey.
 15 Then the next paragraph he says:
 16 "Events were to prove that my advice was
 17 required on many occasions during the next few years
 18 since within one year the relationship between AIDS
 19 and the transfusion of blood and its products was
 20 proven. It must be recognised that my advice on these
 21 matters was on personal basis; responses from The
 22 Service to matters concerning HIV infection amongst
 23 other topics were elicited from the Chairman of the
 24 RTD Committee."
 25 **SIR BRIAN LANGSTAFF:** Just stopping there for a moment, he

1 began his role in October 1981?

2 **MS SCOTT:** Yes.

3 **SIR BRIAN LANGSTAFF:** So when he says "within one year the

4 relationship between AIDS and the transfusion of blood

5 and its products was proven", he's talking about

6 before October '82?

7 **MS SCOTT:** He is, and, sir, we'll come on to look at

8 some of the documentation and how he says -- on later

9 reflection, at what point he says that he was

10 convinced that HIV or AIDS was caused by blood

11 transfusions.

12 **SIR BRIAN LANGSTAFF:** Yes.

13 **MS SCOTT:** We will get on to that tomorrow.

14 So moving on then to the committees and working

15 groups that Dr Gunson participated in and I should

16 say, although there are a lot -- I am going to mention

17 a lot of them, this is not an exhaustive selection.

18 There are other working groups, committees and so on

19 that he participated in.

20 So, as a Regional Transfusion Director, as one

21 would expect he was a regular attender at Regional

22 Transfusion Director meetings, and the Regional

23 Transfusion Directors had various working groups and

24 committees and he was chair of the Regional

25 Transfusion Directors committee, called the UK AIDS

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1 of Scotland and Northern Ireland.

2 He chaired two of its subcommittees, the working

3 party to advise on plasma supplies for

4 self-sufficiency in blood products, in February 1983,

5 and also the working group on AIDS. The names of some

6 of these committees and working groups are quite

7 a mouthful.

8 Once the National Directorate was formed in 1988

9 and the Advisory Committee was abolished, as we heard

10 on Tuesday, he became -- the National Management

11 Committee of the NBTS was formed, in December 1988 it

12 had its first meeting, and he was, as you would expect

13 as National Director, a member of that committee. We

14 looked at their terms of reference on Tuesday.

15 He was a member of the UK Working Party on

16 Transfusion Associated Hepatitis from its inaugural

17 meeting in September 1982, and the terms of reference

18 for that can be found -- and we don't need to turn

19 this up -- CBLA0001625, and I can read those out

20 because they are short.

21 So the terms of reference for that group were to

22 promote the investigation of the epidemiology of

23 transfusion associated hepatitis to promote research

24 and to make recommendations to the director of the UK

25 Transfusion Service regarding procedures and screening

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1 Working Group. The Inquiry, as I understand it, has

2 only found minutes of one meeting of that group to

3 date but investigations continue.

4 He also attended the regional meetings of

5 consultants of the Blood Transfusion Service and, sir,

6 you may recall on Tuesday we heard that Dr Tovey had

7 instituted a system where there were three

8 supra-regional group meetings and Dr Gunson again, as

9 one would expect as a director, attended the relevant

10 one for him, which for Manchester was the northern.

11 He also attended meetings when they occurred

12 between Regional Transfusion Directors and Haemophilia

13 Centre Directors, and we have a number of examples of

14 meetings of that nature.

15 He was a member of the Advisory Committee on the

16 National Blood Transfusion Service, from its inception

17 in December 1980 and, again, we heard about how that

18 was created and circumstances that that was created,

19 on Tuesday and we looked, on Tuesday, at the terms of

20 reference of that group, which for reference, is

21 CBLA0001207, and it was to advise the DHSS and the

22 Welsh Office on the co-ordination of the development

23 and work of Regional Transfusion Centres and Central

24 Blood Laboratories in England and Wales, and the

25 English and Welsh Blood Transfusion Service with those

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1 for its prevention.

2 Between 1982 and 1988 he was a member of the

3 Central Blood Laboratory Authority. He was chair of

4 some of their subcommittees, such as the central

5 committee for research and development in blood

6 transfusion, he was chair of that subcommittee from

7 June 1983. He was chair of their working group on

8 AIDS from October 1983, and the terms of reference for

9 that group -- again, we don't need to go to this --

10 can be found at CBLA0001754, and that document says

11 that it was set up to consider the problem of AIDS in

12 relation to the transfusion of blood and blood

13 products.

14 That was a committee on which Professor Bloom

15 sat and we can see, from the minutes of the document

16 of the first meeting, that I've just given the

17 document reference for, that Professor Bloom was asked

18 to be the link between the CBLA working group on AIDS

19 and the Medical Research Council committee on AIDS

20 because he sat on both of those committees.

21 Now Dr Gunson resigned from the CBLA when he

22 took up his role as national director to avoid any

23 conflict should the CBLA policy materially differ from

24 the aims of the National Blood Transfusion Service.

25 He was a member of the National Blood

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

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

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

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

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1 transmitted by the transfusion of blood and blood
2 products.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 "Draft

23 "Terms of Reference

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

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1 would be covering many of the same issues as the
2 ACTTD. The relationship between the two Committees
3 was formally addressed at the meeting of the ACVSB on
4 24th April 1990, where the Chairman proposed that it
5 would be the responsibility of the ACVSB to advise
6 Ministers on the virological safety of blood, while
7 the ACTTD would consider the operational implications
8 of policy, advise the Department on non-viral threats
9 to blood and contribute to the advice on viral safety
10 through input to the ACVSB. I confirmed that I shared
11 this view not the respective roles of the two
12 Committees and did not believe that it involved any
13 conflict.

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

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

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

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

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

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

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1 groups meeting and making decisions over this period.

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

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

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

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

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

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

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

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

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

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1 or possibly early 1976.

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

5 **MS SCOTT:** Indeed.

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

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

9 **MS SCOTT:** Yes.

10 **SIR BRIAN LANGSTAFF:** "Assuming that the ... building work
11 is completed by November 1976 then the earliest time
12 that the proposals can be implemented is
13 1st January 1977 ..."

14 So this is plainly written before November '76.

15 **MS SCOTT:** Yes.

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

19 **MS SCOTT:** Quite.

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

25 So if we look at that first paragraph, it gives

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1 us some information about what was happening at the
 2 Oxford Regional Transfusion Service at the time:
 3 "At present, the Oxford Regional Transfusion
 4 Service supplies some 5,000 litres of plasma annually
 5 to the Oxford Haemophilia Centre. This is achieved by
 6 separating the plasma from approximately
 7 22,000 donations. Expansion plans are in hand to
 8 increase the volume plasma supplied for fractionation
 9 to 6,500 litres per year. Although this represents an
 10 increase of only 22 per cent it will necessitate the
 11 handling of 36,000 donations annually since it is
 12 proposed to reduce the volume of plasma removed from
 13 each donation to 180ml, instead of the 210-220ml
 14 removed at present. The proposal to further increase
 15 the volume of plasma for fractionation to
 16 10,000 litres per year will involve the separation of
 17 plasma from 55,000 donations. This represents an
 18 increase of 53 per cent above our committed expansion
 19 and an increase of 150 per cent above our present
 20 separation."
 21 Then if we can go down to the section 1, halfway
 22 down, "Availability of Donors", he makes the point
 23 there that:
 24 "The present region serviced by the Oxford BTS
 25 does not conform to the Oxford RHA boundaries."

