

Friday, 3 December 2021

(10.00 am)

PROFESSOR DAME CARMEN MARCELA CONTRERAS (continued)

Questions by MS RICHARDS (continued)

SIR BRIAN LANGSTAFF: Yes?

MS RICHARDS: Professor Contreras, before we pick up where we left yesterday, I understand you might want to add a little more to what you were telling us yesterday afternoon about the educational work that was undertaken at the centre?

A. Yes, it was the -- thank you very much for allowing me to say that, but I think it's important. We published -- together with the National Blood Services in England and Wales and Scotland, published what is the successor to *Notes on Transfusion* that you showed for 1973, and that was more updated and expanded on appropriate use of blood and safe blood et cetera, on clinical transfusion medicine.

We also published, mostly from North London but also with the collaboration of colleagues in the UK Blood Services, and clinicians, the *ABC of Transfusion*. That was a book edited by me and published by the BMJ, and distributed by BPL to all hospitals, so that -- for free to all hospitals, so that they were aware of the risks of transfusion and

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"The leaflet has now been revised, most significantly in extending the high-risk groups who should not donate blood, and the opportunity has been taken to amend the layout and update factual matters."

Then paragraph 4 sets out "Revised distribution arrangements":

"Ministers have decided that it is essential that the revised leaflet be brought to the attention of each donor on an individual basis. This would normally be achieved by sending each donor a copy of the leaflet with his next call-up notification. It is realised that this may not be practicable for industrial sessions (or for new donors presenting at sessions) - in these cases alternative arrangements should be made to ensure that each donor is individually given the leaflet before any blood is taken."

Can you recall what the arrangement was at the centre in relation to this new leaflet in 1985 to ensure it was brought to the attention of each donor?

A. Unfortunately, we could not comply. You know, these rules are made by people who are not at the sharp end of blood centres, and unfortunately, we could not comply with the recommendation of sending the leaflet to every donor. As I said yesterday, we were sending

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transfusion medicine.

Q. In relation to that second publication, the ABC, can you recall roughly when that was?

A. The first edition was 1989/90. 1990.

Q. Then the update on *Notes on Transfusion*, we've certainly looked at one version of that. I can't remember whether it was called the *Handbook [on] Transfusion* or something like that?

A. Yeah, the *Handbook*, yes.

Q. From 1988, does that sound about right?

A. Yes.

Q. So if we then pick matters up in relation to the issue of AIDS and issues relating to leaflets and questionnaires, where we left off yesterday afternoon you told us, as at October 1984, your centre essentially printed over the text of the original leaflet because you were still waiting for the Department of Health to issue the updated leaflet?

A. Yes.

Q. If we can then look at the circular regarding the updated leaflet that the Department of Health issued in '85, DHSC0002159, please.

So we can see this is dated January 1985. Paragraphs 2 and 3 -- sorry, paragraph 2 refers to the previous version. Paragraph 3 explains that:

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postcards to donors and that was a way of reminding them of the donor session.

We educated our donor attendants and receptionists on handing the leaflet, but I cannot say with certainty that it was handed to every single donor, I'm afraid.

Q. As I understand it, Dr Hewitt had some involvement in relation to -- around this time in relation, in particular, to issues regarding donor selection, so it may be that she will be able to assist in that regard.

Could we then just look briefly at the -- what I understand to be a third version of the departmental leaflet issued in September of 1985, CBLA0002255.

We see the date at the bottom of the first page of the leaflet, "September 1985" and then, if we look at the text on this page, we can see that the risk group in relation to being gay is now identified not as "practising" or as "having many partners" but simply being homosexual or bisexual, and then we have the addition of being "a sexual contact of any of these people".

If we go to page 3, please, I'm just going to draw your attention to the question:

"How is AIDS transmitted?"

"The transformation of AIDS is not yet fully

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1 understood, but it is known that one means of
2 transmitting the disease is through blood and blood
3 products. Because of this, all donations are now
4 being tested for antibody to the AIDS virus, but
5 people in the groups most likely to be at risk from
6 AIDS still MUST NOT GIVE BLOOD."

7 The last four words in capitals.

8 That's obviously one means of ensuring that
9 those who were donating blood understood that their
10 blood would be tested, that their donation would be
11 tested for in relation to HIV. Do you know whether,
12 in addition to providing the leaflet to donors, donors
13 were individually told that their blood was going to
14 be tested?

15 **A.** Yes, yes. They were told and they had to sign that
16 the blood was going to be individually tested and, in
17 addition, we still had the self-exclusion
18 questionnaire in isolation. So that they knew that
19 they were at risk and they knew that they were going
20 to be tested.

21 **Q.** We'll look at a document or two in relation to that.

22 **A.** If they were --

23 **Q.** Then if we just look at the question "Can donors get
24 AIDS by giving blood?" The leaflet said:

25 "Absolutely not. Neither AIDS nor any other

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1 **Q.** I was trying to work out, Professor Contreras, when
2 that might have been and I've found, I think, a
3 newspaper article in the Los Angeles Times, which
4 would perhaps indicate the international attention,
5 suggesting that that donation was given by Prince
6 Charles at the Centre on 1 March 1985, and it quotes
7 you saying that:

8 "He was invited to donate blood in an effort to
9 allay public fears about AIDS and in the hope the
10 visit would encourage other people."

11 It had that effect, did it?

12 **A.** It had more or less an immediate effect.

13 **Q.** If we can then just look at NHBT0092834, please. This
14 is the "Minutes of the Meeting of the Eastern Division
15 Consultants", 3 October 1985, and you were in
16 attendance. If we just look down the bottom of the
17 page, under the heading "AIDS" it says:

18 "Each Centre was using their own version of
19 an updated 110 form, which were in the process of
20 being printed."

21 At the bottom of the page, it says:

22 "The new AIDS Leaflet was criticised and most
23 Centres were sending an [over the page] explanatory
24 letter in addition.

25 "The most worrying aspect of the leaflet was

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1 disease can be contracted from giving blood."

2 Do you recall whether that was a concern that
3 was voiced by donors or prospective donors within the
4 area served by your centre, a fear that somehow by
5 giving blood they could contract AIDS?

6 **A.** Oh, yes. There was a shortage of blood in the world.
7 Not only -- you know, because I had contacts and I --
8 and because I'm foreign as well, there was a shortage
9 of blood in the UK, nationally, and in other
10 countries, like the USA and Europe, in European
11 countries.

12 And we didn't know what to, and I said "Who
13 could I call who is a public figure?" and I thought of
14 Princess Diana at the time, but she was too slim and
15 I don't think she was the right person, and I asked
16 Prince Charles to come and donate. It took me a long
17 time to get Buckingham Palace to allow me -- for him
18 to come, and he came and gave his blood at Edgware;
19 and he was in all the newspapers, and it's amazing how
20 our blood stocks increased, not only in England, but
21 in other countries.

22 I got letters from lots of parts in the world
23 saying thank you, because it went round the world,
24 this -- him giving his blood, showing that he was
25 giving his blood.

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1 that it implied that anti HTLV III was a test for
2 AIDS."

3 Do you recall that being an issue of concern?

4 **A.** I can't recall.

5 **Q.** If we just look at the next heading, under the heading
6 "Blood collection and donor recruitment" it records
7 Dr Darnborough saying that the publicity budget had
8 been increased to £350,000.

9 Dr Darnborough was which Transfusion Centre?

10 **A.** Cambridge.

11 **Q.** Then it says:

12 "[You] said this was still grossly inadequate.

13 It was generally agreed that it should be put to the
14 Advisory Committee, via the RTD Meeting, that a larger
15 proportion of available money should go to the London
16 Centres."

17 In terms of the publicity budget, was that
18 a nationally allocated budget from the Department of
19 Health?

20 **A.** Yes, and managed nationally, you see.

21 **Q.** Why was it, if you can recall, that you thought that
22 was grossly inadequate?

23 **A.** It was very little money. For example, we couldn't --
24 we had -- we couldn't advertise on television or on
25 national radio, it was mostly for printing posters and

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1 leaflets and a little bit of local advertising, but
 2 it's not like now when they're appealing for blood in
 3 the radio, daily.
 4 **Q.** Now, just in relation to the exclusion questionnaire
 5 that you told us about, so that we can put some dates
 6 in relation to that. Can we look at JPAC0000140_143,
 7 please. Yeah, JPAC0000140 -- sorry, it's 043, my
 8 fault, Soumik.

9 This is a summary of a later publication from
 10 1992. It's headed "Confidential Unit Exclusion: The
 11 North London Blood Transfusion Centre's Experience",
 12 and then it records that:

13 "A confidential AIDS Questionnaire has been in
 14 use at North London Blood Transfusion Service ...
 15 donor sessions since July, 1985. The purpose of the
 16 questionnaire is to encourage those donors whose
 17 behaviour puts them at risk of HIV infection to
 18 refrain from donating. In a situation where such
 19 individuals cannot avoid donating then they can
 20 indicate, in confidence, that their blood should not
 21 be used for transfusion."

22 Then it goes on to describe the process.

23 Now, other documents indicate, and I think it is
 24 consistent with what you told us yesterday, Professor
 25 Contreras, that you introduced this in July 1984 in

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1 **Q.** Do you recall whether other Regional Transfusion
 2 Centres, whether in your division or nationally,
 3 introduced a similar measure or gave any thought to
 4 introducing a similar measure?

5 **A.** I don't think they did but I'm not quite sure.

6 **Q.** Then if we could look, please, at NHBT0000030_013.
 7 This is an article published in the British Medical
 8 Journal in March 1985, authored by you, Dr Hewitt,
 9 Dr Barbara and a scientific officer at the centre.

10 If we look at the heading "Comment", bottom of
 11 the left-hand column. So there's reference there to
 12 one of the published papers, I'm not going to ask you
 13 to go through the details of that, but if you go to
 14 the top of the next column then, this records that:

15 "Donors in the high risk category said that they
 16 had continued to donate despite the publicity about
 17 AIDS because the original (unrevised) leaflet had
 18 implied that homosexuals with stable partnerships were
 19 still eligible as donors."

20 Then last paragraph:

21 "It is alarming that some male homosexuals still
 22 donate blood, and it is vital that all possible
 23 measures are taken to discourage this."

24 So is it right to understand that your findings
 25 at the centre, which are discussed in a little more

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1 one centre --

2 **A.** Yes.

3 **Q.** -- as it were, on a trial basis and then this would
 4 suggest it was rolled out across the remaining donor
 5 sessions a year later; is that right?

6 **A.** Yes, yes. First at the plasmapheresis clinics and
 7 then to the sessions.

8 **Q.** Can you recall why it was a year before it was rolled
 9 out to the other centres or other sessions?

10 **A.** To the donor -- because it was very difficult to find
 11 sessions that were large enough, if we had to do it,
 12 we had to do it uniformly across all donor sessions,
 13 and sometimes we couldn't find a place for our screens
 14 to screen. We need -- some donor sessions are very
 15 tight. So until we were assured that we could do it,
 16 it took some time.

17 **Q.** Because it's right to understand, I think, that at
 18 this point in time, July 1985, testing of donations
 19 has not yet been introduced. That happened in
 20 October 1985.

21 **A.** Yes.

22 **Q.** So donor selection processes trying to deter high-risk
 23 donors or prevent high-risk donors from donating was
 24 essentially the only tool you had at that point?

25 **A.** Yes.

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1 detail in this paper that I'm going to go through, it
 2 indicated that the original leaflet hadn't deterred
 3 all high-risk donors because of the reason that they
 4 thought it didn't cover them?

5 **A.** Yes.

6 **Q.** Professor Contreras -- oh, actually, before I move on,
 7 let's just look at, I think, two versions of the
 8 questionnaire, just to get a sense of what you were
 9 introducing. PRSE0001398, please.

10 So we can see this is headed "National Blood
 11 Transfusion Service, North London Blood Transfusion
 12 Centre". The text is:

13 "Dear donor,

14 "Because of the current concern about the
 15 disease AIDS, which can be transmitted by blood
 16 products, we are asking all our donors, at each
 17 attendance, to complete the enclosed questionnaire in
 18 order to try and reduce this risk to a minimum."

19 So this appears to be a covering letter. Then
 20 it says:

21 "After booking in, would you please ...

22 "1. Read the AIDS leaflet.

23 "2. Enter the side-room on the left as you
 24 approach the main clinic. (One door at a time.)

25 "3. Complete your questionnaire in confidence.

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1 "4. Post it in the special box provided.
 2 "5. Take a seat outside, ready to enter the
 3 main clinic and donate."
 4 This is the document with the questionnaire
 5 which would be provided at the sessions to the
 6 individual donors.
 7 **A.** Yes. Yeah. But this is not the questionnaire?
 8 **Q.** No. It refers to the questionnaire. Sorry, I thought
 9 we had a copy of the questionnaire but I'm not sure
 10 that we do.
 11 Then there is a further document, a later one,
 12 I think, NHBT0085139_007.
 13 So this post-dates October 1985 because it
 14 refers, in the second paragraph, to the blood being
 15 tested. But it explains:
 16 "AIDS is a very serious disease caused by
 17 a virus HIV."
 18 Then:
 19 "There is no risk of catching AIDS through blood
 20 donation, but HIV can be passed on to a patient by the
 21 transfusion of infected blood. It is therefore very
 22 important that you read and understand what is said in
 23 the AIDS leaflet each time before you donate.
 24 "Your blood will be tested for HIV. It is
 25 possible for the test to be negative in the early

1 **Q.** This is -- sometime in the second half of the 1980s
 2 this is what was provided?
 3 **A.** Yeah.
 4 **Q.** Okay.
 5 **A.** Yes, sorry.
 6 **Q.** What I want to do next, Professor, is move on to the
 7 question of screening, testing of blood donations
 8 for HIV. Can we look first of all, before we go into
 9 the detail of that, at your witness statement,
 10 WITN5711001, and go to page 36.
 11 So, paragraph 139 at the top of the page, you
 12 were here being asked a general question about the
 13 decision-making remit, for example, of Regional
 14 Transfusion Director meetings and you say this in
 15 relation to decision-making generally:
 16 "With respect to the running of the centre, and
 17 meeting demands for products and services as well as
 18 for R&D, those decisions were made by me and my
 19 management team. So, at a local level, we made our
 20 own decisions with the Regional Health Authority as
 21 the overall body overseeing these. With respect to
 22 national standards, these were agreed by consensus at
 23 the Regional Transfusion Directors meetings."
 24 Then you say this, Professor:
 25 "Decisions on the national introduction of

1 stages of infection. All donors are therefore asked
 2 to read this form and complete it carefully.
 3 "All information will be kept strictly
 4 confidential.
 5 "You must not give blood ..."
 6 And then there are a range of different
 7 exclusions there set out.
 8 I don't think we have a date on this document
 9 but it's sometime in the second half of the 1980s
 10 I think, because the issue about having had sex at any
 11 time since 1977 with men or women who live or have
 12 lived in African countries I think is discussed at
 13 various meetings in the second half of the eighties.
 14 This is the kind of document, is it, that was
 15 being provided by way of questionnaire to donors at
 16 the centre?
 17 **A.** Yes. But that was not the self-exclusion
 18 questionnaire.
 19 **Q.** And then -- well, it looks like this might have been
 20 a later version of the self-exclusion questionnaire,
 21 Professor Contreras, because if we look at the very
 22 bottom of the page, it says:
 23 "Please fold this form and place it in the box
 24 provided."
 25 **A.** Yes, sorry -- sorry, yes.

1 screening tests for blood donations were made by the
 2 [Department of Health]."
 3 Now I'm not going to suggest to you,
 4 Professor Contreras, that you're inaccurate there in
 5 what you say about decisions being made about national
 6 introduction of screening by the Department of Health,
 7 but what I wanted to try to understand is why it was
 8 that that category of decision was taken by the
 9 Department of Health rather than being an issue for
 10 Regional Transfusion Directors to decide for
 11 themselves.
 12 **A.** As I understand it, it's because we were a national
 13 service. Although we were regionally managed and we
 14 did things different regionally, but there were
 15 matters of great importance, like the screening, that
 16 it was preferable that every -- that every patient in
 17 the country received the same type of screened blood
 18 for as many agents as were possible. But this needed
 19 funding, as well, from the Department of Health. So
 20 the Department of Health had to more or less instruct
 21 and inform regions that a new test was being
 22 introduced.
 23 **Q.** Now, in relation to funding for screening for
 24 HTLV-III/HIV, your understanding is that was provided
 25 nationally by the Department of Health?

- 1 A. That's my understanding.
- 2 Q. As we'll see when we get on later in the day to the
- 3 introduction of screening for hepatitis C, that wasn't
- 4 funded by the Department of Health, was it? So --
- 5 A. That's correct, it wasn't.
- 6 Q. -- (overspeaking) -- fund it themselves through their
- 7 Regional Health Authorities.
- 8 Can I just explore with you the different types
- 9 of decisions that might need to be made in relation to
- 10 the introduction of screening? This is a general
- 11 discussion, Professor Contreras, before we look at the
- 12 specifics of the decision-making in relation to
- 13 testing for HIV or testing for hepatitis C or, indeed,
- 14 surrogate testing for non-A, non-B hepatitis.
- 15 So there's a decision in principle, should we
- 16 introduce screening for -- in relation to this
- 17 condition. Would you accept that?
- 18 A. Yes.
- 19 Q. There's then the question of how that's going to be
- 20 paid for?
- 21 A. Yes.
- 22 Q. There's the question of what form the screening will
- 23 take, what particular tests to use, what arrangements,
- 24 practical arrangements need to be made?
- 25 A. Yes.

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- 1 A. No, apart from the fact that -- the conscience of the
- 2 director and his or her team to give blood that's
- 3 screened compared with the rest of the country, but --
- 4 Q. We'll probably pick that issue up when we look at the
- 5 introduction of hepatitis C screening.
- 6 Okay, well, let's look, then, at the
- 7 introduction of screening in relation to HIV. I'm not
- 8 going to go through each and every stage of the
- 9 decision-making process; I'm just going to look at
- 10 a handful of documents which indicate the involvement
- 11 of either you or the centre.
- 12 So if we start at CBLA0001914_007, we can see
- 13 here a document dated November 1984:
- 14 "Advisory Committee on the National Blood
- 15 Transfusion Service
- 16 "Working Group on AIDS"
- 17 Then paragraph 1 explains that:
- 18 "A Working Group on AIDS has been set up with
- 19 the following terms of reference: "To consider the
- 20 implications for the National Blood Transfusion
- 21 Service of testing blood donations for antibody to
- 22 HTLV III and to report'."
- 23 Then we have number of members set out,
- 24 including you, Professor Contreras, a couple of
- 25 co-opted members, observers from Department of Health,

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- 1 Q. And then there's the question of what the actual date
- 2 for implementation will be?
- 3 A. Yes.
- 4 Q. Was it your understanding that all of those decisions,
- 5 all of those different categories of decision
- 6 effectively fell to be taken by the Department of
- 7 Health, albeit with Regional Transfusion Directors and
- 8 Dr Gunson expressing views or making recommendations?
- 9 A. I don't think that all those -- the Department had
- 10 a great influence in those. But the decision of
- 11 whether we would test or not test was a Department --
- 12 it could have had advice from the Blood Services. But
- 13 to test or not to test was a decision from the
- 14 Department.
- 15 And then the details of what tests to use, we
- 16 would do the kit evaluation test -- assays, and then
- 17 recommend a certain test. And I cannot remember --
- 18 I think it was also -- it went to the Department, to
- 19 that advisory committee, and then to -- from there to
- 20 the Department.
- 21 Q. Now, if we leave aside for a moment the question of
- 22 funding, was there in principle anything to stop
- 23 a Regional Transfusion Centre, obviously with the
- 24 approval of its Regional Health Authority, introducing
- 25 screening at a time of its choosing?

