

Thursday, 11 November 2021

(10.00 am)

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

**Presentation by Counsel to the Inquiry  
on Professor John Cash**

**MS RICHARDS:** Thank you, sir.

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

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

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

If we then pick the picture up with some letters to The Lancet in 1987, NHBT0000025\_010. I'm not going to go through the detail of these letters but this is the first, April 1987. You will see the heading is "Surrogate Testing for Non-A, Non-B Hepatitis". The authors, if we go just a little further down the page, include Dr Contreras and Dr Barbara, so we will be able to look at this more directly through oral evidence in due course. But it was effectively expressing a degree of caution and if we look at the last two paragraphs of the letter -- so if we go further up, Soumik -- on the right-hand side, it says:

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

So that was the view being expressed by some in

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

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

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

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

So that's the position discussed by the

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

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

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

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

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

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

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

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

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

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(2) Pages 5 - 8

1 major suppliers of blood and blood products in this  
 2 country, cannot afford to ignore the wishes of  
 3 consumers to be slide with 'non-A, non-B tested'  
 4 products, even if it is believed that the real benefit  
 5 in safety which is offered to the patient is marginal.  
 6 Commercial suppliers will not be slow to point out  
 7 that their products are made from tested plasma and  
 8 must therefore be safer. Clinicians and patients can  
 9 hardly be blamed for taking note of this message. And  
 10 this argument may be applied equally to whole blood,  
 11 red blood cells, platelets, and plasma. What better  
 12 marketing ploy for a private blood bank than to  
 13 emphasise that its donors are tested to exclude  
 14 hepatitis using the standards applied in the United  
 15 States, Germany and France? The local NHS blood  
 16 supplier will have trouble shrugging off the  
 17 accusations of providing a second-class product."  
 18 The letter continues. I'm not going to take  
 19 time now going through the rest of it but, if we go to  
 20 the top of the right-hand column, we can see the  
 21 conclusion:  
 22 "Looking at these 3 factors -- producer's  
 23 liability, competition and value for money -- we  
 24 suggest that decision which has to be made is when  
 25 rather than whether the UK transfusion services follow

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1 meeting.  
 2 "Due mainly to your initiative and hopefully  
 3 with some help from me, we have managed to set up  
 4 a core group with NIBSC and the Blood Transfusion  
 5 Services in the UK. I was assuming that this group  
 6 would be able to advise on tests that might be  
 7 required to be carried out on donor blood, at its  
 8 various meetings, and I would have thought that the  
 9 proposals that you and your colleagues have suggested  
 10 in this letter should first have been discussed at  
 11 this core group which is due to meet on 22nd July.  
 12 I think you will find that there will be some adverse  
 13 comments in the Lancet from the suggestions that you  
 14 and your colleagues have made. We all managed to work  
 15 together to introduced HIV antibody testing on the  
 16 same date. I think it is only a shame that we have  
 17 not been able to have the same type of discussion to  
 18 agree whether or not to implement ALT and/or core  
 19 antibody testing in the UK."  
 20 Professor Cash's response was dated 8 July --  
 21 and it's PRSE0001973 -- addressed to Dr Fraser.  
 22 It refers to a telephone conversation that they  
 23 must have had and then he says this -- again, I won't  
 24 go through every point but point 1:  
 25 "The SNBTS Directors do not wish, and currently

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1 the lead of the United States and other European  
 2 countries in donor screening."  
 3 Then we can see there the authors of the letter:  
 4 McClelland, Cash, Mitchell, Urbaniak, Brookes, Whitrow  
 5 and Perry, and Professor Cash's name there.  
 6 This letter caused a degree of consternation  
 7 amongst Regional Transfusion Directors elsewhere. If  
 8 we go to PRSE0004482, this is a letter of 2 July 1987  
 9 from Dr Fraser, who was director of the Regional  
 10 Transfusion Centre in Bristol, and it's addressed to  
 11 Professor Cash. It thanks him for sending a copy of  
 12 the letter that was due to appear in The Lancet, and  
 13 then continues as following:  
 14 "I think that you will find that the Transfusion  
 15 Directors in England and Wales will not be very  
 16 pleased at reading this letter. I recollect that the  
 17 topic was discussed briefly at the Scottish  
 18 Transfusion Directors' meeting on 10 June last and it  
 19 was agreed, I thought, that there was a need for  
 20 synchrony with England and Wales. I have a feeling  
 21 that the Scottish Directors had already made their  
 22 minds up that they were going to suggest that  
 23 surrogate testing for non-A, non-B Hepatitis would be  
 24 carried out in the Scottish services and I think it is  
 25 a pity that this was not actually mentioned at the RTD

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1 have no intention, of introducing [non-A, non-B]  
 2 surrogate testing unilaterally."  
 3 So the Scottish directors weren't going to go it  
 4 alone in Scotland essentially.  
 5 Point 2:  
 6 "Current views, which as you know were  
 7 crystallised last March, are being expressed to  
 8 support our Public Expenditure Survey (PES)  
 9 submissions to SHHD for the next 5 years."  
 10 We will pick this up when we look at the Penrose  
 11 evidence in the course of the morning, but  
 12 a submission was being made, a PES submission for  
 13 funding, in relation to this matter.  
 14 "3. We have no doubt that an important forum  
 15 for the continued debate is indeed the BTS/NIBSC  
 16 group(s) and the current [non-A, non-B] debate (which  
 17 began some 2 years ago here) and the confused central  
 18 management attitudes to the Medicines Act and Product  
 19 Liability had much to do with driving me to seek the  
 20 establishment of this joint enterprise.  
 21 "4. I really don't believe you should view the  
 22 Lancet letter as any more than part of a debate which  
 23 was initiated in this journal's columns by our friends  
 24 colleagues at Edgware. It can also be viewed as yet  
 25 another attempt to persuade central management (DHSS)

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(3) Pages 9 - 12



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

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

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

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

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

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

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1 request was declined."

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

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

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

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

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

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

12 Then it continues:

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

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

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

25 "DHSS have expressed their concern and dismay at

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

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

11 There is then a letter at SBTS0000250\_122, this  
12 is 1 September 1987, "To: Transfusion Directors".  
13 It's from Dr Perry copied to Professor Cash. I don't  
14 need to go through the full detail of it but if we  
15 just look towards the bottom of the page, at paragraph  
16 (b):

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

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

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

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1 had been tested for ALT. I'm not going to go to the  
 2 document but the reference, for the transcript and  
 3 benefit of others, is PRSE0001194.  
 4 If we then pick matters up at PRSE0001159, we  
 5 have a further SHHD internal memo, this is dated  
 6 17 December 1987, it is from Dr Forrester, entitled  
 7 "Screening of blood donations for non-A, non-B  
 8 hepatitis", and it records that:  
 9 "Professor Cash has pointed out to us ... that  
 10 a commercial producer of blood products is being  
 11 allowed by DHSS to include in their product insert  
 12 a statement that that product is derived from  
 13 donations which have been ALT tested. We have  
 14 confirmed that Professor Cash is correct.  
 15 "For some time he has sought funds to screen all  
 16 donations by both ALT testing and another test, as  
 17 a way to exclude some donations likely to transmit  
 18 non-A, non-B hepatitis. He has not received funds,  
 19 for reasons previously explained, and so far as  
 20 I know, no research is being mounted in Scotland or  
 21 England into the cost and value of the screening.  
 22 "The recipients of SNBTS unscreened blood have  
 23 no choice: they cannot get other blood. But the  
 24 recipients of blood products do have a choice, usually  
 25 no doubt made for them by the clinicians treating

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1 it, gradually faded as attention turned to hepatitis C  
 2 screening.  
 3 However, there were some further communications  
 4 between Professor Cash and Dr Gunson on the issue of  
 5 testing. I'm not going to go through them now but I'm  
 6 just going to give you, sir, the relevant references.  
 7 So there's a letter from Professor Cash to Dr Gunson,  
 8 12 January 1990, reference there for the transcript is  
 9 NHBT0000027\_011, and the particular concern being  
 10 expressed by Professor Cash was that, within England  
 11 and Wales, Regional Transfusion Centres were going to  
 12 start using routine ALT testing of plasmapheresis  
 13 donations.  
 14 There's a response from Dr Gunson, January 1990,  
 15 at NHBT0000027\_012, and a further letter back from  
 16 Professor Cash, 30 January, PRSE0001347, and then from  
 17 Dr Gunson again, 2 February, NHBT0000027\_015.  
 18 Before turning then to the issue of hepatitis C  
 19 screening, can we look at Professor Cash's two written  
 20 statements to the Penrose Inquiry on this issue. The  
 21 first in time is relatively uninformative but we'll go  
 22 to it for the sake of completeness. It is  
 23 PRSE0004065. You will see, sir, it is headed  
 24 "C2 Witness Statement (Surrogate Testing)". C2 was  
 25 the Penrose Inquiry's designation for the topic of

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1 them. They can have SNBTS products, apparently  
 2 gratis, made from unscreened donations. Or they can  
 3 have commercial products, at the cost of their Health  
 4 Boards, made from partially screened donations:  
 5 partially, because ALT screening is only one of the  
 6 two tests proposed together to reduce transmission of  
 7 non-A, non-B hepatitis.  
 8 "It is credible that the commercial products,  
 9 derived from the donations of paid donors, are safer  
 10 because of ALT testing than they would otherwise be.  
 11 But it is not clear that a sensible clinician would  
 12 prefer them to SNBTS products.  
 13 "The clinicians, however, stimulated perhaps by  
 14 some of their patients, are likely to press us now to  
 15 'join the club', and SNBTS are sure to resume similar  
 16 pressure."  
 17 So the position again internally within the SHHD  
 18 appears to be a concern that this issue is being  
 19 raised as a means of securing funding and it may be  
 20 thought an unwillingness to provide the funding that  
 21 would enable the testing to take place.  
 22 In his evidence to the Penrose Inquiry,  
 23 Professor Cash recalled that, following the  
 24 identification of hepatitis C in 1988/89, the  
 25 controversy surrounding surrogate testing, as he put

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1 surrogate testing.  
 2 The statement starts on page 4 but the answers  
 3 that are given by Professor Cash, and I don't mean  
 4 this as a criticism, are relatively limited, perhaps  
 5 because the material that he then had available to him  
 6 in order to answer them was relatively limited. So  
 7 I'm not going to go to the detail of any of his  
 8 answers but you have there his first statement on this  
 9 issue.  
 10 His second statement on this issue is rather  
 11 more informative and it's at PRSE0003232. What's set  
 12 out on this first page is not Professor Cash's own  
 13 summary, this is the Penrose Inquiry's summary of what  
 14 are said to be key relevant dates. I'm not going to  
 15 go through the detail of it.  
 16 If we go over to the second page, you'll see, at  
 17 the top of the page, the Penrose Inquiry's summary  
 18 includes reference to some of the correspondence we've  
 19 looked at. Then we have, further down the page,  
 20 underlined, "Queries", and the question that is then  
 21 posed to Professor Cash is:  
 22 "Should a large scale prospective study, as  
 23 originally proposed by Dr McClelland in 1981 ... have  
 24 been carried out in the UK in the early 1980s (or at  
 25 some point thereafter) with the following aims:

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(5) Pages 17 - 20

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

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

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

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

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(6) Pages 21 - 24

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

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

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

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

25

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

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

13 We can then pick that up at NHBT0000076\_003.  
14 This is Dr Gunson to Professor Cash on 26 July 1989.  
15 He says:

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

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

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

27

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

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

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

12 There's then a discussion, if we move to  
13 May 1989, in the Advisory Committee on Transfusion  
14 Transmitted Diseases meeting of 14 May,  
15 NHBT0000088\_001. You'll see that those present  
16 included Professor Cash. If we go to the bottom of  
17 page 3, we'll pick up the heading "Non-A, Non-B  
18 Hepatitis", and there's reference to there being  
19 an oral report by Dr Barbara, that's Dr John Barbara:

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

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

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

26

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

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

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

14 NHBT0000188\_016 is a letter from Professor Cash,  
15 August 1989, 4 August, to Dr McIntyre at the Scottish  
16 Home and Health Department following a meeting he had  
17 had with Ortho. He says at paragraph 1, this is  
18 Professor Cash speaking:

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

28

(7) Pages 25 - 28



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

29

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

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

30

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

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(8) Pages 29 - 32

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

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

8 The second question was:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 (10.52 am)

(A short break)

11 (11.33 am)

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

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

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

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

24 Also in August 1989 there's a letter from  
25

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(9) Pages 33 - 36

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

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

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

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

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1 Then if we look at NHBT0000188\_123, we can see  
2 the next development was Ortho writing to Professor  
3 Cash on 27 November 1989, saying:

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

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

11 There was then a further letter, I'm not going  
12 to go to it, but from Ortho to Professor Cash about  
13 the confirmation testing. The reference for your  
14 note, sir, and for the benefit of anyone who wants to  
15 look at it, is NHBT0000188\_122. Then Professor Cash  
16 wrote again on the issue of confirmatory testing to  
17 Ortho, again no need to put it up on screen but at  
18 NHBT0000188\_127.

19 If we could next have up, please,  
20 SBTS0000155\_102. So this was a letter from Dr Ludlam  
21 to Professor Cash, 5 December 1989, in relation to the  
22 introduction of routine anti-HCV screening of blood  
23 donors and Dr Ludlam set out this perspective, picking  
24 it up in the second line of the letter:

25 "I realise that the present antibody test is not

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

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

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

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

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

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

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

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(10) Pages 37 - 40



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

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1 we'll be picking that up with other witnesses in due  
 2 course over the coming weeks and months.  
 3 In relation to Professor Cash himself, I'm going  
 4 to pick the picture up next in 1991.  
 5 NHBT0000076\_006.  
 6 This is Dr Gunson writing to Regional  
 7 Transfusion Directors in England and Wales on  
 8 22 January 1991 but copied to Professor Cash. We see  
 9 that from the bottom of the letter.  
 10 This is an announcement of the Department of  
 11 Health's position:  
 12 "1. The Department of Health have agreed that  
 13 routine testing of all blood donations for anti-HCV  
 14 can be put into operation.  
 15 "2. I have been asked to try and ensure that  
 16 testing starts simultaneously in [regional transfusion  
 17 centres] in England and Wales and that it is  
 18 co-ordinated with commencement of testing in  
 19 Scotland."  
 20 Then there's a request to the Regional  
 21 Transfusion Directors to let Dr Gunson know what they  
 22 consider to be the earliest date they could commence  
 23 testing.  
 24 Paragraph 4 refers to the need still to conclude  
 25 the financial arrangements to cover both routine

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

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1 screening and supplementary tests.  
 2 Paragraph 5 refers to proposals for a protocol  
 3 for the carrying out of the tests, which is still to  
 4 be discussed within the Department of Health.  
 5 Then 6 says:  
 6 "I will inform Ortho and Abbot that routine  
 7 screening for anti-HCV has been approved and that we  
 8 will inform them of the starting date in due course."  
 9 If we then turn to NHBT0000073\_033 we will see  
 10 Professor Cash's response to Dr Gunson's memo. So  
 11 this is dated 24 January:  
 12 "Many thanks for your memo of 22nd January.  
 13 "I have liaised with SNBTS RTDs and we are  
 14 unanimous in advising, with the greatest respect but  
 15 in the strongest possible terms, that anti-HCV  
 16 donation testing should not be commenced in the UK BTS  
 17 until after the Gulf conflict is over or at least  
 18 until such time as we are confident our blood  
 19 collection and microbiology testing teams can cope  
 20 with what will be quite substantial changes and  
 21 increased workloads.  
 22 "Just at the moment there are a lot of exhausted  
 23 staff in our RTCs and I would judge that when the  
 24 troops go in, our current frenetic activity will be  
 25 sustained.

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(11) Pages 41 - 44

1 "We would be most grateful if you would see  
2 Ministers are appropriately advised. We would wish  
3 you to emphasise that we do not intend to be  
4 obstructive in any way but believe this increased load  
5 (HCV donation tests) in the present circumstances  
6 could lead to GMP [good manufacturing practice]  
7 failures in existing overstretched programmes."  
8 Over the page:  
9 "We remain firmly committed to starting on the  
10 same day as our NBTS colleagues and if pressed by  
11 Ministers I would suggest, in the circumstances,  
12 a May/June date should be considered. However,  
13 I would much prefer to wait another month and then  
14 respond to your letter."  
15 So you will see what appears to be a fairly  
16 unequivocal communication from Professor Cash that it  
17 should not be introduced until later in the course  
18 of 1991, and the reason that's given is essentially  
19 the workload and the need to be in a position to deal  
20 with the screening programme having regard to  
21 additional burdens anticipated in relation to the  
22 impact of the Gulf War.  
23 Dr Gunson replied on 28 January 1991 -- I'm not  
24 proposing to go to that letter; the reference, for the  
25 transcript, is PRSE0004144 -- and Dr Gunson agreed

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1 pursue Dr Metters' Committee on these topics. Once  
2 again we would very much like the SNBTS to stay in  
3 line with NBTS/BPL."  
4 There is then a discussion of the start date at  
5 the meeting of the Advisory Committee on Transfusion  
6 Transmitted Diseases on 25 March 1991.  
7 That's NHBTO000073\_063, please, Soumik.  
8 We'll see it was a meeting chaired by Dr Gunson.  
9 Professor Cash was present, along with Drs Contreras,  
10 Craske, Follett, Mitchell, Wagstaff and  
11 Professor Tedder.  
12 If we go to the second page, paragraph 4 is  
13 headed "Introduction of anti-HCV tests into NBTS and  
14 SNBTS":  
15 "The starting date and its definition.  
16 "The proposed starting date of 1 July [so that's  
17 what's recorded as being the proposed date] presented  
18 difficulties since it was considered essential that  
19 the second generation test from both Ortho and Abbott  
20 should be evaluated prior to the commencement of  
21 routine tests. Ortho tests were being evaluated by  
22 Dr Barbara at North London RTC and he had, to-date,  
23 only received pre-production batches of the tests. It  
24 was known that there was procedural differences  
25 between the pre-production and production batches.

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1 that an immediate start was entirely impractical.  
2 There's then a further letter from  
3 Professor Cash at PRSE0002763, 15 February 1991, and  
4 this is in relation to the discussion of a start date  
5 for the programme. It says:  
6 "Thinking ahead to the end of June 1991 and  
7 checking over previous correspondence I think we need  
8 to do one more thing in the not too distant future.  
9 I refer to defining what 'start date' will mean --  
10 it's a re-run of the HIV-1 programme.  
11 "Whatever the 'start date' will be, do we mean  
12 that by 9 am on that day all RTC products and those in  
13 associated hospital blood banks will be HCV (screen)  
14 negative? The definition of RTC products will, of  
15 course, be those not from BPL or PFC. If we adopt  
16 this definition, then clearly testing will have to  
17 commence well in advance of the 'start date'.  
18 "Next we will have need, as on previous  
19 occasions, to obtain a policy decision with regard to  
20 plasma already in bond at both fractionation centres  
21 and awaiting uplift (at RTCs) for the fractionation  
22 centres. If a decision is made to test aliquots from  
23 these donations, the task is doable but formidable."  
24 Over the page:  
25 "Sorry to pester but I suspect you will have to

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1 These test kits should be available within 10 days to  
2 2 weeks. The situation with Abbott was uncertain  
3 since they had not yet given an official date for  
4 launching their second generation test.  
5 "The preliminary results obtained by Dr Barbara  
6 on the test kits from three manufacturers were  
7 reviewed and it was agreed that further testing at all  
8 three RTCs was essential. It was agreed that  
9 Newcastle RTC would provide samples from their donors  
10 in the study for Dr Barbara and Glasgow RTC would do  
11 the same once Abbott had provided 2nd generation test  
12 kits since this would avoid thawing the samples more  
13 than once.  
14 "The [Chair] was asked to contact Abbott and  
15 from the information he received recommend a starting  
16 date for the commencement of tests."  
17 "4.14. It was agreed that testing of blood and  
18 plasma donations would commence on a specified date.  
19 There would not be retrospective tests carried out on  
20 donations collected prior to that date."  
21 There's then a discussion about confirmatory  
22 testing over the page but I'm not proposing to go  
23 through that. So you will see there, by this point in  
24 time, there was a proposed starting date of 1 July but  
25 a question mark being raised in relation to that

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(12) Pages 45 - 48

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

4 If we look next at SCGV0000163\_053, and we go to  
5 the next page, this is a letter from Professor Cash to  
6 Mr David McIntosh in SNBTS, dated 27 March 1991, and  
7 it refers to the meeting, the minutes of which we have  
8 just looked at, and says this:

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

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

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

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

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

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

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

18 Over the page it says:

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

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

23 Then Professor Cash's response to that is at  
24 NHBT0000191\_133. This is 5 April:

25 "Dear Harold

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

7 Top of the next page:

8 "More anon when things are clearer!"

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

12 There's then a communication from Dr Gunson  
13 NHBT0000073\_065. This is a letter which, as is plain,  
14 is intended to send to all Regional Transfusion  
15 Directors in England and Wales, dated 3 April 1991.  
16 It's copied to Professor Cash. We don't need to look  
17 at it but that is apparent from the second page.