1 Sir, that's a theme that we will see in many of
 2 the documents that when -- as we heard on Tuesday, the
 3 Regional Transfusion Centres were formed first with
 4 their areas, and then the regional health authorities
 5 took them over, and the two boundaries didn't always
 6 coincide precisely.
 7 If we turn over the page, we can see halfway
 8 down that page (i) and (ii), we can see:
 9 "Increasing blood collection up to 19,000
 10 donations per year will result directly in an increase
 11 in the clerical work associated with donor call-up and
 12 records."
 13 Then we have Dr Gunson setting out what the
 14 impact of that will be, dependent on whether or not
 15 computerisation can be brought into the equation, and
 16 it can be inferred from that, perhaps, sir, that he
 17 was a fan of or keen on computerisation of the
 18 Transfusion Service.
 19 Then we go down to (c) "Blood collection", and
 20 we learn from that that, at present in Oxford, there
 21 are mobile blood collection teams which carry out
 22 18 donor collections each week and the proposed
 23 increase will require an additional three and, in some
 24 weeks, four donor clinics.
 25 Then if we go over the page to page 3, at the

1 bottom of page 3 is a section 3 "Disposal of
 2 additional units of blood", it says there:
 3 "The Regional Transfusion Service has
 4 a reasonable balance, at present, with respect to
 5 blood collection and issues to hospitals. The
 6 collection of an additional 15,000 to 19,000 will
 7 affect this balance adversely and it is important that
 8 it is put to effective clinical use."
 9 Pausing there, sir, that is, again, one of the
 10 issues that we will see returned to, that once you
 11 increase the plasma for fractionation, what do you do
 12 with the balance of the blood, the red cells, and
 13 that's what Dr Gunson here is grappling with.
 14 "Out of the various possibilities the one that
 15 I recommend to the Regional Health Authority is that
 16 the Oxford [Blood Transfusion Service] assumes
 17 responsibility for the service of those hospitals in
 18 the East Berkshire [Area Health Authority], at present
 19 receiving their supplies of blood and blood products
 20 from the [North West] Thames [Blood Transfusion
 21 Service]. This line of action has several
 22 advantages", and he then sets those out and we don't
 23 need to go to that.
 24 So we can see there -- here this an example of
 25 Dr Gunson working out how he can improve and increase

1 his plasma supply for fractionation while making use
 2 of the balance of the blood, if I can put it that way,
 3 by taking over supply to other hospitals. I wanted,
 4 sir, to draw your attention to a paragraph that we
 5 find on page 4, just above where it says "Section 4
 6 Laboratory Offices":
 7 "I note that the hospitals in East Berkshire AHA
 8 (in particular, Wexham) receive a considerable supply
 9 of cryoprecipitate. This presumably arises from the
 10 unavailability of AHF concentrate in the [North West]
 11 Thames region. I hope that consideration will be
 12 given to their receiving a supply of concentrate
 13 should these proposals be accepted."
 14 So one of the themes or issues that the Inquiry
 15 will be looking at in the coming hearings is the
 16 extent to which, if at all, Regional Transfusion
 17 Centres had a hand in or an influence over the
 18 products that clinicians were using, and here
 19 Dr Gunson appears to be expressing a view about what
 20 might be an appropriate product, albeit in very
 21 general terms.
 22 On that theme, if we can return -- if we can
 23 look, please, at NHBT0000086_009, which is the
 24 document we looked at earlier, it's the HIV litigation
 25 education course, and we go to page 11 of that

1 document, we can see -- which I now can't find.
 2 (Pause)
 3 Sorry, it is page 15, that's why. So he's
 4 talking here about the functions of the work of the
 5 NBTS and he says, at that second paragraph:
 6 "Another core function of RTCs is to provide
 7 clinical advice to hospitals in all matters relating
 8 to transfusion medicine."
 9 So, sir, precisely what that means is something
 10 that the Inquiry will be considering. It's not clear
 11 but that's something that can be picked up with
 12 witnesses in oral hearings.
 13 Sir, I'm going to now turn to look at a document
 14 or two from Dr Gunson's time in Manchester, and just
 15 reminding ourselves that that's April 1980 to
 16 October 1988. I'm going to turn, first of all, to
 17 NHBT0020196.
 18 This is, as I understand it, a statement from
 19 Dr Gunson in the HIV litigation.
 20 So if we turn, please, to page 29, we can see at
 21 the bottom it's signed -- well, I can tell you that's
 22 Dr Gunson's signature, and dated, it looks like,
 23 11 January 1989, but there are references in the
 24 statement to June; so it may be that that is -- that
 25 says June. It's not very clear.

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

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

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

1 the [BPL] and generally from 1978 these were in
 2 proportion to the region's population."
 3 Then he says:
 4 "In order to monitor the targets we received
 5 monthly statements of the amount of plasma sent to the
 6 BPL had the quantities of products returned."
 7 Then he goes on to say, in addition to this:
 8 "... the DHSS statistical department at
 9 Blackpool received quarterly reports on a range of
 10 blood and plasma collection data from all RTCs and the
 11 results collated for all regions were returned."
 12 The Inquiry has been looking in -- trying to
 13 find this cohort of documents and investigations are
 14 still ongoing.
 15 Then if we go over to page 13, the last
 16 paragraph there:
 17 "Although the use of cryoprecipitate" --
 18 In fact, perhaps we read the paragraph above,
 19 actually:
 20 "From 1974, RTCs removed part of the plasma from
 21 donations of whole blood shortly after its collection
 22 and this was used, in addition to general clinical
 23 requirements, for the preparation of cryoprecipitate
 24 and for issue to BPL for fractionation into products.
 25 Nationally and also in the [North West] region, the

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1 centre itself between 1982 and 1984, when they moved
 2 into a new building, and then in 1985 to 1986, funding
 3 was provided for a plasmapheresis centre and a smaller
 4 one in Lancaster. We will see reference to that in
 5 some of the documents we look at later.
 6 Sir, I'm just going to look also at,
 7 DHSC0002195_044.
 8 This is a document note of a meeting that took
 9 place in September 1979, so shortly before Dr Gunson
 10 moved from Oxford to Manchester. It's a "Note of
 11 [a] meeting of an *ad hoc* group of Regional Transfusion
 12 Directors", and we can see on the attendee list it's
 13 attended by Dr Gunson.
 14 The reason I draw your attention to it, sir, is
 15 because it shows some insight into what certainly this
 16 group of people were discussing about choice of
 17 product in September 1979. We pick it up at the
 18 second paragraph:
 19 "It was reported that there was not universal
 20 acceptance by Directors of the proposition that blood
 21 products should be distributed by BPL proportionally
 22 to plasma supplied, but with some safeguards for
 23 Regions with special problems, eg Regions which
 24 treated Haemophiliacs from other Regions, it was felt
 25 that a distribution scheme on this basis would prove

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1 number of donations from which plasma was removed
 2 increased in numbers. In the latter part of 1983
 3 a nutrient solution became available so that it could
 4 be placed on the red cells after removal of all the
 5 plasma from the donation. This allowed a 50% increase
 6 of plasma to be obtained from each donation."
 7 We will see reference to that as one of the
 8 tools in the charge for self-sufficiency.
 9 He goes on:
 10 "Although the use of cryoprecipitate declined
 11 nationally between 1975 and 1985, the usage in the
 12 [North West] region remained high, as a result of the
 13 policies adopted by the Regional Haemophilia Service.
 14 Cryoprecipitate competed with plasma sent for
 15 fractionation so that the latter targets were not
 16 achieved. However, Factor VIII from cryoprecipitates
 17 was used to treat haemophilia patients and this
 18 supplemented the supplies of NHS and commercial
 19 Factor VIII concentrate. Details of the production of
 20 cryoprecipitate and plasma for fractionation are
 21 available at the RTC ..."
 22 He goes to say:
 23 "... although for some years the RTC supplied
 24 Lancaster with cryoprecipitate."
 25 Then he goes on to set out the changes to the

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1 generally acceptable."
 2 So we saw Dr Gunson earlier saying that the
 3 targets were set on the basis of population, and then
 4 here we see there being discussion about the blood
 5 products you receive back being pro rata effectively
 6 for the plasma that you provided, with some
 7 exceptions, for example for the area that served
 8 Lord Treloar's College, for example.
 9 Then if we miss out the next paragraph it goes
 10 on:
 11 "A tendency to revert to cryoprecipitate was
 12 discernible in some regions due, in part, to lack of
 13 money to buy commercial concentrate or to collect more
 14 plasma for fractionation at BPL. It was agreed that
 15 this was yet another example of the way in which the
 16 use of blood products and the development of blood
 17 product production was being distorted by the
 18 availability of products which were apparently 'free'.
 19 "Dr Tovey said that the NBTS was at a stage
 20 where it must be decided whether the service went
 21 forward as a truly national service, properly
 22 co-ordinated, or as a number of regional services each
 23 going their own way."
 24 It's noted Dr Lane put forward his views in
 25 a paper.