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- 1 Welsh Office, Scottish Home & Health Department,
- 2 Dr McClelland from the Scottish National Blood
- 3 Transfusion Service, and then the secretariat being
- 4 provided by the Department of Health, Dr Smithies and
- 5 Mr Williams.
- 6 Can you recall whose idea it was to set this up?
- 7 Was this a Dr Gunson or RTD initiative or was it
- 8 a Department of Health initiative?
- 9 A. I don't recall.
- 10 Q. And what can you recall about the purpose of this
- 11 working group, other than what we see set out in
- 12 paragraph 1 terms in terms of the terms of reference?
- 13 What was it that this working group was actually going
- 14 to be doing?
- 15 A. I think it is what it states there: to consider the
- 16 implications of testing for anti-HTLV-III, or
- 17 anti-HIV, I think, (*unclear*).
- 18 Q. Can you recall whether the plan was that this group
- 19 would make recommendations that would then be
- 20 considered by the Department of Health?
- 21 A. Yes.
- 22 Q. Can we then look at DHSC0001677, please. If we go to
- 23 page 2, a letter from Dr Gunson to Dr Smithies,
- 24 July 1984. We looked at this yesterday because one of
- 25 the documents attached was about the organisation of

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1 the National Blood Transfusion Service.
 2 But if we go to the next page, what we have here
 3 is a document -- perhaps if we go over the page, we
 4 can see the authorship first of all. So authored by
 5 Dr Gunson, copied to a number of people, including
 6 you. The document itself is not dated, unfortunately,
 7 but if we go back to the preceding page, there's a
 8 plan set out, if we look at the first three
 9 paragraphs, Stage I is the sending of samples from the
 10 North West Thames Regional Transfusion Centre, so
 11 that's your transfusion centre, to the
 12 Middlesex Hospital:

13 "... where performance of the tests will be
 14 proved and evaluated.

15 "Stage II. The performance of the tests will be
 16 transferred to the [North West Thames Regional
 17 Transfusion Centre] and experience gained on its use."

18 Then Stage III was donations being tested at
 19 Manchester, Bristol and continuing at the North London
 20 Centre.

21 Do you have any recollection now of what work
 22 was undertaken at the North London Centre in terms of
 23 evaluating or contributing to the evaluation of the
 24 HTLV-III tests?

25 **A.** Yes, I can vaguely remember that the microbiology

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1 Then if we look at the text of the letter, it
 2 refers to believing:

3 "... that the current commercial kits for
 4 HTLV-III antibody tests are likely to give a high rate
 5 of false-positive results."

6 Again, I don't know whether this is something
 7 you can remember without looking through lots of
 8 underlying documents. Do you recall what the
 9 evidential basis was for the concern that the tests
 10 were likely to give a high rate of false-positive
 11 results?

12 **A.** Yes, that I remember. It was for approximately ten
 13 initially reactive or positives on the screening test.
 14 We found one confirmed positive by Professor Tedder.

15 **Q.** Then you go on to say:

16 "We would therefore recommend that careful
 17 consideration be given before they are introduced for
 18 the screening of all voluntary blood donors, for the
 19 amount and degree of unnecessary stress and hardship
 20 that a fair number of our donors and their families
 21 would thus have to undergo is unacceptable."

22 So concern there about the impact of false
 23 positives on donors; is that right?

24 **A.** Yes.

25 **Q.** "This in turn could lead to a sizeable drop in the

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1 laboratory was the first one to do the screening tests
 2 on this donations. It was the first generation assay,
 3 and we sent the repeatedly reactive samples to
 4 Professor Tedder at the Middlesex.

5 **Q.** So the work that was being undertaken by the North
 6 London Centre in that regard would have been under the
 7 auspices of Dr Barbara?

8 **A.** Yes.

9 **Q.** Well, no doubt we can ask him hopefully in relation to
 10 that.

11 Now, this is probably not a question you're
 12 going to be able to answer without looking at lots and
 13 lots of documents. Can you recall when the North
 14 London Centre was involved in the evaluations: did it
 15 start in 1984 or was it later in 1985?

16 **A.** I cannot -- no.

17 **Q.** Can we then pick matters up, then, in March 1985, at
 18 PRSE0004824. You'll see, Professor, this is The
 19 Lancet, 2 March 1985. If we go to the second page,
 20 right-hand column, about halfway down the page there's
 21 a letter there signed -- sorry, if we can have the
 22 list of names. So we can see it's signed by a number
 23 of Regional Transfusion Directors. We looked at this
 24 with Dr Napier, whose name appears, and we can see
 25 that your name is there as well, Professor Contreras.

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1 supply of blood and blood products."

2 So there concern about the impact upon the Blood
 3 Transfusion Service. Then the next point, the third
 4 point that's made and described as being "for the
 5 safety of transfused patients", is that there should
 6 be essentially GUM clinics in the community where
 7 ordinary members of the population could get tested so
 8 they don't donate blood for the specific purpose of
 9 getting tested; is that right?

10 **A.** Yes.

11 **Q.** Again, was there an evidential basis for that concern,
 12 or was that just a fear that it might happen?

13 **A.** The -- in the USA they had -- they called it the
 14 magnet effect. Our colleagues in the USA who had
 15 started to test had evidence that people in high-risk
 16 groups for transmitting HIV were giving blood in order
 17 to know whether they were positive or negative.

18 **Q.** So the next paragraph says:

19 "We do support, strongly, the screening of all
 20 blood donors for HTLV-III antibody testing, but we
 21 would advise that this is delayed until test systems
 22 have been appropriately evaluated and efforts have
 23 been made to give all members of the public access to
 24 HTLV-III antibody testing."

25 In relation to those two points in that last

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1 paragraph, evaluation of test systems and providing
 2 public access, can we just take those separately?
 3 **A.** And providing ... sorry?
 4 **Q.** Public access to testing.
 5 **A.** Yes.
 6 **Q.** In terms of providing public access to testing, whose
 7 responsibility would it be, essentially, to ensure
 8 that was available? Was that a Department of Health
 9 responsibility?
 10 **A.** I believe the Department of Health asking regions to
 11 introduce alternative test sites.
 12 **Q.** Do you have any knowledge or recollection yourself of
 13 what efforts were made by the Department of Health or
 14 what steps were taken, and when, in that regard?
 15 **A.** I've read lots of documents that were sent to me by
 16 the Inquiry, and I believe I saw a memorandum or
 17 a letter to regional general managers to introduce
 18 alternative testing clinics and I think they said that
 19 this -- the best -- this best could be done at GUM
 20 clinics.
 21 **Q.** Do you recall whether you or your colleagues, either
 22 your colleagues at the centre or your colleagues in
 23 the -- at other centres, do you recall whether you
 24 thought the Department of Health was moving quickly
 25 enough in that regard or whether you had concerns that

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1 people who fear they may have been exposed to the
 2 disease."
 3 So that's -- this reads at least as though
 4 that's an announcement being made June/July 1985. Do
 5 you know of any reason why that couldn't have been
 6 done earlier?
 7 **A.** No.
 8 **Q.** Then the next paragraph of this letter talks about the
 9 evaluation of the test:
 10 "The first stage of the evaluation of
 11 commercially available test kits has now been
 12 completed on behalf of DHSS by the Public Health
 13 Laboratory Service. The outcome of that evaluation
 14 has been considered by a panel of experts and
 15 a summary of their recommendations is attached. The
 16 National Blood Transfusion Service is now taking its
 17 own 2nd stage evaluation covering aspects peculiar to
 18 the use of kits in the blood donation screening
 19 context."
 20 So we've got there a two-stage evaluation, with
 21 the second stage essentially only commencing in the
 22 summer of 1985. Do you know why it took until the
 23 summer of 1985 for that second stage evaluation to be
 24 initiated?
 25 **A.** No, but I think it was too late.

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1 it was taking too long to sort out?
 2 **A.** I think in some areas it took too long be set out.
 3 I think that my region acted quite promptly in
 4 establishing -- in offering HTLV-III testing but there
 5 were parts of the country, I remember some of my
 6 transfusion director colleagues, and I think that in
 7 Scotland, as well, it took some time for GUM clinics
 8 to be test -- alternative sites.
 9 **Q.** Then the other point that you made in this last
 10 paragraph, you and your colleagues made in this last
 11 paragraph, was about the need for the test systems to
 12 be appropriately evaluated.
 13 Can we just go, please, to PRSE0002078. This is
 14 a letter of 30 July 1985, from the Department of
 15 Health to Regional General Managers, Regional Medical
 16 Officers, Regional Transfusion Directors and others.
 17 It may be that this is the document you were referring
 18 to a few moments ago, Professor Contreras. It says in
 19 the first paragraph:
 20 "In his press release dated 27 June the Minister
 21 for Health announced that a test would be introduced
 22 to screen all blood given by blood donors for
 23 antibodies to the virus which causes AIDS.
 24 Arrangements would also be made for Sexually
 25 Transmitted Disease clinics to provide a test for

26

1 **Q.** Just in terms of some dates, I'm not going to go to
 2 the detailed subsequent evaluation report, but we --
 3 I'll just give the reference for the transcript, it's
 4 PRSE0002716. But it shows the North London Centre was
 5 one of the centres involved in that second-stage
 6 evaluation and, as I understand it at that point, what
 7 was being done in the North London Centre and,
 8 I think, Manchester was a comparison between different
 9 tests. So there was a testing or evaluation of the
 10 Wellcome Test and then of the Organon Test.
 11 **A.** Yes.
 12 **Q.** Do you know why what we see here is the evaluation
 13 being done sequentially? In other words, you've got
 14 the PHLS and then the evaluation being undertaken by
 15 yourselves and Manchester? Could that have been done
 16 simultaneously?
 17 **A.** I don't think so because what the PHLS did was look at
 18 sensitivity and specificity but also at durability,
 19 the length of -- that the tests took. So some tests
 20 are good for diagnostic purposes in diagnostic
 21 laboratories but some tests are good for screening.
 22 So in screening donations you need sensitivity and
 23 specificity in order to get the right donors positive.
 24 With diagnostic testing, you try to get as much
 25 sensitivity as possible.

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1 So -- and the length -- with diagnosis, it
 2 doesn't matter very much if you have a test taking
 3 three or six hours, but with -- in blood donations, if
 4 you're giving platelets. So there are several reasons
 5 why you should assess which tests are convenient for
 6 the Transfusion Service and then hand those one to the
 7 testing laboratories in the blood services.

8 **Q.** Although it might have involved more work for your
 9 centre under the auspices of Dr Barbara or Manchester
 10 or other centres to do it, as it were, simultaneously,
 11 is there any reason why there couldn't have been
 12 an evaluation of the practical implications, as it
 13 were, looking at all the diagnostic tests, whilst the
 14 PHLS was doing its own evaluation from its
 15 perspective? Did it have to wait until PHLS had
 16 narrowed it down to two tests, in other words?

17 **A.** Yes, it had to wait because we couldn't have been
 18 comparing, you know, a test that took too long with
 19 a test that was shorter. You know, they had to choose
 20 what was adequate for us, for the blood services. But
 21 it should -- it could have been done quicker.

22 **Q.** If we just, then -- if I can just ask you to have in
 23 mind again that March 1985 Lancet letter. We can put
 24 it back on screen if we need to but what I want to do,
 25 and indeed some questions I've been asked to ask you,

29

1 or however many it is, Regional Transfusion Directors?
 2 "A. It is not all of them.
 3 "Q. It is most of them?
 4 "A. They are all transfusion centre directors
 5 in either England or Scotland."
 6 Then there is a question about false positives,
 7 so there is a quote from the Lancet letter, and at
 8 line 173 the question is:
 9 "Was that, in fact, the case?"
 10 Dr Gunson says:
 11 "There were false positive.
 12 "Q. Was it a high rate?
 13 "A. I am not sure at this time now whether you
 14 would describe it as a 'high rate', which is a rather
 15 indefinite adjective to put before it."
 16 If we can see the rest of the page, please.
 17 Thank you.
 18 Question -- this is line 179, there is then
 19 another quote from the letter:
 20 ""We would therefore recommend that careful
 21 consideration be [I am not sure what it is, probably
 22 "given"] before they are introduced for the screening
 23 of all voluntary donors for the amount and degree of
 24 unnecessary stress and hardship that a fair number of
 25 our donors and their families will thus have to

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1 is to look at what Dr Gunson was asked about that
 2 letter in his oral evidence in the hepatitis C A v
 3 *National Blood Authority* litigation and ask you to
 4 comment on that.
 5 So NHBT0000148_001, please.
 6 So this is an extract from Dr Gunson's
 7 testimony. If we could go, please, to page 4, I'm
 8 just going to read -- starting from the third line,
 9 I'm going to read the passages and then ask you about
 10 it.
 11 So this is a letter written in -- this is part
 12 of the question that's being put to him:
 13 "This is a letter written in March 1985, just
 14 over six months before screening was actually
 15 introduced. Is that right?
 16 "A. This is the Ala [that's a reference to
 17 Dr Ala] et al letter.
 18 "Q. Yes. It is just over six months before
 19 screening for HIV is introduced?
 20 "A. Yes.
 21 "Q. It is about the time that other countries,
 22 France, America, Australia, the list we looked at
 23 yesterday, are, in fact, introducing screening?
 24 "A. Indeed.
 25 "Q. The signatories are probably all of the 14,

30

1 undergo is unacceptable. This in turn could lead to a
 2 sizeable drop in supply."
 3 So there's the quote, Professor, from the March
 4 letter. Then the question continues:
 5 "The importance of the supply is then stressed.
 6 Then the problems of the clinics, by which I mean the
 7 blood clinics, blood donation clinics, having to do
 8 the work. Really what they were really looking for
 9 was a different body to do the counselling?
 10 "A. Yes."
 11 Just pausing there, can you recall whether that
 12 was part of your thinking, that external support in
 13 relation to the counselling was required?
 14 **A.** No, because we had -- at least from what I recall in
 15 my centre, we had a team of doctors that dealt with
 16 the counselling, and they went to St Mary's Hospital
 17 to -- you know, it's not the collection teams that
 18 were going to be doing the counselling, it's a group
 19 of experts at the centre.
 20 **Q.** But the position may have been different in relation
 21 to other centres?
 22 **A.** It may have been different.
 23 **Q.** And then line 192:
 24 "They [that's you and your co-authors of the
 25 letter] conclude:

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1 "We do support, strongly, the screening ... But
2 we would advise that this is ask [I think it must be
3 "delayed"] until test systems have been appropriately
4 evaluated'."

5 Then the question continues:

6 "I simply wanted you to comment. Here we are
7 with a much more serious condition [I think that's
8 a comparison with HIV and hepatitis C that's being
9 referred to there], other countries already
10 introducing, but directors being primarily, apparently
11 concerned about problems for donors and for
12 practicalities within clinics. Is that a fair
13 comment?"

14 If we go to the next page:

15 "A. Yes, I think the transfusion service is
16 concerned with the health and welfare of their donors.

17 "Q. There's not any mention there about, as it
18 were, the possible impact upon recipients, is there?"

19 "A. Well, it does say, 'We do support strongly
20 the screening of all blood donors'.

21 "Q. 'We are going to delay'. There is no, as
22 it were, weighing up on the one hand the disadvantage
23 of a donor being told, perhaps wrongly, that he had
24 AIDS, and on the other hand a recipient getting AIDS
25 while you delay. There is no balancing exercise done

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1 because I had the problem of telling those ... you
2 know, it's ... it's about which of the one in ten was
3 the infectious one, was the one who was transmitting?
4 That was a -- yeah, but I wished there had been
5 a better test. It was a test that was done -- it was
6 performed -- cultured in cells and lots of women
7 have -- you know, young women who have had children
8 have HLA antibodies, and this test was contaminated
9 with HLA tissue antigens.

10 So women having anti-HLA antibodies, that are
11 many, would have tested positive, having a very pure
12 life. So I wished there had been a better test.

13 Q. Can I then turn to the specific arrangements that were
14 made in the centre in relation to the introduction of
15 the testing. Can we start by looking at a Regional
16 Transfusion Directors meeting on 9 October 1985. So
17 that's about a week before the date is set for the
18 introduction of the testing nationally.

19 DHSC0002365_002.

20 So we've got there the meeting date,
21 9 October 1985, and we can see that you, amongst
22 others, were in attendance.

23 If we go to the bottom of the second page,
24 please. We have a heading "AIDS Update". Picking it
25 up in the second paragraph:

35

1 in that letter, is there?

2 "A. In this letter there is not, no."

3 So you'll see from that exchange, Professor,
4 that what was being explored with Dr Gunson was
5 whether that March 1985 letter was essentially
6 concerned with the impact upon donors and Blood
7 Service in terms of the arrangements that would have
8 to be made or loss of supplies, and insufficiently
9 weighing into the balance the risks to the recipients
10 of blood. Do you have any observations or comments to
11 make on that?

12 A. No. I wished that, with hindsight -- but I wouldn't
13 have known what to tell those nine donors that I
14 couldn't confirm, you know. That -- you know, I would
15 have created an army of worried well. You know, the
16 people who, if they're told they've got something like
17 cancer or a fatal infection, they might throw
18 themselves in front of the tube, or anything. So it
19 was those considerations. But perhaps we were wrong.

20 Q. I think you started to say, "I wished with
21 hindsight" --

22 A. Yes.

23 Q. Do you wish with hindsight that the screening had been
24 introduced earlier than October 1985?

25 A. Yes. I wish that that there had been a better test

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1 "Anti HTLV-III screening is in hand and training
2 completed. All RTCs will start full testing by
3 the 14th October 1985. Discuss took place over fresh
4 blood products in stock, ie FFP cryo and Frozen Blood.
5 The matter had been raised at Divisions and RTCs
6 differed. Some felt they would not support discarding
7 untested donations. Wherever possible back-testing
8 would be carried out on in-date material. It was felt
9 important that BPL should accept and process FFP and
10 time-expired plasma for heat-treated products.
11 Dr Lane stressed that such material must be clearly
12 identified and BPL given notice."

13 Before we look at the rest of this, is it right,
14 Professor, to understand that the -- although there
15 was the date of 14 October as the date upon which any
16 donor coming into centres at that point in time, their
17 donation should be tested, that left unresolved, and
18 for individual centres to decide, what they did about
19 everything they already had in stock?

20 A. Yes.

21 Q. So that question wasn't nationally mandated, it was
22 left to be determined on a local basis?

23 A. Yes.

24 Q. And we can see here, in the fourth line of that
25 paragraph, some directors not wanting to discard

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1 untested donations. So it would seem from that, that
 2 in some parts of the country untested materials may
 3 have been supplied for use in patients after
 4 14 October 1985; is that right?
 5 **A.** Yes.
 6 **Q.** Then we see, and the next paragraph is a contribution
 7 from you:
 8 "Dr Contreras reported that all accredited
 9 donors of frozen red cells for boosting had been
 10 screened five months ago by a number of tests and
 11 expert opinions were that these were safe to use."
 12 What does that refer to?
 13 **A.** We had accredited red cells to -- it's something
 14 amazing that donors do, that they accept -- they are
 15 Rhesus negative or RH Negative volunteers who accept
 16 to be boosted with -- immunised with Rh positive red
 17 cells in order to produce anti-RhD or anti-D
 18 immunoglobulin. And these donors are injected with
 19 red cells regularly so that they maintain a very high
 20 level of antibodies and, in this way, we were
 21 self-sufficient -- this country was self-sufficient in
 22 anti-D immunoglobulin to protect RhD negative mothers
 23 from having children affected with haemolytic disease
 24 of the foetus or newborn.
 25 So this -- because they were volunteers and they

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1 had also especially typed cells for people with rare
 2 blood groups. Those were frozen and they could be
 3 frozen for 10 years.
 4 So the only way to make sure that they were --
 5 that those frozen cells were negative, unless they
 6 were going to be for an autologous donation, was to
 7 contact the donors of those frozen red cells and test
 8 them and, if they were not extremely special, they had
 9 to be discarded.
 10 **Q.** And is that what was done at the North London Centre?
 11 **A.** Yes.
 12 **Q.** Do you know the extent to which it was done elsewhere
 13 at other centres?
 14 **A.** No.
 15 **Q.** Then if we go to the top of the next page, the first
 16 paragraph, it says:
 17 "The role of the Department and the Press
 18 Releases over the next few weeks was the subject of
 19 discussion. Dr Smithies requested the advice of the
 20 meeting as obviously there would be much Press
 21 interest. Directors were concerned that in spite of
 22 publicity high risk persons were still coming to donor
 23 sessions in order to find out their HTLV-III antibody
 24 status. Many groups have made it clear that they will
 25 not attend STD clinics or GPs and most Districts have

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1 were being injected with Rh positive donor cells, we
 2 accredited those red cells, and so we managed to ask
 3 them, and they were -- fortunately, they were all
 4 negative for HTLV and all the markers.
 5 **Q.** But this tends to suggest that as long ago as
 6 five months before October 1985, there had been some
 7 form of HTLV-III testing that you were able to use in
 8 relation to this particular category; is that right?
 9 **A.** Yes, it was the ones that we used in the screening
 10 assays, in the kit evaluation tests.
 11 **Q.** Okay. And then there's reference to:
 12 "Frozen donations -- many had been stored for
 13 years before high risk donors appeared in the
 14 population. Could perhaps testing of these people now
 15 clear their previous donations?"
 16 Do you recall what that referred to, and what,
 17 if anything, was done in relation to that?
 18 **A.** Yes, some centres, including ours, had frozen red
 19 cells in glycerol. They're very special red cells.
 20 For example, there's a blood group called Bombay
 21 that -- I think we have one or two subjects in this
 22 country, in the UK, in the 56 million population,
 23 that -- who are Bombay. So we have to freeze the
 24 cells from them, because if they need a transfusion
 25 they die if they get anybody's blood. So -- and we

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1 not made clear arrangements for persons to have ready
 2 access to testing."
 3 Then this:
 4 "Dr Contreras reported her findings that GPs did
 5 not have clear instructions."
 6 Can you recall what that refers to?
 7 **A.** I don't recall clearly, but we had quite a lot of
 8 communication with GPs through Dr Hewitt's department,
 9 and I think that many of them said: no, we haven't
 10 received any instructions about HIV.
 11 **Q.** And the responsibility to ensure that GPs or other
 12 clinicians outside of transfusion centres were fully
 13 aware of what was happening and able to offer whatever
 14 services were required, that would be the
 15 responsibility, would it, of the Regional Transfusion
 16 Centres and/or the Department of Health?
 17 **A.** Yeah.
 18 **Q.** That's not something over which the Regional
 19 Transfusion Directors would have direct control?
 20 **A.** No, we had no control over GPs, just contact with some
 21 of them.
 22 **Q.** Then if we could please next go to BPLL0010763, this
 23 is a letter you wrote in February 1986 to Dr Snape at
 24 BPL. You say in the first paragraph:
 25 "We commenced total anti-HTLV-III screening of

40

1 our donor panel on the 23rd September 1985. From that
2 date on, all donors L will have been screened for
3 anti-HTLV-III."

