

Thursday, 24 March 2011

1

2 (9.30 am)

3 THE CHAIRMAN: Good morning.

4 MR MACKENZIE: Good morning, sir. The first witness this  
5 morning is Dr Gillon.

6 DR JOHN GILLON (affirmed)

7 Questions by MR MACKENZIE

8 MR MACKENZIE: Good morning, Dr Gillon.

9 A. Good morning.

10 Q. From April 1985 to date you have been a consultant  
11 physician in Edinburgh and Southeast Scotland Blood  
12 Transfusion Service and Department of Transfusion  
13 Medicine. Is that correct?

14 A. Yes.

15 Q. We looked at your CV last week and I don't propose  
16 taking you back through that. As a preliminary matter,  
17 doctor, the chairman has raised the question of seeking  
18 to pin down the various guidance documents which were in  
19 existence in the 1970s, 1980s and perhaps early 1990s,  
20 in respect of donor selection, manufacture of blood  
21 products and other matters and, doctor, I will undertake  
22 to produce a brief note specifying all the documents we  
23 are aware of, which I will then send to yourself and  
24 your colleagues for revisal or agreement. We can deal  
25 with that, I think, in that manner.

1           But perhaps as an overview or summary of the  
2 documents we are aware of to date, doctor, firstly we  
3 have seen NBTS guidelines and donor selection,  
4 essentially dealing with the collection of blood and the  
5 selection of donors, and we saw a 1977 edition.  
6 A second category we are aware of are notes on  
7 transfusion and we looked with Professor Cash at the  
8 1973 edition, and that category of document, I think,  
9 deals with the use of blood.

10           A third category of document we saw with  
11 Professor Cash were DHSS standards for the collection  
12 and processing of blood and blood components, and we saw  
13 a 1979 edition. Fourthly, I think, there has also been  
14 discussion of a Handbook of Transfusion Medicine which  
15 came in later, I think, perhaps in the late 1980s or  
16 early 1990s. So there are, doctor, at least, four  
17 categories which I will specify in my note in due  
18 course.

19           I think in addition, doctor, the 1977 guidelines and  
20 donor selection. I think the guidelines are an NBTS  
21 document, ie the National Blood Transfusion Service for  
22 England and Wales. I think what we are perhaps missing  
23 so far in our bundle of documents is any Scottish  
24 documentary guidelines, in particular from any of the  
25 five Scottish transfusion regions. It may be that we

1 can both perhaps, doctor, do some further searches and  
2 thinking in that regard.

3 So that's really by way of a preamble, doctor. As  
4 I say, I hope the note that I will produce in due course  
5 in conjunction with you and your colleagues can try and  
6 specify these matters still further.

7 A. I'm not sure you mentioned the red book which came up in  
8 discussion from time to time yesterday and I think that  
9 needs to be pinned down exactly, when the first red  
10 book --

11 MR MACKENZIE: Perhaps do that --

12 THE CHAIRMAN: Before we pin down when, could we please pin  
13 down what it was, because it's quite clear that it is  
14 a description applied to documents which cannot be the  
15 same, if I can put it that way.

16 A. We can provide a hard copy of the book from its  
17 inception.

18 MR MACKENZIE: In short, what's the title of the red book?

19 A. The red book is "Guidelines for the UK Transfusion  
20 Services". I think that's correct.

21 THE CHAIRMAN: Just in general terms, is that what I might  
22 call the "Dr McClelland book" or is it something  
23 different?

24 A. No. It is a book that Professor Cash mentioned a lot  
25 yesterday. His role in initiating it in the late 1980s.

1           We haven't had time since yesterday to look out the hard  
2           copy, but I think it dates from 1989 or thereabouts and  
3           we will pin that down. That is guidelines covering the  
4           whole of transfusion centres' activities really.

5   THE CHAIRMAN: But when you do look at this whole issue, it  
6           would be a great help if you could interpret the  
7           references to the red book at much earlier periods in  
8           the documents, because I think that's where a lot of my  
9           confusion started.

10   A. I think -- yes, I noticed those comments. I think they  
11           mean orange guide rather than red book, because the  
12           orange guide was the guide to good manufacturing  
13           process. I expect that sometimes that was the  
14           confusion.

15   THE CHAIRMAN: Perhaps "orange book" is not an expression  
16           used much in the West of Scotland.

17   A. Indeed, maybe in certain quarters.

18   THE CHAIRMAN: That's perhaps an inappropriate comment.

19           So it was Dr Mitchell who started it off. Right,  
20           Mr Mackenzie.

21   MR MACKENZIE: Thank you, sir. Could we now, please,  
22           doctor, turn to your statement, which is reference  
23           [\[WIT0030129\]](#). The next page, please.

24           You set out some helpful biographical details. In  
25           short you explain that you commenced training in

1 internal medicine initially and became interested in  
2 gastroenterology. Over the page, please, paragraph 1.3,  
3 we see that in 1983 through professional contacts with  
4 Dr Brian McClelland and Dr Peng Lee Yap you became aware  
5 of the challenges facing the blood transfusion services  
6 as a result of hepatitis and AIDS. At that time you had  
7 almost completed your training and begun the search for  
8 a consultant post. The post of consultant responsible  
9 for the selection and medical care of donors in the  
10 Southeast Blood Transfusion Service was then vacant and  
11 after discussion you agreed to an informal rotation to  
12 that service during late 1983/early 1984 with a view to  
13 deciding whether you might be interested in a career in  
14 transfusion medicine. In short, you were.