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1 Dr Bird then expresses a strong view:
2 "... that the NBTS should generate its own
3 revenue."
4 Then Dr Lane draws attention to the fact that:
5 "... supplies of fresh frozen plasma were
6 beginning to tail off in many regions. It was agreed
7 that this was not the result of any shortage of donors
8 but was generally due to shortage of money needed to
9 maintain the level of plasma supplies."
10 Notes that:
11 "Regional Health Authorities were not
12 sympathetic to requests by Directors for money to
13 finance plasma collection if they are not to receive
14 a proportional part of the finished factor VIII or PPF
15 in return."
16 So we can see there a suggestion that the use of
17 cryoprecipitate is, at least in some regions, thought
18 to be high because of a lack of money for either
19 buying commercial product or an ability to provide
20 plasma to BPL in order to receive products back.
21 I'm just going to draw your attention, sir,
22 to some of the comments -- or not comments, some of
23 the evidence, rather, that Dr Gunson gave in the
24 hepatitis litigation which paints his view of the
25 general picture facing the Blood Transfusion Service

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1 "Q. Sticking with England and Wales, if at any
2 rate that is the figure you have, about how many
3 donors does that represent?
4 "A. Something in the order or 1.5 to
5 1.6 million.
6 "Q. So on an average, an individual donor would
7 give blood slightly less often than twice a year?"
8 He says:
9 "Many donors give blood twice a year, but there
10 were some particularly commercial sites that we only
11 visited once a year because you could not disrupt the
12 work of the factory."
13 Then it goes on to question at 3939:
14 "Just to get an idea of sizes, about how many
15 donations would be collected by the largest of the
16 Centres?
17 "A. I think the largest Centre was undoubtedly
18 South London, and they collected something at that
19 time in the order of 250,000 donations a year."
20 The question:
21 "The smallest, I think --
22 "A. Something in the order of 80,000 to
23 100,000."
24 Then if we go over the page:
25 "Q. Just one other general question: what is

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1 while -- I presume -- it's a little bit clearer what
2 period he is talking about, but I presume while he was
3 working there, working full time, but it's a little
4 bit unclear.
5 If we can go, first of all, please to
6 NHBT0000143 and page 79 of that. So we can see that's
7 Thursday, 19 October 2000, so that's the date on which
8 Dr Gunson was giving evidence. He was giving
9 evidence, I think, for about five and a half days in
10 all. This was the first day of his evidence and if we
11 turn to page 79, if we go to line 3917, which is about
12 a third of the way down, so "Q" is the barrister
13 asking the question. He is being examined-in-chief at
14 this stage:
15 "Something which does not appear in your
16 statement, but is perhaps useful for the court to
17 have -- it has been given already informally by my
18 learned friend -- can we have in very round figures at
19 the relevant times how many donations per year were
20 made in England and Wales, or collected?"
21 It is little bit unclear what the relevant times
22 means. He says:
23 "In England and Wales it was roughly
24 2.5 million. The figures including Scotland was
25 3 million.

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1 the broad turnover in the donor population? How many
2 donors do you lose a year?
3 "A. From retirement, illness, donors moving
4 from one venue to another, it is something in the
5 order of 12 to 15 per cent per year.
6 "Q. People just getting busier and --
7 "A. And stopping, yes."
8 Then if we go, please, to NHBT0000146, it is at
9 page 95, this is Dr Gunson giving evidence on
10 24 October 2000, and if we go to the bottom of that
11 page, he is still being examined-in-chief, at this
12 stage, by his counsel Mr Underhill:
13 "Q. What you say in paragraph 20 is that the
14 blood supply within the service was a constant source
15 of concern and during the period with which we are [go
16 over the page] concerned here, you spent several hours
17 most days ensuring that blood supply met demand
18 throughout the country.
19 "Is that an exaggeration?
20 "A. No, it is not an exaggeration at all.
21 I spent a long time, and so did many other members of
22 the staff at the Directorate, trying to locate centres
23 who could supply blood to other centres, where there
24 was a shortage."
25 So we know here that he's talking about

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1 post-creation of the National Directorate:
 2 "The critical day, I have to tell you, in the
 3 week was Friday, when most of our time was spent on
 4 this activity, and it was made more difficult because
 5 even those centres who had a good stock of blood did
 6 not particularly want to give it away, in case they
 7 had emergencies they were unaware of come in during
 8 the weekend and they could find themselves then short,
 9 so it took a great deal of persuasion to obtain
 10 agreement to transfer blood from, say, Sheffield to
 11 London.
 12 "Q. Yes.
 13 "A. But the London centres all had
 14 difficulties, virtually, on a daily basis,
 15 particularly, I have to say, North London, where they
 16 have to supply a large number of teaching hospitals."
 17 Then the last passage, sir, is NHBT0000148_001,
 18 and this is evidence given on Thursday, 26 October,
 19 you can see at the top there, and this is during
 20 cross-examination.
 21 If we go to page 5, he gives some evidence about
 22 the supply in Manchester. If we go down to
 23 line 226 -- in fact, 221, we had better start at the
 24 question. Halfway through line 223:
 25 "... just give us a feel for how you say the
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1 problem of supply was between these years 1987 and
 2 1991, that sort of period?
 3 "A. Well, between 1987 and 1988 I was the
 4 director of the centre in Manchester and I was not the
 5 national director. Therefore I just ran a transfusion
 6 centre like my colleagues. We had considerable
 7 difficulties at certain times of the year,
 8 particularly during the school holidays and
 9 particularly around Christmas time, when we had
 10 a significant drop in donors, and it was always
 11 extraordinarily difficult then to catch up and there
 12 were several instances during that period, 1987/1988,
 13 that hospitals had to cancel routine surgery because
 14 there was insufficient blood available and this got
 15 into the press on a number of occasions."
 16 Then he says:
 17 "When I became the National Director, I
 18 established this system of having --"
 19 Then there's a discussion about when that was
 20 and he says down at 243:
 21 "I established a system whereby each transfusion
 22 centre sent me their stock levels for that day and any
 23 requests that they had for shortages of blood and we
 24 then, in the National Directorate, endeavoured to
 25 supply this blood from other centres and indeed from
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1 Scotland as well.
 2 "Q. Were you successful during that period?
 3 "A. During that period we were extremely
 4 successful. There was not, I do not think, one
 5 critical report in the press during the whole of the
 6 periods until 1993."
 7 Sir, then can we turn now to DHSC0002195_044.
 8 This is a document -- I think this is the document we
 9 just looked at.
 10 **SIR BRIAN LANGSTAFF:** I think, yes, it is.
 11 **MS SCOTT:** Forgive me. That's the document we just looked
 12 at. So let's not look at that again.
 13 Can we look now at DHSC0002207_040.
 14 Sir, this is -- I'm looking now at documents
 15 concerned with -- or parts of documents concerned with
 16 the drive towards self-sufficiency. This is
 17 a report -- or at the top of the page it calls itself
 18 a "Draft for discussion" of the -- for the Advisory
 19 Committee for the National Blood Transfusion Service
 20 Working Party to Advise on Plasma Supplies for
 21 Self-sufficiency in Blood Products in England and
 22 Wales", and can see, under "Membership of the Working
 23 Party", that includes Dr Gunson, and at the bottom of
 24 that page we can see that it is dated June 1981.
 25 If we go over to page 2, and at paragraph 2.1 we
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1 can see there that the "Requirement for Factor VIII"
 2 is set out. It says:
 3 "Representatives of the Haemophilia Directors
 4 estimate that by the mid-1980s the annual requirement
 5 for FVIII will reach 100 M units for the
 6 United Kingdom. Forecasting beyond that time could
 7 not be accurate but it was considered that by the
 8 1990s the need for FVIII could reach 150 M units per
 9 year."
 10 It then goes on to set out some requirements for
 11 albumin.
 12 Then at paragraph 3 it says:
 13 "It was agreed that the estimates for plasma
 14 supply should be based upon that required to produce
 15 100 M units. Although this total was estimated for
 16 the UK for the mid-1980s ... it was considered to be
 17 unnecessary to correct this for that required in
 18 Scotland or to consider a higher figure than this
 19 since estimates were vague for a longer period."
 20 Then we go over the page to page 4, where there
 21 is a discussion about the type of Factor VIII
 22 preparation required. So what is that 100 million
 23 units going -- sorry, to page 3. I beg your pardon.
 24 Thank you.
 25 How is that 100 million units going to be made
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1 up? It says there:
 2 "The Working Party has examined the various
 3 products available and considered the advantages and
 4 disadvantages of each, which are discussed in
 5 Appendix 1."
 6 It's just worth going to have a look at what is
 7 said at appendix 1. It's page 9 of the report and it
 8 sets out the different kinds of products provided and
 9 produced at the RTCs:
 10 "1. Fresh frozen plasma prepared at RTCs, and
 11 whilst it is a valuable source of coagulation factors
 12 it cannot play a part in the treatment of
 13 haemophilia A.
 14 "2. Frozen cryoprecipitate is presented for
 15 clinical use in the transfer pack in which it is
 16 prepared. It is prepared in RTCs but it is difficult
 17 to have a national programme based on this product
 18 because:
 19 "2.1 the high yield is not always attained in
 20 large-scale production ... lack of confidence in the
 21 FVIII content leads to over-ordering and waste.
 22 "2.2 there is a significant incidence of adverse
 23 reactions due to the presence of residual plasma.
 24 "2.3 the product is not convenient to store,
 25 transport and infuse particularly for home or