4 So is it correct then that, in fact, you at
5 North London didn't wait for the nationally agreed
6 date; you brought testing forward by, I think, three
7 weeks, that would be?

8 **A.** Three weeks, yeah.

9 **Q.** Why was that?

10 **A.** We were not the only ones. Because we had the
11 facility to do it and because we knew that we had to
12 issue HIV -- anti-HTLV-III negative blood by a certain
13 date. So -- and I think that there were other centres
14 that -- who did the same as us.

15 **Q.** So because you were ready you decided to go a little
16 earlier than the national date?

17 **A.** Yeah. In order to have everything screened on the
18 date that we were going to tell the public blood is
19 tested. But we were not going to tell them the blood
20 that we're giving today is negative.

21 **Q.** Then if we look at NHBT0057018_001, this is on the
22 same topic, this a letter, 29 October 1985, to
23 Dr Smithies at the Department of Health, and if we can
24 just look at the second paragraph, you say:

25 "... we were able to start anti-HTLV-III

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1 whether they had larger stocks of untested material
2 than you did?

3 **A.** I do not know but I think I've seen a letter where at
4 least one centre was -- did the same thing that we
5 did.

6 **Q.** Then you referred a few moments ago to the fact that
7 a lot of your stock would actually not be being held
8 in the centre; it would have been supplied to the
9 hospital so the hospitals would have stocks of
10 blood/blood products that, as the 14 October 1985, may
11 not have been tested.

12 **A.** Yeah, like fresh frozen plasma, for example, and if
13 they had that and we asked them to return it.

14 **Q.** Can we just look at a couple of letters, in fact
15 I think we probably any need to look at one letter.
16 DHSC0101818. This is a letter you wrote in
17 October 1985 to all consultant haematologists "Re:
18 Anti-HTLVIII testing of blood donations":

19 "You will probably have heard that the date for
20 the introduction of routine anti-HTLVIII testing of
21 all blood donations has been announced as
22 October 14th. All blood donations taken on or after
23 that date will undertaken routine anti-HTLVIII
24 testing, and no blood components taken on or after
25 that date will be released in advance of a negative

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1 screening unofficially from the 23rd September 1985.
2 Since we rarely have the luxury of too much blood
3 gathering dust in the 'fridge and since our supplies
4 of fresh frozen plasma get snapped up very quickly our
5 only stored material is cryoprecipitate. We have been
6 storing serum samples from donors for several months
7 now and we are going through the records of our
8 cryoprecipitate stocks to check which stored donors
9 samples correspond to the stocked material. In
10 addition we will be test those cryoprecipitate donors
11 who return to give further donations so this problem
12 is in hand."

13 You are, as I understand it, describing
14 a situation in which, perhaps because of the location
15 of the centre and the number of hospitals you serve,
16 you didn't carry large numbers of stock that would be
17 untested.

18 **A.** Yeah, most of our stock was in the hospitals and, as
19 we've seen in other documents, I think, that you've
20 sent to me, we -- although we were collecting
21 a great -- much more per thousand population, we --
22 than the rest of the country, we still -- the demand
23 was so high that it rotated very quickly. So only had
24 cryo to --

25 **Q.** Do you know what the position was in other centres,

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1 anti-HTLVIII test, with one exception."

2 Then you describe the exception, as I understand
3 it, in the next sentence:

4 "The logistics of anti-HTLVIII testing combined
5 with rapid release of fresh components (in particular
6 platelets) are such that it will be difficult to
7 continue our present practice of same-day release. We
8 are trying our best to circumvent the problems, but
9 the anti-HTLVIII test is more time consuming than
10 other tests currently performed."

11 Then you go on to explain that platelets may not
12 effectively be released on the same day for that
13 reason.

14 Next paragraph:

15 "We have severely run down stocks of FFP and
16 cryoprecipitate over the last month, in anticipation
17 of the start of testing. It is impossible to
18 retrospectively test all stock currently held at the
19 RTC, but field trials of the anti-HTLVIII tests have
20 been carried out over the few weeks, and a large
21 proportion of the current stock of blood has already
22 been tested."

23 Then you say this:

24 "There will be no facility for return of
25 untested blood or components, but it is anticipated

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1 that the overlap period will be short, except in the
 2 case of rare blood held as frozen units of red cells."
 3 Which I think is the example you gave us few
 4 minutes ago.
 5 So what was the expectation as to what hospitals
 6 holding untested stock should do with that, given that
 7 you say here there wasn't a facility for returning it?
 8 **A.** I'm afraid it might have been if they had untested
 9 blood. Later on, we accepted fresh frozen plasma, and
 10 sent it as time expired plasma for production of PPF
 11 or albumin but, you know, I'm afraid that they would
 12 have been considered as perhaps suitable for
 13 transfusion.
 14 **Q.** So after 14 October 1985, hospitals may have been
 15 using, to treat patients, products that had not been
 16 tested?
 17 **A.** Yeah. Very few, but yeah.
 18 **Q.** Do you know whether other centres operated any
 19 facility for return of untested blood or blood
 20 products?
 21 **A.** I do not know.
 22 **Q.** I'm going to ask you now to consider -- we can take
 23 that down, thank you -- the issue of surrogate testing
 24 for non-A, non-B hepatitis, and just so those who are
 25 following and, indeed, I am clear about what we mean

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1 **Q.** It wasn't introduced in the UK, was it, in the course
 2 of the 1980s at all?
 3 **A.** No, it wasn't.
 4 **Q.** Now, if we can then look at a handful of documents,
 5 again, ones which reflect meetings to which you
 6 contributed or letters which you wrote on this issue.
 7 I'm not going to go through the entirety of decision
 8 making or aspects of it that you weren't involved in.
 9 But, again, going back to some of the general
 10 questions I asked you earlier, whose decision did you
 11 regard it as being, as to whether surrogate testing
 12 should be introduced: Department of Health, Regional
 13 Transfusion Directors, Regional Health Authorities;
 14 who would be taking that decision?
 15 **A.** Department of Health.
 16 **Q.** Would that be because you would be looking to the
 17 Department of Health for funding or would it be for
 18 some other reason?
 19 **A.** I think for -- especially for funding but also for
 20 uniformity across the UK.
 21 **Q.** Can we look, then, first of all, at an article in
 22 1984. It's at NHBT0000030_008. So we can see the
 23 date of publication, I don't think we have the precise
 24 date in fact but it's 1984, in any event, and it's
 25 entitled "Necessary Tests on Blood Donations to Detect

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1 by surrogate testing, until the late 1980s, and we'll
 2 come on to this later, there was no test which could,
 3 as it were, directly test for hepatitis C. So
 4 surrogate testing refers to an indirect means of
 5 identifying donors who may be infected. Is that a
 6 fair summary?
 7 **A.** Yes.
 8 **Q.** There were two surrogate markers relevant in relation
 9 to non-A, non-B hepatitis: raised ALTs or antibody to
 10 hepatitis B core, anti-HBc; is that right?
 11 **A.** Yes.
 12 **Q.** You could, in principle, test both for ALT and
 13 anti-HBc, or you could test for one or the other?
 14 **A.** Yes.
 15 **Q.** Is it also right to understand that, in the 1980s,
 16 there wasn't a universal picture across other
 17 countries as to what they did but some countries used
 18 surrogate testing in the course of the 1980s; indeed,
 19 I think Germany had been using ALT testing for a
 20 couple of decades?
 21 **A.** Yes.
 22 **Q.** We'll see, when we look at some documents, that
 23 testing for both of those markers was introduced in
 24 the USA in 1986?
 25 **A.** Yes.

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1 Infectious Agents".
 2 You explain in the first paragraph that:
 3 "Transmission of infectious agents is a major
 4 hazard of blood transfusion."
 5 Then you go on to talk about the approach that
 6 could be taken in relation to screening and to
 7 identify a number of factors.
 8 If we go on to page 3, we can see the heading,
 9 "Non-A, non-B hepatitis". You say there:
 10 "Most cases of [non-A, non-B hepatitis] are mild
 11 or asymptomatic and there is no general agreement
 12 about the severity of the acute illness or its
 13 long-term effects."
 14 We discussed that yesterday,
 15 Professor Contreras, so I'm not going to ask you about
 16 that again:
 17 "There are no specific serological markers for
 18 the agent(s) of [non-A, non-B] hepatitis. There is
 19 an epidemiological association between HBV and [non-A,
 20 non-B] hepatitis. It has been estimated that up to
 21 a 50% reduction in [non-A, non-B] TTH [so transfusion
 22 transmitted hepatitis] could be achieved by
 23 eliminating units from donors with markers for past
 24 HBV infection; this measure could mean a 2-4%
 25 rejection of units. In the absence of prospective

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1 randomised trials, no general recommendations can be
2 made regarding routine use of anti-HBc tests."

3 You're dealing there, as I understand it, simply
4 with anti-HBc and not with ALT testing?

5 **A.** Yes, I should have dealt with ALT as well.

6 **Q.** The last sentence of that paragraph would appear to
7 suggest that your view was that a recommendation
8 couldn't be made in the absence of further trials,
9 prospective randomised trials.

10 **A.** Yes. For -- in each country, for each country, yes.

11 **Q.** Why did you think it was important to have prospective
12 randomised trials?

13 **A.** To see whether there was, you know -- whether the
14 incidence of non-A, non-B hepatitis was higher in
15 recipients, like the TTV study in the United States,
16 to see whether there was a higher incidence of
17 non-A, non-B in people who retrospectively tested
18 positive for anti-hepatitis B core. Because this was
19 up to 50% but different countries had different
20 estimations.

21 **Q.** So the purpose of the trials that you're talking -- or
22 that you were envisaging could be undertaken here
23 would be to establish what the extent of the problem
24 for an individual nation of non-A, non-B hepatitis?

25 **A.** Sorry, could you repeat the question?

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1 **MS RICHARDS:** I'm going to then pick matters up in 1986,
2 but I note the time, sir, so perhaps we can take the
3 break now and then I can do that after the break?

4 **SIR BRIAN LANGSTAFF:** Yes, well, we will take a break now
5 until 11.45. 11.45.

6 (11.14 am)

(A short break)

8 (11.46 pm)

9 **MS RICHARDS:** Professor, if we can pick matters up in
10 relation to discussion of surrogate testing in 1986 at
11 NHBT0057025_001, please. This a letter dated
12 23 May 1986 from you to Dr Smithies at the Department
13 of Health. If we pick it up in the third line of the
14 first paragraph:

15 "Now that we have routine anti-HTLV-III
16 screening of blood donations, which has reduced a very
17 small risk of transfusion-transmitted HTLV-III
18 infection even further, there is pressure to introduce
19 screening to reduce the incidence of post-transfusion
20 non-A, non-B hepatitis."

21 Just pausing there, from whom was there pressure
22 and on whom was there pressure?

23 **A.** I -- if I remember correctly, it was from the liver
24 disease specialists and from the haemophilia directors
25 group.

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1 **Q.** What was the -- was the purpose of saying there needed
2 to be these trials as at 1984 because you wanted to
3 understand or you thought it was important for
4 a country to understand the extent of non-A, non-B
5 hepatitis in its population?

6 **A.** Of post-transfusion non-A, non-B hepatitis in the
7 population. We did not know what the problem was in
8 this country, with an all-volunteer donor. And so we
9 did not know whether we had the same problem as the
10 United States had -- or, I think, Spain, and I think
11 there were some trials done in France as well, in
12 Toulouse. But we did not know whether there was
13 a correlation between anti-core or ALT testing and
14 reduction of transmission in this country.

15 **Q.** I'm going to pick up what happened in the second half
16 of the eighties, perhaps after the break, but as at
17 1984, in the first half of the 1980s, can you recall
18 what, if any, studies were undertaken involving the
19 North London Centre?

20 **A.** We did studies of anti-core and ALT, but -- to see
21 what the prevalence was in blood donors, and it was
22 lower than -- much lower than the United States. But
23 we did not do studies of transmissibility, then. And
24 this paper must have been written in 1983, as I said
25 in my statement. I don't think I wrote it in 1984.

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1 **Q.** And then the letter continues:

2 "We know that there is under-reporting in this
3 country, but it appears that there is a much lower
4 incidence of post-transfusion non-A, non-B hepatitis
5 than in the [US]. On the other hand, the reports of
6 the sometimes severe sequelae of this type of
7 hepatitis particularly in recipients who have received
8 blood products originating from large donor pools,
9 have caused concern."

10 Then you go on to talk about the position in the
11 states:

12 "In the [US], the American Association of Blood
13 Banks has announced this month that routine screening
14 of blood donors for anti-HBc and ALT levels (as
15 surrogate markers for donors at high risk of
16 transmitting non-A, non-B hepatitis) has been approved
17 as a requirement, and will be introduced into the
18 Association's 'Standards'. The FDA is also
19 considering this subject. Yet in this country we do
20 not even know the current prevalence of anti-HBc in
21 blood donors and we might predict that the rate has
22 decreased since the introduction of measures to
23 exclude 'high-risk' donors. We need to carry out
24 a study of these surrogate 'high risk' markers in
25 British blood donors -- and anti-HBc is a practical

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1 marker to choose, as it relates not only indirectly to
2 HTLV-III and non-A non-B hepatitis, but also very
3 directly to Hepatitis B. We would also need to
4 follow-up recipients of anti-HBc positive donations
5 and this will entail a great deal of work and medical
6 time. Once we had this information we could then
7 start making informed decisions about the need for
8 this surrogate screening and the implications in terms
9 of cost, donations, lost, etc.

10 "I know that Dr Fraser of the Bristol RTC shares
11 our concern over this matter, and would be willing to
12 co-operate in a joint study of anti-HBc prevalence in
13 donors. Could you let me know what your feelings are
14 on this subject please? We can hardly start deciding
15 policies on our approach to anti-HBc and ALT screening
16 when we do not know the background data!"

17 I think it's right to understand from this
18 letter that the approach you were urging on the
19 Department of Health, in this document at least, is to
20 say, before a decision is taken, there must be further
21 studies of the type outlined in the letter; is that
22 fair?

23 **A.** Before a decision is taken we need to know whether we
24 have a problem in this country. We need to know what
25 the problem is in this country.

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1 different pieces of work: a study of the high-risk
2 markers in British blood donors, using anti-HBc as
3 your marker; but then you talk about also needing to
4 follow up.

5 So let me take this in stages. That was to
6 establish the extent of -- in which anti-HBc would be
7 found in the donor population?

8 **A.** Yes.

9 **Q.** And then you say:

10 "We ... also need to follow-up recipients of ...
11 positive donations ... [which] would entail a great
12 deal of work and medical time."

13 The purpose of that, as I understand your
14 thinking, was to see the extent to which it was being
15 transmitted through donation?

16 **A.** Yes.

17 **Q.** That would not be a short exercise. You say yourself
18 there it would entail a great deal of work and medical
19 time?

20 **A.** Yes, yes.

21 **Q.** And what you were saying to the Department of
22 Health -- obviously it was for them to make their own
23 mind up, but you were saying was you needed both those
24 before you could start making informed decisions?

25 **A.** I think that's what I meant.

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1 **Q.** Was it not already the case that you knew there was
2 a problem? You may not have been able to quantify it,
3 but there could have been no doubt, could there, by
4 1986 that non-A, non-B hepatitis post-transfusion did
5 occur with potentially, as your letter says, severe
6 sequelae?

7 **A.** Yes, yes. It did occur, but we didn't know the
8 magnitude of it. As I said yesterday, we had about
9 four cases a year and not all of them were
10 non-A, non-B. Some of them were hepatitis B.

11 **Q.** And the kind of study you were describing in this
12 letter is -- it's not a study that could be undertaken
13 quickly, is it? It would be something that would take
14 place over -- if it was ever authorised and funded,
15 would take place over quite a long period of time,
16 would it not?

17 **A.** No, the first -- the original study was to know the --
18 to test donations for anti-core, and to see whether
19 those previous donations had -- because most of our
20 donors were repeat, to see if previous donations
21 had -- go back to the patients and see whether they
22 had transmitted.

23 **Q.** If we just look at the previous page, if we look at
24 the last six lines or so. Seven or eight lines,
25 sorry. So you talk there, I think, about two

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1 **Q.** And that's what I'm suggesting would, as at 1986, mean
2 you'd be looking at a decision-making process that
3 would not be a matter of weeks or months; it would be
4 a matter of years, would it not, before what you're
5 describing could enable the Department to start making
6 informed decisions?

7 **A.** I think that in a year we would have had -- not years,
8 but in -- I remember discussing this, and -- because
9 our Scottish colleagues had said that it would take
10 many years, and I -- we believed that we could have
11 a reply by -- in a year.

12 **Q.** If we go to PRSE0003557, this is a little later in
13 1986, September 1986. You wrote again to Dr Smithies
14 at the DHSS enclosing a proposed pilot study of
15 post-transfusion non-A, non-B hepatitis. You say:

16 "I have already had some semi-political
17 questions asked about the lack of screening in the UK
18 when compared with the USA ..."

19 Do you know what you were referring to when you
20 talked about semi-political questions?

21 **A.** I can't remember.