18 Then you will see what Dr Gunson sets out:

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

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

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

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

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

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

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

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(13) Pages 49 - 52



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

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1 right it may have repercussions for the accuracy of  
 2 the start date adopted for Skipton.  
 3 **MS RICHARDS:** It might indeed, sir, yes, absolutely.  
 4 **SIR BRIAN LANGSTAFF:** Although no-one, of course, would  
 5 have had that in contemplation at this stage, but yes,  
 6 thank you.  
 7 **MS RICHARDS:** Now, what then happened in May of 1991 is  
 8 that the director of the Newcastle regional  
 9 transfusion centre decided not to await the universal  
 10 start date for the autumn of 1991, and he explains his  
 11 position at NHBT0000074\_014.  
 12 This is a communication from Dr Lloyd, director  
 13 of the Regional Transfusion Centre in Newcastle, from  
 14 whom we hope the Inquiry will be hearing.  
 15 It's 2 May 1991, directed to all directors of  
 16 transfusion services, copied to, amongst others --  
 17 well, copied to Dr Gunson and Professor Cash.  
 18 It says this:  
 19 "As you know there was a date of 1st July set  
 20 for Hepatitis C Antibody testing. Fairly recently  
 21 this was changed with a provisional date set for  
 22 September 1991.  
 23 "In view of the fact that we were already set up  
 24 for testing, I have decided to keep to the July date.  
 25 By 1st July, all units of blood for transfusion in the

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1 Northern Region will be negative for Hepatitis C  
 2 antibody.  
 3 "My personal view is that not to test now that  
 4 we have the ability to test would be indefensible  
 5 under the current Product Liability Legislation.  
 6 I appreciate that individual Directors may take  
 7 a different view on the potential liability under the  
 8 Consumer Protection Act, but the fact that this Centre  
 9 is testing should not materially alter that judgment.  
 10 "I would be interested to know if any Centre is  
 11 currently carrying out any additional tests such as  
 12 Hepatitis B core testing or ALT testing and if so,  
 13 what criteria are being used to select donors/samples  
 14 for testing."  
 15 Now I'm not going to explore to any extent the  
 16 decision taken by Dr Lloyd. As I say, that will be  
 17 for future hearings. I draw attention to it because  
 18 it's the response from Professor Cash that's relevant  
 19 for today's purposes.  
 20 In what you may think are characteristically  
 21 powerful terms, Professor Cash wrote to Dr Lloyd on  
 22 7 May 1991, NHBT0000074\_019.  
 23 He says this:  
 24 "I received your copy letter to the UK BTS  
 25 Directors ... with quite profound dismay, which

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

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(14) Pages 53 - 56

1 Dr Lloyd responded to Professor Cash at  
 2 NBBT0000192\_031 in what you may think are quite  
 3 dignified terms:  
 4 "Dear John ...  
 5 "Thank you for your colourful letter. Your  
 6 views are graphically put, as I would have expected.  
 7 "I too have spent many hours looking at material  
 8 relating to HIV litigation, but my conclusion is  
 9 different to the one that you appear to be drawing.  
 10 The situation now is quite different to that which  
 11 existed when HIV 1 testing commenced, and I personally  
 12 believe that to start HCV testing to the original  
 13 schedule is the correct decision, even if it appears  
 14 unpalatable to some.  
 15 "To suggest that my action was in your words  
 16 'mischievous', is to impart motives to this action  
 17 which were not mine. If you wish to question motives,  
 18 then perhaps you should be asking why a vague  
 19 September start date has replaced with little  
 20 explanation, a firm date in July."  
 21 Then, continuing with the position in relation  
 22 to May of 1991, Professor Cash wrote to Dr Gunson on  
 23 8 May, NHBT0000074\_024.  
 24 He referred to "the Newcastle saga". That's  
 25 obviously a reference to Dr Lloyd's decision. Then he

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1 Then he goes on to talk about the confirmatory  
 2 testing associated with the study.  
 3 Also in May of 1991 Dr Gunson advised -- I don't  
 4 propose to go it but I will just give you the  
 5 reference -- NHBT0000192\_024 -- that the Department of  
 6 Health had reviewed the position in light of  
 7 Dr Lloyd's decision to commence testing early and had  
 8 concluded that the September date should remain and  
 9 they were awaiting, amongst other matters, the second  
 10 generation tests receiving FDA licences.  
 11 If we pick matters up still in May of 1991 with  
 12 a further letter from Professor Cash to Dr Gunson at  
 13 NHBT0000192\_039, this raises some wider concerns.  
 14 So the first paragraph says:  
 15 "I can well understand that last week there's  
 16 a time of preoccupation with the immediate tasks  
 17 associated with damage limitation, following the  
 18 unilateral actions of Newcastle RTC.  
 19 "On the first cold and wet Monday morning after  
 20 that eventful week, I feel bound to raise with you and  
 21 colleagues a matter of fundamental importance to the  
 22 future of the UK [Blood Transfusion Service].  
 23 "It has always been the view in Scotland, both  
 24 in the Scottish Office and throughout the SNBTS, that  
 25 the introduction of additional microbiology donation

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

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

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(15) Pages 57 - 60

1 of my knowledge, this is a development in the  
 2 management of blood transfusion services which is  
 3 unique in Europe."  
 4 Then the next paragraph:  
 5 "You will recall that I proposed several years  
 6 ago that there be established an authoritative  
 7 ministerial advisory group which concerned itself with  
 8 all policy issues relating to the safety of blood  
 9 donations. I do believe this matter now requires  
 10 urgent consideration. Such a group should not be  
 11 restricted to virus transmission and must, above all,  
 12 be authoritative.  
 13 "It is just possible that this issue, perhaps  
 14 more than any other, can only be resolved  
 15 satisfactorily UK by the establishment of a centrally  
 16 managed [National Blood Transfusion Service], for  
 17 authority is ultimately achieved by the allocation of  
 18 funds. It is difficult not to conclude that we are  
 19 rapidly reaching a situation where all the UKBTS  
 20 Groups we have established, particularly those  
 21 associated with BTS Guidelines, should be abandoned.  
 22 It is every man for himself time and, against the  
 23 background of the developments on harmonising quality  
 24 in Europe, the recent episodes in the UK must surely  
 25 be a matter for grave concern."

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1 he says:  
 2 "The standard set by the UK BTS in the [HIV]  
 3 exercise have been extended to the HCV kits. The  
 4 SNBTS has contributed substantially to this exercise.  
 5 The results have been interesting (and a little  
 6 worrying)."  
 7 Then he goes on to give detail of that and also  
 8 to refer to the outcomes in relation to confirmatory  
 9 testing.  
 10 Then if we pick it up in that fourth paragraph:  
 11 "As the UK BTS validating team was in the  
 12 process of advising Ministers and RTCs that both these  
 13 kits could be used and that UK BTS should commence  
 14 full scale screening on 1st July 1991, the kit  
 15 manufacturers announced their intention to withdraw  
 16 their kits and replace them with second generation  
 17 kits. These new kits were claimed by the  
 18 manufacturers to be an improvement over those tested  
 19 by the UK BTS validation team, but no satisfactory  
 20 data was available to confirm this at this time and it  
 21 was noted that the FDA had not yet approved their use  
 22 ... It was concluded that an evaluation of these  
 23 second generation kits should be undertaken as  
 24 a matter of urgency and a scheduled start time (for  
 25 full RTC screening) was estimated to be

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1 That was a more general observation on the  
 2 organisation and structure of the National Blood  
 3 Transfusion Service. Returning to the specific issue  
 4 about hepatitis C donation testing and its  
 5 introduction, Professor Cash authored a document at  
 6 NHBT0000192\_144.  
 7 This was 14 May 1991, addressed by Professor  
 8 Cash to SNBTS board members, and you will see the  
 9 subject is "HCV Donation Testing".  
 10 It refers to an article in the Sunday Times on  
 11 11 May, and then says this in the first main  
 12 paragraph:  
 13 "Since early 1984, there has been growing  
 14 concern throughout the UKBTS that microbiology  
 15 donation screening kits should be appropriately  
 16 evaluated before their large scale use is instituted.  
 17 The primary concern, in this context, has been for the  
 18 UK BTS to ensure, as much as is possible, that every  
 19 effort has been made by kit manufacturers to maximise  
 20 both sensitivity and specificity."  
 21 Then he refers to the need for the task to  
 22 evaluate which kits might give rise to false negatives  
 23 or false positives.  
 24 If we then go further down -- sorry, if we go  
 25 over the page, picking it up in the second paragraph,

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1 1st September 1991."  
 2 Then he sets out conclusions, saying:  
 3 "If we extend these UK observations to Scotland  
 4 then each year we can predict (without HCV donation  
 5 testing) the following:  
 6 "There will be approximately 170 donations ...  
 7 infected with HCV and placed at issue ..."  
 8 Then he goes on to give further details in  
 9 relation to that. Top of the next page, he then sets  
 10 out various figures, and fourth paragraph down says:  
 11 "... in simple terms, we would have  
 12 approximately 1,900 donors to deal with who we  
 13 believed were false positives."  
 14 It goes on then to talk about costs and then, in  
 15 the last paragraph, says this:  
 16 "It would seem prudent and responsible to pursue  
 17 the idea of full evaluation of the second generation  
 18 (HCV) test kits."  
 19 Then skipping a sentence:  
 20 "Beyond this, representations are being made, in  
 21 the light of the developments in Newcastle RTC, as to  
 22 whether, in future, the SNBTS is bound to a UK BTS  
 23 approach with regard to donation testing, against  
 24 a background of Ministerial involvement."  
 25 Then the document concludes over the page but

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(16) Pages 61 - 64



1 I don't need to trouble you with that. So it would  
 2 appear from this document that Professor Cash was  
 3 effectively agreeing with the need for there to be  
 4 this further evaluation of the second generation kits,  
 5 for the reasons which he there set out.  
 6 There were some further communications between  
 7 Gunson and Cash in relation to the suggestion of the  
 8 need for a ministerial advisory group but I'm not  
 9 proposing to trouble you with that.  
 10 There was then a further meeting of the Advisory  
 11 Committee on Transfusion Transmitted Diseases on  
 12 10 June 1991. I'm not going to go to it. The  
 13 reference, for the transcript, is NHBT0000044\_003.  
 14 There was a discussion there of a number of matters,  
 15 including how to handle donations and donors found to  
 16 be hepatitis C positive.  
 17 If we then look at PRSE0001183, it's a further  
 18 letter from Dr Lloyd to Professor Cash. This is dated  
 19 4 July. It says:  
 20 "I was pleased to see you at the recent meeting  
 21 in York and thank you for 'burying the hatchet'. May  
 22 I respond by apologising for any problems that I have  
 23 caused you by starting testing this April."  
 24 Then Dr Lloyd sets out his broader concern:  
 25 "On a wider theme, I'm concerning that the UK

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1 There are, however, just two documents further  
 2 to look at on the issue of hepatitis screening. The  
 3 first is NHBT0000077\_061. It's a letter from  
 4 Professor Cash to Dr Gunson, 8 August 1991, headed  
 5 "[Post-transfusion hepatitis] (HCV): Future  
 6 Litigations", so anticipating that there may be  
 7 litigation in the future, arising out of the delay in  
 8 introducing hepatitis C screening, and he says this:  
 9 "I do believe it is important that consideration  
 10 is given to the formulation of an agreed statement of  
 11 the UK BTS professional position with regard to HCV  
 12 donation testing.  
 13 "It seems to me that the key elements which need  
 14 to be addressed, in the context of a defence position  
 15 in subsequent litigations, are as follows:  
 16 "1. Why didn't UK BTS introduce surrogate  
 17 (ALT/Anti-HBc) testing?  
 18 "2. Why was anti-HCV testing delayed until  
 19 1st September 1991?"  
 20 Those obviously are the two key questions. He  
 21 doesn't give his answer in this letter but simply  
 22 says:  
 23 "Perhaps we might wish to give this a run round  
 24 at the next ACTTD meeting [that's the Advisory  
 25 Committee on the Transfusion Transmitted Diseases].