15 At paragraph 1.5 we can see you spent three months  
16 of a training period abroad. You list the various  
17 individuals and bodies and centres that you saw during  
18 that period, including, in particular, the community  
19 blood centre in greater Kansas City under the direction  
20 of Dr William Bayer. You were involved in the question  
21 of the introduction of testing for HIV, which was,  
22 presumably, being considered at that centre.

23 In paragraph 1.6 you then, during your final month  
24 in the US, you travelled round various centres. We can  
25 see in Washington DC. Over the page, you met

1 Dr Gerard Sandler and Dr Roger Dodd of the  
2 American Red Cross and others, and also you spent some  
3 time at the National Institutes of Health, where you met  
4 the director of the blood bank, Dr Harvey Klein and also  
5 Dr Harvey Alter.

6 Then 1.7, you also travelled to the centres for  
7 disease control in Atlanta, Georgia for discussions on  
8 epidemiology of AIDS and hepatitis. That must have been  
9 an interesting time, doctor, to be travelling round  
10 these centres?

11 A. It was fascinating actually and it was -- I guess the  
12 crucial time in transfusion medicine in the  
13 United States was just about when HIV testing was about  
14 to be introduced and the realisation that non-A non-B  
15 was a more significant problem than perhaps had been  
16 realised previously. One of the most interesting things  
17 then was the visit to the CDC in Atlanta, which was  
18 partly to look at HIV epidemiology, because that was the  
19 equivalent of HPS in Scotland, HPA in England, as they  
20 now are. But what I hadn't realised ahead of time was  
21 that they had a major laboratory research project going  
22 on there, to look into non-A non-B hepatitis.

23 I don't know if this is are a digression but it may  
24 interest you to know that one of the researchers I spent  
25 time with was called Dan Bradley and he described to me

1 the process that would ultimately reveal the virus which  
2 caused non-A non-B hepatitis. And that was the  
3 culmination of years of work, when, starting in the late  
4 1970s, researchers in the various parts of the world  
5 really established a research community, trying to track  
6 down this virus and sending each other samples which  
7 they regarded as pedigreed from patients with  
8 post-transfusion hepatitis, presumed non-A non-B, and  
9 trying to use conventional test methods based on the  
10 serum from other patients with hepatitis to show an  
11 antibody/antigen reaction. Nobody could do it. It was  
12 like wine tasting, it was totally subjective and it was  
13 almost always wrong. You couldn't tell using  
14 conventional methods which was the real sample and which  
15 was the control.

16 It was after years of passaging the material from  
17 patients infected by blood transfusions, through  
18 chimpanzees whom they had immuno-depleted, that they  
19 arrived at what they thought was a superconcentrated  
20 version of the agent causing this condition, which they  
21 thought was a virus, it could pass through certain  
22 filters, and they were then ultra-centrifuging it.

23 It was like listening to a Horizon programme. It  
24 made no sense to me. They were looking for bits of DNA  
25 that matched or didn't match this, that or the other DNA

1 probe. Four or five years later and a couple of  
2 Nobel Prizes later, we saw the result of that in the  
3 paper from Houghton and others, from Chiron, in science,  
4 which was a description of the virus.

5 Q. Thank you, doctor, I think that is very interesting  
6 background. I think we will come back to that topic in  
7 due course, thank you.

8 We can see that you did produce a paper setting out  
9 your secondment to the US in appendix 1 of your  
10 statement. We don't need to go to that but I'll provide  
11 the court book reference. It is [\[PEN0100326\]](#).

12 Returning then, to paragraph 2 of your statement,  
13 you then address the issue of the acceptance of blood  
14 from higher risk donors, in particular prisoners. You  
15 explain that you took up your post as consultant in  
16 Southeast BTS on 1 April 1985 and that your first  
17 attachment to Southeast BTS was an informal rotation for  
18 a period of approximately six months from late 1983 to  
19 early 1984. Your role at that time was essentially that  
20 of an observer but you were allowed to attend virtually  
21 all departmental meetings and discussions.

22 You say:

23 "In the course of meetings and discussions, I recall  
24 that the issue of accepting blood from prisoners, ie  
25 scheduling blood donor sessions in prisons and



1           correctional institutions, was still being discussed at  
2           national level, although I was aware that SEBTS had  
3           discontinued these sessions some years earlier."

4           So, doctor, when you were there in late 1983/early  
5           1984 and were aware of discussions about collecting  
6           blood in prisons, can you indicate the nature of those  
7           discussions?

8    A.   What I can recall with absolute certainty is that during  
9           that part of my observational period -- training if you  
10          like -- I spent some time in the donor office finding  
11          out how we scheduled blood donor sessions, how we went  
12          about collecting enough blood from day to day. I'm  
13          certain that that's when I heard that we used to go to  
14          Saughton. So by then in Southeast it was a dead issue,  
15          really. But I think I can recall mention at meetings  
16          and so on where Brian McClelland was feeding back to us  
17          from what was going on nationally, that there was still  
18          a bit of an issue, but more than that I can't recall.