22 **Q.** Then you say:

23 "Furthermore I am optimistic that a well
24 designed trial may show that a surrogate screening for
25 NANB hepatitis carriers in blood donations in this

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1 country is neither indicated nor cost effective."
 2 It might be said that's quite a curious way of
 3 putting it, "optimistic" that this wouldn't be
 4 required.
 5 Why would that be a cause for optimism?
 6 **A.** That if we were not transmitting it, that would be
 7 wonderful, if we are not transmitting non-A, non-B.
 8 **Q.** Then you ask:
 9 "If money is forthcoming, I would be grateful
 10 for an early reply. I leave any involvement of the
 11 Bristol RTC to you. The maximum number of RTCs
 12 involved should be two."
 13 I'm not going to go to the details of the
 14 proposal but it's over the page. It continues for
 15 several pages. But that sets out there the
 16 provisional plan.
 17 Perhaps I should just look at the bottom of the
 18 page, where item 7 is:
 19 "To follow-up both donors and recipients with
 20 any evidence of hepatitis to assess the long term
 21 implications."
 22 Now, did you receive funding from the Department
 23 of Health for this study?
 24 **A.** I do not remember if it was this study or there was
 25 a three-centre study for -- to test for ALT and

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1 accreditation of Blood Banks in the USA. The Chairman
 2 proposed that the RTDs should approach the DHSS to
 3 fund a prospective study of 10,000 donations to see if
 4 the incidence of anti-HBc had changed since this was
 5 last examined. He added that Haemophilia Directors
 6 were pressing for plasma for fractionation to be
 7 tested for both anti-HBc and for abnormal ALT levels.
 8 It was agreed that a further trial should be taken at
 9 Edgware, Bristol and possibly Manchester and that an
 10 approach be made to Dr Smithies and Dr Moore for
 11 assistance with this. It was recognised however, that
 12 even if the incidents had reduced significantly since
 13 the last trial, because of self-exclusion or for other
 14 reasons, the introduction of anti-HBc/ALT screening
 15 seemed very likely."
 16 Did you share the view in the autumn of 1986
 17 expressed here, that whatever the study showed, the
 18 introduction of screening was very likely?
 19 **A.** I cannot remember when my views changed.
 20 **Q.** Then, if we go to CBLA0002358_0001. This is the next
 21 RTD meeting, January 1987, at which you were present.
 22 Now, the documents -- this document, the pages are out
 23 of order. So if we go first of all to the bottom of
 24 the second page, we've got the heading "Anti-HBc and
 25 ALT screening":

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1 anti-core, but I can't remember whether it was related
 2 to this letter or whether it was something different.
 3 **Q.** And my understanding in terms of timing is that the
 4 funding for the study that was undertaken at the three
 5 centres was approved in 1988. Does that accord with
 6 your recollection? If you can't say, don't worry.
 7 **A.** I think so.
 8 **Q.** So it was -- again, it was a -- there's -- on any
 9 view, you didn't get a quick response and quick
 10 funding for this, for what you were asking for?
 11 **A.** No, no.
 12 **Q.** Can we then go, still in '86, to a discussion at
 13 an RTD meeting, CBLA0002345, please. This is
 14 8 October 1986. You were in attendance and if we turn
 15 to page 7, bottom of the page, we can see the
 16 discussion under the heading "Anti-HBc and/or ALT
 17 Testing":
 18 "The Chairman reminded Directors that the
 19 possibility of screening for anti-HBc had been
 20 discussed previously, and that studies of the
 21 incidence of anti-HBc in the donor population had been
 22 undertaken at Edgware, Bristol and Manchester about
 23 three years ago. Developments in America meant that
 24 this topic must be considered again as anti-HBc/ALT
 25 screening was soon to be essential for the

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1 "Dr Gunson reported that the Working Party on
 2 Transfusion Associated Hepatitis was due to meet on
 3 the following day to finalise a proposal to the DHSS
 4 to fund a limited study of 12,000 donors, looking for
 5 anti-HBc and abnormal ALT with follow-up of selected
 6 donors and possibly recipients."
 7 Then there's a further discussion in relation to
 8 that. Dr Napier raises a question about a study
 9 beginning with transfused patients:
 10 "Dr Gunson reported that this had been
 11 discussed, but it was felt to be costly, difficult,
 12 and not practical. The proposed approach would give
 13 information [can we then go to page 4, please, because
 14 page 3 is out of order] about the effect of anti-HBc
 15 and ALT screening on donor panels and blood
 16 collection."
 17 So if we can just go back to the bottom of the
 18 second page, if we just look at those last couple of
 19 lines, as far as you can recall, had you been party to
 20 discussions about -- the discussions that Dr Gunson
 21 refers to about it being costly, difficult, and not
 22 practical to undertake a study beginning with
 23 transfused patients?
 24 **A.** I don't recall having discussed it with him.
 25 **Q.** In any event, we're now, it's fair to say, in

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1 January 1987 and what's being talked about is still
2 the making of an approach for funding for a study to
3 be undertaken, the study hasn't yet been funded or
4 begun. Looking at it now, do you think this was being
5 considered quickly enough or was it all taking far too
6 long?

7 **A.** The latter. It was taking far too long.

8 **Q.** Can we then, please, go to PRSE0001444. If you look
9 at the bottom half of the page, right-hand side,
10 you'll see, Professor Contreras, there's an article by
11 Professor Cash and his colleagues, or a letter, about
12 non-A, non-B surrogate testing, with the "irrational,
13 perhaps, but inescapable" heading. I'm not going to
14 go through it because we've looked at it already in
15 the Inquiry and you've seen it in advance of your
16 evidence, but the purpose of putting it on screen is
17 I think you and Dr Barbara wrote a response to this
18 and that's what I want to ask you about?

19 So if we have PRSE0003767, 1 August 1987,
20 right-hand column. "Testing of blood donations for
21 non-A, non-B hepatitis". We'll see when we go over
22 the page that it's authored by you and Dr Barbara.
23 You say:

24 "In their contribution to the current debate in
25 *The Lancet* our Scottish colleagues ... argue the case

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1 "How far can the arguments stretch that 'all
2 known methods' should be used to avoid the risk of
3 [non-A, non-B hepatitis] after transfusion? The bulk
4 of [non-A, non-B hepatitis] may still be transmitted
5 even after surrogate screening. Are we certain that
6 patients would succeed in a legal action if they
7 contract [non-A, non-B] hepatitis after the
8 transfusion of blood untested for anti-HBc? Why
9 should [non-A, non-B] post-transfusion hepatitis be
10 such a special case that we have to make tremendous
11 efforts to prevent occasional infections? What about
12 the transmission by transfusion of agents such as
13 cytomegalovirus or HTLV-I for which they are *specific*
14 tests but which are not screened for routinely?

15 "With regard to pooled plasma products, can
16 anyone really feel confident that the 30% decrease in
17 virus load predicted from US studies as a result of
18 surrogate testing would have any obvious impact on
19 transmission of [non-A, non-B hepatitis] when 70% of
20 virus remains in the plasma pool?

21 "How can the impact of transfusion-transmitted
22 AIDS be compared with that of transfusion-transmitted
23 [non-A, non-B hepatitis], whose consequences seem
24 minor? We doubt if the public (since consumer
25 reassurance is being invoked) sees [non-A, non-B

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1 for surrogate testing of blood donations for non-A,
2 non-B hepatitis ... We take issue with several
3 points."

4 Then this is your first point:

5 "Has the time for a prospective study already
6 passed? This seems to imply that the longer an
7 unproven test is used, the greater becomes the
8 pressure to use it. This is not an argument that
9 should commend itself to those practising transfusion
10 medicine. Why should we have to wait 3-4 years for an
11 answer? If the problem is serious this will be
12 revealed, in *acute* [non-A, non-B hepatitis], within a
13 year of initiating the study. The need for controlled
14 studies of the incidence of [non-A, non-B]
15 post-transfusion hepatitis will not disappear with the
16 introduction of routine screening of blood donations
17 with tests of unproven value. Indeed, trials are
18 necessary in different countries where the incidence
19 of [non-A, non-B] post-transfusion hepatitis is likely
20 to vary as widely as does the incidence of positivity
21 for putative markers such as anti-HBc."

22 In fact, I'll read the whole letter, Professor
23 Contreras, and then ask you about it. So that's
24 your -- the first question that you pose. Next
25 paragraph:

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1 hepatitis] in the same light as AIDS. The
2 significance of HBV and HIV infection are well known;
3 the clinical importance of [non-A, non-B hepatitis]
4 has to be sought.

5 "Transfusion services must not bow to irrational
6 pressure for measures whose efficacy is unproven. In
7 the UK, transfusion centre directors resisted
8 commercial pressure for premature introduction of
9 unsatisfactory screening tests for anti-HIV; they show
10 the same resolution with [non-A, non-B hepatitis].

11 "At our transfusion centre 400,000 blood
12 components are available for transfusion per annum.
13 We have received an average of only 4 reports of
14 [non-A, non-B] post-transfusion hepatitis annually for
15 the past 10 years, and we repeatedly remind clinicians
16 of the need to report infective complications of blood
17 transfusion. A realistic estimate of the annual cost
18 of surrogate screening for [non-A, non-B hepatitis] in
19 the UK would be £9 million. Our colleagues' estimate
20 of £2 per test (which test?) seems too low, and to it
21 must be added the cost of counselling 3-4% of blood
22 donors.

23 "It is vital to extend the few available studies
24 of transfusion recipients with more complete follow-up
25 of untransfused patients to find out what role

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1 sporadic [non-A, non-B hepatitis] has in the hepatitis
2 attributed to transfusion. And before we accept that
3 50% of cases of [non-A, non-B] post-transfusion
4 hepatitis progress to chronicity and that 10% of
5 chronic cases progress to liver cirrhosis, larger
6 studies must be done. New studies are also essential
7 because the published data on [non-A, non-B hepatitis]
8 transmission by transfusion relate to transfusions
9 given before the 'clean-up' of donor panels in the
10 wake of the AIDS epidemic."

11 Over the page, last paragraph, top of the page:

12 "Even those arguing most forcefully for the
13 significance of [non-A, non-B] post-transfusion
14 hepatitis, recognise that studies on the natural
15 history of chronic [non-A, non-B hepatitis] have been
16 limited both in size and duration of follow-up and
17 that the ultimate prognosis of this disease has not
18 been established."

19 So if we just go back to the previous page, you
20 appear to be -- you and Dr Barbara -- very clearly
21 advocating here that surrogate testing should not be
22 introduced until such time as further studies had been
23 undertaken; is that fair?

24 **A.** Yes.

25 **Q.** One of the reasons you articulate for that is one of

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1 you wait for a more complete understanding of the
2 problem.

3 **A.** Yes. I have to admit that.

4 **Q.** Can I then just ask you to look next at a comment in
5 a Regional Transfusion Directors meeting, July 1987.
6 CBLA00028 -- CBLA0002383.

7 **A.** Can I just say that, unfortunately, perhaps, we did
8 not see the problem, and you know -- and also I don't
9 know when the study by Seeff and by Harris, those
10 studies of the long-term effects and survival, were
11 done. But that confirmed what we were thinking at the
12 time, that apparently it wasn't causing more problems
13 in the general -- from the point of view of mortality,
14 more problems in the general population.

15 I admit that I was wrong in not having
16 introduced screening before but, unfortunately, we
17 were not seeing the problem.

18 **Q.** This is the minutes of a meeting, July 1987, of the
19 Regional Transfusion Directors. So it's after
20 Professor Cash's and his colleagues' letter has been
21 published in The Lancet but before the response that
22 we were just looking at from you. If we go, please,
23 to page 8, bottom half of the page, there's a heading
24 "Letter to Lancet from SNBTS":

25 "The Chairman referred to both his own

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1 the issues to which you've already referred, that
2 there was more that -- there was a lot that was
3 unknown, if I can put it that way.

4 **A. (Witness nodded)**

5 **Q.** You were also concerned about costs and about the
6 potential to lose donors, and the need to make
7 arrangements for counselling donors found to be
8 showing one or other of the surrogate markers; is that
9 right?

10 **A.** Yes.

11 **Q.** Was it right to say, even in -- given everything you
12 told us yesterday about your evolving understanding in
13 relation to non-A, non-B hepatitis, that, in relation
14 to non-A, non-B hepatitis as at 1987, the consequences
15 seemed minor. Was that not underplaying, on any view,
16 the risks in relation to non-A, non-B hepatitis?

17 **A.** Yes, I admit -- yeah.

18 **Q.** Can I suggest, Professor Contreras, that a problem
19 with the approach described in this letter, of
20 undertaking more studies and only then deciding
21 whether or not to introduce the screening, would be
22 that you would be perpetuating a state of affairs in
23 which there was no screening or testing whatsoever in
24 relation to non-A, non-B hepatitis. You're running
25 the risk of people continuing to be infected, while

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1 reservations and those of other Directors about the
2 letter recently published in The Lancet to which all
3 the Scottish Directors were signatories on the subject
4 of anti-HBc and ALT screening of all donations. There
5 was disappointment that unilateral action had been
6 taken and it was this, rather than the contents of the
7 letter, to which exception was taken, though it was
8 pointed out that the costings quoted in the letter
9 could be challenged. Professor Cash indicated that
10 although he was concerned about the views being
11 expressed that he had had no alternative. Dr Whitrow
12 indicated that he perceived a different attitude to
13 product liability by SHHD north of the border which
14 was one of the factors which had prompted the letter."

15 Now, I don't know whether you've got any
16 independent recollection of this meeting at which you
17 were present, Professor Contreras, but the way in
18 which the first half of that paragraph is expressed
19 tends to suggest that the mood of the RTDs was not
20 profound disagreement with what the Scottish -- their
21 Scottish colleagues were saying but just
22 disappointment that there had been, as it were,
23 a breaking of ranks by the letter being sent.

24 Do you have any recollection of whether that is
25 an accurate reflection of the mood of the meeting?

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1 **A.** I might -- it might have been the mood of the meeting
2 but I cannot remember.

3 **Q.** We've got a couple of letters that you wrote to
4 Dr Rotblat at the Department of Health in late 1987.
5 I'm not going to go to them because they're on
6 a similar theme to the materials we've already
7 looked at, I'll just give the reference for those who
8 might wish to look at them. They're NHBT0000187_008
9 and NHBT0000187_010 and they're letters from you to
10 Dr Rotblat 14 and 22 November 1987.

11 I want to then pick matters up in 1988, if we go
12 to NHBT0000187_024. Again, I'm not going to go
13 through the detail of this but we can see it's headed
14 "Multi-Centre Study of ALT and anti-HBc Screening of
15 Blood Donations, Minutes of meeting of steering
16 committee, Manchester, 8th June 1988". We can see
17 a number of people in attendance, including from North
18 London yourself and Dr Barbara, and then there's
19 an invitation just below the list of attendees for you
20 to chair the steering committee. Then we can see at
21 paragraph 3:

22 "Centres participating in the study:
23 "Manchester ...
24 "Bristol
25 "Edgware

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1 1989. I'm not going to go to it but just so we can
2 get the chronology right.

3 Then if we go to NHBT0000043_002. This is the
4 first meeting of something called the UK Advisory
5 Committee on Transfusion Transmitted Diseases. If we
6 go over the page, we've got the date of the meeting,
7 24 February 1989, and those present: it's
8 Professor Cash, you, Dr Follett, Dr Gunson,
9 Dr Mitchell and Dr Mortimer, and Dr Wagstaff giving an
10 apology for absence.

11 Then if we can look at paragraph 2:
12 "Dr Gunson introduced the meeting by saying that
13 he had, about a year ago, discussed the forming of
14 a UK Group to determine policy with respect to
15 transfusion transmitted diseases with Drs McClelland
16 and Pickles. The Department of Health were in the
17 process of forming such a group but its brief would be
18 wider than blood transfusion medicine, embracing
19 transplantation and other aspects of disease
20 transmission.

21 "This present Committee had been formed to
22 discuss transfusion transmitted diseases and to
23 provide advice to the Departments of Health."

24 So this committee, the Advisory Committee on
25 Transfusion Transmitted Diseases, was a new committee,

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1 "(Edinburgh has withdrawn ...)"

2 Then there's a discussion about how the study is
3 going to be undertaken. I'm not going to go through
4 the detail of it but is it right to understand that,
5 essentially, it's taken until the middle of 1988 for
6 the funding to be made available to enable the study
7 to even commence?

8 **A.** Yes.

9 **Q.** Can you recall what the scope of the study was? We
10 can look at the documents if we need to but do you
11 have any broad recollection?

12 **A.** It was that three centres would test donations from
13 males and females for the prevalence of anti-core and
14 ALT raised above a certain level. I think it was
15 45 international units per litre but, yeah.

16 **Q.** Is it right to understand that it was a more limited
17 study than the bigger two-stage prospective study --

18 **A.** Yes.

19 **Q.** -- that you'd been discussing earlier?

20 **A.** Yes, it was just the prevalence in donations.

21 **Q.** Then if we move on to 1989, NHBT000000 -- sorry,
22 I should just say I'm going to give a reference and
23 not go to it. There's an RTD meeting in October 1988
24 at NHBT0018189, which says that the results of the
25 trial won't be available until the late spring of

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1 set up, as described by Dr Gunson there, to provide
2 advice to the Department of Health.

3 What was, as far as you understand the
4 interrelationship between this committee and its work,
5 and the work of the Advisory Committee on the
6 Virological Safety of Blood, which you didn't sit on?

7 **A.** Yeah.

8 **Q.** Did you have a clear understanding of their relative
9 roles?

10 **A.** As far as I can remember, the Advisory Committee had
11 more power, more teeth, and this was just an advisory
12 committee to the ... to the main Department of Health
13 committee.

14 **Q.** So this committee that we're looking at, the ACTTD,
15 would have discussions, but its thinking might then be
16 communicated to the Advisory Committee on the
17 Virological Safety of Blood?

18 **A.** Yes.

19 **Q.** And then the latter's recommendations might then go to
20 the Department of Health?

21 **A.** Yeah. Well, that was chaired, the advisory committee,
22 I learnt later, because the information from the
23 ACV --

24 **Q.** ACVSB.

25 **A.** -- was never shared with us as transfusion directors,

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1 but I learnt that the Department was -- it was the
 2 Deputy Chief Medical Officer who chaired those
 3 meetings. I learned from my reading.
 4 **Q.** Was that Dr Metters?
 5 **A.** Dr -- first it was Dr Harris and then Dr Metters.
 6 **Q.** And so is it right to understand that what was
 7 happening in the Advisory Committee on the Virological
 8 Safety of Blood might get reported back to you by some
 9 extent by Dr Gunson?
 10 **A.** Yes.
 11 **Q.** But there was no -- its minutes, its recommendations,
 12 its thinking, wasn't formally shared with you?
 13 **A.** No, they were secret minutes.
 14 **Q.** And do you know why that was? It doesn't seem
 15 necessarily conducive to the most joined-up
 16 decision-making?
 17 **A.** I wish knew, but there's so many things on the
 18 Department of Health I never was able to understand.
 19 **Q.** Then if we go in this meeting to page 5 and we can
 20 look at the discussion about surrogate testing. So
 21 we've got the heading "Non-A, non-B hepatitis":
 22 "Dr Contreras outlined the results of the study
 23 in England and Wales ..."
 24 So that's the three-centre study in which
 25 North London had been one of the participants.

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1 this was something that would inevitably have to come.
 2 **A.** Yeah.
 3 **Q.** And then we see paragraph 7.5:
 4 "Dr Gunson reported that Ortho Pharmaceutical
 5 Company had approached him with respect to trials with
 6 the Chiron Test in the UK."
 7 Now that's not talking about surrogate testing
 8 but about the newly developed test for hepatitis C.
 9 **A.** Yes, anti-HCV.
 10 **Q.** Anti-HCV.
 11 Although paragraph 7.4 refers to the
 12 inevitability about the introduction of -- at least
 13 for ALT testing, that didn't happen, did it?
 14 **A.** No.
 15 **Q.** The -- is it right to understand that active
 16 consideration in relation to surrogate testing
 17 essentially fell into the background because the focus
 18 then shifted to anti-HCV testing?
 19 **A.** Yes, that's correct.
 20 **Q.** Can I then just ask you, just a little, in terms of
 21 reflections, about surrogate testing more generally in
 22 relation to non-A, non-B hepatitis.
 23 It's right, I think, to understand that in
 24 relation to both ALT testing and anti-HBc testing,
 25 those were tests which were relatively well known and

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1 At 7.2:
 2 "Dr Mitchell reported that in a Glasgow study of
 3 5,000 donations the ALT exceeded 50 iu in 2.8%. With
 4 respect to anti-HBc tests in a separate study, 17 out
 5 of 2,000 donations were found positive, of which 15
 6 were reproducible."
 7 So there was a study being undertaken in
 8 Scotland which was largely in parallel with the study
 9 that you were taking in England and Wales?
 10 **A.** Yes.
 11 **Q.** Then there's a report from Dr Cash about the
 12 methodology for ALT testing, and then 7.4:
 13 "It was agreed that there would be no
 14 recommendation to institute ALT testing until the
 15 current study was completed in England. However,
 16 there was a degree of inevitability about the
 17 introduction of the test which was required by
 18 regulatory authorities in other countries to determine
 19 the acceptability of fractionated plasma products.
 20 This would be discussed with BPL in the near future."
 21 So at this stage, in February 1989, it's right
 22 to understand from this, I think, that this committee
 23 is not making any recommendation that a decision be
 24 made to introduce ALT testing. The plan was: complete
 25 the study. But there seems to be a recognition that

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1 understood?
 2 So you weren't -- when I say "you", the Blood
 3 Transfusion Service, the Department of Health, wasn't
 4 in the position that it had been with HTLV-III testing
 5 and that it might be with anti-HCV testing, where
 6 there had to be an evaluation of how well tests
 7 worked. It was known that ALT testing and anti-HBc
 8 testing could be undertaken relatively simply and
 9 straightforwardly.
 10 **A.** Yes.
 11 **Q.** And other than through donor screening, which we've
 12 already discussed in some detail, it would be right to
 13 understand that there was no other way, was there, of
 14 reducing the possibility of transmission of non-A,
 15 non-B hepatitis at this point in time, other than
 16 using either ALT or anti-HBc or both?
 17 **A.** Well, as we showed later on with John Barbara and my
 18 team, the introduction of self -- of exclusion of
 19 donors -- prospective donors in high-risk groups, that
 20 decreased the prevalence of anti-core -- anti-HBc in
 21 blood donations. But that was like a benefit that we
 22 didn't expect, or -- yeah, but --
 23 **Q.** As an incidental benefit of what was already being
 24 done?
 25 **A.** Incidental, yes.