1 large pool, again of about 1,000 donations. Then it
 2 says:
 3 "Advantages over small pools are greater
 4 consistency of the product and are potentially more
 5 secure and a representative sample can be taken for
 6 quality control. However, a sterilising filtration is
 7 expensive in yield and 10% may be lost in rigorous
 8 quality control and the GMP problems are spin-freezing
 9 remain."
 10 Then over the two pages, please, to page 11, we
 11 then get:
 12 "intermediate purity concentrates ... begin with
 13 large-pool (500-5000 donations) cryoprecipitation of
 14 plasma ... plasma processed to give high potency ..."
 15 Then:
 16 "It has been estimated at BPL that approximately
 17 27% of the initial [Factor VIII] activity is lost in
 18 this preparation which does not occur in freeze-drying
 19 large pool cryoprecipitate. Methods being examined to
 20 reduce those losses."
 21 Then it goes to talk about high purity
 22 concentrate, further purification "expensive in
 23 yield".
 24 There is a table that accompanies this appendix,
 25 which we find at page 10, which sets out on the

1 self-therapy.
 2 "2.4 there are difficulties in ensuring adequate
 3 quality assurance and control."
 4 Sir, you've heard similar evidence from a number
 5 of haemophilia clinicians.
 6 "3. Freeze-dried cryoprecipitate:
 7 "3.1 Small pool (8-12 donations) is produced in
 8 the Central Laboratories as the primary FVIII product
 9 in Finland, Switzerland and the Netherlands. The aim
 10 is to obtain a high yield and minimum donor exposure.
 11 However, all production methods involve multiple
 12 aseptic connections without terminal sterilising
 13 filtration of the product and spin-freezing of
 14 a relatively dilute solution of FVIII before drying
 15 introduces intractable problems of hygiene and thus
 16 maintenance of good manufacturing practice ...
 17 required in the UK will be very difficult.
 18 "3.2 Large pool. Two approaches have been
 19 used.
 20 "(a) In Belgium, about 1,000 cryoprecipitates,
 21 prepared at RTCs, are transported to the fractionation
 22 centre, pooled aseptically without sterilising
 23 filtration, the pool dispensed in 50-100 ml volumes,
 24 spin frozen and freeze-dried."
 25 Then it sets out what the process is France of

1 left-hand side the different products and, across the
 2 top, pool size yield, et cetera, advantages and
 3 disadvantages. The reason I want to draw your
 4 attention to this, sir, is because there is only one
 5 reference in this document and, in fact, from the
 6 whole appendix, when looking at the advantages and
 7 disadvantages of the different products, to infection
 8 via transmission, and we see that at "Freeze-dried
 9 [cryoprecipitate] (b) large pool", and if you go over
 10 to the disadvantages we see there "GMP problems",
 11 which we've just seen in the text "Larger pool for HB
 12 transmission", hepatitis B transmission, and then the
 13 hygiene problems, sterilisation, and so on. So that's
 14 what that appendix says.
 15 So, if we then come back to page 3 of the
 16 document, where they are talking about types of
 17 Factor VIII preparation required, if we go halfway
 18 down:
 19 "It was agreed that, although the above
 20 proportions of the various products were not fully
 21 agreed they served as a good basis for the
 22 determination of plasma needs."
 23 They then set out that in total of the
 24 100 million units of Factor VIII, they would have
 25 10 million units of freeze-dried cryoprecipitate,

1 80 million of intermediate purity concentrate, and 10
 2 of high purity. Then they set out what the different
 3 yields are for the different product: freeze-dried
 4 cryoprecipitate, 350 units per kilo, then that reduces
 5 down to 90 for the high purity.
 6 Then at section 6 they discuss the amount of
 7 plasma that would be required in order to meet those
 8 targets and so, to get the 10 million units of
 9 freeze-dried cryoprecipitate, it involves
 10 28,500 kilograms of plasma; for the intermediate
 11 purity concentrate 350,000 kilograms; and for the high
 12 purity 110,000; making a total of 488,500 kilos, which
 13 they round up at the bottom, for an annual aim of
 14 500,000 kilograms of plasma.
 15 Then, over the page, they set out the methods of
 16 obtaining that. First of all, looking at the yield of
 17 plasma from donations of whole blood, and they set out
 18 there that, during 1980, just over 2 million donations
 19 of whole blood were collected by the RTCs and they go
 20 on to say that it's difficult to forecast the need for
 21 red cells in the mid-1980s, but the working party
 22 consider a total of 2.2 million donations was
 23 a reasonable estimate, and so -- and they estimate
 24 that plasma from 51 per cent of the donations could be
 25 separated within 18 hours, with adequate facilities

1 and staff, which will realise some 200,000 kilograms
 2 of plasma for fractionation. So 200,000 out of the
 3 500,000 from whole blood.
 4 Then they go on to look at how to produce the
 5 balance of the 300,000 kilograms of fresh plasma.
 6 First of all, increase the collection of whole blood,
 7 and they say there that that would require 5.5 million
 8 donations annually, which would inevitably lead to
 9 waste and the working party do not consider this to be
 10 a viable proposition. So that's the waste of the
 11 balance of the red cells, and so on.
 12 Then they go on to look at the introduction of
 13 plasmapheresis and set out the two different methods
 14 of plasmapheresis, manual and machine, and the
 15 advantages and disadvantages: manual is slower,
 16 machine is much faster and, at the bottom there:
 17 "The Working Party recommends that the balance
 18 of 300,000 Kg fresh plasma is collected by
 19 plasmapheresis. This will require the establishment
 20 of Plasmapheresis Centres in the regions and the
 21 recruitment of donor panels to service them. Machine
 22 procedures were, in general, preferred but manual
 23 pheresis could be undertaken in certain circumstances.
 24 Then the report concludes over the page at
 25 page 6, "Regional self-sufficiency":

1 "If it is assumed that the usage of Factor VIII
 2 concentrates will be pro-rata to population, the
 3 amounts of plasma to be collected by each region by
 4 plasmapheresis and the estimated number of
 5 plasmapheresis units is shown in Table 3. This
 6 assumes that 10,000 Kg (approximately) will be
 7 collected in an eight-bedded unit per year.
 8 "However, it is known that the use of FVIII is
 9 not the same in each region which will lead to
 10 anomalies. Thus some regions would have to expend
 11 large sums to achieve self-sufficiency while others
 12 could achieve this state relatively easily. Until
 13 self-sufficiency is reached, every region has an
 14 incentive to produce as much fresh plasma as possible;
 15 thereafter there is no incentive unless surplus plasma
 16 can be offered elsewhere with suitable financial
 17 recompensation. Also, the situation may arise where
 18 an RTC cannot provide sufficient plasma due to lack of
 19 facilities which cannot easily be remedied. It is
 20 clear that further consideration must be given to this
 21 aspect."
 22 Sir, I understand the reference there to every
 23 region having an incentive to produce as much fresh
 24 plasma as possible until self-sufficiency is reached
 25 to be a reference to regional self-sufficiency, not

1 national self-sufficiency.
 2 Sir, I note the time. Is --
 3 **SIR BRIAN LANGSTAFF:** Yes. Well, self-sufficiency across
 4 the board I think is what it could be meaning,
 5 couldn't it?
 6 **MS SCOTT:** The incentive for the region to produce plasma
 7 is because they will get back pro rata what they give.
 8 Once they have made enough --
 9 **SIR BRIAN LANGSTAFF:** I follow the point.
 10 **MS SCOTT:** Yes.
 11 **SIR BRIAN LANGSTAFF:** It doesn't much matter because the
 12 view is the same that, unless and until there's enough
 13 produced in each region, that there won't be any
 14 incentive or there won't be an achievement of
 15 self-sufficiency across the board.
 16 **MS SCOTT:** Yes. Sir, would now be a convenient time for
 17 a break?
 18 **SIR BRIAN LANGSTAFF:** Yes, it would. So we will meet
 19 again then at 3.50.
 20 **(3.22 pm)**
 21 **(A short break)**
 22 **(3.50 pm)**
 23 **MS SCOTT:** Sir, the next document I want to take you to is
 24 DHSC0002211_030. It's a supplement to the report that
 25 we looked at before and my understanding is that it