19   Q.   At the top of page 5 of your statement, three lines  
20          down, you say:

21                 "I therefore had no first-hand knowledge of the  
22                 discussions leading to the adoption of this policy, nor  
23                 the correspondence in other matters referred to in  
24                 certain paragraphs of the preliminary report."

25                 On to paragraph 3. You were asked to consider

1           whether the SNBTS accepted the recommendation in the  
2           second Maycock report in 1975 in relation to the  
3           acceptance of donors with a history of jaundice or  
4           hepatitis, who had tested negative for Hepatitis B and  
5           whose episode of jaundice was more than 12 months  
6           previously. Again you explain you had no first-hand  
7           knowledge of that, of course, because you weren't with  
8           the service at the time. But you did do some research  
9           on the historical position. Then paragraph 4, you were  
10          asked to consider:

11                 "The consideration given by the SNBTS between 1975  
12                 and 1991 to the exclusion of donors at a higher risk of  
13                 transmitting NANB including the exclusion of donors with  
14                 a history of jaundice or hepatitis."

15                 Again you explain that you have no first-hand  
16                 knowledge of the period from 1975 to 1981 and have had  
17                 to rely on archive documentation. You explain in  
18                 paragraph 4.1 there is documentary evidence that the  
19                 policy of accepting donors with a history of jaundice  
20                 was implemented in SEBTS by 1982:

21                 "It is apparent from the documents in the archive,  
22                 the file of donor selection materials compiled some  
23                 years later, that all five Scottish  
24                 regional transfusion centres had adopted the policy by  
25                 1983 at the latest."

1           But you also explain:

2           "The earliest date of implementation is unknown as  
3 no such documents exist from the years prior to 1982."

4           In terms, doctor, of the SNBTS archives of donor  
5 selection guidance documents, does the archive really  
6 start in 1982? Is that when you were first able to find  
7 records relating to these matters?

8   A. Yes. The archive was compiled retrospectively. I think  
9 some time around 1990, when Mairi Thornton was appointed  
10 national donor services manager she compiled  
11 a historical archive from the individual archives in the  
12 five regional centres and that is the file to which  
13 I have referred here, and I can find no materials with  
14 specifics about donor selection procedures prior to  
15 round about 1982.

16           It is hard to be absolutely precise about dates  
17 because none of the forms have dates on them at that  
18 time, but we can infer from some of the surrounding  
19 materials, for instance, the one that was shown  
20 yesterday from Glasgow and the West of Scotland which  
21 had a sticker about AIDS on it. Which indicates that  
22 was a form which must have been in existence in 1983 and  
23 the accompanying comment was that it was about to be  
24 revised.

25           Therefore, we could assume that was in use in round

1           about 1982 and all of the forms by then -- so what we  
2           are talking about is the forms that were used on the  
3           blood donor sessions and they all have a statement in  
4           all five regions that a history of jaundice in the donor  
5           would not disqualify so long as it was 12 months  
6           previously.

7    Q.   Yes, and you are, I think, doctor, able to speak to the  
8           practice after 1985, after your arrival in the service.  
9           In paragraph 4.2 you explain:

10                 "In spite of the intense focus from 1983 onwards on  
11           donor selection as a vital safety measure in response to  
12           the threat of AIDS, the policy of accepting donors with  
13           a history of jaundice seems to have received little  
14           discussion between 1985 and 1991, though there was  
15           a discussion among SNBTS directors based on a paper  
16           presented by Dr Brian Dow in 1986."

17                 You then explain:

18                 "In the draft guidelines on donor selection  
19           dated May 1987, the wording had changed to allow  
20           acceptance of donors with a history of childhood  
21           jaundice, later clarified as before the age of 12,  
22           without further qualification."

23                 If we could look at that document, please, the  
24           reference is [\[SNB0066410\]](#). This document is dated in  
25           the bottom right-hand corner, November 1987. The title

1 is "Guidance for the selection, medical examination and  
2 care of blood donors". Who authored this document,  
3 doctor?

4 A. I think this was the first attempt by us to produce  
5 a single comprehensive document for SNBTS, which would  
6 supersede the individual -- it has to be said, similar  
7 documents in all five regions, which were in place from  
8 the time that I had first come into the BTS.

9 So from 1983/1984-ish I knew that each individual  
10 region had its own guidelines which were present on the  
11 donor session for the doctors and nurses there to use  
12 and refer to.

13 So we were trying to bring that together and  
14 Professor Cash asked me to review all of that and I  
15 produced a report late in 1985, which wasn't a total  
16 success, it has to be said. I was a bit green and  
17 I think me going into the various centres and trying to  
18 suggest that we should pull all this together -- I think  
19 perhaps people took the underlying assumption that it  
20 was going to be the Edinburgh document that would  
21 supersede all others, which was not necessarily going to  
22 be the case. But it took a while to get from that point  
23 to 1987, when we produced this first draft, and then  
24 that went through various further drafts and I think was  
25 issued in 1988.

1 Q. Thank you, doctor. We will come back to look at your  
2 report, I think, you made in 1985 in due course, but  
3 simply sticking with this document, if I may, if we can  
4 go, please, to page 6418, and look at hepatitis, we can  
5 see the document states:

6 "Childhood jaundice/hepatitis with full recovery,  
7 accept.