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1 **Q.** I absolutely understand, Professor Contreras, that
2 donor selection, donor screening measures, in relation
3 to high-risk groups, introduced for other reasons,
4 might then have incidental benefits in terms of non-A,
5 non-B hepatitis. But if one leaves aside those
6 measures in relation to selection and screening of
7 donors, there was nothing else available in the 1980s,
8 until we get to the anti-HCV test, other than
9 surrogate markers. So if anything was going to be
10 done, it would have to have been one or other or both
11 of those?

12 **A.** Yes. And I -- with hindsight, I would have chosen
13 anti-core, because it was more specific, and because
14 we later showed with -- well, the virologist, the
15 microbiologist showed that anti-core was also
16 beneficial to exclude the transmission of hepatitis B
17 that was still occurring.

18 **Q.** Yes. And if time permits, we might come on to
19 anti-HBc as -- in relation specifically to hepatitis B
20 this afternoon.

21 But before I turn to ask you about, then, the
22 decision-making in relation to anti-HCV screening, can
23 I just ask you about two matters relating to
24 registers? So there came a point -- let's -- if we
25 look at the letter it will give us the date.

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1 obviously at a later stage, because as at 1987 the
2 anti-HCV test hadn't yet been identified -- there was
3 a hepatitis C register.

4 If we just look at your statement, at
5 WITN5711001, page 83. It's paragraph 328, bottom half
6 of the page. You refer there to the HCV National
7 Register collecting data from transfusion recipients
8 traced during the HCV look-back exercise.

9 Did you have any direct involvement with the
10 establishment or operation of the HCV register?

11 **A.** I believe we had, because we had meetings with the
12 CDSC and the PHLS. So Dr Barbara and Dr Hewitt and
13 myself were always in conversation with the CDSC and
14 the PHLS.

15 **Q.** And the question I've been asked to ask you about the
16 HCV register, I don't know if you'll know the answer
17 to this or not, was about patient consent, whether
18 patients were told that their details were being
19 entered on the register or whether it was done without
20 patient knowledge?

21 **A.** I cannot remember, but -- I do not know whether they
22 were, no.

23 **Q.** If we then come to the question of hepatitis C
24 screening, and I think if we pick matters up with
25 a letter that you wrote to Dr Gunson in January 1989,

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1 BPLL007760_001.

2 This is September 1987. You were writing to
3 Dr Fraser, who was the Regional Transfusion Director
4 in Bristol but also chair of the Regional Transfusion
5 Directors, I think, at this point in time.

6 You were writing suggesting the formation of
7 a national register for hepatitis B, and Dr Barbara
8 had volunteered to be the central coordinator of that.

9 Now I'm not proposing to go through the detail
10 of what you set out here and how it could work, but
11 could you just set out for us your recollection of why
12 you thought that this would be a useful idea, and
13 whether it was established in due course?

14 **A.** Yes. I supported firmly the idea of a national
15 register, because we should have national registers
16 for all transfusion-transmitted diseases, infections,
17 particularly transmission by labile blood components.
18 So -- and we did not know what the extent of -- we
19 knew in our centre, but what the extent nationally of
20 hepatitis B transmission was. And this register did
21 take effect, although not all centres contributed in
22 the same way, but it had -- I thought it was a very,
23 very good proposal, and it would have taught the
24 country a great deal.

25 **Q.** And then in relation to hepatitis C there was --

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1 it's at NHBT0000187_042, please. So 15 January, you
2 to Dr Gunson, and you say:

3 "On Thursday I had a meeting with my Treasurer
4 who said that it would be very difficult to find the
5 monies for the introduction of anti-HCV screening of
6 blood donations in 1990. He asked whether the
7 provision of central funding would be considered by
8 the Department of Health. Most districts in the
9 North-West Thames region are overspent and he is
10 doubtful whether the 2% growth given to all Regions
11 for 1990/91 will cover most of the immediate
12 programmes in the North-West Thames Region. He asked
13 whether I would consider anti-HCV testing as top
14 priority (ie more important than shortening of the
15 waiting lists) and I had to admit that I do not.

16 "As you well know the sums of money involved for
17 anti-HCV screening are considerable and it would be
18 very difficult, if not impossible, to find the funding
19 within existing resources."

20 Now that's one of a number of letters that -- or
21 occasions over the course of the next three years in
22 which you raised the concern about the cost of
23 anti-HCV screening and your view that it should be
24 funded by the Department of Health. We know it never
25 was. It wasn't funded by the Department of Health.

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1 Why was it that you thought this should be
2 a Department of Health centrally funded initiative?
3 **A.** Because it was a central decision, and because that
4 had happened with previous screenings. For anti-HIV
5 there was money for everything, and for anti-HCV there
6 was no money.

7 **Q.** And did you ever learn why it was that the Department
8 decided that funding for this testing programme was to
9 be met regionally rather than centrally?

10 **A.** I don't know what -- how the Department saw it, but
11 I -- you know, I would be speculating that ...
12 Perhaps they didn't see it as they saw HIV, and
13 as they later saw variant CJD.

14 **Q.** Now, in the course of 1989 there were a number of
15 things that happened in relation to consideration of
16 anti-HCV screening. There was, I think, some
17 participation by the North London Centre in the course
18 of 1989 in evaluation of the Ortho assay, is that
19 right?

20 **A.** Yes.

21 **Q.** And then --

22 **SIR BRIAN LANGSTAFF:** Can I just for a moment understand
23 the dates here. My understanding is that it wasn't
24 until May 1988 that the Chiron Corporation announced
25 that it had cloned the -- a virus which was -- became

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1 stage.

2 **MS RICHARDS:** Yes. We don't, unfortunately, have a single
3 witness with whom -- who was involved in every aspect
4 of it with whom we can go through a comprehensive
5 chronological account. There will be some gaps that
6 Dr Barbara may be able to fill in and there will be,
7 no doubt, I think, Department of Health witnesses next
8 year who we'll be able to, again, fill in a lot of the
9 gaps with.

10 Perhaps the figure most centrally involved in
11 terms of attendance at committees and involvement in
12 discussions and so on was Dr Gunson.

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS RICHARDS:** And we have, of course, his written and oral
15 testimony to Mr Justice Burton in *A v National Blood
16 Authority*, but there isn't a single witness with whom
17 we can, I'm afraid, give the overall chronology. But
18 there are meetings in which I know Dr Barbara was
19 involved in the course of 1988 in which the Chiron
20 discovery was being considered and discussed, and he
21 may be able to assist us with how his knowledge of it
22 developed over the second half of 1988 and the course
23 of 1989.

24 **SIR BRIAN LANGSTAFF:** Well, it would certainly seem that
25 without there being the test actually physically

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1 known as hepatitis C, it was the cause of non-A, non-B
2 hepatitis. And it wasn't then reported quite what the
3 details were until the following year, and it wasn't
4 until, I think, April of 1989, my earliest note is, of
5 any report to there being an assay, a test which could
6 be used to screen.

7 But the letter we've just been looking at
8 NHBT0000187_042 comes from January 1989 and is talking
9 about the costs of screening, without an actual test
10 being marketed at that stage. When was the test
11 marketed, as far as you can recall? Was it before the
12 details of the cloning were ever published or not?

13 **A.** No, no.

14 **SIR BRIAN LANGSTAFF:** And plainly it would seem Ortho had
15 been working on what an assay would look like without
16 the details having been published, except to them, by
17 the Chiron Corporation. Is that probably right?

18 **A.** I think perhaps yes, sir, I ...

19 **SIR BRIAN LANGSTAFF:** So they would, as it were, corner
20 the market?

21 **A.** Yes, sir.

22 **SIR BRIAN LANGSTAFF:** Yes. But the question then is what
23 happened in -- when, in 1989, after April, when the
24 first -- or the assay was announced or announced
25 available for sale or whatever it actually was at that

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1 there, everyone was anticipating there would be one.

2 **THE WITNESS:** No, I don't think that was the case, sir.

3 **SIR BRIAN LANGSTAFF:** Right.

4 **A.** I think that they had a test, but it hadn't been
5 approved in the USA --

6 **SIR BRIAN LANGSTAFF:** I see.

7 **A.** -- by the FDA. And so they more or less secretly had
8 a test, you know? But I think that was the case.

9 **SIR BRIAN LANGSTAFF:** Right. I understand.

10 **MS RICHARDS:** Yes. And at the meeting that we looked at
11 a few minutes ago, the first meeting of the advisory
12 committee in relation to transfusion-transmitted
13 diseases in February 1989, Dr Gunson described there
14 an approach he'd received from Ortho with respect to
15 conducting trials of the test in the UK.

16 **SIR BRIAN LANGSTAFF:** Yes.

17 **MS RICHARDS:** I only looked at the surrogate testing when
18 we looked at it earlier but there is a passage in
19 those minutes which record Dr Gunson's conversations.

20 **SIR BRIAN LANGSTAFF:** It was -- this is a comment, really,
21 but it was curious that that should come immediately
22 after a discussion of whether there should be
23 a surrogate test -- or a study to see if there should
24 be a surrogate test, rather.

25 **A.** Yes.

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1 **SIR BRIAN LANGSTAFF:** Because you might have thought the
 2 purpose of the surrogate test is to identify something
 3 which you're now going to trial direct test for.
 4 **A.** Yeah.
 5 **MS RICHARDS:** And, sir, you're right to think in relation
 6 to -- April 1989 was the publication in Science.
 7 **SIR BRIAN LANGSTAFF:** Yes, 21st April, was it?
 8 **MS RICHARDS:** I've only got April, I'm afraid, written
 9 down in my notes, sir, but the publication in the
 10 articles in Science about the -- the details of the
 11 specific screening test.
 12 Dr Gunson had, in advance of that, drawn up
 13 protocols for a proposed trial of the Ortho test.
 14 **SIR BRIAN LANGSTAFF:** Yes. So there was, if I can
 15 summarise it this way: is it a fair summary to say
 16 there was developing appreciation that a test was
 17 likely and there were candidates or a candidate under
 18 consideration in early -- from the beginning of 1989
 19 onwards? Would that be fair?
 20 **A.** Yes.
 21 **SIR BRIAN LANGSTAFF:** Thank you.
 22 **A.** Yes, sir.
 23 **MS RICHARDS:** And, sir, my notes again record, April 1989,
 24 Dr Gunson meeting with Chiron, at which it was
 25 agreeing that Ortho test kits would be supplied to the

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1 on the results of an anti-HCV UK study on surrogate
 2 markers for NANB post-transfusion hepatitis in blood
 3 donors ..."
 4 If we go to the top of the next page:
 5 "After a wide ranging and careful consideration
 6 of the many problems regarding the test and its
 7 introduction for routine screening of donations, it
 8 was agreed that Dr Gunson's paper should be used as
 9 the basis of the paper to be submitted to the
 10 Department's Committee.
 11 "It was also agreed that Dr Gunson's paper
 12 should incorporate information from the papers
 13 prepared by Drs Mitchell and Raafat as well as
 14 a number of textual amendments proposed by the
 15 Committee."
 16 It might be said to be a somewhat laborious
 17 decision-making process but what we appear to have
 18 here is Dr Gunson putting together a paper with -- I'm
 19 not going to take you to the details of his paper, but
 20 putting together a paper with his views,
 21 recommendations, in relation to testing.
 22 That's, as it were, considered by this committee
 23 upon which you sit, the ACTTD, but then it's going to
 24 go then to the ACVSB, because, is this right, it's the
 25 ACVSB which is charged with -- not making the decision

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1 North London Regional Test Centre to enable the trial
 2 and evaluation to be undertaken.
 3 Perhaps -- well, again, I think we can probably
 4 pick this up with other witnesses but we know one of
 5 the things that happens later in 1989,
 6 Professor Contreras, was a symposium in Rome in
 7 September 1989, which I think Dr Barbara attended. Do
 8 you recall whether you attended that or not?
 9 **A.** No, I did not.
 10 **Q.** Okay, well, then we can pick that up hopefully with
 11 him.
 12 And then if we get to October 1989,
 13 NHBT0000043_034, this is the Advisory Committee on
 14 Transfusion Transmitted Diseases, 9 October 1989. If
 15 we go to the bottom of page 2, we can see the heading
 16 "Anti-HCV testing of blood donors". So this gives us
 17 a sense of the way in which the decision-making
 18 process was being undertaken.
 19 "The Committee were informed that the Department
 20 of Health's Advisory Committee on the Virological
 21 Safety of Blood had requested a briefing paper on
 22 policy regarding Anti-HCV testing of blood donors.
 23 "The Committee considered two papers summarising
 24 the first international meeting on the Hepatitis C
 25 virus prepared by Drs Gunson and Mitchell, and a paper

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1 but making with formal recommendations to the
 2 Department of Health?
 3 **A.** Yes.
 4 **Q.** And then it's the Department of Health that makes the
 5 decision. Is that your understanding of it?
 6 **A.** Yes.
 7 **Q.** Whether at the time or having looked back at the
 8 material now, do you have any thoughts or observations
 9 upon the speed or lack of speed with which the
 10 decisions were taken over this period from 1989
 11 through to 1991?
 12 **A.** Yes, the lack of speed.
 13 **Q.** We can then, I think, see you reporting back to
 14 a divisional meeting in October '89 at
 15 NHBT0017553_001. So this is a meeting of the Eastern
 16 Division of Consultants, chaired by you.
 17 And if we turn to page 6, at the bottom of the
 18 page:
 19 "Anti-HCV testing
 20 "Not yet licensed by FDA, but the UK is likely
 21 to commence testing around June/July 1990. Concern
 22 was expressed that there is no confirmatory test.
 23 Dr Contreras informed the meeting that Dr Gunson's
 24 recommendation to the DHSS were that the UK should
 25 start testing (i) only after FDA licensing, (ii) when

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1 confirmatory testing is available and (3) there is
 2 provision for counselling. The financial implication
 3 for the UK is likely to be over 5 1/2 million pounds.
 4 It's been estimated that it would cost the [North
 5 London Blood Transfusion Service] over £600,000 per
 6 year at the rate of £1.70 [plus] VAT per test. This
 7 cost excludes the replacement of the 1% or so donors
 8 who would be lost."

9 If we leave aside the financial issue,
 10 Professor Contreras, there are three pre-conditions
 11 here identified in terms of what's going to be, it's
 12 said, recommended through Dr Gunson to the Department
 13 of Health. The first relates to FDA licensing. Why
 14 was the UK's commencement of testing to be dependent
 15 upon the grant of a licence from the FDA?

16 **A.** Because they, like the MCA, can -- they're very strict
 17 in the approval of a test. So they would have, very
 18 sensibly, looked at all the aspects of the testing
 19 before approving it for use in the United States, and
 20 we didn't have that mechanism here.

21 **Q.** The second pre-condition is when confirmatory testing
 22 is available. Is this because of the concern about
 23 false positives?

24 **A.** Yes.

25 **Q.** Then (3), "provision for counselling". Counselling

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1 doctors.

2 **Q.** Can you recall -- bearing in mind this is a meeting as
 3 at October 1989 and the expectation at this point is
 4 the UK is likely to commence testing in mid-1990. Can
 5 you recall when at the North London Centre you started
 6 making the arrangements or putting in place the
 7 arrangements for counselling?

8 **A.** As -- I think it must have been as soon as we knew
 9 that we were going to start testing.

10 **Q.** Because is it right to understand that, perhaps in
 11 contrast with the position relating to surrogate
 12 testing, there was never any doubt, was there, that
 13 testing for HCV would be introduced, really? The
 14 question was always going to be --

15 **A.** When.

16 **Q.** -- when. So centres would know, on any view, that
 17 this was coming?

18 **A.** Yes.

19 **Q.** Then if we look at -- again, there are various
 20 publications, some of which you contribute to over the
 21 following months but I don't think we need to go
 22 through the details of them all, and we've got them in
 23 the papers that the Inquiry has.

24 Perhaps we could pick it up at NHBT0071870_002,
 25 which is January 1990. So we've now got the National

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1 would take what form in relation to an anti-HCV
 2 positive test?

3 **A.** It would -- we would have to contact the donor, ask
 4 him to come to the blood centre or to go to somewhere
 5 where he could be counselled. We would have to test
 6 him -- tell him that he or she was anti-HCV positive,
 7 that he might be carrying an infection, that he would
 8 not be able to donate again, and we would refer that
 9 patient -- we would advise that patient to go to
 10 hepatologist that we would have contacted.

11 **Q.** Now, I can see that there are obviously resource
 12 implications in relation to that. But it's not
 13 a particularly complex system, is it, to set up?
 14 Leaving aside the question of obviously funding and
 15 it'll take a certain amount of time, and you need to
 16 have the doctors who have the capacity to do that, but
 17 it's not a difficult system. Indeed, it's a system
 18 you'd have been familiar with --

19 **A.** -- (overspeaking) --

20 **Q.** -- at other centres because of other testing?

21 **A.** Yes.

22 **Q.** So is there any particular reason why the need to make
 23 provision for counselling should have held things up?

24 **A.** The cost, again. It's always cost. Because we would
 25 have needed a great deal of manpower to -- and it's

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1 Directorate established for the National Blood
 2 Transfusion Service and this is its National
 3 Management Committee of which you were a member, and
 4 the meeting is 4 January 1990, and you were present at
 5 the meeting.

6 We can see what's happened in relation to
 7 anti-HCV at page 4 under the heading "Pilot trial on
 8 anti-HCV testing", bottom half of the page:

9 "Dr Gunson tabled a report which summarised the
 10 findings of the pilot studies on anti-HCV tests in the
 11 [North East] Thames, Trent and [West] Midlands Regions
 12 and which included comments on the test from [North
 13 East] Thames and Trent."

14 So some pilot studies, obviously, by this point
 15 in time have been completed. I'm not going to go
 16 through the detail of the discussion then.

17 If we go to the top of the next page, the first
 18 paragraph tells us Dr Gunson was going to:

19 "... prepare a more comprehensive report for
 20 distribution to all RTCs and to the [Advisory
 21 Committee on the Virological Safety of Blood]."

22 He then advises that:

23 "... the [Advisory Committee on the Virological
 24 Safety of Blood] was to complete a cost benefit
 25 exercise on the introduction of anti-HCV testing."