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1 seems to be dragging its feet over testing  
 2 I appreciate that many questions are not answered and  
 3 for some Transfusion Centres, their organisation  
 4 will find it difficult to introduce another test. By  
 5 waiting until everyone's problems etc are sorted out,  
 6 we run the risk of accepting the lowest common  
 7 denominator. I somehow doubt that you would be happy  
 8 to accept the lowest common denominator approach. The  
 9 attitude of UK Transfusion Centres has often not been  
 10 very positive and when we look at the plasma  
 11 procurement situation (South of the border) over the  
 12 years, it presents a very dismal picture. A little  
 13 more fire and enthusiasm for Transfusion is required  
 14 and a little less local protectionist activity and  
 15 negative thinking."  
 16 There were then various communications -- again  
 17 we've set them out in our written presentation,  
 18 I don't think I need to go to them -- in relation to  
 19 some of the detailed working out of the introduction  
 20 of the hepatitis C screening. So there's a letter  
 21 from Professor Cash in July to SNBTS directors and  
 22 communications between Professor Cash and Dr Gunson in  
 23 August in relation to the position regarding  
 24 confirmatory testing. But I'm not going to trouble  
 25 you with looking at those now.

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1 On the other hand, you may feel this would be the most  
 2 appropriate forum."  
 3 I think there's a "not" missing from that  
 4 letter.  
 5 Then over the page, he continues:  
 6 "You will see from the enclosed (which I'm sure  
 7 you've seen) [and that's a reference to an article in  
 8 the Independent 'Patients may sue over hepatitis C in  
 9 blood'] the cause for my concern and why I feel this  
 10 matter is of some urgency. You promised to send me  
 11 a set of Dr Metters' Committee Minutes: they haven't  
 12 yet arrived."  
 13 We can see that the enclosure is the extract  
 14 from The Independent newspaper.  
 15 So the other document I wanted to ask you to  
 16 look at, sir, on this issue is Professor Cash's  
 17 Penrose Inquiry witness statement on this topic of  
 18 screening for hepatitis C. It's at PRSE0002529. We  
 19 looked at some of Professor Cash's observations about  
 20 the advisory committees, which he sets out on the  
 21 first two pages of this statement, yesterday. I'm not  
 22 going to go back to that.  
 23 If we go to the third page, if I pick it up on  
 24 the bottom half of the page, there's what might be  
 25 described as a general set of observations from

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(17) Pages 65 - 68

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

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

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

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

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

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

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

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

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(19) Pages 73 - 76



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

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

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

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

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(20) Pages 77 - 80



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

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

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

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

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

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

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

13 There's PRSE0000529, statement about the PFC.

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

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

17 PRSE0001411 is concerned with ALT testing.

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

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

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

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

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1 questions of surrogate testing, essentially.  
2 PRSE0003395 is HIV/AIDS.  
3 PRSE0003463 is a further statement in relation  
4 to the PFC.

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

8 PRSE000465, statement about surrogate testing.

9 PRSE0004252 is an updated statement about  
10 HIV/AIDS.

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

13 Also on the topic of donors, PRSE0004558.

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

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

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

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

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1 collection from donors with a history of jaundice.

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

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

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

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

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

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(21) Pages 81 - 84

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

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1 in relation to either of those positions.  
 2 If we then look at NHBT0000073\_007, this is  
 3 a letter, October 1990, Professor Cash to Dr Gunson.  
 4 It's primarily concerned with the issue of donor  
 5 counselling and a report from Jack Gillon, but if we  
 6 go over the top of the next page, we can see the issue  
 7 of look-back. He says:  
 8 "... I would much appreciate your thoughts on  
 9 the issue of 'look-back'. You will have noted that  
 10 our team have indicated the need for a policy  
 11 statement and in their view 'look-back' should be  
 12 attempted."  
 13 There were then discussions or -- sorry, there  
 14 was then a letter from Dr Gunson saying this will be  
 15 considered by the Advisory Committee on Transfusion  
 16 Transmitted Diseases in January 1991. The reference  
 17 for that, I'm not proposing to go to it, is  
 18 NHBT0000073\_028.  
 19 If, however, we look at -- sorry, just give me  
 20 a moment.  
 21 PRSE0001573. We can see Professor Cash writing  
 22 to Dr Metters, Deputy CMO, in November 1990:  
 23 "In anticipation of the commencement of HCV  
 24 blood donation testing throughout the UK in the  
 25 foreseeable future, the Scottish National Blood

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

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

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(22) Pages 85 - 88

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

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1 took any action, AK asked to be given the opportunity  
 2 to discuss the issues with SHHD colleagues to seek  
 3 their views and asked that the SNBTS take no formal  
 4 action until she had subsequently contacted JDC."  
 5 That's Professor Cash.  
 6 "vi. Once AK had communicated the SHHD position  
 7 to JDC and provided SHHD were in agreement that the  
 8 SNBTS should implement this policy, JDC would write to  
 9 D [McClelland] to provide details of the SNBTS policy,  
 10 thereby allowing a decision to be taken on a starting  
 11 date for the process. [Professor Cash] also would  
 12 formally advise NBA, NIBTS, SACTTI and MSBT of the  
 13 SNBTS policy."  
 14 We are definitely in acronym soup by now.  
 15 "vii. If SHHD agreed that SNBTS should develop  
 16 and implement a lookback policy for HCV, [Dr Keel]  
 17 subsequently would communicate this to [the Department  
 18 of Health].  
 19 So that's the discussion which took place there,  
 20 and again we'll be able to unpick some of the  
 21 decision-making here with later witnesses.  
 22 There's a reference at NHBT0095526\_0026 to there  
 23 being pressure to promote a look-back policy.  
 24 Do you need that reference again, Soumik?  
 25 NHBT0095526 --

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

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

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(23) Pages 89 - 92

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

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

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

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

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

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

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

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

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

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

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

5 MS RICHARDS: We will hear from Ms Scott.

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

8 MS RICHARDS: Exactly, yes.

9 (1.04 pm)

(Luncheon Adjournment)

11 (2.05 pm)

12 SIR BRIAN LANGSTAFF: Yes.

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

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

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

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1 presentation, are selective.

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

8 I'm going to start by looking at his CV, which  
9 is NHBOT0000025\_002, and it's page 16 of that document.  
10 We can see there his name and, if we go over to the  
11 following page and pick it up at the bottom of that  
12 page, we can see, beginning in 1953, Resident Clinical  
13 Pathologist, and then a number of appointments in  
14 Canada, returning in 1959 to take up a role as  
15 a Senior Hospital Medical Officer in a Regional  
16 Transfusion Centre in Manchester.

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

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

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1 Transfusion Service, which was based in Manchester.

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

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

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

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

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1 that paragraph, what he does there is he describes the  
 2 different administrative arrangements there are going  
 3 to be, namely that he is going to discharge his role  
 4 from Manchester not from London, because he is going  
 5 to continue in his role as director of the Manchester  
 6 centre. I'll pick it up, it says:  
 7 "Where statements had to be made on behalf of  
 8 the DHSS this would be done by DHSS and not by the  
 9 consultant adviser to the DHSS. Dr Gunson expressed  
 10 his willingness to attend any meetings of working  
 11 parties or regional groups at which his contribution  
 12 would be useful ..."  
 13 So echoing what he says in his later letter but,  
 14 importantly, he says this:  
 15 "... he saw his role as reflecting the views of  
 16 the RTDs and NBTS at large and communicating these to  
 17 the DHSS where appropriate."  
 18 So a slightly different complexion there to the  
 19 role. In that later letter he says it's a personal  
 20 one, and "I'll be expressing my personal views", but  
 21 here he seems to be suggesting that he may be rather  
 22 more of a representative voice of RTDs to the DHSS.  
 23 Then I'll just take you to a document,  
 24 NHBT0000086\_009, again which gives us a bit of  
 25 information about the role.

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

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

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

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

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

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

25 Then skipping down to two thirds of the way down

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

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

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

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

15 Then the next paragraph he says:

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

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

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1 began his role in October 1981?

2 **MS SCOTT:** Yes.

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

4 relationship between AIDS and the transfusion of blood

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

6 before October '82?

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

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

9 reflection, at what point he says that he was

10 convinced that HIV or AIDS was caused by blood

11 transfusions.

12 **SIR BRIAN LANGSTAFF:** Yes.

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

14 So moving on then to the committees and working

15 groups that Dr Gunson participated in and I should

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

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

18 There are other working groups, committees and so on

19 that he participated in.

20 So, as a Regional Transfusion Director, as one

21 would expect he was a regular attendee at Regional

22 Transfusion Director meetings, and the Regional

23 Transfusion Directors had various working groups and

24 committees and he was chair of the Regional

25 Transfusion Directors committee, called the UK AIDS

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1 of Scotland and Northern Ireland.

2 He chaired two of its subcommittees, the working

3 party to advise on plasma supplies for

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

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

6 of these committees and working groups are quite

7 a mouthful.

8 Once the National Directorate was formed in 1988

9 and the Advisory Committee was abolished, as we heard

10 on Tuesday, he became -- the National Management

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

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

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

14 looked at their terms of reference on Tuesday.

15 He was a member of the UK Working Party on

16 Transfusion Associated Hepatitis from its inaugural

17 meeting in September 1982, and the terms of reference

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

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

20 because they are short.

21 So the terms of reference for that group were to

22 promote the investigation of the epidemiology of

23 transfusion associated hepatitis to promote research

24 and to make recommendations to the director of the UK

25 Transfusion Service regarding procedures and screening

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

2 only found minutes of one meeting of that group to

3 date but investigations continue.

4 He also attended the regional meetings of

5 consultants of the Blood Transfusion Service and, sir,

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

7 instituted a system where there were three

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

9 one would expect as a director, attended the relevant

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

11 He also attended meetings when they occurred

12 between Regional Transfusion Directors and Haemophilia

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

14 meetings of that nature.