8 "Hepatitis/Adult jaundice, defer and obtain more  
9 information from GP. If not Hepatitis B, accept one  
10 year after full recovery. If donor is known to have had  
11 Hepatitis B and wishes to donate, should be referred to  
12 the centre for individual consideration."

13 Can you talk us through that guidance, please,  
14 doctor? What exactly does it mean?

15 A. This is fairly strict compliance with the policy that  
16 was promulgated post 1975, if you like, which at some  
17 point was adopted as SNBTS policy; that is to say that  
18 people presenting as donors who had had hepatitis in the  
19 past could donate provided it was more than a year in  
20 the past and they had no evidence of Hepatitis B.

21 This implies, however, that the staff on the session  
22 could take the donor's word for it that it was not  
23 Hepatitis B. I don't think we ever operated that policy  
24 and the wording of this had changed, I think, by the  
25 1988 document to make it more explicit that all of these

1           should be referred to the centre for further  
2           consideration. In fact, that was built into this in the  
3           sense that when the session staff produced what was  
4           known as a GP letter -- in other words they would defer  
5           the donor on the day and say we need to get more  
6           information from your GP -- that automatically referred  
7           the matter back to the doctors in the centre. So it was  
8           only once the information came through -- and the system  
9           still exists today, from the GP -- that the doctors in  
10          the centre could make decisions about the acceptance or  
11          permanent deferral of that donor.

12        Q. If a donor had presented who had a history of jaundice  
13          as a result of non-A non-B hepatitis, would this  
14          guidance prevent their donation being accepted or would  
15          their donation go through based on this guidance?

16        A. It's quite hard to imagine a situation where we would  
17          end up with a history of a donor having had jaundice as  
18          a result of non-A non-B hepatitis. That's a very rare  
19          event. But if that happened, say in the context of  
20          a patient who had a transfusion and then developed  
21          jaundice and no other cause was found for it, we would  
22          not have accepted that patient as a donor at a later  
23          date.

24        Q. You say that it would be a very rare event for someone  
25          to develop jaundice as a result of non-A non-B

1 hepatitis. If it isn't within your field then please  
2 say so, but are you able to tell us approximately what  
3 percentage of people who contract Hepatitis C developed  
4 jaundice?

5 A. I have looked at the literature and it is very difficult  
6 to get a figure for that in fact. Most papers talking  
7 about, for instance, post-transfusion non-A non-B  
8 hepatitis don't mention jaundice as a factor. In the  
9 very earliest papers from the TTV study, the cohort of  
10 post-transfusion patients identified at the NIH and  
11 other places in the United States, I think there is  
12 a comment about jaundice being infrequent but I couldn't  
13 put a figure on it. It is a very small figure and  
14 I think most authorities accept that jaundice is an  
15 occasional but rare feature in non-A non-B hepatitis.

16 Q. Thank you.

17 THE CHAIRMAN: Doctor, can we just pause on the document for  
18 a moment. A recurring concern of mine is that the use  
19 of the expression "hepatitis" communicates different  
20 things at different periods. Now, in this document we  
21 have a reference to childhood jaundice/hepatitis and  
22 then "hepatitis/adult jaundice". At this time what  
23 would have been understood within SNBTS about hepatitis  
24 from a reference like this?

25 A. In this setting, the donor setting, it would be



1           understood that this was clinical hepatitis, of which  
2           the main feature was jaundice.

3   THE CHAIRMAN:   So it is jaundice of which there are clinical  
4           signs?

5   A.   Yes.

6   THE CHAIRMAN:   Typically jaundice, which would characterise  
7           the condition?

8   A.   Yes.

9   THE CHAIRMAN:   But Hepatitis B, of course, would have been  
10          identified in some cases by testing?

11  A.   That's correct, because as we now know, and indeed knew  
12          by the late 1970s, I guess, the vast majority of even  
13          Hepatitis B is clinically silent.

14  THE CHAIRMAN:   But the person would in fact have had  
15          a certificate of some kind from the test, not paper but  
16          knowledge from the test that there had been a positive  
17          test at some stage.

18  A.   Possibly.   This wouldn't be a very frequent event.

19  THE CHAIRMAN:   Mr Mackenzie?

20  MR MACKENZIE:   Thank you, sir.

21           Doctor, returning, please, to your statement.  To  
22          complete the end of paragraph 4.2, you say:

23           "This is likely to have been the outcome of the  
24          SNBTS directors' discussion referred to above and will  
25          also have been influenced by the data in the letter

1 published in 1982 by Barr et al".

2 That reference, please, is [\[PEN0140067\]](#). While we  
3 are waiting for it to appear, doctor, I should say that,  
4 if we look at the bottom right-hand corner, we can see  
5 the authors are Mr Barr and others, including Dr Dow,  
6 and we will come back to go over some of these papers  
7 with Dr Dow as he is the co-author of a number of them.  
8 If we can look at this one, we can see that is a paper,  
9 or rather a letter, in the British Medical Journal of  
10 23 October 1982. We can see that from the very top of  
11 the screen. Can we scroll down, please?