1 was provided for a meeting that took place in
 2 September 1981, and just on -- if we go over to
 3 page 2, paragraph 1, since the last report that -- the
 4 Haemophilia Centre Directors have said that the
 5 quantity of cryoprecipitate had been over-estimated,
 6 and so they've reduced the amount of plasma required
 7 down to 435,000 kilos, which can be processed to
 8 provide 95 million international units of intermediate
 9 concentrate and 5 million international units of
 10 cryoprecipitate at current yield.
 11 So that's the figure they are working from.
 12 I just wanted to draw your attention, sir, to page 4
 13 of the report. Pages 2 and 3 set out how they get to
 14 the figures at the page 4. I don't think we need to
 15 go through the detail but "Summary and Conclusions",
 16 they set out in the report how much it will cost to
 17 produce the 435,000 units -- kilograms of plasma via
 18 the different processes that they looked at in the
 19 first report. Processing cost of doing it via whole
 20 blood, so your 200 kilograms of plasma from whole
 21 blood plus your 235 kilograms from whole blood,
 22 discarding the red cells, will cost you £28.1 million.
 23 So it seems that the discarding of the red cells is
 24 an expensive process.
 25 Cost of producing a balance of 235,000 kilograms

1 by machine pheresis is 19.1 million and the cost of
 2 the producing it by manual pheresis is 17.3 million.
 3 **SIR BRIAN LANGSTAFF:** The significant figures are really
 4 not the headline figures but they are the difference
 5 between.
 6 **MS SCOTT:** Indeed.
 7 **SIR BRIAN LANGSTAFF:** Getting out of the whole blood
 8 donations that's 20.6, machine pheresis is almost half
 9 that, 11.6, and less than half the original by manual
 10 pheresis, 9.8.
 11 **MS SCOTT:** Indeed. Then at the bottom of that page, it
 12 says:
 13 "Apart from the ethical considerations of
 14 discarding red cells from whole donations and the
 15 difficulties that will be encountered in recruiting
 16 sufficient donors, this option would be prohibitively
 17 expensive. From the data analysed, manual pheresis
 18 seems to be the most economical way to achieve the
 19 required plasma volume. It is significant in this
 20 regard that commercial manufacturers of blood products
 21 use manual plasmapheresis to obtain their raw
 22 material."
 23 Then if we go over to page 5, we can see what
 24 the committee are recommending at the bottom. It says
 25 there:

1 "The ADVISORY COMMITTEE is asked to approve the
 2 supplementary report to AC(81)11 and to seek
 3 Ministers' agreement with respect to consultation with
 4 RHAs with a view to determining the supply levels of
 5 plasma for the redeveloped BPL. The Advisory
 6 Committee is also asked to consider the future role of
 7 the Working Party with respect to discussions with
 8 RTDs on the supply of plasma and a consideration in
 9 detail of the plasma requirements for the preparation
 10 of specific immunoglobulins."
 11 That seems to be the position in September 1981.
 12 We can see that when we trace the documents through
 13 that indeed the Advisory Committee did approve the
 14 supplementary report, we can see that and we don't
 15 need to go to it, DHSC001136 -- sorry, 0001136, and
 16 they did indeed agree to consultation with the
 17 Regional Health Authorities.
 18 I'm going to take you now, sir, to a document in
 19 October 1983, so two years on. It's NHBT0001066_004.
 20 This is a document, it's entitled "Departmental
 21 Memorandum", so we can see it is from Dr Gunson to
 22 Dr Acheson, the CMO, dated 18 October 1983. So we can
 23 understand, I think, probably from the fact that it's
 24 a departmental memorandum, that this must be
 25 Dr Gunson, as Consultant Adviser to the CMO, providing

1 his views to the CMO.
 2 It's entitled "Subject -- Speciality: Blood
 3 Transfusion; Five Years Back and Five Years Forward".
 4 So he sets out an introduction and he sets out some
 5 history at the beginning of that page, and then, at
 6 the second half of the page, in a paragraph:
 7 "It would be useful to review the developments
 8 which have taken place in the use of these products.
 9 "Red cell concentrates. Clinical acceptance of
 10 this product has been subjected to some controversy
 11 since in order to provide sufficient plasma for
 12 fractionation, the red cell concentrates have to be
 13 administered to certain patients suffering from blood
 14 loss."
 15 Then picking up at the bottom of that page:
 16 "The principle involved is to remove as much
 17 plasma from the donation as possible and replace part
 18 of this with a solution of saline, adenine, glucose
 19 and mannitol or sorbitol. The resultant red cells can
 20 be stored for up to 35 days and their administration
 21 is facilitated. This approach also has the benefit
 22 that from an individual donation of whole blood,
 23 50 per cent more plasma can be obtained."
 24 Then he goes on to talk about platelet
 25 concentrates and the -- he says:

1 "The use of an increasing pharmacopoeia of
 2 chemotherapeutic agents has resulted in patients
 3 suffering from leukaemia and certain other
 4 malignancies requiring supportive therapy for longer
 5 periods. One problem with this product is that it has
 6 had a self-life of only three days and with variable
 7 demand it has been difficult to either avoid wastage
 8 or meet demands. During the past two years new
 9 plastics have been developed which allow the storage
 10 period to be extended to five days. Whilst this will
 11 be a benefit, the increasing demand for this product
 12 is causing problems at present and alternative methods
 13 for the preparation of platelet concentrates will have
 14 to be considered, particularly with the increase in
 15 such procedures as bone marrow transplantation."
 16 So, again, another sort of technical advance,
 17 which has made a difference to the blood service.
 18 **SIR BRIAN LANGSTAFF:** By new plastics it means plastic
 19 bags, does it, to contain it?
 20 **MS SCOTT:** That's my understanding. I may be corrected by
 21 another witness but that's my understanding.
 22 Then:
 23 "With regard to Factor VIII concentrate there
 24 has been an increasing production of this material at
 25 the Blood Products Laboratory from plasma collected

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1 developments occurring in the field of blood
 2 transfusion, some of which will be referred to below,
 3 I think the major advance that can be made is to
 4 achieve self-sufficiency in blood products for the
 5 UK."
 6 Then he sets out the implications for the
 7 service of self-sufficiency, and then he goes on below
 8 (2):
 9 "In order to achieve this goal, investment will
 10 be required, but it is important that advantages are
 11 taken of recent developments to minimise this."
 12 So he speaks about the role of the additive
 13 solution in increasing plasma collection. He then
 14 talks at 2.2 about the use of plasmapheresis, which
 15 was what we see his committee -- what we saw his
 16 committees championing two years previously, in 1981:
 17 "Although this is used in the Transfusion
 18 Service at present on a small scale, largely for
 19 donors whose plasma contains a high titre of specific
 20 antibodies, it is by view that in order to obtain
 21 sufficient plasma for self-sufficiency in fractionated
 22 products, without excessive blood collection and
 23 wastage of red cells, plasmapheresis will be needed."
 24 Then he explains that that will be costly, in
 25 the next two paragraphs, and equipment will be

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1 Regional Transfusion Centres during the past five
 2 years. At present approximately 40 per cent of the
 3 Factor VIII used it derived from this source; the
 4 remainder is purchased from commercial firms and their
 5 products are imported largely from the USA."
 6 Then it mentions Factor IX concentrate and
 7 immunoglobulins and albumin. Then, at the bottom of
 8 that page, it comes on to disease transmission:
 9 "Certain products have always carried the danger
 10 of transmission of hepatitis. With the introduction
 11 of sensitive screening tests on all donations, e.g. by
 12 radio-immune assay, the incidence of hepatitis B has
 13 been reduced, although not eliminated. The
 14 administration of the vaccine to high risk groups may
 15 also assist in this regard. However, the problem of
 16 non-A, non-B hepatitis remains and there is now the
 17 potential transmission of AIDS, about which I spoke at
 18 the last consultant Advisers' Meeting."
 19 So it is clear that Dr Gunson has been keeping
 20 Dr Acheson -- or been providing advice to him about
 21 AIDS by October 1983.
 22 Then can we go over the page then, please, to
 23 page 3 and we see what Dr Gunson says about the next
 24 five years:
 25 "Whilst I think there will be several