15 He was a member of the Advisory Committee on the

16 National Blood Transfusion Service, from its inception

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

18 was created and circumstances that that was created,

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

20 reference of that group, which for reference, is

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

22 Welsh Office on the co-ordination of the development

23 and work of Regional Transfusion Centres and Central

24 Blood Laboratories in England and Wales, and the

25 English and Welsh Blood Transfusion Service with those

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1 for its prevention.

2 Between 1982 and 1988 he was a member of the

3 Central Blood Laboratory Authority. He was chair of

4 some of their subcommittees, such as the central

5 committee for research and development in blood

6 transfusion, he was chair of that subcommittee from

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

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

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

10 can be found at CBLA0001754, and that document says

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

12 relation to the transfusion of blood and blood

13 products.

14 That was a committee on which Professor Bloom

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

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

17 document reference for, that Professor Bloom was asked

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

19 and the Medical Research Council committee on AIDS

20 because he sat on both of those committees.

21 Now Dr Gunson resigned from the CBLA when he

22 took up his role as national director to avoid any

23 conflict should the CBLA policy materially differ from

24 the aims of the National Blood Transfusion Service.

25 He was a member of the National Blood

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1 Transfusion Service and CBLA Liaison Committee from  
 2 January 1989. He was a member of the NIBSC, the  
 3 National Institute for Biological Standards and  
 4 Control, and the UK Blood Transfusion Service Liaison  
 5 Group, which first met in March 1987.  
 6 The purpose of that committee is set out at  
 7 NHBT0108865\_010. We don't need to go to that now. In  
 8 essence, it was a committee set up to formulate  
 9 scientific guidelines for the standardisation and  
 10 safety of blood and blood products, and subsequently  
 11 became, as I understand it, the Standing Advisory  
 12 Committee on Transfusion Transmitted Infections or  
 13 SACTTI. He attended a couple of SACTTI meetings  
 14 before his retirement.  
 15 He was also a member of the SNBTS NBTS -- so the  
 16 Scottish National Blood Transfusion Service and the  
 17 National Blood Transfusion Service -- Liaison  
 18 Committee, as Ms Richards made clear yesterday, and  
 19 the chairmanship of that committee alternated, as  
 20 I understand it, every meeting between Scotland and  
 21 England, and when it was England's turn he was chair.  
 22 They had their first meeting in January 1989.  
 23 He was also a member, as you heard yesterday,  
 24 sir, on the Advisory Committee on the Virological  
 25 Safety of Blood, or ACVSB, from 1988 to 1994.

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1 transmitted by the transfusion of blood and blood  
 2 products.  
 3 "2. To determine the appropriate policy which  
 4 should be implemented by the UK Blood Transfusion  
 5 Services for the control of transfusion transmitted  
 6 disease.  
 7 "3. To advise the Departments of Health  
 8 accordingly."  
 9 If we go back to page 2, we can see the  
 10 membership includes both Professor Cash, Dr Contreras,  
 11 Dr Gunson, Dr Wagstaff, Dr Mortimer, Dr Mitchell, and  
 12 so on.  
 13 Dr Gunson, in his statement for the HCV  
 14 litigation, which we find at NHBT0000026\_009 addressed  
 15 the relationship between those two committees, so the  
 16 relationship between the Advisory Committee on the  
 17 Virological Safety of Blood and the UK Advisory  
 18 Committee on Transfusion Transmitted Disease.  
 19 So we can see that's the header of his witness  
 20 statement for the *Re A and Others* HCV (hepatitis C)  
 21 litigation.  
 22 If we turn, please, to page 29 at paragraph 73,  
 23 he says this:  
 24 "The ACVSB was a powerful committee. As was  
 25 noted at the outset ... it was appreciated that it

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1 If we can just look at the terms of reference to  
 2 that committee, because I don't think we went to those  
 3 yesterday, it's PRSE0003956.  
 4 So we can see there "Advisory Committee on the  
 5 Virological Safety of Blood", and if we go to page 4  
 6 of that document, you can see it's:  
 7 "To advise to the Health Departments of the UK  
 8 of measures to ensure the virological safety of blood,  
 9 whilst maintaining adequate supplies of appropriate  
 10 quality for both immediate use and for plasma  
 11 processing."  
 12 He was also chair of the UK Advisory Committee  
 13 on Transfusion Transmitted Disease, ACTTD, and we  
 14 heard yesterday that Professor Cash, in his Penrose  
 15 evidence, described that the existence of that  
 16 committee as Dr Gunson's brainchild.  
 17 That committee was formed in February 1989. The  
 18 terms of reference are worth looking at. It's  
 19 NHBT0027680.  
 20 If we go, please, to page 3 of that document,  
 21 we've got there:  
 22 "Draft  
 23 "Terms of Reference  
 24 "1. To consider the epidemiological, clinical  
 25 and laboratory aspects of disease which may be

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1 would be covering many of the same issues as the  
 2 ACTTD. The relationship between the two Committees  
 3 was formally addressed at the meeting of the ACVSB on  
 4 24th April 1990, where the Chairman proposed that it  
 5 would be the responsibility of the ACVSB to advise  
 6 Ministers on the virological safety of blood, while  
 7 the ACTTD would consider the operational implications  
 8 of policy, advise the Department on non-viral threats  
 9 to blood and contribute to the advice on viral safety  
 10 through input to the ACVSB. I confirmed that I shared  
 11 this view not the respective roles of the two  
 12 Committees and did not believe that it involved any  
 13 conflict.  
 14 "It was accordingly the ACVSB which was the  
 15 leading Committee in formulating policy with regard to  
 16 introduction of HCV testing. Of course neither the  
 17 Committee nor I, as explained in Section A, had any  
 18 direct authority to impose decisions on the Regions,  
 19 which retained operational responsibility for the  
 20 RTCs. It was my role, once policy had been determined  
 21 within the Committee, and where necessary approved by  
 22 Ministers, to communicate the decision to the RTDs and  
 23 to make every effort to ensure their co-operation."  
 24 He was also a member of some of the Medical  
 25 Research Council committees. He was a member of the

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1 Blood Transfusion Research Committee Working Party on  
2 Post-Transfusion Hepatitis, which had its first  
3 meeting in February 1980, and the terms of reference  
4 are set out, we don't need to go to this, in  
5 MRCO000029\_003 and they were to promote research and  
6 to assess the nature and size of the problem of  
7 post-transfusion hepatitis in the UK, with particular  
8 reference to changes in transfusion practices.

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

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

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

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

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

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

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

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1 groups meeting and making decisions over this period.

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

10 I'm going to now look at a document, one of the  
11 few documents I think that we've got from his time in  
12 Oxford. DHSC0100006\_130.

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

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

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

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1 or possibly early 1976.

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

5 **MS SCOTT:** Indeed.

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

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

9 **MS SCOTT:** Yes.

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

14 So this is plainly written before November '76.

15 **MS SCOTT:** Yes.

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

19 **MS SCOTT:** Quite.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On that theme, if we can return -- if we can look, please, at NHBT0000086\_009, which is the document we looked at earlier, it's the HIV litigation education course, and we go to page 11 of that

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(30) Pages 117 - 120

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

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

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

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

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(31) Pages 121 - 124



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

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1 centre itself between 1982 and 1984, when they moved  
 2 into a new building, and then in 1985 to 1986, funding  
 3 was provided for a plasmapheresis centre and a smaller  
 4 one in Lancaster. We will see reference to that in  
 5 some of the documents we look at later.  
 6 Sir, I'm just going to look also at,  
 7 DHSC0002195\_044.  
 8 This is a document note of a meeting that took  
 9 place in September 1979, so shortly before Dr Gunson  
 10 moved from Oxford to Manchester. It's a "Note of  
 11 [a] meeting of an *ad hoc* group of Regional Transfusion  
 12 Directors", and we can see on the attendee list it's  
 13 attended by Dr Gunson.  
 14 The reason I draw your attention to it, sir, is  
 15 because it shows some insight into what certainly this  
 16 group of people were discussing about choice of  
 17 product in September 1979. We pick it up at the  
 18 second paragraph:  
 19 "It was reported that there was not universal  
 20 acceptance by Directors of the proposition that blood  
 21 products should be distributed by BPL proportionally  
 22 to plasma supplied, but with some safeguards for  
 23 Regions with special problems, eg Regions which  
 24 treated Haemophiliacs from other Regions, it was felt  
 25 that a distribution scheme on this basis would prove

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

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

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(32) Pages 125 - 128



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

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

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

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

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1 post-creation of the National Directorate:  
 2 "The critical day, I have to tell you, in the  
 3 week was Friday, when most of our time was spent on  
 4 this activity, and it was made more difficult because  
 5 even those centres who had a good stock of blood did  
 6 not particularly want to give it away, in case they  
 7 had emergencies they were unaware of come in during  
 8 the weekend and they could find themselves then short,  
 9 so it took a great deal of persuasion to obtain  
 10 agreement to transfer blood from, say, Sheffield to  
 11 London.  
 12 "Q. Yes.  
 13 "A. But the London centres all had  
 14 difficulties, virtually, on a daily basis,  
 15 particularly, I have to say, North London, where they  
 16 have to supply a large number of teaching hospitals."  
 17 Then the last passage, sir, is NHBT0000148\_001,  
 18 and this is evidence given on Thursday, 26 October,  
 19 you can see at the top there, and this is during  
 20 cross-examination.  
 21 If we go to page 5, he gives some evidence about  
 22 the supply in Manchester. If we go down to  
 23 line 226 -- in fact, 221, we had better start at the  
 24 question. Halfway through line 223:  
 25 "... just give us a feel for how you say the

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1 problem of supply was between these years 1987 and  
 2 1991, that sort of period?  
 3 "A. Well, between 1987 and 1988 I was the  
 4 director of the centre in Manchester and I was not the  
 5 national director. Therefore I just ran a transfusion  
 6 centre like my colleagues. We had considerable  
 7 difficulties at certain times of the year,  
 8 particularly during the school holidays and  
 9 particularly around Christmas time, when we had  
 10 a significant drop in donors, and it was always  
 11 extraordinarily difficult then to catch up and there  
 12 were several instances during that period, 1987/1988,  
 13 that hospitals had to cancel routine surgery because  
 14 there was insufficient blood available and this got  
 15 into the press on a number of occasions."  
 16 Then he says:  
 17 "When I became the National Director, I  
 18 established this system of having --"  
 19 Then there's a discussion about when that was  
 20 and he says down at 243:  
 21 "I established a system whereby each transfusion  
 22 centre sent me their stock levels for that day and any  
 23 requests that they had for shortages of blood and we  
 24 then, in the National Directorate, endeavoured to  
 25 supply this blood from other centres and indeed from