12 Can we then go to the body of the letter, please?

13 It is headed "Blood donors with a history of  
14 jaundice". The authors write:

15 "The leading article from Dr P M Jones reopens the  
16 question of whether blood from donors with a stated  
17 history of jaundice are safe for transfusion. In an  
18 earlier studies from the West of Scotland we found that  
19 these donors were much more likely to have had an  
20 infection with Hepatitis A virus than with Hepatitis B  
21 virus. In addition, we found that a history of jaundice  
22 was no more common among carriers of Hepatitis B surface  
23 antigen and hence was of little use as a marker of  
24 Hepatitis B activity. A history of jaundice is obtained  
25 from 2.8 per cent of blood donors in the West of

1 Scotland. Alter's American figure is hardly relevant to  
2 the UK. We have now studied a group of donors according  
3 to the age at which the jaundice occurred. Almost all  
4 the episodes of jaundice occurring before the age of  
5 13 years were due to Hepatitis A infection but about 20  
6 per cent of those with jaundice in adolescence or later  
7 had no markers for Hepatitis A or B. Other viruses can  
8 cause jaundice, for example Epstein-Barr virus,  
9 cytomegalovirus, Coxsackie virus, adenovirus and many  
10 other agents can cause liver problems. We cannot,  
11 therefore, equate unexplained jaundice with infection  
12 caused by the elusive non-A non-B viruses. Indeed, it  
13 is uncertain whether sporadic non-A non-B hepatitis is  
14 caused by the same agent as the form of the disease  
15 transmitted by transfusion and it is not known how often  
16 a carrier state follows sporadic infection.  
17 Furthermore, it is possible that, as with Hepatitis B,  
18 clinical jaundice may be an indicator of the elimination  
19 of virus rather than carriage."

20 Just beneath the table:

21 "The risk of post-transfusion hepatitis at  
22 10 per cent is an American estimate and cannot be  
23 extrapolated to European transfusion services. In the  
24 last three years this region as transfused nearly 400,000  
25 donations of blood and derivatives. Only 12 cases of

1 overt post-transfusion hepatitis, possibly attributable  
2 to non-A non-B agents, have been notified. Of these,  
3 four were haemophiliacs who had been receiving imported  
4 blood products in addition to Scottish large pool factor  
5 concentrate. None of the donors involved in the eight  
6 cases associated with red cell transfusion have given  
7 a history of jaundice."

8 The final column:

9 "As the sensitivity and specificity of serological  
10 tests for non-A non-B carriers have yet to be proved, we  
11 could find ourselves excluding 2.8 per cent of donors  
12 because of a history of jaundice, perhaps 2 per cent  
13 because of serological findings, and a further 3 per  
14 cent on the strength of alanine aminotransferase  
15 concentrations. The use of alanine aminotransferase  
16 concentrations has not been validated for UK volunteer  
17 donors."

18 We start to see a reference here to surrogate  
19 testing. Then the authors conclude:

20 "The present British policy appears to be correct  
21 and any change could cause a serious loss of blood  
22 products when some regions are still struggling to make  
23 80 per cent of the blood plasma they collect available  
24 for Factor VIII production. We endorse Dr Jones's  
25 encouragement to doctors to report all cases of

1 post-transfusion jaundice."

2 So that's an example, doctor, of the consideration  
3 which was given by the SNBTS to the question of  
4 accepting blood donors with a history of jaundice at the  
5 time. On the basis of those findings there was  
6 certainly not found to be any reason to revisit the  
7 policy of accepting donors with a history of jaundice  
8 who were negative for Hepatitis B.

9 A. Except in as much as I think this is what led us to  
10 start accepting donors who had jaundice below the age of  
11 12.

12 Q. Because?

13 A. Because effectively they had demonstrated that that's  
14 all Hepatitis A really.

15 THE CHAIRMAN: Would that view have been held throughout the  
16 SNBTS or does it reflect a particular attitude from  
17 a particular region?

18 A. I don't know that I could speak for all five centres but  
19 clearly it was the view in the West of Scotland. It was  
20 the view in the Southeast as well. I'm sure that we  
21 were operating that policy probably prior to that 1986  
22 meeting of the directors. But I have no documentary  
23 evidence of that.

24 THE CHAIRMAN: And it refers, of course, to overt signs of  
25 jaundice.

1 A. Yes.

2 THE CHAIRMAN: Which we now know wouldn't have been expected  
3 in NANB hepatitis.

4 A. You wouldn't expect that, no.

5 MR MACKENZIE: Thank you, sir.

6 Going back, please, to your statement in  
7 paragraph 4.3 you explain:

8 "Until a test for Hepatitis C became available, the  
9 epidemiology of non-A non-B hepatitis, as it was then  
10 known, was poorly understood. By far the commonest  
11 cause of jaundice in the community was Hepatitis A, the  
12 common cause of childhood jaundice, and this was known  
13 not to be transfusion-transmitted once the acute illness  
14 had resolved (hence the 12-month exclusion from blood  
15 donation). In the 1980s, Scottish transfusion centres  
16 were receiving very few reports of post-transfusion  
17 jaundice/hepatitis. For the most part, the concern in  
18 such cases was to exclude Hepatitis B for which there  
19 was a test."

20 To pause there, doctor. It would be unsurprising  
21 that Scottish transfusion centres were receiving very  
22 few reports of post-transfusion non-A non-B, or as we  
23 now call it Hepatitis C, given, as you say, that very  
24 few people will develop jaundice as a result of  
25 contracting that virus.