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1 There's then reference to the Abbott test, so
 2 there's a second test now available for evaluation, is
 3 that right?
 4 **A.** Yes.
 5 **Q.** Then, if we go just to the next paragraph further
 6 down, it says:
 7 "With regard to the absence of a confirmatory
 8 test, Dr Gunson advised the Committee that the ACVSB
 9 did not see this necessarily as a barrier to the
 10 introduction of routine screening, but the ACVSB would
 11 insist that any test for routine use must have been
 12 licensed by the FDA."
 13 . You have told us already, I think, that you
 14 didn't see the minutes of the ACVSB meeting, those
 15 were regarded as secret or confidential.
 16 Did you have any particular understanding,
 17 through Dr Gunson or through any other means, of the
 18 ACVSB's approach to the question of confirmatory
 19 testing?
 20 **A.** No.
 21 **Q.** So you don't know whether their thinking was: well, we
 22 can start screening and perhaps deal with the
 23 availability of confirmatory testing as and when it
 24 becomes available, but it shouldn't hold up the
 25 introduction of screening? You don't know if that's

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1 introduced or were about to introduce anti-HCV
 2 screening into their nations?
 3 **A.** Yes.
 4 **Q.** Do you recall being concerned or your fellow Regional
 5 Transfusion Directors being concerned that the UK was
 6 taking longer, was lagging behind what was happening
 7 in other developed nations?
 8 **A.** Unfortunately, I wasn't concerned at the time, if
 9 I remember correctly, unfortunately. Because of the
 10 nature of the beast, because the test was -- had no
 11 confirmatory assay, and because it had so many false
 12 positives. I should have been concerned, but
 13 I wasn't.
 14 **Q.** Then -- again, without taking you, I think,
 15 unnecessarily to meetings, if I just give a couple
 16 of -- or a reference for the transcript --
 17 NHBT0000043_047 is the March 1990 meeting of the
 18 Advisory Committee on Transfusion-Transmitted
 19 Diseases, which reports that the ACVSB had deferred
 20 making a decision until its next meeting at the end of
 21 April.
 22 Then the next, I think, date of significance,
 23 again, I'm not going to take you to the underlying
 24 documents because it relates to a meeting you didn't
 25 attend, but the ACVSB, I think, in July 1990 decided

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1 what they were thinking?
 2 **A.** I think that's what I read.
 3 **Q.** Then if we go further down the page there's
 4 a reference to you:
 5 "Dr Contreras said that about 1% of those tested
 6 in the [North West] Thames region had found to be
 7 repeatedly positive, but that not all of these were
 8 found to be infectious and it appeared to be that not
 9 all of those who had received blood donated by such
 10 people had developed HCV."
 11 So is it right to understand that's a finding it
 12 from the pilot study that was undertaken in your
 13 region?
 14 **A.** It must have been, yes.
 15 **Q.** Then it's described:
 16 "The prevalence of HCV in England and Wales
 17 appeared to be similar to that experienced in some
 18 states in the USA, but lower than the estimated
 19 prevalence in Denmark, Italy, Spain and about the same
 20 as in Finland."
 21 Now, I'm not going to go through the details of
 22 all the countries which introduced hepatitis C
 23 screening before the UK did, but you would have
 24 presumably have become aware, particularly in the
 25 course of 1990, that a number of other countries had

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1 that there needed to be a pilot study of both the
 2 Ortho and the Abbott tests.
 3 So what I want to do, then, is just pick matters
 4 up with a document or authored by you at the end of
 5 1990, Professor Contreras. It's NHBT0000190_067, so
 6 it's 17 December 1990 from you to Dr Barbara and
 7 Dr Brennan.
 8 "I have read the FDA regulations for anti-HCV
 9 and the revised recommendations for the prevention of
 10 HIV transmission.
 11 "I must admit that the Americans have put
 12 themselves in a very awkward position regarding
 13 anti-HCV testing with no recommendations for
 14 supplementary tests."
 15 Is "supplementary" there a synonym for
 16 confirmatory tests?
 17 **A.** Yes, yes.
 18 **Q.** "When will they learn? I pity those physicians who
 19 will have to explain the 'possible significance of
 20 positive test results' to repeatably reactive donors."
 21 Then the next paragraph deals with an issue
 22 relating to HIV. Then in the last paragraph you say:
 23 "I am bemused after reading these two documents.
 24 I just cannot understand the FDA thinking."
 25 Looking at that now, Professor Contreras, why

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1 were you so bemused or perplexed at what was being
2 done in the USA?

3 **A.** If I remember correctly, at that time, I said this --
4 we knew that the test had a lot of false positives or
5 that there were too many positives to the number of
6 real positives, and that there was no way of knowing
7 which one -- which of those units/donations was the
8 one that was transmitting HCV. So I was bemused that
9 the FDA was not insisting on a confirmatory test or
10 not mentioning it.

11 **Q.** I'm going to then pick the chronology up in 1991 with
12 a series of letters.

13 Sir, rather than do one of them now and then
14 come back to the rest of them after lunch, perhaps we
15 can take lunch now, a couple of minutes early and then
16 do them as a coherent sequence.

17 **SIR BRIAN LANGSTAFF:** Well, we'll do that and come back at
18 two o'clock. So two o'clock, please, for lunch.

19 After lunch.

20 **(12.56 pm)**

21 **(The Luncheon Adjournment)**

22 **(2.00 pm)**

23 **MS RICHARDS:** Professor Contreras, we'll pick up the
24 chronology of decision-making in relation to the
25 introduction of hepatitis C screening, in 1991, with

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1 You replied the same day to Dr Gunson saying:

2 "I am unable to give you a date in which we
3 could commence testing for anti-HCV, until we have
4 definitive information on financial arrangements to
5 cover screening, supplementary tests, counselling,
6 follow up, etc. We are extremely busy with our
7 Business Plans and contracts as well as dealing with
8 the extra workload incurred as a result of the
9 Gulf War and we cannot give anti-HCV screening the
10 priority required by the Department of Health."

11 That wasn't, I think, probably what Dr Gunson
12 was hoping for by way of response. He did write to
13 you later saying -- later in 1991, saying, "We can't
14 really start without you", because the North London
15 Centre was a big and important centre.

16 Why did you feel unable to give Dr Gunson a date
17 by which you could start?

18 **A.** Because in fact we were really, really busy with our
19 business plans. I don't know whether it was true,
20 cross-charging the internal market that had been
21 introduced, or that we were introducing notional
22 charging to hospitals. So everybody was working, and
23 then the Gulf War on top of that.

24 So, you know, we were coming to work at 8.00 in
25 the morning and leaving after 10.00 in the evening.

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1 NHBT0000076_006.

2 This is a memo from Dr Gunson to all Regional
3 Transfusion Directors, 22 January 1991, and in
4 paragraph 1, he says:

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

8 Looking at it now, and bearing in mind this is
9 now January 1991, had it taken too long to get to that
10 stage?

11 **A.** Yes.

12 **Q.** Then we can see, paragraph 2, Dr Gunson says:

13 "I have been asked to try and ensure that
14 testing starts simultaneously in England and Wales ...
15 coordinated with ... Scotland."

16 Then he asks, in paragraph 3, directors to
17 advise "what you consider to be the earliest date that
18 you could commence testing".

19 Then he explains in 4 that:

20 "Financial arrangements to cover routine
21 screening and supplementary tests have still to be
22 concluded ..."

23 If we then look at your response,
24 Professor Contreras.

25 NHBT0000073_030.

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1 We were really -- we were not coping with the work we
2 had and I think I must have shot from the hip.

3 **Q.** And it would appear -- no, let me put it a different
4 way.

5 When you said, "until we have definitive
6 information on financial arrangements", did you mean
7 by that "until we know if the Department of Health
8 will pay"?

9 **A.** Yes.

10 **Q.** In relation to the comments in the last sentence, "we
11 cannot give anti-HCV screening the priority required
12 by the Department of Health", it's right to note -- I
13 don't think we need to put it up on the screen -- that
14 Dr Gunson wrote back to you and said, "The Department
15 of Health has not asked for any priority to be given
16 to anti-HCV screening."

17 The reference for that, just for the transcript,
18 is NHBT0000073_039.

19 Now if we look at NHBT0000073_047 -- oh, we've
20 got it. Thank you.

21 So this is a letter from you, 12 February 1991,
22 to Dr Sheila Adam, the public health director at the
23 Regional Health Authority, and the second paragraph
24 says:

25 "As you can see from the attached copy of

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1 Harold Gunson's letter of 5 February, the Department
2 of Health proposes that the costs for anti-HCV
3 screening should be charged onto products issued from
4 RTCs and be borne by users. At NLBTC, we think that
5 this is simply appalling."

6 Then if we skip down a few lines, you say:
7 "The additional £600,000 or more needed for
8 anti-HCV screening are just not there."

9 Bottom of the page, last two lines you say:
10 "We feel that the Department does not understand
11 the full implications of screening for anti-HCV."

12 Then, over the page -- sorry, in fact, can we go
13 back to the bottom of the previous page. I should
14 have read the whole of the last two lines.

15 You say:
16 "It is not only that the blood derivatives [go
17 over the page] will be more expensive but donors who
18 are found to be positive will have to be counselled
19 and, if necessary, referred to liver specialists who
20 will treat them with expensive drugs such as
21 Interferon. Who will pay for this?"

22 Then you continue to set out a number of
23 concerns in relation to the funding.

24 You, I think, sent this letter to the chair of
25 the various Blood Transfusion Service divisions, for

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1 reluctantly."

2 Why were you reluctant to start screening, as
3 described in that letter?

4 **A.** Again, it's the cost, you know. I had to juggle with
5 all the things -- the expenses of the centre, and
6 I didn't have those 600,000.

7 **Q.** If a decision had been taken by the Department of
8 Health at a rather earlier stage, a different
9 decision, whereby they said the costs would be met out
10 of central funds, do you think that could have
11 accelerated the whole programme overall?

12 **A.** Yes, evidently.

13 **Q.** Were other centres, to your knowledge, also struggling
14 to find the finance to pay for the cost of
15 establishing screening?

16 **A.** They must have been.

17 **Q.** Now, when we get to March of 1991 -- perhaps we'll
18 look at NHBT0000073_063. Minutes of the Advisory
19 Committee on Transfusion Transmitted Diseases at its
20 meeting of 25 March 1991. If we go to page 2 we can
21 see under the heading "Introduction of anti-HTLV tests
22 into NBTS and SNBTS":

23 "4.1. The starting date and its definition.

24 "4.11. The proposed starting date of 1st July
25 presented difficulties since it was considered

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1 them to circulate to others in the hope that there
2 would be a reconsideration on the part of the
3 Department of Health about its refusal to fund the
4 cost, is that right?

5 **A.** Yes.

6 **Q.** But that didn't get anywhere in terms of getting
7 a different decision from the Department?

8 **A.** No. They insisted that the hospitals -- that users
9 had -- that we had to add it to the price of blood.

10 **Q.** If we then go to NHBT0000191_089, please. This is
11 from you to Dr Gunson, 22 February 1991. Second
12 paragraph you say:

13 "When I spoke to you regarding anti-HCV
14 screening, I said that if forced we would be able to
15 start on 1 July 1991 if the money was available.
16 Apart from having to employ additional staff and make
17 modifications to our computer and release systems, we
18 are confident that we could start screening, but if we
19 have to find the monies ourselves, this will be later
20 than 1 July 1991. So far I have not received
21 instructions from my Regional General Managers to add
22 on the cost of screening to the handling charges for
23 blood derivatives.

24 "Hence, I repeat that if we are forced to start
25 screening, we would be able to start but very

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1 essential that the second generation test from both
2 Orth and Abbott should be evaluated prior to the
3 commencement of routine tests."

4 Then if we go to the next paragraph it refers to
5 preliminary results obtained by Dr Barbara, and it was
6 agreed that further testing at all three RTCs was
7 essential.

8 Now, without going to lots of other materials,
9 in around March 1991 it appears the Department of
10 Health agreed there should be a second round
11 comparative evaluation of the tests at the three
12 centres.

13 **A.** I think it was of the second generation tests.

14 **Q.** Yes, sorry, I've got my second in the different -- in
15 the wrong place. An evaluation of the -- so a further
16 evaluation, now of the second generation tests, to be
17 carried out at all three of the Regional Transfusion
18 Centres there. That caused further delay, did it not,
19 in the introduction of the screening?

20 **A.** Yes.

21 **Q.** It meant it was put back from July to September?

22 **A.** Yes.

23 **Q.** Why was it thought necessary to undertake the
24 evaluation of the second generation tests?

25 **A.** Thinking about it now, I think we could have started

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1 in July. But again, with hindsight.

2 **Q.** I just want to ask you about a letter you wrote to
3 Dr Gunson in April of 1991. NHBT0006421_002.
4 This is a letter, 22 April. You say in the
5 first paragraph, in the second line, that:
6 "[You] have ... consulted with Pat Hewitt and
7 John Barbara and the three of us are of the opinion
8 that we are going 'over the top' with the proposed
9 screening of anti-HCV."
10 You then say in the next paragraph that you
11 accept that the Blood Transfusion Service has no
12 option but to introduce screening of blood donations,
13 and then you talk about being disappointed about the
14 issue in relation to costs.
15 If we go over the page, I don't need to go
16 through the detail but you set out a number of
17 observations about the procedure for confirmatory
18 testing and various other matters.
19 And then if we go to page 3, under the heading
20 "Monitoring test results", you say:
21 "The more we think about it, the more we think
22 we are going over the top with this testing for
23 a virus that has not been shown by anybody to cause
24 immense healthcare problems in the UK. Why should we
25 monitor anti-HCV results when no-one has been the

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1 delay or was it resolved relatively expeditiously?

2 **A.** I think it was resolved quickly when we suggested that
3 RIBA -- RIBA is the confirmatory test for anti-HCV,
4 the first confirmatory test, that could be done at
5 Transfusion Centres and then you could go -- a very
6 few would go for PCR. So that, I think that Philip
7 realised that his method was totally impractical and
8 expensive.

9 **Q.** In relation to the confirmatory test, the RIBA test,
10 am I right in understanding that that was a test that
11 had in fact been available for some time, that was
12 a test available from 1990?

13 **A.** Yeah, but not really as a routine test as
14 an experimental or confirmatory assay.

15 **Q.** Can we then look at a letter that Dr Lloyd wrote to
16 all directors of transfusion services on 2 May,
17 NHBT0000076_041. Dr Lloyd referred in the first
18 paragraph to the original July date having been
19 changed to a provisional September date and then said
20 in the second paragraph:
21 "In view of the fact that we [so in Newcastle]
22 were already set up for testing, I have decided to
23 keep to the July date. By 1st July, all units of
24 blood for transfusion in the Northern Region will be
25 negative for Hepatitis C antibody."

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1 slightest bit interested in monitoring HBsAg results?"
2 You were asked about this in your statement,
3 Professor Contreras, and what you said in your
4 statement was that when you talked about going "over
5 the top" for the proposed screening, you were not
6 talking about the principle of introducing screening
7 but the particular arrangements that were proposed; is
8 that right?

9 **A.** Yes, it was so, so complicated that, you know,
10 the patients needing platelet transfusions, for
11 example, would have suffered. We would have made
12 mistakes because Philip -- I respect Philip Mortimer
13 a great deal, he is a great scientist and a great
14 microbiologist, but he never worked in a transfusion
15 centre. So to take aliquots of frozen -- you know, it
16 was so, so complicated that we would have certainly
17 made mistakes and we would have wasted a lot of units
18 unnecessarily.

19 **Q.** So is it right to understand this letter as seeking to
20 influence the way in which the screening would be
21 undertaken, not whether, and not the date of its,
22 introduction?

23 **A.** Yes, certainly the way.

24 **Q.** Did the way in which it was originally proposed that
25 it would be introduced, did that contribute to further

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1 Now, you and number of other transfusion
2 directors wrote to Dr Lloyd disagreeing with his
3 course of action. If we can look at NHBT0000192_009.
4 You wrote the next day, 3 May, describing yourself as
5 "very sad and disturbed to receive your letter":
6 "Your decision will erode the concept of
7 a National Blood Transfusion Service. The majority of
8 Regional Transfusion Directors have decided to start
9 testing when the data on the current national
10 comparative studies of the available test are
11 accessible to analysis.
12 "With the national consensus approach, the
13 threat of Product Liability should not arise. We
14 think under current legislation it would be defensible
15 to postpone testing. Moreover a national approach
16 might well have prompted the [DH] to provide
17 appropriate funding for testing with all its
18 ramifications such as confirmatory assays,
19 counselling, and donor referral. Now, I can see no
20 hope of presenting a united front in pursuit of
21 central funding."
22 Then you describe it as a "potentially divisive
23 step", if we just go over the page. You then talk
24 about surrogate testing, and say your view:
25 "... has always been that this would be a waste

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1 of resources, especially with the imminent
2 introduction of a specific assay for anti-HCV."

3 So if we just go back to the first page, you
4 weren't alone in writing to Dr Lloyd in terms such as
5 this but Professor Contreras, why was Dr Lloyd's
6 decision one that triggered such a reaction from you?

- 7 **A.** I really do not know why, because thinking about it
8 now, I recognise that I am really sorry to have
9 written this letter, because I think we could have
10 introduced anti-HCV testing in July.
11 **Q.** It could be said that the Regional Transfusion
12 Directors who expressed their concern to Dr Lloyd --
13 we've looked in earlier hearings, for example, at the
14 terms in which Professor Cash wrote to Dr Lloyd, and
15 there were others. It could be said that the Blood
16 Transfusion Service was prioritising the importance of
17 consensus over considerations of patient safety. Do
18 you have any comment in relation to that?
19 **A.** I didn't see it like that. Now, I could see it but,
20 at the time, I didn't see as prioritising consensus
21 over safety. Yeah, but now, you know, externally,
22 I could see it like that and, for us, it was, you
23 know, the national service and the costing. But as
24 I said, we -- if we had -- if we could introduce it in
25 September with no funding, we could have introduced it

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- 1 worried well", this is the point about false
2 positives?
3 **A.** Yes.
4 **Q.** Perhaps if we look at the way you put it in your
5 witness statement, WITN5711001. If we go to page 97,
6 the last paragraph on that page. So you say in
7 paragraph 389:

8 "It is unsafe to inform blood donors of a false
9 positive test that would label them for a lifetime,
10 hence the need for confirmatory testing."

11 Then, if we go to page 104, paragraph 415, you
12 say:

13 "As I have said above the false positive rate
14 was seven to every one donor who actually had the
15 virus; therefore we would have to be telling
16 potentially seven people that they might be carrying
17 a virus which they did not have and discarding their
18 blood unnecessarily."

19 Can I ask you to look at it in this way,
20 Professor Contreras: why would the prospect of telling
21 people they might have a virus that they didn't have,
22 and once confirmatory testing was available you could
23 tell them they didn't have it, why does that outweigh
24 the risk of infecting people with a virus that they
25 would not otherwise have, with potentially serious

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1 in July with no funding.

- 2 **Q.** You did, I think, then, at the centre, make the
3 arrangements for its introduction at the beginning of
4 September 1991.
5 **A. (Witness nodded)**
6 **Q.** It's clear from the evidence you've given,
7 Professor Contreras, that you think hepatitis C
8 screening could have been introduced earlier than it
9 was. If you leave aside the position of your own
10 centre and the difference between July and September,
11 if funding had been different, if the decision-making
12 process had been quicker, do you have a sense of how
13 early testing could have been introduced, in your
14 view, bearing in mind a number of other countries had
15 introduced it really in the early part of 1990 and
16 then some others later in 1990?
17 **A.** I do not know whether my -- my thinking at the time
18 and my position at the time, and that of my
19 colleagues, would have induced me to introduce the
20 first generation test because, as I said, you know,
21 I didn't -- the same as with HIV. I didn't want to
22 create an army of worried well. So -- but perhaps we
23 could have introduced it as soon as their second
24 generation test had been tried and was available.
25 **Q.** Then, just if I can pick up the point of the "army of

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- 1 and, indeed, fatal consequences?
2 **A.** I do not think that it outweighs the risk but, you
3 know, as somebody who was collecting this blood or in
4 charge of the collection of blood, I cared for
5 patients and for donors, and I did not want to create
6 a psychological illness in those donors. But, yeah,
7 perhaps I should have weighed the risks.
8 **Q.** Can I then just ask you, still on this topic, just to
9 look at a couple of further materials. The first is
10 an email from you in 2000, NHBT0086471. So you say
11 here:

12 "Just a short note to remind you that Harold
13 Gunson is very hurt and disillusioned with the
14 [Department of Health] and [National Blood Authority]
15 after the 'grilling' during the HCV litigation court
16 case. I have spoken to him twice and he felt he was
17 defending the [Department of Health] and
18 Dr Jeremy Metters, previous Chairman of MSBT for
19 decisions that he was not party to."

20 Then you go on to talk about him as someone who
21 dedicated a lifetime to the National Blood Service.
22 Are you able to recall further any conversations that
23 you had with Dr Gunson about this issue and about how
24 he felt about the litigation?

- 25 **A.** You know, I can't remember any of this, and I'm proud

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1 of this email, but I cannot -- you know, because he
2 took the brunt of the criticism there at the Penrose
3 Inquiry when it was no fault of his own, more or less.
4 But I do not remember either this email or the
5 conversations.

6 **Q.** Then I just need to ask you about some observations
7 Dr Barbara made in the note of a meeting in the
8 context of the litigation, and then one aspect of
9 Dr Gunson's evidence, because there's some
10 observations from both of them about your approach to
11 hepatitis C screening that I want to give you an
12 opportunity to comment on.

13 If we look, first of all, at NHBT0036250_025.
14 It's an attendance note of a solicitors meeting with
15 Dr Barbara. I'm not going to ask you about what he
16 says about his own personal views, on issues relating
17 to screening, but just about some observations he made
18 about your thinking.