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1 Scotland as well.  
 2 "Q. Were you successful during that period?  
 3 "A. During that period we were extremely  
 4 successful. There was not, I do not think, one  
 5 critical report in the press during the whole of the  
 6 periods until 1993."  
 7 Sir, then can we turn now to DHSC0002195\_044.  
 8 This is a document -- I think this is the document we  
 9 just looked at.  
 10 **SIR BRIAN LANGSTAFF:** I think, yes, it is.  
 11 **MS SCOTT:** Forgive me. That's the document we just looked  
 12 at. So let's not look at that again.  
 13 Can we look now at DHSC0002207\_040.  
 14 Sir, this is -- I'm looking now at documents  
 15 concerned with -- or parts of documents concerned with  
 16 the drive towards self-sufficiency. This is  
 17 a report -- or at the top of the page it calls itself  
 18 a "Draft for discussion" of the -- for the Advisory  
 19 Committee for the National Blood Transfusion Service  
 20 Working Party to Advise on Plasma Supplies for  
 21 Self-sufficiency in Blood Products in England and  
 22 Wales", and can see, under "Membership of the Working  
 23 Party", that includes Dr Gunson, and at the bottom of  
 24 that page we can see that it is dated June 1981.  
 25 If we go over to page 2, and at paragraph 2.1 we

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1 can see there that the "Requirement for Factor VIII"  
 2 is set out. It says:  
 3 "Representatives of the Haemophilia Directors  
 4 estimate that by the mid-1980s the annual requirement  
 5 for FVIII will reach 100 M units for the  
 6 United Kingdom. Forecasting beyond that time could  
 7 not be accurate but it was considered that by the  
 8 1990s the need for FVIII could reach 150 M units per  
 9 year."  
 10 It then goes on to set out some requirements for  
 11 albumin.  
 12 Then at paragraph 3 it says:  
 13 "It was agreed that the estimates for plasma  
 14 supply should be based upon that required to produce  
 15 100 M units. Although this total was estimated for  
 16 the UK for the mid-1980s ... it was considered to be  
 17 unnecessary to correct this for that required in  
 18 Scotland or to consider a higher figure than this  
 19 since estimates were vague for a longer period."  
 20 Then we go over the page to page 4, where there  
 21 is a discussion about the type of Factor VIII  
 22 preparation required. So what is that 100 million  
 23 units going -- sorry, to page 3. I beg your pardon.  
 24 Thank you.  
 25 How is that 100 million units going to be made

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1 up? It says there:  
 2 "The Working Party has examined the various  
 3 products available and considered the advantages and  
 4 disadvantages of each, which are discussed in  
 5 Appendix 1."  
 6 It's just worth going to have a look at what is  
 7 said at appendix 1. It's page 9 of the report and it  
 8 sets out the different kinds of products provided and  
 9 produced at the RTCs:  
 10 "1. Fresh frozen plasma prepared at RTCs, and  
 11 whilst it is a valuable source of coagulation factors  
 12 it cannot play a part in the treatment of  
 13 haemophilia A.  
 14 "2. Frozen cryoprecipitate is presented for  
 15 clinical use in the transfer pack in which it is  
 16 prepared. It is prepared in RTCs but it is difficult  
 17 to have a national programme based on this product  
 18 because:  
 19 "2.1 the high yield is not always attained in  
 20 large-scale production ... lack of confidence in the  
 21 FVIII content leads to over-ordering and waste.  
 22 "2.2 there is a significant incidence of adverse  
 23 reactions due to the presence of residual plasma.  
 24 "2.3 the product is not convenient to store,  
 25 transport and infuse particularly for home or

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

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

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

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1 80 million of intermediate purity concentrate, and 10  
2 of high purity. Then they set out what the different  
3 yields are for the different product: freeze-dried  
4 cryoprecipitate, 350 units per kilo, then that reduces  
5 down to 90 for the high purity.

6 Then at section 6 they discuss the amount of  
7 plasma that would be required in order to meet those  
8 targets and so, to get the 10 million units of  
9 freeze-dried cryoprecipitate, it involves  
10 28,500 kilograms of plasma; for the intermediate  
11 purity concentrate 350,000 kilograms; and for the high  
12 purity 110,000; making a total of 488,500 kilos, which  
13 they round up at the bottom, for an annual aim of  
14 500,000 kilograms of plasma.

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

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1 and staff, which will realise some 200,000 kilograms  
2 of plasma for fractionation. So 200,000 out of the  
3 500,000 from whole blood.

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

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

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

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

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

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

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

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1 national self-sufficiency.

2 Sir, I note the time. Is --

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

6 **MS SCOTT:** The incentive for the region to produce plasma  
7 is because they will get back pro rata what they give.

8 Once they have made enough --

9 **SIR BRIAN LANGSTAFF:** I follow the point.

10 **MS SCOTT:** Yes.

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

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

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

20 (3.22 pm)

(A short break)

22 (3.50 pm)

23 **MS SCOTT:** Sir, the next document I want to take you to is  
24 DHSC0002211\_030. It's a supplement to the report that  
25 we looked at before and my understanding is that it

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

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

25 Cost of producing a balance of 235,000 kilograms

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

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

6 **MS SCOTT:** Indeed.

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

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

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

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

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

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

18 I'm going to take you now, sir, to a document in  
19 October 1983, so two years on. It's NHBT0001066\_004.  
20 This is a document, it's entitled "Departmental  
21 Memorandum", so we can see it is from Dr Gunson to  
22 Dr Acheson, the CMO, dated 18 October 1983. So we can  
23 understand, I think, probably from the fact that it's  
24 a departmental memorandum, that this must be  
25 Dr Gunson, as Consultant Adviser to the CMO, providing

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1 his views to the CMO.

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

7 "It would be useful to review the developments  
8 which have taken place in the use of these products.  
9 "Red cell concentrates. Clinical acceptance of  
10 this product has been subjected to some controversy  
11 since in order to provide sufficient plasma for  
12 fractionation, the red cell concentrates have to be  
13 administered to certain patients suffering from blood  
14 loss."

15 Then picking up at the bottom of that page:

16 "The principle involved is to remove as much  
17 plasma from the donation as possible and replace part  
18 of this with a solution of saline, adenine, glucose  
19 and mannitol or sorbitol. The resultant red cells can  
20 be stored for up to 35 days and their administration  
21 is facilitated. This approach also has the benefit  
22 that from an individual donation of whole blood,  
23 50 per cent more plasma can be obtained."

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

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

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

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

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

22 Then:

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

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

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

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

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

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

25 "Whilst I think there will be several

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

6 Then he sets out the implications for the  
7 service of self-sufficiency, and then he goes on below  
8 (2):

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

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

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

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

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1 required. Then he goes on to say:

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

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

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

13 I beg your pardon, yes.

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

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

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

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

3 He says:

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

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

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

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

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

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

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

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

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

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

13 We can see at the top:

14 "Plasma supply for self sufficiency in blood  
15 products.

16 "Analysis of options by HH Gunson.

17 "Supplement to report to CBLA ... [made] on  
18 25th January, 1984."

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

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

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

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1 obtaining the necessary funds."

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

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

10 Then he sets out factors of significance:

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

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

18 I'm not quite sure what that says:

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

22 I'm not quite sure what that says.

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

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

3 So the first option is to:

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

8 He goes on to say in that next paragraph:

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

11 But he concludes:

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

16 Then, second option:

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

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

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

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

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

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

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

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backed by actions and financial support. We firmly believe that the time has come to reassess the situation regarding self-sufficiency. Members of the Division feel strongly that there is no reason why the plasma donated voluntarily by British donors should not go back to British patients. There are very good ethical and financial reasons for the encouragement of self-sufficiency. Why should we be paying twice for albumin and clotting factor concentrates? We are paying the commercial companies for imported products and at the same time are spending vast sums of money in apheresis and routine blood collection, as well as in the sophisticated running of BPL. Isn't it about time the Department made up its mind that the only way to succeed in self-sufficiency is by subsidising BPL?

"If we continue with current practices, we will be cutting our own throats. We already have the precedent of BPL competing with a Regional Transfusion Centre for the supply of products to a particular hospital, with BPL undercutting the 'NBTS discounted price'. We feel that it might be too late to turn the clock backwards. As core providers within the NHS, we feel that the NBTS should be excluded from charging.

"I have been asked to tell you that consultants in the Division are willing to go public on the issue

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agreement is, in most instances, working well. Also, although it is early in the financial year, it will be pointed out that the supply of albumin to hospitals is above target.

"If one targets Factor VIII (or even albumin) as a product which is not being used in quantities which are available from BPL, the argument will be put forward that the DH cannot interfere with clinical freedom and since we are not a totalitarian state no person can be forced to use a particular product.

"If in the coming months it is apparent that there is an increasing stockpile of products at BPL and no action is being taken to ensure their distribution to hospitals for use, then I would agree that this should be brought to public attention. To do so now I think would be counter-productive and I hope that the members of the Eastern Division will agree with this conclusion."

So just before we finish, sir, just to draw out some of the themes in this piece of correspondence, it seems that Professor Contreras is raising concerns that the cross-accounting that, as I understand that -- the process of cross-accounting has effectively put Regional Transfusion Centres in direct competition with BPL for -- in terms of providing

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of self-sufficiency and are even prepared to stage a parliamentary lobby campaign. I would be grateful if could reply within the next two weeks."

The reply from Dr Gunson can be seen at NHBT0015645. It is dated 13 June 1990, and it says:

"If this matter were made public at the present time, in my view the scenario is likely to be as follows:

"The Department will reiterate that Ministers are in full support of self-sufficiency and illustrate this by citing the recent Executive letter ..."

For those that want to look at that it is DHSC0003978\_009. We don't need to look at that now but that's the reference for it.

"They will point out also that financing has been provided for RTCs to collect the required quantity of plasma to provide sufficient products to achieve self-sufficiency. Moreover, they have told BPL to make every effort to ensure that their products are the preferred product for use in the NHS.

"It is true that when we asked for a financial supplement for either the cost of plasma or for BPL, the Department refused on the grounds that they were not convinced that this was necessary at the present time and evidence will be cited that the National

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products to hospitals, and she also raises the concern about that cost to Regional Transfusion Centres from effectively having to pay twice for product, once through the functions of the RTC by collecting blood through whole blood collections and plasmapheresis and, secondly, because they then don't get enough product back from BPL and have to buy in commercial products.

Dr Gunson seems to be raising a slightly different issue, and it's a little unclear to me how he gets to that from Professor Contreras' letter, but he seems to be raising an issue in relation to a stockpiling of product by BPL and that one of the reasons why -- perhaps why regions are not receiving the product that they need is because of stockpiling. So that is likely to be an issue that we will need to come back to in the forthcoming hearings.

**SIR BRIAN LANGSTAFF:** Does he say there is actually stockpiling taking place at the present?

**MS SCOTT:** No, he doesn't say that, but he seems to raise it himself. It seems to be something that he has raised himself as potentially a reason.