1 A. That's correct. Most post-transfusion hepatitis would  
2 have gone unrecognised.

3 Q. We may come back to look at this question after the  
4 summer on surrogate testing.

5 Then at the bottom of page 6, paragraph 4.3, you  
6 say:

7 "I have no recollection or knowledge of the  
8 discussions which led to the amendment to the policy  
9 which led to the acceptance without qualification of  
10 donors with a history of jaundice occurring before the  
11 age of 12."

12 Paragraph 4.4:

13 "It is highly probable that the decision to accept  
14 the earlier recommendation on donors with a history of  
15 jaundice was influenced by the work in the  
16 West of Scotland ..."

17 That's the article we have looked at, the letter by  
18 Barr et al in 1982:

19 "... in which it was shown that 2.8 per cent of  
20 donors in the West of Scotland had a history of  
21 jaundice. Ninety-nine per cent of those whose jaundice  
22 occurred before the age of 12 had anti-bodies to  
23 Hepatitis A virus compared with 55 per cent of those  
24 with jaundice after 13 years of age. Thus, virtually  
25 all jaundice occurring before the age of 13 years was

1 due to Hepatitis A. About 20 per cent of donors with  
2 a history of jaundice in adolescence or later had no  
3 markers for Hepatitis A or Hepatitis B. The authors  
4 pointed out that many other viruses can cause hepatitis  
5 in the community ..."

6 We have looked at them:

7 "... and that many other agents can cause liver  
8 problems. Therefore, though indirect, this evidence  
9 suggested that the putative agents carrying NANB would  
10 only likely be present in a small minority of donors  
11 with a history of jaundice and this was later borne out  
12 by the SNBTS experience after HCV testing was introduced  
13 in 1991."

14 There is then a reference to a paper published in  
15 1994 by Crawford. Again, we will come back to this  
16 later in the Inquiry, but in short, of the donors who  
17 were positive for Hepatitis C antibodies after the  
18 introduction of screening in September 1991, only  
19 5.9 per cent of those positive donors had a history of  
20 jaundice, and it is not known what proportion of these  
21 occurred in childhood. There is then a reference to the  
22 work of Dr Dow in his PhD thesis. Again, we will come  
23 back to that perhaps, but Dr Dow:

24 "... showed that few donors with a history of  
25 jaundice had levels of ALT greater than 92 units per



1           litre. That's 0.2 per cent of donors with a history of  
2           jaundice. This compared with prison donors  
3           (0.96 per cent), and intravenous drug users  
4           (18.4 per cent)."

5           Over the page, please, question 5 then asked:

6           "The procedures in place within the SNBTS between  
7           1975 and 1991 for the exclusion of donors at a higher  
8           risk of transmitting NANB hepatitis, including the  
9           exclusion of donors with a history of jaundice or  
10          hepatitis."

11          You explain in paragraph 5.1 that during your  
12          informal attachment to the SEBTS from late 1983 to 1984  
13          you were able to familiaris yourself with the procedures  
14          in place for the selection of appropriate donors:

15          "The process was at that time heavily reliant on the  
16          donor volunteering any health or behavioural issues  
17          which might have been relevant, prompted by a form which  
18          listed the conditions which might debar or defer them  
19          from giving blood."

20          Doctor, I think you referred earlier to having  
21          attended donor sessions during this period?

22    A.    Yes, indeed.

23    Q.    Can you just explain what happened in terms of the  
24          interaction with donors and what questions they were  
25          asked and what leaflets or documents they were given?

1 A. At that time it all depended on a single form, which was  
2 the donor session record, and I'm speaking here for  
3 practice within Southeast Scotland. I didn't visit  
4 donor sessions in other regions at that stage. But  
5 I think the process was broadly the same, given that we  
6 have looked at the documentary evidence although the  
7 forms look a bit different.

8 So the donor was presented with a form which  
9 welcomed them and outlined the conditions that might  
10 debar them from giving blood. That was not presented as  
11 something that they had to give specific answers to by  
12 ticking a box or saying yes or no. That form also  
13 identified the donor and asked the donor to sign. But  
14 it contained no specific questions to which they had to  
15 give any sort of written answer.

16 There was no attempt at that stage to ask those  
17 questions directly. There were general questions asked  
18 about health but it was not until the late 1980s that  
19 donors were specifically asked directly the questions  
20 that were on the form. Until that time it was always  
21 done by a written statement and signature from the donor  
22 that they were fit and well.

23 Q. Yes. So you are talking about the period when you  
24 attended sessions in late 1983/1984?

25 A. Yes.

1 Q. Essentially, was the donor given a form and asked to  
2 read it?

3 A. They were asked to read it and sign it, yes.

4 Q. And sign the form as well?

5 A. Yes.

6 Q. And was the signed form then given back to those  
7 undertaking the donor session or what happened to those  
8 signed forms?

9 A. Yes, the forms then followed the donation and the donor  
10 through the process and came back into the transfusion  
11 centre, where it was separated into -- well, it was  
12 separated at the session into two parts, one part which  
13 accompanied the donation back into the laboratory side  
14 and the other part, which was the donor's personal  
15 details, which went into the donor office. In the case  
16 of a new donor, that would give rise to registration in  
17 the formal sense on the computer system, as it was by  
18 1983/1984. We had the computer logging all details of  
19 donors by then and in the case of a previous donor it  
20 would be to update the details and make sure that the  
21 details matched what was previously known about that  
22 donor.