19 So if we go to page 2, fourth paragraph:
20 "He [Dr Barbara] said that he thought we should
21 get a statement from Marcela Contreras because she was
22 very vocal in her reluctance to introduce screening."

23 Then the last paragraph of that paragraph:
24 "He said that Marcela Contreras still believes
25 that Hepatitis C infection was overrated."

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1 **Q.** So this is the same extract -- sorry, the same
2 transcript we looked at earlier, but if we go to
3 page 66, and it's the first ten lines or so.

4 So this part of a question to Dr Gunson:
5 "By this time, early 1991, the Department had
6 taken over the evaluation process. We looked at that
7 letter.

8 "A. Yes. I now know what you are referring to.

9 "Q. There is local resistance still, is there
10 not?

11 "A. There are some centres who were not happy
12 even with the July start date.

13 "Q. Some people still wanted to fight the
14 battle as to whether it was worth doing at all, did
15 they not?

16 "A. There is correspondence to that effect
17 available.

18 "Q. Particularly from Dr Contreras?

19 "A. Yes.

20 "Q. Let us be plain about this, because we can
21 look at the letter and indeed I think perhaps we
22 should: unless Dr Contreras agreed, nobody else could
23 do anything; that is the position, is it not?"

24 Then there is a further discussion about some of
25 the documents we've looked at.

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1 Do you -- let me show you one other paragraph
2 and then ask you. If we go three paragraphs further
3 down:

4 "Dr Barbara said that Marcela would give
5 a vigorous account of the perception at the time that
6 Hepatitis C was not worth the candle."

7 Those are his words but do you have any comment
8 to make upon what's being said was your approach at
9 the time?

10 **A.** Well, unfortunately, at the time I did not see it as
11 a major problem in the transfusion of labile blood
12 components, you know, I saw it as a problem in the
13 transfusion of concentrate. But we were not -- we had
14 no evidence of the problem, and perhaps I was wrong,
15 but ...

16 **Q.** And then if we look at -- just one further extract
17 from Dr Gunson's oral evidence in the NBA litigation.
18 NHBT0000148_001.

19 **A.** Sorry, and there John Barbara quotes Seeff again
20 about -- you know, Seeff -- that's in the USA --
21 followed up for over 20 years the recipients, the
22 patients who acquired hepatitis C or non-A, non-B, by
23 transfusion, and didn't find any difference in -- the
24 mortality was the same in controls and in the patient
25 groups.

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1 So it might be said that Dr Gunson regarded
2 there as being some directors, including you, who
3 still in 1991 were unconvinced that hepatitis C
4 screening was worth doing at all. Was that your view
5 in 1991?

6 **A.** At the beginning of 1991, unfortunately, yes.

7 **Q.** And am I right in understanding your evidence that
8 you -- looking at it now, you think you were wrong in
9 that regard?

10 **A.** Yes.

11 **Q.** Can we then just move away from hepatitis C screening
12 to an issue relating to anti-HBc screening. Not now
13 as a surrogate marker for non-A, non-B hepatitis but,
14 as it were, in its own right in relation to detecting
15 possible hepatitis B infections.

16 If we look at NHBT0000044_095, this is a short
17 discussion paper prepared by you and Dr Barbara,
18 Professor, for the ACTTD. It's dated 23 January 1992.
19 I just want to ask you to look at the first paragraph,
20 where you say:

21 "The question of the likely benefit of anti-HBc
22 screening of blood donations continues to reappear,
23 especially so in the light of the introduction of
24 anti-HCV screening. The attitude towards transfusion
25 safety has veered away from the concept of 'maximum

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1 benefit at minimal cost' towards the notion that if
2 a procedure shown to prevent transfusion-transmitted
3 infection and disease is available, it should be
4 introduced. The latter approach is reinforced by loss
5 of Crown Immunity, the introduction of Product
6 Liability and the emphasis on Quality, Audit and
7 licensing by the MCA."

8 Then you go on to talk about the potential for
9 introducing routine anti-HBc screening.

10 Can I just ask you about what you describe there
11 as a shift in attitude from a concept of what you've
12 termed "maximum benefit at minimal cost" towards the
13 idea of, "Well, if there is a measure that reduces
14 risk, we should take it". Are you describing there
15 a shift simply in your own thinking, or it was your
16 understanding that there was a wider shift in
17 attitude?

18 **A.** It was both, I think. It was my own thinking and my
19 team's thinking, and general thinking as well, that we
20 had to introduce any testing, regardless of cost.

21 **Q.** And the concept you've described of maximum benefit at
22 minimal cost, and that attitude to transfusion safety,
23 is it right to understand that describes essentially
24 the approach that you and colleagues had taken
25 previously in the eighties in relation to issues such

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1 HBsAG negative) were being reported.

2 "It was agreed that a recommendation to ACVSB
3 for the introduction of routine anti-HBc screening of
4 donations should be made."

5 Is it right to understand that there is
6 exemplifies the shift in attitude that you had
7 described in that earlier document?

8 **A.** Yes.

9 **Q.** And the committee of which you were a member was now
10 advocating the introduction of anti-HBc screening
11 because you were conscious that there were still
12 hepatitis B infections being transmitted through
13 blood?

14 **A.** Yes.

15 **Q.** If we then move on -- so that's January 1993. We can
16 see the recommendation to the ACVSB is going to be
17 made. We then move to NHBT0018427. This is you
18 writing to Dr Gunson on 3 June 1993.

19 "In your letter of 3 June 1993 you reported that
20 the Advisory Committee on Transfusion Transmitted
21 Diseases will advise ACVSB that anti-HBc testing of
22 blood donation should commence."

23 You say that:

24 "On logistical and scientific grounds, we could
25 commence screening as soon as funds are available,

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1 as surrogate testing and anti-HCV testing, but now you
2 were convinced of the need to be more proactive?

3 **A.** Yes.

4 **Q.** And then if we can just look at and see, in relation
5 to then the particular issue of anti-HBc screening,
6 I'm going to give a reference that we don't need to go
7 to, and then pick up a couple of documents.

8 So at the ACTTD meeting of 7 May 1992 -- for the
9 transcript it's NHBT0017532:

10 "The Committee agreed that the introduction of
11 anti-HBc donor screening had a high priority."

12 So that was May '92. Then I want to ask you to
13 look at a meeting of the same committee in
14 January 1983 at DHSC0006982_049.

15 So we had Dr Gunson in the chair. You are
16 there, it's 12 January 1993, and then we have the
17 heading "Anti-HBc screening". There's a reference to
18 results from Glasgow, Cambridge and North London not
19 being available, but then it says this:

20 "However, on the basis that

21 "(i) the knowledge from the trials to date have
22 revealed that potentially infectious donations for
23 hepatitis B were being transfused.

24 "(ii) that patients who had suffered from
25 transfusion associated hepatitis B (when the blood was

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1 but ..."

2 Then there's an issue in relation to funding.

3 You refer in the next paragraph to having
4 discussed the matter with Dr Hewitt and Dr Barbara,
5 and then you say:

6 "We firmly believe that anti-HBc testing of
7 blood donations is the necessary and logical step to
8 reduce further the already small number of HBV
9 transmissions by blood transfusion. We feel that this
10 is the obvious progression for reduction of PTH, given
11 the implementation of HCV screening almost 2 years
12 ago."

13 So is it right to understand you are continuing,
14 with Dr Hewitt and Dr Barbara, to advocate for
15 anti-HBc screening to be introduced?

16 **A.** Yes.

17 **Q.** Then if we move to DHSC0004709_151.

18 DHSC0004709_151.

19 This is October 1993, you to Dr Gunson. Second
20 paragraph:

21 "I was dismayed that the DH Advisory Committee
22 on MSBT ..."

23 That was, I think, the successor to the ACVSB:

24 "... has decided not to introduce routine
25 testing of all donations for anti-HBc. I have had

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1 a long discussion with Dr David Dane and John Barbara
2 and we have concluded that some of the reasons that
3 the Committee has given are very difficult to
4 defend ..."

5 The first deals with false positives and then
6 the second you say:

7 "The primary object of donor testing is to
8 provide safe blood."

9 Then you go on to make a number of other points
10 in the course of the two-and-a-half-page letter. I'm
11 not proposing to go through all of those.

12 Do you recall what happened after that in terms
13 of anti-HBc screening? You obviously were
14 disappointed with the decision that had been taken not
15 to introduce it. Was that resolved, and if so, how?

16 **A.** No, it wasn't resolved, we never introduced anti-core
17 screening. But it was later on superseded by the PCR,
18 the very sensitive test that would have excluded those
19 donations that were carriers for hepatitis B -- most,
20 not -- most but not all. So it was never totally
21 solved.

22 **Q.** Because the reason, as I understand the documents,
23 that you were advocating anti-HBc testing and the
24 hepatitis B infections were still occurring was
25 because, although the sensitivity of testing had

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1 Magdi Yacoub, and I should say, sir, we do have
2 a witness statement from Professor Yacoub which sets
3 out his perspective in relation to his use of blood,
4 and it may be an issue which we explore in future
5 hearings. In any event, Professor Contreras, you say:

6 "For a very long time, Mr Yacoub has insisted on
7 the use of 'fresh, warm blood' for his difficult
8 cardiac surgery operations. A large proportion of the
9 operations performed by Mr Yacoub seemed to be of
10 a difficult and complicated nature and, in his
11 opinion, when the patients bleed, the only form of
12 effective therapy is the use of 'fresh, warm blood'.
13 I have tried to convince him that there are
14 alternatives to 'fresh, warm blood' in these times of
15 blood component therapy, but to no avail.

16 "Only quite recently, Mr Yacoub's team was
17 bleeding large number of donors at Harefield hospital
18 and was not complying with the routine pre-transfusion
19 testing required by the National Blood Transfusion
20 Service. He was bleeding donors and transfusing their
21 blood within minutes of collection. Hence, all
22 microbiological screening of blood donations was done
23 retrospectively in the Pathology Laboratory at
24 Harefield. The Haematologist at Harefield approached
25 us for help since this practice was against her

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1 improved since the early seventies, the tests were
2 still not sufficiently sensitive to detect all cases.

3 **A.** Yeah, because the tests were for surface antigen.

4 **Q.** Yes.

5 **A.** And surface antigen in -- what we were transmitting
6 was what we call -- well, what Dr Dane and Dr Barbara
7 called tail-end carriers. So those carriers of
8 hepatitis B that have lost detectable surface antigen
9 but still have anti-hepatitis B core antibody, and
10 still have some virus in the body. So you cannot
11 detect it in a small tube, but you can transmit it by
12 the pint.

13 **Q.** Now I'm going to move now to a different topic which
14 concerns an issue about the supply of what was
15 sometimes called fresh warm blood, for the purposes of
16 certain forms of significant cardiac surgery.

17 Can I start with a letter you wrote to the
18 Medical Defence Union because it contains, I think,
19 a useful summary of the history. It's NHBTO093056.
20 You wrote this letter, 19 May 1988, to Dr Beresford at
21 the Medical Defence Union. You say:

22 "Following our telephone conversation and your
23 helpful advice, I am writing with relevant information
24 on my saga with Mr Yacoub."

25 Now, that is Magdi Yacoub, now Professor Sir

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1 principles, and her laboratory was unable to cope with
2 the increasing demands for testing imposed by
3 Mr Yacoub's team. In view of this, I attended several
4 meetings with Mr Yacoub, the General Manager at
5 Harefield, the Anaesthetists and Dr Amin, the
6 Consultant Haematologist at Harefield. I said that I
7 would try to do everything possible for Mr Yacoub's
8 difficult cases and that, whenever it was impossible
9 for us to supply same-day blood, that had been
10 screened and tested, one of the Consultants at this
11 end would authorise the issue of same-day untested
12 blood, (ie not tested for [hepatitis B surface
13 antigen], HIV and syphilis). The issue of untested
14 blood could only be authorised by one of the 4
15 Consultants at this Centre. Although the issue of
16 untested blood is totally against the good practice
17 of Blood Transfusion Medicine and against my own
18 principles [over the page], I gave in in order to
19 avoid the collection of blood by Dr Yacoub's team.
20 I found that it was better to supply blood from
21 established blood donors who had gone through our
22 verbal screening procedure and who had answered
23 a confidential questionnaire stating they did not
24 belong to a group at high risk of HIV infection.
25 However, despite all our efforts, Mr Yacoub continued

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1 bleeding people at Harefield and requesting 'Fresh,
2 warm blood' more often than he had previously
3 anticipated at our meetings."

4 You were asking for advice from the Medical
5 Defence Union about your own position, I think, in
6 that regard. Now, am I right in understanding that by
7 this time, May 1988, this was an issue that had been
8 ongoing for a couple of years?

9 **A.** Yes.

10 **Q.** I'm not going to go to the documents themselves but
11 I'll just give a couple of references. You'd written
12 in February 1988 to the National Heart and Chest
13 Hospitals -- to Dr Berman at the National Heart and
14 Chest Hospitals expressing your concern about this
15 issue. The reference for the transcript is
16 NHBT0085681_039 and you'd written to Mr Yacoub
17 himself, copied it to the Department of Health.
18 Again, we don't need it on screen, DHSC0002841.

19 Can I, however, then put up on screen a letter
20 you then wrote to the Department of Health because you
21 wanted the Department's assistance, I think, in
22 helping you to resolve this issue, DHSC0002841_009.
23 So 19 July 1988, you wrote to Mr Harris at Department
24 of Health, second paragraph, you say:

25 "Since I was appointed Director of this Centre,

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1 written that down wrong, Soumik.

2 Oh, no. What I'm going to do, because I don't
3 think the text of the letter is terribly material,
4 I'll read out:

5 "We in DHSS share your general concerns but the
6 local problem as described you at Harefield is
7 essentially a problem for the Regional Health
8 Authority to tackle and we are in contact with them."

9 Then there is agreement with a number of your
10 concerns. I just want to get an understanding of what
11 the problem was, as you saw it, and then how you
12 sought to resolve it. Because Professor Yacoub
13 thought that the use of what was termed in the
14 correspondence "fresh, warm blood" was a necessary and
15 appropriate course to take in relation to some of the
16 complex cardiac surgery he was undertaking, I think it
17 came to your attention that staff at the hospital, and
18 on occasion others, were effectively being bled there
19 and then at the hospital and the blood immediately
20 used for the patient without it having undergone any
21 testing whatsoever; is that right?

22 **A.** Yes.

23 **Q.** You were very troubled by this, and there's a range of
24 other correspondence and communications. I'm not
25 going to go into all of them. I'm going to paraphrase

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1 I have had to deal with problems regarding the use of
2 fresh blood by Professor Yacoub. I have expressed to
3 Professor Yacoub on numerous occasions my concern and
4 disapproval of this practice which I consider to be
5 against the best principles of blood transfusion
6 medicine. Unfortunately, Professor Yacoub continues
7 bleeding members of staff, visiting doctors and
8 members of the Armed Forces for his numerous
9 'emergencies'. I have told him that am not prepared
10 to issue from this Centre any more untested blood
11 unless the DHSS is prepared to agree to this."

12 Then you continue in the next paragraph:

13 "We have had three cases of HIV infection
14 apparently transmitted by blood transfusion that we
15 have been unable to follow-up fully since the three
16 patients concerned were given, in addition to blood
17 supplied by the Transfusion Service, fresh warm blood
18 collected at Harefield hospital. We have followed up
19 the donors of the units issued by this Centre but it
20 will be impossible to follow up the donors who gave
21 the fresh blood in view of the poor record keeping by
22 Professor Yacoub's team."

23 Then, just before I ask you about the issue
24 overall, the reply from the DHSS is at
25 DHSC0006312_0036. It's entirely conceivable I've

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1 but is this right: you essentially went for the lesser
2 of two evils, in your view, to avoid completely
3 untested unscreened blood being taken there and then
4 from nurses and doctors, and so on, at the hospital
5 and immediately transfused, you reluctantly made
6 available same-day blood on occasions to
7 Professor Yacoub, which also hadn't been tested fully,
8 but which at least came from your established donor
9 panel with the donor screening and selection
10 procedures in place. Is that right?

11 **A.** Yes, it was -- first of all, I have to start by saying
12 that I was convinced by -- although I say in my
13 letters that it is against my principles, but I was
14 convinced, when I went to several meetings with
15 Professor Yacoub and I went to theatre, and I remember
16 going once at 2.00 or 3.00 in the morning when he was
17 asking for -- so, and I could see that little babies,
18 you know, newborn babies were -- that were -- had to
19 be done through the extracorporeal machine, they were
20 bleeding, and bleeding, and he gave them this fresh,
21 warm blood and it was like a miracle, the bleeding
22 stopped. And that happened with babies and with
23 heart/lung transplants, difficult heart/lung
24 transplants as well.

25 So I had -- although I believed in component

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1 therapy but, for these cases, I thought, well, he's
 2 right, in what he's -- he's the expert. He was doing
 3 surgery that nobody else in the world was doing.
 4 He was saving life -- you know, I went to see
 5 those patients in the wards and, you know, they
 6 wouldn't have had a chance to live for more than
 7 a month, perhaps. They were on respirators or the
 8 babies -- you know, the babies would have died within
 9 days and I saw this, like miracles in medicines. So
 10 he convinced -- that convinced me that I had to help
 11 in some way.
 12 So the best of both evils was to give him blood
 13 from known donors that we knew, from lots of
 14 publications, by us and Dr Barbara especially and
 15 everybody, that repeat donors, known donors, carry
 16 a much lesser risk of transfusion-transmitted
 17 infection than new donors or family replacement
 18 donors, or donors who are not volunteers.
 19 So I said, well, it's better to give him blood
 20 that in the majority of cases might have been tested
 21 when we issued it, because we were testing daily. So
 22 very few case, very few units were untested when they
 23 went to -- when they went to -- when they were issued
 24 to Harefield, but most of them were tested before they
 25 were transfused to the patient because we tested them

1 **Q.** Is it right to understand that, in relation to any
 2 blood that was used in surgery from people who were
 3 bled within the hospital, over which you and your
 4 colleagues had no control, you've no way of knowing
 5 whether any of that was infected?
 6 **A.** Yeah. No way. And also, we do not know whether all
 7 those units were -- samples from all those units were
 8 sent to Dr Amin, the pathologist.
 9 **Q.** Now the correspondence we looked at was from 1988.
 10 There's a document from Dr Hewitt in 1995 showing it's
 11 still an ongoing issue. I can ask her about that.
 12 But can I just ask you to look at a document in 1999.
 13 NHBT0101360.
 14 The date here is 18 March 1999, and it's a memo
 15 from you and it refers to having attended a meeting at
 16 Harefield with Professor Yacoub and others.
 17 It would appear from this that the use of
 18 untested fresh warm blood from volunteers' blood at
 19 Harefield Hospital was still happening, is that right?
 20 **A.** Yes.
 21 **Q.** It wasn't, as I think we see in the last two lines of
 22 that paragraph, happening at the Royal Brompton
 23 Hospital but it was still happening at Harefield.
 24 And then if we go over the page, if you look at
 25 the last paragraph, it would appear that at this stage

1 as soon as possible, but if we issued them in the
 2 middle of the night something that had been collected
 3 that evening, we might not have.
 4 But all the units that we gave to him, that we
 5 gave to Harefield, as fresh blood, it was never warm,
 6 in our case, it was room temperature. All those units
 7 were tested on the day of transfusion if they hadn't
 8 been tested prior to transfusion.
 9 Then, from product liability came -- you know,
 10 I couldn't continue providing him. But I -- when
 11 I think retrospectively, I wish I had been able to
 12 help him with fresh, same-day blood, tested.
 13 **Q.** In relation to the blood or blood components that you
 14 supplied to Professor Yacoub on those occasions when
 15 you did, am I right in understanding that they were --
 16 where they weren't tested before use, there was
 17 testing after use?
 18 **A.** I think the majority of them were tested during --
 19 were tested either on -- before they were issued, the
 20 majority of them, but some of them were tested
 21 immediately after issue or when they were on transit,
 22 or when they were being -- some of them might have
 23 been when they were transfused. But they were all
 24 tested and they were all found negative for all the
 25 markers.