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1 required. Then he goes on to say:
 2 "It will be an advantage when all blood products
 3 can be derived from the UK donor population.
 4 Nevertheless, the transmission of non-A, non-B
 5 hepatitis, particularly from the products derived from
 6 pooled plasma will still be a problem in groups of
 7 patients, such as haemophiliacs, who receive these
 8 products regularly. I expect from the work which is
 9 now being carried out, that by the time five years has
 10 elapsed, a diagnostic test [will] be available."
 11 **SIR BRIAN LANGSTAFF:** "... may be available."
 12 **MS SCOTT:** "... may be available."
 13 I beg your pardon, yes.
 14 "However, in the meantime, we must examine ways
 15 in which in certain groups of patients exposure to the
 16 minimum number of donors can be effected. With
 17 respect to AIDS, it is too early to anticipate the
 18 effects in the UK, but it is important that every
 19 opportunity is taken to investigate possible ways in
 20 which the blood donor population can be screened."
 21 Then he goes on to talk about on an
 22 organisational level. He says:
 23 "On the organisational level, there has been
 24 a noticeable degree of collaboration between the
 25 Regional Transfusion Centres in recent years and there

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1 are now an increasing number of functions which are
 2 nationally based rather than regionally."
 3 He says:
 4 "The supply of plasma, referred to above, is
 5 one ..."
 6 Just pausing there, it's right that we've seen
 7 the supply of plasma being expressed as a national
 8 figure, but of course we still have regional funding
 9 and the difficulties that -- and I'm going to come on
 10 and look at some documents now which show it is
 11 difficulties that that gives rise to.
 12 So if we can look then at CBLA0001800, which is
 13 a report to the CBLA by Dr Gunson, and we can see at
 14 bottom there it's dated January 1984, and he explains
 15 that he had a meeting in June 1983 with Regional
 16 Transfusion Directors to discuss plasma targets and
 17 the results were encouraging and that they thought at
 18 that time that they would be able to meet the targets
 19 and get financing.
 20 Then he goes on in the second paragraph to
 21 explain that:
 22 "During the latter part of 1983 ... informal
 23 comments from some RTDs gave cause for concern in that
 24 the targets which had been agreed as a planned
 25 programme were in jeopardy because of difficulties in

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1 quantity [I think that says] of Factor VIII required."
 2 I think that that last sentence is the key part
 3 to that paragraph 2, and:
 4 "It is doubtful whether the quantity of plasma
 5 in 1984/5 will exceed that of the current year."
 6 So that's the position and the concern that has
 7 arisen in January 1984, despite six months previously
 8 Regional Transfusion Centres being optimistic that
 9 they would be able to meet their targets.
 10 If we can then turn to a report that Dr Gunson
 11 wrote in February 1984 arising out of this, and that's
 12 DHSC0001967.
 13 We can see at the top:
 14 "Plasma supply for self sufficiency in blood
 15 products.
 16 "Analysis of options by HH Gunson.
 17 "Supplement to report to CBLA ... [made] on
 18 25th January, 1984."
 19 If we go to the bottom of page 2, we can see
 20 that it's dated 13 February 1984.
 21 Then if we go back to page 1, he says:
 22 "My conclusions following a survey of RTCs was
 23 that it was unwise to assume at the present time that
 24 a sufficient quantity of plasma will be available for
 25 the successful operation of the new BPL."

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1 obtaining the necessary funds."
 2 So he wrote to the RTDs in December 1983, and he
 3 goes on in the next paragraph to explain that only
 4 three of the RTDs are confident that their RHA will
 5 support the programme for increasing the plasma
 6 supply.
 7 The remaining replies range between not hopeful
 8 or the necessary finance to an inability to predict
 9 the outcome of discussions with the RHA.
 10 Then he sets out factors of significance:
 11 "(1) Many RHAs are not willing to consider
 12 proposals on more than a year by year basis. Plans
 13 for the plasma supply require a programme based on
 14 a three to five year period.
 15 "(2) Several regions are finding that with the
 16 current national plasma supply of 150,000 Kg per year,
 17 the demand for PPF is satisfied ..."
 18 I'm not quite sure what that says:
 19 "... apparently so, since in my view,
 20 insufficient time has passed with the increased supply
 21 of PPF to make a valid judgment."
 22 I'm not quite sure what that says.
 23 "... conclusion, however, has led to the view
 24 that the most economical way to achieve
 25 self-sufficiency is to purchase the additional

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1 So he gives considerations to the options which
 2 may be available.
 3 So the first option is to:
 4 "Pursue the present policies of encouraging RTDs
 5 to apply to their RHAs for finance for the increase in
 6 plasma supply with the assistance of Dr Lane and
 7 Mr Armour where this is appropriate."
 8 He goes on to say in that next paragraph:
 9 "This approach could be supplemented by
 10 additional advice from the DHSS."
 11 But he concludes:
 12 "... this has already been tried and although
 13 most RHAs agreed in principle, few have actually
 14 allocated finance for the purpose of the additional
 15 supply of plasma."
 16 Then, second option:
 17 "The CBLA scheduling assume managerial
 18 responsibility for the entire work of the RTCs."
 19 He thinks this has "considerable merit" because
 20 it would lead to a true national service, with
 21 a greater degree of standardisation, but goes on to
 22 conclude at that second paragraph that:
 23 "From a practical point of view ... the
 24 necessary administrative infrastructure could not be
 25 achieved by 1986 when the new BPL is due to be in full

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1 production."
 2 So he comes up with what might be described as
 3 a hybrid option at option 3, which is the option that
 4 he plumps for, which is that the CBLA should finance
 5 the collection of plasma in excess of that harvested
 6 by the ... (RTCs) in 1983/4. This would require
 7 funding for the collection of approximately
 8 300,000 litres of plasma annually."
 9 He describes it as a "promising option", and:
 10 "Each RTC would be assessed with respect to its
 11 potential for producing plasma and the necessary
 12 financing agreed. Regional Health Authorities could
 13 purchase from the CBLA the products which they
 14 require ..."
 15 Then he goes over the page to set out that he
 16 doesn't underestimate the difficulties that that would
 17 involve because:
 18 "RTCs would be acting on an agency basis for the
 19 CBLA and there would have to be accountability for
 20 investment", and so on.
 21 "A proportion of the plasma would have been paid
 22 for by the RHAs and the products derived from those
 23 would have to be supplied on a different basis from
 24 those derived from plasma financed by the CBLA."
 25 Then the issue of clinical freedom, which may

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1 For reasons of time, I'm going to pick the story up,
 2 in broad terms, once he becomes the National Director
 3 in 1988, not by reference to any documents but we can
 4 see in the documentation, in the minutes of the
 5 meetings that he attends as National Director, indeed
 6 the first minute of a first meeting he attends as
 7 National Director, that, unsurprisingly,
 8 self-sufficiency is high on the agenda and the steps
 9 that he can take in his new role.
 10 Of course, one of the key policy decisions that
 11 was made was in relation to cross-accounting, which
 12 was -- came in on 1 April 1989, whereby BPL bought
 13 plasma from the Regional Transfusion Centres and then
 14 Regional Transfusion Centres could charge hospitals
 15 for the products that they produced, and I'm just
 16 going to refer you to one document which shows that
 17 there is a difference in the way that was applied by
 18 different areas, and we can see that at NHBT0007355.
 19 It's a minute of a meeting on 10 August 1989,
 20 NBTS, CBLA liaison committee and if we turn over to
 21 page 4 we can see at paragraph 5 that it's reported
 22 that:
 23 "... differences between regions on whether or
 24 not product costs were passed on to District users was
 25 leading to confusion. Where costs were passed on to

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1 result in the continuation of purchases of blood
 2 products from commercial firms.
 3 That is a theme that we will see in some of the
 4 documents, undoubtedly as we go through the hearings,
 5 that the principle of clinical freedom raises
 6 a concern to the blood service because, while there
 7 may be BPL product available, clinicians may choose
 8 not to use it.
 9 He says:
 10 "Despite the problems I submit that this option
 11 is worthy of consideration ..."
 12 Then at the bottom of that document he discounts
 13 the option of purchasing plasma from the United States
 14 to fill the gap left by the national supply.
 15 So that is the position that Dr Gunson is
 16 advancing in February 1984. I think it might be
 17 a suitable time, sir, now, to play the -- we've got
 18 a couple of extracts from the World in Action
 19 documentary, entitled *Bad Blood*, which aired on
 20 22 July 1985, in which Dr Gunson is asked some
 21 questions.
 22 *(Video played)*
 23 Sir, in the written presentation there it traces
 24 through a number of other documents, the story, if you
 25 like, of self-sufficiency in relation to Dr Gunson.