23 Q. I'm not sure we have an example of that form, doctor,  
24 but we do have this document at [\[PEN0131395\]](#). This form  
25 is from Glasgow in the west and appears to be

1           dated June 1983. I think you have seen this form  
2           before?

3    A. Yes.

4    Q. Is this similar to the type of form you have just  
5           described or is this a different type of form?

6    A. It is similar but actually just seeing this and  
7           describing the process has jogged my memory. I'm almost  
8           certain in the West at the time they had a separate  
9           session record form, where the donor signed on a single  
10          sheet. All the donors signed their details on this  
11          sheet.

12   Q. In the West?

13   A. In the West. I think that's the way they did it rather  
14          than have the forms signed.

15   Q. So the form we are looking at now on the screen, is that  
16          similar to the type of form you have just described in  
17          use in the East?

18   A. In terms of its content, yes.

19   Q. Yes. And would the donor sign that page of the form or  
20          a different page?

21   A. My recollection is there were various versions and  
22          updates of the forms but by and large the system we used  
23          in the Southeast had a detachable bit at the bottom,  
24          which was the donor details and signature.

25   Q. Thank you.

1           Now, could we go back, please, to your statement  
2           from, I think, page 8. We have reached paragraph 5.2  
3           where you explain that:

4           "At that time I had no knowledge of the procedures  
5           in place in any of the other Scottish centres. I was  
6           aware that the regions were essentially autonomous,  
7           interpreting national guidelines and producing and  
8           printing their own materials. Review of the historical  
9           archive shows that the system was essentially the same  
10          in all regions, though the printed materials look  
11          different. The earliest such documents to survive are  
12          individual session records from 1982 but it should be  
13          noted that many of the official documents from the 1980s  
14          are undated; formal document control procedures had not  
15          become the norm until 1991."

16          Next paragraph, 5.3. You explain:

17          "Although the epidemiology of NANB hepatitis was  
18          poorly understood until a test for Hepatitis C appeared  
19          in 1989, there was good reason to believe that at least  
20          one parenterally transmitted virus was involved ...  
21          intravenous drug users were therefore considered to be  
22          the most significant group for carriage of NANBH.  
23          Recommendations for their exclusion from donor panels  
24          first appeared in the late 1970s:"

25          You refer to a further paper you have produced, we

1 will come to shortly:

2 "Evidence of how this was applied on donor sessions  
3 is lacking for the period 1975 to 1982 but in June 1983  
4 the first SNBTS ..."

5 Is the word "AIDS" missing there? Five lines from  
6 the top of the page, doctor, after the word "SNBTS",  
7 should the word "AIDS" be inserted there?

8 A. It would be appropriate, yes. It was specifically about  
9 AIDS, the next sentence goes on to describe that.

10 Q. I'm not going to go over the following paragraph because  
11 we then come to the question of donor exclusion for  
12 AIDS, which will be covered tomorrow. So if we could  
13 then, please, go over the page again and go on to  
14 paragraph 6. The question there is asked:

15 "Whether there were national policies in that  
16 regard, ie in respect of excluding donors at a higher  
17 risk of transmitting NANB hepatitis or whether each  
18 SNBTS region had their own practices and policies."

19 You perhaps, doctor, read from paragraph 6.1  
20 onwards.

21 A. Do you want me to read out loud?

22 Q. Yes, save me speaking, doctor, thank you.

23 A. "As described in appendix 2, there is no doubt that from  
24 the late 1970s national policies on these and other  
25 issues existed, whether in the form of UK DOH memoranda

1 or in guidelines agreed by consensus decisions arrived  
2 at in meetings of the SNBTS and UK BTS  
3 regional transfusion centre directors, or in advisory  
4 committees and working parties whose views would require  
5 endorsement by RTDs. At the same time, however,  
6 regional transfusion centres were essentially  
7 autonomous. Thus RTDs might agree high level policy, eg  
8 the risk groups on AIDS and how implementation should be  
9 approached (eg a leaflet), but regional centres had  
10 their own donor session policies, procedures and  
11 documentation with different methods for managing donor  
12 records and communications. It was only in 1990, when  
13 the establishment of the general management..."

14 The system that Professor Cash described yesterday:

15 "... was instituted at national level and the  
16 appointment of a national donor services manager and a  
17 national quality manager that a system of common policy  
18 documentation and document control was put in place.  
19 The first nationally branded donor selection materials  
20 were issued in 1991, if one excepts the successive AIDS  
21 information leaflets."

22 Q. Thank you, doctor, then in the next question you were  
23 asked:

24 "Whether, if all donors with a history of jaundice  
25 or hepatitis had been excluded from giving blood, (a),

1 that is likely to have caused any difficulties in  
2 maintaining a sufficient supply of blood and (b), the  
3 extent to which post-transfusion Hepatitis C in Scotland  
4 is likely to have been reduced."

5 You then explain:

6 "There was research in the West of Scotland at  
7 around the time of the introduction of the policy to  
8 accept donors with a history of jaundice (with strict  
9 provisos), showing that 2.8 per cent of donors gave such  
10 a history."

11 A few lines down you pick up:

12 "It is likely that the impact on the blood supply of  
13 reversing the policy of acceptance of donors with  
14 a history of jaundice would have been significant, given  
15 that 2.8 per cent of the donor population equates to  
16 close to 10,000 donors annually."