**SIR BRIAN LANGSTAFF:** He may be perhaps addressing the questions of the internal market which Dr Contreras raises, saying that the internal market means that one

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

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

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1 leisure and work out perhaps what the dispute is  
 2 really about, and perhaps evidence will help us, from  
 3 Dr Contreras, I expect -- Professor Contreras now.  
 4 **MS SCOTT:** Yes.  
 5 So, sir, those are the last documents I wanted  
 6 to draw your attention to in relation to  
 7 self-sufficiency. Tomorrow I'm going to deal with the  
 8 issues of testing for HIV and hepatitis C and then  
 9 a handful of very short topics.  
 10 **SIR BRIAN LANGSTAFF:** Yes. Let's break now then and come  
 11 back tomorrow at 10.00. 10.00. Thank you.  
 12 (4.26 pm)  
 13 (Adjourned until 10.00 am the following day)

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[9] 20/23 21/11 50/4 111/25 125/8 126/23 137/20 153/22 156/23 ... although [1] 126/23 ... the [1] 125/8  ' /   'ribavirin [1] 94/10  <b>0</b>  0001136 [1] 147/15 001 [2] 26/15 133/17 002 [1] 99/9 0026 [1] 91/22 003 [3] 27/13 65/13 113/5 004 [1] 147/19 006 [1] 43/5 007 [1] 87/2 009 [4] 103/24 111/14 120/23 162/13 010 [2] 3/4 109/7 011 [1] 19/9 012 [1] 19/15 014 [1] 54/11 015 [1] 19/17 016 [1] 28/14 019 [1] 55/22 024 [2] 57/23 59/5 026 [1] 92/2 028 [1] 87/18 030 [1] 144/24 031 [1] 57/2 033 [1] 44/9 039 [1] 59/13 040 [1] 135/13 044 [2] 127/7 135/7 053 [1] 49/4 061 [1] 67/3 063 [1] 47/7 065 [1] 50/13  <b>1</b>  1 April 1989 [1] 159/12 1 December 2011 [1] 85/2 1 July [2] 47/16 48/24 1 July 1991 [1] 52/11 1 October [1] 30/5 1 October 1989 [1]  30/5 <b>1 September [1]</b> 53/20 <b>1 September 1987 [1]</b> 16/12 <b>1,000 [2]</b> 138/20 139/1 <b>1,900 [1]</b> 64/12 <b>1-3 [1]</b> 24/6 <b>1.04 pm [1]</b> 98/9 <b>1.5 [1]</b> 131/4 <b>1.6 million [1]</b> 131/5 <b>10 [5]</b> 42/17 48/1 139/7 139/25 141/1 <b>10 August 1989 [1]</b> 159/19 <b>10 June [1]</b> 10/18 <b>10 June 1991 [1]</b> 65/12 <b>10 million [2]</b> 140/25 141/8 <b>10,000 Kg [1]</b> 143/6 <b>10,000 litres [1]</b> 117/16 <b>10.00 [4]</b> 1/2 167/11 167/11 167/13 <b>10.50 [1]</b> 1/8 <b>10.52 [1]</b> 36/10 <b>100 [1]</b> 51/1 <b>100 M [2]</b> 136/5 136/15 <b>100 million [3]</b> 136/22 136/25 140/24 <b>100,000 [2]</b> 123/10 131/23 <b>102 [1]</b> 39/20 <b>11 [7]</b> 74/12 102/22 104/6 120/25 124/8 139/10 147/2 <b>11 January 1989 [1]</b> 121/23 <b>11 January 2012 [1]</b> 85/5 <b>11 May [1]</b> 62/11 <b>11 November [1]</b> 1/4 <b>11 November 2021 [1]</b> 1/1 <b>11.00 [1]</b> 1/7 <b>11.25 [2]</b> 36/9 36/9 <b>11.33 [1]</b> 36/12 <b>11.6 [1]</b> 146/9 <b>110,000 [1]</b> 141/12 <b>12 [3]</b> 124/8 132/5 138/7 <b>12 January 1990 [1]</b> 19/8 <b>122 [2]</b> 16/11 39/15 <b>123 [1]</b> 39/1 <b>127 [1]</b> 39/18 <b>13 [1]</b> 125/15 <b>13 February 1984 [1]</b> 155/20 <b>13 June 1990 [1]</b>  162/5 <b>130 [1]</b> 115/12 <b>133 [1]</b> 51/24 <b>14 May [1]</b> 26/14 <b>14 May 1991 [1]</b> 62/7 <b>144 [1]</b> 62/6 <b>15 [1]</b> 121/3 <b>15 February 1991 [1]</b> 46/3 <b>15 per cent [1]</b> 132/5 <b>15,000 [1]</b> 119/6 <b>150 M [1]</b> 136/8 <b>150 per cent [1]</b> 117/19 <b>150,000 Kg [1]</b> 154/16 <b>15th February [1]</b> 50/20 <b>16 [1]</b> 99/9 <b>16 November 1981 [1]</b> 101/7 <b>16 November 2011 [1]</b> 84/15 <b>17 [1]</b> 33/3 <b>17 December 1987 [1]</b> 17/6 <b>17 January 2012 [1]</b> 85/9 <b>17 June [1]</b> 5/6 <b>17 October [1]</b> 29/3 <b>17.3 million [1]</b> 146/2 <b>170 [1]</b> 64/6 <b>17th October [1]</b> 30/20 <b>17th October 1989 [1]</b> 30/19 <b>18 donor [1]</b> 118/22 <b>18 hours [1]</b> 141/25 <b>18 October 1983 [1]</b> 147/22 <b>180ml [1]</b> 117/13 <b>19 October 2000 [1]</b> 130/7 <b>19,000 [2]</b> 118/9 119/6 <b>19.1 million [1]</b> 146/1 <b>1953 [1]</b> 99/12 <b>1959 [1]</b> 99/14 <b>1964 [1]</b> 99/18 <b>1974 [1]</b> 125/20 <b>1975 [5]</b> 99/18 99/22 115/15 115/25 126/11 <b>1976 [2]</b> 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[30]</b> 26/11 26/13 27/9 27/14 28/15 29/4 30/5 30/19 31/9 31/16 31/20 31/25 36/24 36/25 37/3 38/23 39/3 39/21 41/12 69/8 70/1 70/9 71/24 72/12 109/2 109/22 110/17 121/23 159/12 159/19 <b>1990 [21]</b> 19/8 19/14 31/10 34/16 41/18 42/25 69/21 69/23 72/12 72/14 74/20 78/23 86/8 86/22 87/3 87/22 112/4 160/13 160/14 160/19 162/5 <b>1990' [1]</b> 30/12 <b>1990s [1]</b> 136/8 <b>1991 [44]</b> 43/4 43/8 45/18 45/23 46/3 46/6 47/6 49/6 50/15 50/20 51/14 51/17 52/4 52/11 54/7 54/10 54/15 54/22 55/22 57/22 59/3 59/11 62/7  63/14 64/1 65/12 67/4 67/19 74/14 74/17 74/19 74/21 75/5 75/9 76/6 76/10 76/23 78/11 79/10 79/13 87/16 88/6 95/15 134/2 <b>1993 [4]</b> 88/21 100/7 113/12 135/6 <b>1994 [7]</b> 89/23 94/16 95/10 100/9 100/10 100/21 109/25 <b>1995 [2]</b> 96/5 96/12 <b>1st [1]</b> 54/19 <b>1st April 1990 for [1]</b> 31/12 <b>1st January 1977 [1]</b> 116/13 <b>1st July [3]</b> 49/11 49/19 54/25 <b>1st July 1991 [3]</b> 50/20 51/14 63/14 <b>1st June 1989 [1]</b> 31/9 <b>1st September 1991</b> <b>[3]</b> 51/17 64/1 67/19  <b>2</b>  <b>2 February [1]</b> 19/17 <b>2 July 1987 [1]</b> 10/8 <b>2 May 1991 [1]</b> 54/15 <b>2 million [1]</b> 141/18 <b>2 weeks [1]</b> 48/2 <b>2.05 [1]</b> 98/3 <b>2.05 pm [1]</b> 98/11 <b>2.1 [2]</b> 135/25 137/19 <b>2.2 [3]</b> 137/22 141/22 151/14 <b>2.3 [1]</b> 137/24 <b>2.4 [1]</b> 138/2 <b>2.5 million [1]</b> 130/24 <b>20 [1]</b> 132/13 <b>20.6 [1]</b> 146/8 <b>200 kilograms [1]</b> 145/20 <b>200,000 [1]</b> 142/2 <b>200,000 kilograms [1]</b> 142/1 <b>2000 [2]</b> 130/7 132/10 <b>2011 [7]</b> 83/24 84/3 84/8 84/10 84/15 84/18 85/2 <b>2012 [2]</b> 85/5 85/9 <b>2021 [1]</b> 1/1 <b>21 February [1]</b> 74/25 <b>21 February 1990 [1]</b> 41/18 <b>21 is [1]</b> 73/23 <b>21 July 1987 [1]</b> 13/18 <b>210-220ml [1]</b> 117/13 <b>22 January [1]</b> 76/7</p>
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(43) MS RICHARDS: - 22 January

F:

<b>2</b>	<b>28 January 1991 [1]</b> 45/23 <b>28,500 kilograms [1]</b> 141/10 <b>28.1 million [1]</b> 145/22 <b>29 [2]</b> 111/22 121/20 <b>29 November 2011 [1]</b> 84/18 <b>2nd [1]</b> 48/11	<b>5 million [1]</b> 145/9 <b>5,000 [2]</b> 27/11 117/4 <b>5.5 million [1]</b> 142/7 <b>50 [1]</b> 126/5 <b>50 per cent [1]</b> 148/23 <b>50-100 ml [1]</b> 138/23 <b>500,000 [1]</b> 142/3 <b>500,000 kilograms [1]</b> 141/14 <b>500-5000 [1]</b> 139/13 <b>5000 [2]</b> 27/16 139/13 <b>51 per cent [1]</b> 141/24 <b>53 per cent [1]</b> 117/18 <b>55,000 [1]</b> 117/17 <b>5th [1]</b> 95/9	129/19 <b>able [15]</b> 3/10 11/6 11/17 14/16 14/18 26/10 39/4 41/18 75/20 82/7 88/8 91/20 124/17 153/18 155/9 <b>abnormal [1]</b> 2/13 <b>abolished [1]</b> 107/9 <b>about [95]</b> 1/8 2/1 2/13 6/24 7/13 13/15 24/19 25/24 27/2 29/6 32/18 34/9 34/14 34/20 34/25 35/3 37/5 38/19 39/12 40/16 41/19 42/17 48/21 52/10 52/22 56/4 56/18 56/25 58/6 59/1 62/4 64/14 68/19 69/12 70/23 73/12 77/6 77/11 78/11 82/13 82/14 82/15 82/25 83/8 83/9 83/11 83/25 84/22 84/24 85/20 88/12 92/7 96/6 98/6 98/16 98/22 99/3 101/24 102/16 103/25 105/5 106/17 117/1 120/19 121/4 122/2 127/16 128/4 130/2 130/9 130/11 131/2 131/14 132/25 133/21 134/19 136/21 138/20 139/1 139/21 140/16 148/24 150/17 150/20 150/23 151/12 151/14 152/21 160/22 161/13 164/2 165/11 165/22 166/16 167/2 <b>above [15]</b> 22/1 22/16 31/5 51/10 60/14 61/11 70/22 116/7 117/18 117/19 120/5 125/18 140/19 153/4 163/4 <b>abroad [2]</b> 6/14 81/5 <b>absence [1]</b> 37/18 <b>absolute [1]</b> 29/10 <b>absolutely [2]</b> 54/3 77/15 <b>absorbing [1]</b> 160/5 <b>abundantly [1]</b> 35/9 <b>AC [1]</b> 147/2 <b>academic [1]</b> 72/25 <b>accept [4]</b> 3/15 37/23 50/4 66/8 <b>acceptable [3]</b> 31/6 70/19 128/1 <b>acceptance [2]</b> 127/20 148/9 <b>accepted [3]</b> 49/22 120/13 165/3 <b>accepting [1]</b> 66/6	<b>accompanies [1]</b> 139/24 <b>accompli [1]</b> 14/14 <b>according [1]</b> 14/24 <b>accordingly [2]</b> 111/8 112/14 <b>account [6]</b> 31/24 32/2 32/7 36/1 36/6 36/22 <b>accountability [1]</b> 157/19 <b>accounting [3]</b> 159/11 163/22 163/23 <b>accounts [1]</b> 49/10 <b>accuracy [1]</b> 54/1 <b>accurate [1]</b> 136/7 <b>accurately [2]</b> 7/19 56/8 <b>accusations [1]</b> 9/17 <b>Acheson [2]</b> 147/22 150/20 <b>achieve [8]</b> 22/16 143/11 143/12 146/18 151/4 151/9 154/24 162/18 <b>achieved [5]</b> 22/7 61/17 117/5 126/16 156/25 <b>achievement [1]</b> 144/14 <b>acquire [1]</b> 60/6 <b>acronym [1]</b> 91/14 <b>acronyms [1]</b> 89/21 <b>across [3]</b> 140/1 144/3 144/15 <b>act [4]</b> 12/18 13/2 28/5 55/8 <b>acted [1]</b> 114/18 <b>acting [1]</b> 157/18 <b>action [13]</b> 42/17 56/3 56/6 57/15 57/16 60/15 69/10 91/1 91/4 99/5 119/21 158/18 163/13 <b>actions [7]</b> 1/16 38/14 59/18 97/21 98/16 102/12 161/1 <b>activity [5]</b> 44/24 60/7 66/14 133/4 139/17 <b>ACTTD [6]</b> 67/24 76/5 76/15 110/13 112/2 112/7 <b>actually [8]</b> 7/7 10/25 42/15 71/18 100/11 125/19 156/13 164/18 <b>acute [2]</b> 3/21 4/10 <b>ACVSB [22]</b> 33/7 69/15 69/22 72/1 72/10 72/13 72/17 72/24 73/4 74/19 74/25 75/2 75/22 76/12 78/22 79/3	109/25 111/24 112/3 112/5 112/10 112/14 <b>ad [3]</b> 94/15 95/9 127/11 <b>add [1]</b> 41/21 <b>added [2]</b> 124/18 124/18 <b>addition [2]</b> 125/7 125/22 <b>additional [11]</b> 15/9 45/21 51/1 55/11 59/25 118/23 119/2 119/6 154/25 156/10 156/14 <b>additive [1]</b> 151/12 <b>addressed [7]</b> 10/10 11/21 32/1 62/7 67/14 111/14 112/3 <b>addressing [3]</b> 58/8 116/21 164/23 <b>adds [1]</b> 24/17 <b>adenine [1]</b> 148/18 <b>adequate [3]</b> 110/9 138/2 141/25 <b>adhere [1]</b> 77/13 <b>Adjourned [1]</b> 167/13 <b>Adjournment [1]</b> 98/10 <b>administered [1]</b> 144/13 <b>administration [3]</b> 39/7 148/20 150/14 <b>administrative [2]</b> 103/2 156/24 <b>adopt [1]</b> 46/15 <b>adopted [6]</b> 13/14 40/21 54/2 79/9 126/13 160/6 <b>Adopting [1]</b> 95/6 <b>advance [5]</b> 28/10 35/24 46/17 149/16 151/3 <b>advancing [1]</b> 158/16 <b>advantage [2]</b> 21/15 152/2 <b>advantageous [1]</b> 40/2 <b>advantages [7]</b> 119/22 137/3 139/3 140/2 140/6 142/15 151/10 <b>adverse [5]</b> 11/12 14/21 15/7 94/12 137/22 <b>adversely [1]</b> 119/7 <b>advice [14]</b> 30/14 32/23 33/6 93/22 101/15 101/17 104/9 104/11 104/16 104/20 112/9 121/7 150/20 156/10 <b>advise [11]</b> 11/6
<b>22 January 1991 [1]</b> 43/8 <b>22 July [1]</b> 158/20 <b>22 per cent [1]</b> 117/10 <b>22,000 donations [1]</b> 117/7 <b>220ml [1]</b> 117/13 <b>221 [1]</b> 133/23 <b>223 [1]</b> 133/24 <b>226 [1]</b> 133/23 <b>22nd January [1]</b> 44/12 <b>22nd July [1]</b> 11/11 <b>23 April 1990 [1]</b> 72/14 <b>23 April 2011 [1]</b> 83/24 <b>23 August 1989 [1]</b> 29/4 <b>23 March 1991 [1]</b> 75/5 <b>235 kilograms [1]</b> 145/21 <b>235,000 kilograms [1]</b> 145/25 <b>24 [1]</b> 78/11 <b>24 January [1]</b> 44/11 <b>24 May 1990 [1]</b> 160/19 <b>24 October 2000 [1]</b> 132/10 <b>243 [1]</b> 134/20 <b>24th April 1990 [1]</b> 112/4 <b>25 [1]</b> 76/15 <b>25 August 1989 [1]</b> 31/25 <b>25 February 1991 [1]</b> 74/19 <b>25 June 1986 [1]</b> 1/24 <b>25 March [1]</b> 47/6 <b>25 March 1991 [1]</b> 76/6 <b>250,000 [1]</b> 131/19 <b>25th January [1]</b> 155/18 <b>26 August 1989 [1]</b> 37/3 <b>26 July 1989 [1]</b> 27/14 <b>26 October [1]</b> 133/18 <b>27 [1]</b> 139/17 <b>27 March 1991 [1]</b> 49/6 <b>27 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(64) rest - self-sufficiency

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<p><b>W</b></p> <p><b>will...</b> [77] 90/11 92/8 93/2 94/7 94/8 94/12 94/17 95/24 97/15 97/16 97/24 98/3 98/4 98/4 98/5 98/6 100/16 101/23 102/2 102/3 102/6 105/13 115/23 117/10 117/16 118/1 118/10 118/14 118/23 119/6 119/10 120/11 120/15 121/10 123/3 123/4 126/7 127/4 136/5 138/17 142/1 142/19 143/2 143/6 143/9 144/7 144/18 145/16 145/22 146/15 149/10 149/13 150/25 151/2 151/9 151/23 151/24 151/25 152/2 152/6 152/10 154/4 155/5 155/24 158/3 160/10 161/16 162/9 162/15 162/25 163/2 163/7 163/17 164/16 165/4 166/18 167/2 <b>will find</b> [1] 66/4 <b>William</b> [1] 104/14 <b>willing</b> [3] 33/25 154/11 161/25 <b>willingness</b> [1] 103/10 <b>wish</b> [20] 1/7 5/21 11/25 15/10 27/22 29/16 29/21 34/3 35/22 45/2 50/4 52/2 52/21 57/17 60/19 60/23 67/23 75/15 85/19 102/1 <b>wish/insist</b> [1] 29/21 <b>wished</b> [1] 60/6 <b>wishes</b> [2] 9/2 76/11 <b>with</b> [174] <b>withdraw</b> [1] 63/15 <b>withdrawn</b> [1] 16/9 <b>within</b> [20] 13/17 18/17 19/10 42/24 44/4 48/1 71/8 86/8 96/2 104/18 105/3 112/21 116/3 122/8 122/13 124/12 132/14 141/25 161/22 162/3 <b>within SNBTS</b> [1] 86/8 <b>without</b> [17] 7/19 14/13 14/17 15/17 15/17 40/20 64/4 69/18 75/2 76/11 85/13 85/17 116/23 124/21 138/12 138/22 151/22</p>	<p><b>witness</b> [5] 19/24 68/17 78/9 111/19 149/21 <b>witnessed</b> [2] 60/11 60/18 <b>witnesses</b> [9] 43/1 75/21 75/22 88/10 91/21 93/7 96/4 97/25 121/12 <b>won't</b> [6] 11/23 33/13 95/16 96/7 144/13 144/14 <b>wonder</b> [1] 40/14 <b>word</b> [1] 56/6 <b>wording</b> [1] 53/1 <b>words</b> [3] 57/15 165/7 165/16 <b>work</b> [12] 11/14 13/13 98/16 106/23 116/10 116/17 118/11 121/4 131/12 152/8 156/18 167/1 <b>worked</b> [1] 124/12 <b>working</b> [36] 42/23 56/14 66/19 71/1 100/17 102/1 102/2 102/7 103/10 105/14 105/18 105/23 106/1 107/2 107/5 107/6 107/15 108/7 108/18 113/1 113/10 113/25 114/21 114/25 119/25 130/3 130/3 135/20 135/22 137/2 141/21 142/9 142/17 145/11 147/7 163/1 <b>workload</b> [1] 45/19 <b>workloads</b> [1] 44/21 <b>world</b> [3] 80/14 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123/4 128/5 128/6 131/2 131/11 132/2 132/13 132/16 133/2 133/19 133/25 135/2 136/24 140/9 144/23 145/22 147/18 158/24 159/16 161/24 165/9 166/11 166/18 167/11 <b>you'll</b> [5] 13/19 20/16 26/15 71/22 95/3 <b>you're</b> [3] 77/15 165/8 166/14 <b>you've</b> [2] 68/7 138/4 <b>your</b> [31] 11/2 11/9 11/14 32/3 37/8 38/7 39/13 44/12 45/14 52/1 55/24 56/6 56/12 56/13 57/5 57/5 57/15 77/6 80/25 87/8 120/4 127/14 129/21 130/15 136/23 140/3 145/12 145/20 145/21 152/13 167/6</p> <p><b>Z</b></p> <p><b>Z8</b> [3] 82/11 82/11 82/14</p>	
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(70) will... - Z8