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1 Districts, commercial suppliers were sometimes being
 2 considered as alternatives to BPL. Dr Moore expressed
 3 the hope that following a meeting of Regional
 4 Transfusion *[sic]* representatives on 8th May, a common
 5 policy of Regions absorbing all cost and supplying
 6 'free' product to districts would be adopted. In some
 7 cases however it was difficult for Regions to claw
 8 back from District budgets money previously
 9 allocated."
 10 So that, I suspect, is an issue that we will be
 11 coming back to in forthcoming hearings.
 12 I just want to pick up some correspondence from
 13 1990, NHBT0015646 between Dr Gunson and Marcela --
 14 Dr Contreras or Professor Contreras, 31 May 1990,
 15 "Dear Harold, National self-sufficiency in blood and
 16 blood derivatives", and she says there:
 17 "I am writing on behalf of the Eastern Division
 18 of Consultants ... following [their] meeting on ...
 19 24 May 1990."
 20 She says:
 21 "Members of the Division expressed their
 22 dissatisfaction about the lack of interest of the
 23 Department of Health in self-sufficiency. It was
 24 stated that it is not enough to say that 'ministers
 25 are committed to self-sufficiency' if this is not

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1 backed by actions and financial support. We firmly
 2 believe that the time has come to reassess the
 3 situation regarding self-sufficiency. Members of the
 4 Division feel strongly that there is no reason why the
 5 plasma donated voluntarily by British donors should
 6 not go back to British patients. There are very good
 7 ethical and financial reasons for the encouragement of
 8 self-sufficiency. Why should we be paying twice for
 9 albumin and clotting factor concentrates? We are
 10 paying the commercial companies for imported products
 11 and at the same time are spending vast sums of money
 12 in apheresis and routine blood collection, as well as
 13 in the sophisticated running of BPL. Isn't it about
 14 time the Department made up its mind that the only way
 15 to succeed in self-sufficiency is by subsidising BPL?
 16 "If we continue with current practices, we will
 17 be cutting our own throats. We already have the
 18 precedent of BPL competing with a Regional Transfusion
 19 Centre for the supply of products to a particular
 20 hospital, with BPL undercutting the 'NBTS discounted
 21 price'. We feel that it might be too late to turn the
 22 clock backwards. As core providers within the NHS, we
 23 feel that the NBTS should be excluded from charging.
 24 "I have been asked to tell you that consultants
 25 in the Division are willing to go public on the issue

1 agreement is, in most instances, working well. Also,
 2 although it is early in the financial year, it will be
 3 pointed out that the supply of albumin to hospitals is
 4 above target.
 5 "If one targets Factor VIII (or even albumin) as
 6 a product which is not being used in quantities which
 7 are available from BPL, the argument will be put
 8 forward that the DH cannot interfere with clinical
 9 freedom and since we are not a totalitarian state no
 10 person can be forced to use a particular product.
 11 "If in the coming months it is apparent that
 12 there is an increasing stockpile of products at BPL
 13 and no action is being taken to ensure their
 14 distribution to hospitals for use, then I would agree
 15 that this should be brought to public attention. To
 16 do so now I think would be counter-productive and
 17 I hope that the members of the Eastern Division will
 18 agree with this conclusion."
 19 So just before we finish, sir, just to draw out
 20 some of the themes in this piece of correspondence, it
 21 seems that Professor Contreras is raising concerns
 22 that the cross-accounting that, as I understand
 23 that -- the process of cross-accounting has
 24 effectively put Regional Transfusion Centres in direct
 25 competition with BPL for -- in terms of providing

1 of self-sufficiency and are even prepared to stage
 2 a parliamentary lobby campaign. I would be grateful
 3 if could reply within the next two weeks."
 4 The reply from Dr Gunson can be seen at
 5 NHBT0015645. It is dated 13 June 1990, and it says:
 6 "If this matter were made public at the present
 7 time, in my view the scenario is likely to be as
 8 follows:
 9 "The Department will reiterate that Ministers
 10 are in full support of self-sufficiency and illustrate
 11 this by citing the recent Executive letter ..."
 12 For those that want to look at that it is
 13 DHSC0003978_009. We don't need to look at that now
 14 but that's the reference for it.
 15 "They will point out also that financing has
 16 been provided for RTCs to collect the required
 17 quantity of plasma to provide sufficient products to
 18 achieve self-sufficiency. Moreover, they have told
 19 BPL to make every effort to ensure that their products
 20 are the preferred product for use in the NHS.
 21 "It is true that when we asked for a financial
 22 supplement for either the cost of plasma or for BPL,
 23 the Department refused on the grounds that they were
 24 not convinced that this was necessary at the present
 25 time and evidence will be cited that the National

1 products to hospitals, and she also raises the concern
 2 about that cost to Regional Transfusion Centres from
 3 effectively having to pay twice for product, once
 4 through the functions of the RTC by collecting blood
 5 through whole blood collections and plasmapheresis
 6 and, secondly, because they then don't get enough
 7 product back from BPL and have to buy in commercial
 8 products.
 9 Dr Gunson seems to be raising a slightly
 10 different issue, and it's a little unclear to me how
 11 he gets to that from Professor Contreras' letter, but
 12 he seems to be raising an issue in relation to
 13 a stockpiling of product by BPL and that one of the
 14 reasons why -- perhaps why regions are not receiving
 15 the product that they need is because of stockpiling.
 16 So that is likely to be an issue that we will need to
 17 come back to in the forthcoming hearings.
 18 **SIR BRIAN LANGSTAFF:** Does he say there is actually
 19 stockpiling taking place at the present?
 20 **MS SCOTT:** No, he doesn't say that, but he seems to raise
 21 it himself. It seems to be something that he has
 22 raised himself as potentially a reason.
 23 **SIR BRIAN LANGSTAFF:** He may be perhaps addressing the
 24 questions of the internal market which Dr Contreras
 25 raises, saying that the internal market means that one

1 supplier is compared to another on price by saying
 2 that, "Well, if it's the case that BPL products are
 3 not accepted, then obviously at the production levels
 4 which it's required it will build up a stockpile."
 5 **MS SCOTT:** Yes.
 6 **SIR BRIAN LANGSTAFF:** Once it does that, then that should
 7 be brought to public attention. In other words,
 8 you're putting public pressure on the market to do
 9 what you want.
 10 **MS SCOTT:** Yes. It's slightly -- I suppose the point
 11 I wanted to make is it's slightly odd to talk about it
 12 in those terms when Professor Contreras seems to be
 13 saying: we're having to buy commercial products
 14 because we're not getting the product that we want --
 15 enough of the product that we want from BPL. In other
 16 words, there's a lack of product coming from BPL,
 17 which is forcing us to purchase commercial
 18 concentrate.
 19 She uses the phrase -- she talks in terms of
 20 having to --
 21 **SIR BRIAN LANGSTAFF:** Is she doing that or is she really
 22 complaining about the problems created by the internal
 23 market? That is, that there are suppliers competing
 24 with each other on price and BPL is not necessarily
 25 succeeding and yet they are supplying BPL with plasma?

1 **MS SCOTT:** I think she is doing both of those things, but
 2 she says in terms: why should we be paying twice?
 3 **SIR BRIAN LANGSTAFF:** Twice. That is, paying the costs of
 4 plasma collection.
 5 **MS SCOTT:** Yes.
 6 **SIR BRIAN LANGSTAFF:** And paying for some other product.
 7 **MS SCOTT:** Yes.
 8 **SIR BRIAN LANGSTAFF:** Then the answer given to that by
 9 Dr Gunson -- I'm not expressing any view upon the
 10 merits of these different points of view, just trying
 11 to identify what they are because, I agree with you,
 12 I don't think it's entirely clear. But it may be that
 13 what he is saying is: well, if we do raise this, as
 14 you're threatening to do by the consultants raising
 15 a public awareness, going to the press or whatever
 16 about it, these are the answers which I think the
 17 Department's going to give and, amongst other things,
 18 they will say, well, you can't tell the clinicians
 19 what product to use if they think there's something
 20 better that their patients should have.
 21 **MS SCOTT:** Yes.
 22 **SIR BRIAN LANGSTAFF:** Or something different their
 23 patients should have.
 24 **MS SCOTT:** Yes.
 25 **SIR BRIAN LANGSTAFF:** So I think we can look at these at

1 leisure and work out perhaps what the dispute is
 2 really about, and perhaps evidence will help us, from
 3 Dr Contreras, I expect -- Professor Contreras now.
 4 **MS SCOTT:** Yes.
 5 So, sir, those are the last documents I wanted
 6 to draw your attention to in relation to
 7 self-sufficiency. Tomorrow I'm going to deal with the
 8 issues of testing for HIV and hepatitis C and then
 9 a handful of very short topics.
 10 **SIR BRIAN LANGSTAFF:** Yes. Let's break now then and come
 11 back tomorrow at 10.00. 10.00. Thank you.