1 you came up with a different solution, which was the
 2 supply of apheresis platelets and leucodepleted red
 3 cells.
 4 Do you know whether that then resolved this
 5 issue or donors continued to be bled and untested
 6 blood used?
 7 **A.** I do not know but I think that he continued to bleed
 8 the occasional donor.
 9 **Q.** I should say again, for the benefit of the transcript,
 10 that the statement that we have from
 11 Professor Sir Magdi Yacoub, it's at WITN4129001 and
 12 explains his reasons for proceeding in the way that he
 13 did.
 14 **A.** May I say that the older I get, the more I think that
 15 the use of fresh -- of whole blood, that perhaps we
 16 might have gone, with component therapy, a little bit
 17 too far, and for acute haemorrhage or for the type of
 18 operations that Professor Yacoub was doing and that
 19 I am not alone in -- and he is not alone in thinking
 20 that fresh warm blood -- fresh blood -- full, whole
 21 blood, is a better option. Because it decreases the
 22 number of -- it decreases the risk, instead of giving
 23 three components, of giving one, and it doesn't add to
 24 the volume also, and it doesn't add so many additive
 25 solutions. So there is some reason for using.

1 Q. And it's right to point out that you've referred to
 2 some of that literature, I think, in your witness
 3 statement.
 4 A. *(Nodded)*
 5 Q. To some of the literature that post-dates the events
 6 that we've been talking about.
 7 A. *(Nodded)*
 8 Q. I've then just got a small number of, as it were,
 9 miscellaneous topics to ask you about now,
 10 Professor Contreras.
 11 If we could have your witness statement on
 12 screen, WITN5711001 again. If we could go, please, to
 13 page 77, paragraphs 308 and 309. You say there:
 14 "With regard to donors found to be HBsAg
 15 positive, we included them in a panel of donors who
 16 were seen annually with full medical examinations and
 17 LFTs. If alterations were found, they were referred
 18 to a hepatologist at their local hospital. These
 19 investigations contributed a great deal to our
 20 understanding of Hepatitis B carriers and the
 21 long-term effects of the infection ..."
 22 Then 309:
 23 "We also collected, under strict isolation
 24 conditions, plasma from subjects with high levels of
 25 HBe antigen, in a collaborative effort with

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1 Q. And then in relation to paragraph 309, where you talk
 2 about collecting plasma from subjects with high levels
 3 of antigen with Professor Zuckerman in a project to
 4 make a hepatitis B vaccine, at what period of time are
 5 you talking about there? Do you know?
 6 A. I cannot remember. I think it was before I became
 7 professor of the Royal Free. I cannot remember.
 8 Q. Do you know how that plasma was used in the production
 9 of a hepatitis B vaccine, or was it simply provided to
 10 Professor Zuckerman?
 11 A. It was provided to Professor Zuckerman, who was an
 12 expert in hepatitis. But it never came to anything.
 13 Q. And then if we just turn on to page 91, paragraph 363,
 14 you say there:
 15 "We had a panel of donors with high titres of
 16 microbial antibodies, such as anti-HBV, anti-Tetanus,
 17 anti-VZ, who we plasmapheresed regularly for the
 18 production of specific immunoglobulins by BPL."
 19 Were any products other than immunoglobulins
 20 produced from that panel of donors?
 21 A. I don't think so.
 22 Q. And were there processes in place to ensure that such
 23 plasma did not enter the -- in a general pool?
 24 A. I do not think so, but -- because these are very safe
 25 donations, they've got antibodies, they -- they were

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1 Professor Arie Zuckerman ... in a project to make an
 2 HBV vaccine."
 3 I've got a handful of questions I've been asked
 4 to ask you on this issue.
 5 In relation to the practice described in 308 of
 6 taking blood from this panel of donors found to be
 7 HBsAg positive, what was done with the donations that
 8 were collected from them?
 9 A. No, it was samples. We followed them up and took
 10 samples from them, annually, because we didn't know
 11 the natural history of hepatitis B. You know, when --
 12 for how long were they carriers, when they cleared the
 13 virus, et cetera and, since we were so strongly
 14 associated with Dr Dane, then we could follow these
 15 donors -- with their consent, because they want to
 16 know as well whether they had cleared the --
 17 Q. So it was only samples. You weren't collecting
 18 further donations for use in the manufacture or
 19 processing into products to -- for --
 20 A. Oh no, no, no.
 21 Q. -- transfusion?
 22 A. No, no, never, no. This was separately, and they were
 23 not done with the routine donors, not bled with the
 24 routine donors, because we knew that they were
 25 infectious donors.

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1 not infectious. They were -- it was -- you know, we
 2 wanted to concentrate the antibodies in those
 3 donations. So it's not antigen. These were not
 4 infectious donors. They were the best donors you
 5 could find, because they were protecting people from
 6 hepatitis B. So if you knew that you were
 7 transfusing -- that somebody was at risk, you would
 8 give them a concert, an immunoglobulin containing
 9 antibodies to hepatitis B or to tetanus or to
 10 varicella-zoster or to rabies.
 11 Q. And then on a completely different topic in your
 12 statement, if we go to page 88, the paragraph at the
 13 bottom of the page. This now in relation to
 14 the look-back. I'm not going to ask you any detailed
 15 questions about it, Professor Contreras, because
 16 I think Dr Hewitt is more likely to be able to assist
 17 with the detail of it.
 18 A. Yes, she is the expert.
 19 Q. And we're hearing from her next week. But you say
 20 here in paragraph 351, your recollection was that you
 21 wanted to start the look-back earlier but that the
 22 Department of Health would not provide the funding for
 23 the programme at an earlier point in time.
 24 And you've pointed to a memo where you talked
 25 about a -- you suggested to colleagues applying for

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1 a grant.
 2 Can you recall any more about that, about any
 3 approaches to or discussions with the Department of
 4 Health about a look-back?
 5 **A.** No, what I remember is that we applied and we were not
 6 successful. But I don't remember discussing it any
 7 further with the Department of Health.
 8 **Q.** Now, the national look-back began in 1995. We know,
 9 of course, that the hepatitis C screening was
 10 introduced in 1991. What's your view, if any, on the
 11 appropriateness of the delay between the introduction
 12 of routine screening, the availability of testing, and
 13 the start of the formal look back?
 14 **A.** Totally inappropriate.
 15 **Q.** The last question, Professor Contreras, from me for
 16 the time being, is just in relation to SHOT, Serious
 17 Hazards Of Transfusion, I think that's the right
 18 description of the acronym. You were involved in its
 19 inception and until, I think, 2007, when you retired
 20 from NHSBT. Could you just tell us in broad terms
 21 what the purpose of SHOT was, why it was set up?
 22 **A.** The purpose was -- it had been started in a very
 23 rudimentary way in Italy and I was invited to a
 24 meeting in Italy by Dr Marconi and I couldn't go
 25 (I think I had surgery, or something like that) and

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1 their legal representatives to suggest any further
 2 lines of questions. So perhaps we could take a break
 3 now, and I can consider any questions that I am asked
 4 to put to Professor Contreras.
 5 **SIR BRIAN LANGSTAFF:** Yes. Let me just explain to
 6 Professor Contreras, there are a lot of Core
 7 Participants in an Inquiry. An Inquiry is rather
 8 different from a legal case, because participants have
 9 no particular case to put to you, they have
 10 perspectives. Each may very well be different from
 11 the other but they're all entitled to ask questions
 12 through counsel to the Inquiry. We just want to know
 13 what happened as best we can from the witnesses.
 14 To let that happen, we take time for them to
 15 discuss with counsel what additional questions they
 16 may want to ask.
 17 So we'll need, what do you think, about 40
 18 minutes?
 19 **MS RICHARDS:** Yes, 40 minutes would be ideal.
 20 **SIR BRIAN LANGSTAFF:** So 3.50, do you think?
 21 **MS RICHARDS:** Yes.
 22 **SIR BRIAN LANGSTAFF:** It is likely, I can't promise at
 23 all -- it depends how many questions there are, there
 24 may be quite a lot, there may be very few -- but
 25 I think you are likely to be away from here by 4.30 or

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1 I asked two of my colleagues, Dr Williamson and
 2 Dr Love to go to Italy and then we discussed -- SHOT
 3 was the Serious Hazards Of Transfusion Haemovigilance,
 4 it means the vigilance, the follow up, or the
 5 knowledge on the risks, the real risks of transfusion
 6 in the patient population.
 7 So it was for us to learn what was happening
 8 with our blood, and collating it throughout the UK,
 9 and reporting it to a central reporting base,
 10 secretary and then follow and analyse those risks of
 11 transfusion, and we realised that, you know, our main
 12 problem at the time when we started SHOT, and I think
 13 still is, was errors, giving the wrong blood to the
 14 wrong patient.
 15 **Q.** Again, looking at it now, with the benefit of
 16 hindsight, would it have been beneficial, do you
 17 think, to have something like SHOT established at
 18 a rather earlier stage so that it would have been
 19 available as a forum for decision making in, say, the
 20 1980s when some of the key decisions fell to be taken
 21 in relation to blood safety?
 22 **A.** Yes, definitely, yes.
 23 **MS RICHARDS:** Sir, those are the questions I currently
 24 have for Professor Contreras but we obviously need to
 25 give the opportunity to Core Participants through

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1 thereabouts, just to give you some idea.
 2 But for the moment, would you like to go and
 3 have a cup of tea.
 4 **THE WITNESS:** Thank you, sir.
 5 **SIR BRIAN LANGSTAFF:** 3.50.
 6 **(3.09 pm)**
 7 **(A short break)**
 8 **(3.50 pm)**
 9 **MS RICHARDS:** Professor Contreras, just a few further
 10 questions. In the course of your evidence, you've
 11 referred on a handful of occasions to "labile blood
 12 components" as contrasted with, for example,
 13 fractionated with concentrates. Could you just assist
 14 us in understanding what you're talking about when you
 15 talk about "labile blood components" and what the
 16 significance was of the distinction you were seeking
 17 draw.
 18 **A.** Labile blood components are those components that are
 19 taken from a unit of blood and processed at the
 20 transfusion centre, that means red cells, platelets --
 21 you know, if you spin a unit of blood in the
 22 centrifuge, then you get the heaviest particles at the
 23 bottom and those are the red cells. Then there is
 24 a layer that we called the buffy coat, because it's
 25 got a buffy colour and that buffy coat is rich in

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1 platelets and white cells. White cells are the ones
2 that defend us against infections and -- particularly
3 bacterial infections, but at the same time, they cause
4 lots of febrile transfusion reactions, so they've got
5 two edges to it and on top of it, is the plasma.

6 And the plasma we use it either as fresh frozen
7 plasma, that we freeze immediately within 8 hours of
8 collection, ideally, or 6 hours of collection, and --
9 or we make cryoprecipitate out of it, and that means
10 processing the plasma and freezing it and then thawing
11 it, very slowly, and getting a concentrate of
12 Factor VIII. That is the precipitate, the
13 cryoprecipitate, that is in a much smaller volume than
14 a unit of plasma that will have 200 or -- or 250 or
15 300 millilitres, and the cryo will have all the
16 Factor -- or most of the Factor VIII and fibrinogen in
17 it for coagulation, and it will only have 50 to
18 55 millilitres.

19 **Q.** So when you talked about labile blood components,
20 that's what you're describing as a --

21 **A.** Yes.

22 **Q.** -- group of components, as distinct from the
23 fractionated products that might be produced at BPL
24 from the plasma sent there for fractionation?

25 **A.** Yes. And the fractionated products are factor --

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1 decision-making as regards the introduction of
2 hepatitis C screening?

3 **A.** I do not think so. I think it would have been even
4 more complicated, you know. It was 15 decisions, and
5 there was a national management committee. I don't
6 think -- no, because it was not a directors' decision.
7 It was ...

8 **Q.** Next I'm just going to ask you about some matters
9 arising out of the introduction of the hepatitis C
10 screening in September 1991.

11 Do you know whether all Regional Transfusion
12 Centres adopted a hundred per cent HCV testing of all
13 blood on 1 September 1991, or whether it was rolled
14 out with effect from 1 September 1991?

15 **A.** I believe, but I'm not totally sure, that we all
16 introduced anti-HCV screening on the same day or
17 around the same day.

18 **Q.** In terms of use-by dates for blood, blood components,
19 there's guidance about that in a handbook of
20 transfusion, and other sources. I don't need to ask
21 you about the detail of that, but do you know whether
22 those dates were always followed in practice or was
23 there a variable position in terms of whether they
24 were adhered to or not?

25 **A.** I don't think that anybody used blood beyond its

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1 albumin, that used to be called, in all of this, PPF,
2 Factor VIII, Factor IX, immunoglobulins, et cetera.

3 **Q.** Yes, thank you.

4 Now, completely different topic, I asked you
5 yesterday about the organisation of the National Blood
6 Transfusion Service, and you talked about your view
7 that there should have been a properly funded National
8 Blood Transfusion Service, as I understand it, earlier
9 than there was.

10 When do you consider that a properly funded
11 national service should have been established?

12 **A.** As early as possible. You know. In the 1980s,
13 perhaps. Yeah, when we saw that there were so many --
14 there was evidence of discrepancies and also of some
15 centres being -- having lots of blood and some centres
16 collecting more blood than others and not being able
17 to supply the demand. So yes, as early as possible.

18 **Q.** And then I asked you yesterday about the
19 discontinuance of the regular Regional Transfusion
20 Directors' meetings, which came to an end in
21 January 1984 -- sorry, '89, after the National
22 Directorate was set up.

23 If Regional Transfusion Director meetings had
24 continued beyond January 1989, do you think that would
25 have made a difference to or possibly improved

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1 expiry date. So it could have been 28 days or 38,
2 35 days, depending on the anti-coagulant and the
3 additive solutions and, for fresh frozen plasma, as
4 well, you know, a year. And platelets, they
5 wouldn't -- I believe that most hospitals would not
6 have taken the risk of using it after -- I know that
7 some of the private hospitals that we supplied tried
8 to return blood to us as soon as possible so that they
9 were not charged.

10 **Q.** Just for the sake of clarity, that would have been
11 decision-making by the hospitals that had the products
12 in storage and were actually going to use them. It
13 wouldn't necessarily come to your attention if
14 hospitals were using stocks beyond their --

15 **A.** No, it wouldn't come to our attention. But that's
16 where education was so important.

17 **Q.** In terms of the possibility of untested blood,
18 blood components, being in the NHS system in the weeks
19 or months after 1 September 1991, are there reasons
20 why there might have remained untested components in
21 the system beyond that 1 September date? Are there
22 types of frozen components, for example, that would
23 have already been in stock?

24 **A.** Yes.

25 **Q.** Are there any other reasons you can think of as to why

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1 there might have been untested components still in use
 2 beyond 1 September '91?

3 **A.** Because the hospitals had stocks. Platelets not, but,
 4 you know, red cells, cryo and fresh frozen plasma.

5 **Q.** In terms of frozen red cell concentrates, I think
 6 that's something you referred to at an earlier stage
 7 of your evidence, how long could they be stored in the
 8 frozen state before being used?

9 **A.** 10 years. Or perhaps more, if -- very rare.

10 **Q.** This is then the final cohort of questions, again on
 11 a completely different topic. This is about apheresis
 12 donors. How were apheresis donors selected or
 13 identified?

14 **A.** First of all because they had been donors in the past.
 15 So at least for our centre, they should have given at
 16 least two donations before they became apheresis
 17 donors. And usually it was their interest, when going
 18 to a static clinic, one of our three static clinics,
 19 and seeing other donors connected to these machines,
 20 they say, "What is he or she doing?" And so it was --
 21 they volunteered. Sometimes we asked a donor who was
 22 large enough and a good donor, who had given several
 23 donations, "Would you be interested in
 24 plasmapheresis?" So we tried to increase the number
 25 of apheresis donors.

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1 And they needed to have very good veins, have
 2 a certain size, and have a good history of donation,
 3 and -- yes.

4 **Q.** Is it right to understand that apheresis donors were
 5 ALT tested?

6 **A.** Yes.

7 **Q.** How frequently was that the case?

8 **A.** At every -- so there were a number of plasma donors
 9 and platelet donors who gave blood fortnightly. They
 10 were amazing. But you couldn't collect more than
 11 15 litres a year -- of plasma a year. But until they
 12 reached the limit they donated every fortnight.

13 Sorry, what was your question?

14 **Q.** The first question was how often they were tested,
 15 which I think you've answered: each time they donated.

16 **A.** Yes, each time.

17 **Q.** Why were apheresis donors ALT tested when standard
 18 donors, if I can use that term for the moment, were
 19 not?

20 **A.** Because they went into pools, into plasma pools. But
 21 if one unit had the possibility, remote possibility,
 22 of infecting somebody, it could be distributed to
 23 thousands of Factor VIII concentrates.

24 **Q.** If an apheresis donor attended to donate as part of
 25 the apheresis panel and had raised ALTs and were asked

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1 to defer donating, would they also be advised not to
 2 give blood by way of standard donation?

3 **A.** The problem -- not problem but the thing that
 4 apheresis donors, once they became apheresis donors,
 5 they hardly ever -- we hardly ever asked them to give
 6 a unit of blood because every time they came to give
 7 their donation we had to take samples, so we had to
 8 control their red cell levels to control that they
 9 were not anaemic. So if they gave plasma or
 10 platelets, they did not give whole blood.

11 **MS RICHARDS:** Sir, those are the questions I am proposing
 12 to ask from those put forward by Core Participants.

13 Do you have questions for Professor Contreras?

14 **SIR BRIAN LANGSTAFF:** I don't. Thank you very much, no.

15 **MS RICHARDS:** Professor, do you have anything you would
 16 wish to add?

17 **THE WITNESS:** Yes, if you could bear with me --

18 **MS RICHARDS:** Of course.

19 **THE WITNESS:** -- and yes, I would like to say a few words.
 20 I know it's Friday evening, and everybody wants
 21 to go home. But, you know, I fully appreciate the IBI
 22 efforts and enormous amount of work that has gone into
 23 trying to thread all this complicated matter together,
 24 for the benefit of those infected and affected.
 25 I am very sorry that this Inquiry has come so

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1 late when many of the infected and affected have died,
 2 are too ill, or too old to benefit in any way from the
 3 conclusions arrived at by Sir Brian.

4 The same applies to the witnesses. It would
 5 have been better for all concerned if this Inquiry had
 6 taken place 30 years ago. The UK blood services have
 7 always been risk averse but the tragic incidents in
 8 the 1970s and 1980s that led to this Inquiry have
 9 changed the services beyond recognition, making the
 10 blood services one of the most risk averse services in
 11 the NHS.

12 I have always lived by the principle of what all
 13 doctors say: first, do no harm. And I am sincerely
 14 sorry if any of my actions, decisions or omissions
 15 harmed any patients or their relatives. That was
 16 never my intention.

17 This has been difficult for us all but I hope
 18 what I have said, and I tried to remember, has thrown
 19 a little more light into the Inquiry's efforts to
 20 arrive at the truth. Thank you for listening to me.

21 **MS RICHARDS:** Thank you, Professor.

22 Sir Brian?

23 **SIR BRIAN LANGSTAFF:** I have to say I am rather surprised
 24 that you haven't been asked to give evidence before,
 25 either in a case or in an inquiry. I think there may

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1 be a lot of people now who realise what they've been
2 missing, because what they'll have missed is the
3 straightforward, honest, helpful way in which you've
4 given your evidence.

5 A lesser person may have been more defensive
6 about past decisions by the various bodies of which
7 they were part, so I just want thank you for your
8 courage and your intellectual honesty in not ducking
9 the question of whether mistakes were made and
10 unacceptable delays caused in the past. But I think
11 it goes further than that.

12 It is truly refreshing for me, for us, to see
13 someone who has so obviously thought about what
14 happened in the past and has been candid enough to
15 admit that, on some matters, they themselves were
16 wrong.

17 I'd just like to thank you for having had the
18 strength of character to do that. It is really
19 appreciated.

20 **THE WITNESS:** Thank you so much, sir.

21 **MS RICHARDS:** Sir, that's obviously it for today.

22 We will resume next week, sitting every day next
23 week, so we resume on Monday with the evidence of
24 Dr Entwistle, yes. Then we have a full day of
25 different witnesses, for the rest of the week.

1 **SIR BRIAN LANGSTAFF:** Yes, so it's ten o'clock on Monday,
2 and I expect it will be ten o'clock every other day
3 next week.

4 **(4.07 pm)**

5 **(Adjourned until 10.00 am on Monday)**

I N D E X

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2	PROFESSOR DAME CARMEN MARCELA	1
3	CONTRERAS (continued)	
4	Questions by MS RICHARDS (continued)	1
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