12 (4.26 pm)

13 (Adjourned until 10.00 am the following day)

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2 **I N D E X**

3 Presentation by Counsel to the Inquiry on 1

4 Professor John Cash

5 Presentation by Counsel to the Inquiry on 98

6 Dr Harold Gunson

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<p>MS RICHARDS: [15] 1/13 36/13 36/19 52/24 53/7 53/24 54/3 54/7 77/9 78/3 78/7 92/3 92/13 98/5 98/8</p> <p>MS SCOTT: [26] 98/15 105/2 105/7 105/13 116/5 116/9 116/15 116/19 135/11 144/6 144/10 144/16 144/23 146/6 146/11 149/20 152/12 164/20 165/5 165/10 166/1 166/5 166/7 166/21 166/24 167/4</p> <p>SIR BRIAN LANGSTAFF: [42] 1/3 36/8 36/18 52/20 53/6 53/12 53/25 54/4 77/3 78/2 78/6 92/1 92/9 98/1 98/6 98/12 104/25 105/3 105/12 116/2 116/7 116/10 116/16 135/10 144/3 144/9 144/11 144/18 146/3 146/7 149/18 152/11 164/18 164/23 165/6 165/21 166/3 166/6 166/8 166/22 166/25 167/10</p> <p>'76 [3] 116/3 116/14 116/18</p> <p>'77 [1] 116/3</p> <p>'82 [1] 105/6</p> <p>'burying [1] 65/21</p> <p>'consensus [1] 81/2</p> <p>'disaster [1] 79/20</p> <p>'free [2] 128/18 160/6</p> <p>'in [1] 39/9</p> <p>'infectious [1] 40/13</p> <p>'join [1] 18/15</p> <p>'known [2] 21/7 90/4</p> <p>'look [8] 87/9 87/11 88/2 88/18 92/17 94/19 95/6 95/11</p> <p>'look-back [3] 87/9 87/11 95/6</p> <p>'ministers [1] 160/24</p> <p>'mischievous [1] 57/16</p> <p>'missed [1] 90/9</p> <p>'NBTS [1] 161/20</p> <p>'non [1] 9/3</p> <p>'non-A [1] 9/3</p> <p>'Patients [1] 68/8</p> <p>'Research [1] 39/10</p> <p>'science [1] 42/3</p> <p>'second [1] 51/5</p>	<p>'sensitive [1] 40/2</p> <p>'shambles [1] 56/6</p> <p>'start [3] 46/9 46/11 46/17</p> <p>'stickiness [1] 41/23</p> <p>'the [1] 16/9</p> <p>'towards [1] 30/11</p> <p>'unilaterally [1] 15/15</p> <p>'What [1] 33/9</p> <p>.</p> <p>... [9] 20/23 21/11 50/4 111/25 125/8 126/23 137/20 153/22 156/23</p> <p>... although [1] 126/23</p> <p>... the [1] 125/8</p> <p>/</p> <p>/ribavirin [1] 94/10</p> <p>0</p> <p>0001136 [1] 147/15</p> <p>001 [2] 26/15 133/17</p> <p>002 [1] 99/9</p> <p>0026 [1] 91/22</p> <p>003 [3] 27/13 65/13 113/5</p> <p>004 [1] 147/19</p> <p>006 [1] 43/5</p> <p>007 [1] 87/2</p> <p>009 [4] 103/24 111/14 120/23 162/13</p> <p>010 [2] 3/4 109/7</p> <p>011 [1] 19/9</p> <p>012 [1] 19/15</p> <p>014 [1] 54/11</p> <p>015 [1] 19/17</p> <p>016 [1] 28/14</p> <p>019 [1] 55/22</p> <p>024 [2] 57/23 59/5</p> <p>026 [1] 92/2</p> <p>028 [1] 87/18</p> <p>030 [1] 144/24</p> <p>031 [1] 57/2</p> <p>033 [1] 44/9</p> <p>039 [1] 59/13</p> <p>040 [1] 135/13</p> <p>044 [2] 127/7 135/7</p> <p>053 [1] 49/4</p> <p>061 [1] 67/3</p> <p>063 [1] 47/7</p> <p>065 [1] 50/13</p> <p>1</p> <p>1 April 1989 [1] 159/12</p> <p>1 December 2011 [1] 85/2</p> <p>1 July [2] 47/16 48/24</p> <p>1 July 1991 [1] 52/11</p> <p>1 October [1] 30/5</p> <p>1 October 1989 [1]</p>	<p>30/5</p> <p>1 September [1] 53/20</p> <p>1 September 1987 [1] 16/12</p> <p>1,000 [2] 138/20 139/1</p> <p>1,900 [1] 64/12</p> <p>1-3 [1] 24/6</p> <p>1.04 pm [1] 98/9</p> <p>1.5 [1] 131/4</p> <p>1.6 million [1] 131/5</p> <p>10 [5] 42/17 48/1 139/7 139/25 141/1</p> <p>10 August 1989 [1] 159/19</p> <p>10 June [1] 10/18</p> <p>10 June 1991 [1] 65/12</p> <p>10 million [2] 140/25 141/8</p> <p>10,000 Kg [1] 143/6</p> <p>10,000 litres [1] 117/16</p> <p>10.00 [4] 1/2 167/11 167/11 167/13</p> <p>10.50 [1] 1/8</p> <p>10.52 [1] 36/10</p> <p>100 [1] 51/1</p> <p>100 M [2] 136/5 136/15</p> <p>100 million [3] 136/22 136/25 140/24</p> <p>100,000 [2] 123/10 131/23</p> <p>102 [1] 39/20</p> <p>11 [7] 74/12 102/22 104/6 120/25 124/8 139/10 147/2</p> <p>11 January 1989 [1] 121/23</p> <p>11 January 2012 [1] 85/5</p> <p>11 May [1] 62/11</p> <p>11 November [1] 1/4</p> <p>11 November 2021 [1] 1/1</p> <p>11.00 [1] 1/7</p> <p>11.25 [2] 36/9 36/9</p> <p>11.33 [1] 36/12</p> <p>11.6 [1] 146/9</p> <p>110,000 [1] 141/12</p> <p>12 [3] 124/8 132/5 138/7</p> <p>12 January 1990 [1] 19/8</p> <p>122 [2] 16/11 39/15</p> <p>123 [1] 39/1</p> <p>127 [1] 39/18</p> <p>13 [1] 125/15</p> <p>13 February 1984 [1] 155/20</p> <p>13 June 1990 [1]</p>	<p>162/5</p> <p>130 [1] 115/12</p> <p>133 [1] 51/24</p> <p>14 May [1] 26/14</p> <p>14 May 1991 [1] 62/7</p> <p>144 [1] 62/6</p> <p>15 [1] 121/3</p> <p>15 February 1991 [1] 46/3</p> <p>15 per cent [1] 132/5</p> <p>15,000 [1] 119/6</p> <p>150 M [1] 136/8</p> <p>150 per cent [1] 117/19</p> <p>150,000 Kg [1] 154/16</p> <p>15th February [1] 50/20</p> <p>16 [1] 99/9</p> <p>16 November 1981 [1] 101/7</p> <p>16 November 2011 [1] 84/15</p> <p>17 [1] 33/3</p> <p>17 December 1987 [1] 17/6</p> <p>17 January 2012 [1] 85/9</p> <p>17 June [1] 5/6</p> <p>17 October [1] 29/3</p> <p>17.3 million [1] 146/2</p> <p>170 [1] 64/6</p> <p>17th October [1] 30/20</p> <p>17th October 1989 [1] 30/19</p> <p>18 donor [1] 118/22</p> <p>18 hours [1] 141/25</p> <p>18 October 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