17 Over the page at paragraph 7.2 you explain:

18 "As described previously, Hepatitis A was by far the  
19 commonest cause of community-acquired jaundice in  
20 Scotland at the time of these events, around the early  
21 1980s. Donors with a history of jaundice were no more  
22 likely to have a significantly raised level of ALT (to  
23 a level considered possibly indicative of carriage of  
24 NANBH in the absence of other potentially causative  
25 factors) than 'control' or unselected donors. These



1 data suggested that a history of jaundice was likely to  
2 be a very insensitive surrogate test for identifying  
3 donors who might be carrying the putative NANBH agent.  
4 It was only in 1991 after a test for HCV was implemented  
5 that this supposition could be examined in detail."

6 Paragraph 7.3 you explain that:

7 "Questioning of donors found to be anti-HCV positive  
8 in the first six months of routine HCV donor testing  
9 revealed that 5.9 per cent had a history of jaundice.  
10 It is not known what proportion of these cases of  
11 jaundice occurred from childhood, but based on the  
12 information in Barr and others' 1982 letter, jaundice in  
13 many of these donors could have been the result of  
14 Hepatitis A or B."

15 Then at the bottom of page 12, four lines from the  
16 bottom, you explain:

17 "One can, to an extent, estimate retrospectively the  
18 effect that exclusion of donors with a history of  
19 jaundice might have had on the risk of transmission  
20 while at the same time estimating the impact on the  
21 blood supply and on blood donors."

22 Over the page you carry out that estimate and that  
23 exercise. Paragraph 7.3 you explain:

24 "The data on HCV positivity in the Scottish blood  
25 cover population post-screening are shown in

1 appendix 3."

2 I'm not going to take you to that, doctor, but for  
3 the records the reference number is [\[PEN0100385\]](#):

4 "Examination of data for the period from the  
5 implementation of testing on 1 September 1991 to the end  
6 of 1992 can be taken to represent the prevalence of HCV  
7 in the donor population in the period prior to  
8 1 September 1991."

9 You also explain:

10 "It should be noted that the number of donations  
11 does not equate to the number of donors tested since  
12 regular donors with negative tests may have donated more  
13 than once during the 15-month period (the average rate  
14 of donation being 1.5 per annum)."

15 Can you explain that sentence, doctor?

16 A. Yes. If you just crudely take the number of donations  
17 we take in a year, you cannot assume that that is the  
18 number of donors tested because regular donors come back  
19 up to three times in a year, and for regular donors  
20 a reasonable average, we have found over the years, is  
21 about 1.5 donations per annum.

22 So you have to make an adjustment downwards to get an  
23 estimate of the number of donors who were tested during  
24 that period.

25 Q. I understand.

1           Then you set out a calculation. I think, in short,  
2           the two important figures used in this calculation. We  
3           can see in the third paragraph a figure of 5.9 per cent.  
4           That essentially represents the figure you referred to  
5           previously, that after screening for Hepatitis C  
6           antibody was introduced, of those donors who were  
7           positive for Hepatitis C antibody, 5.9 per cent of those  
8           positive donors give a history of jaundice. That's  
9           where that figure comes from, I think; is that correct?

10    A. Yes, that's 5.9 per cent of the 256.

11    Q. Yes. Then the next paragraph, the figure of  
12           2.8 per cent, that comes, I think, from the Barr and  
13           others letter of 1982, being those donors who gave  
14           a prior history of jaundice.

15    A. Yes. And that's the only figure we have for the number  
16           of donors presenting with a history of jaundice. So  
17           that was putting two bits of evidence together from  
18           different time periods, obviously. So that is an  
19           assumption.

20    Q. Yes. And using, in particular, those two assumptions,  
21           your conclusion in paragraph 7.5 is:

22           "Summing up, around 9,000 donors would be lost each  
23           year in order to prevent, at best, 15 Hepatitis C  
24           virus-infected donations from entering the blood supply,  
25           while failing to prevent the vast majority of HCV

1 infected donations from being made available for  
2 transfusion."

3 At the top of page 14 you explain:

4 "The exclusion of 15 donations capable of  
5 transmitting HCV is clearly desirable but it must be  
6 remembered, however, that the significance of NANBH in  
7 clinical terms was far from clear in the early 1980s,  
8 with most of the evidence suggesting it was a relatively  
9 benign condition. Furthermore, the nature of the agent  
10 and its rate of transmission were unknown and it was  
11 thought (correctly as it turned out) that a history of  
12 jaundice was unusual in NANBH."

13 Then the next paragraph, 7.6:

14 "In assessing the possible impact on the blood  
15 supply of exclusion of donors with a history of  
16 jaundice, it is the case that not only would around  
17 9,000 donors be lost annually, the loss of donations  
18 would be cumulative as the regular donors in the initial  
19 testing period would be lost and a substantial number of  
20 perfectly safe new donors, with the potential to donate  
21 on average 1.5 times yearly for many years, would be  
22 lost to the system."

23 That perhaps is the corollary of what you explained  
24 earlier.

25 A. Yes.

1 Q. You also say in paragraph 7.7:

2 "As stated, these wrongly excluded donors can be  
3 described as 'false positives'. In any screening tests  
4 applied to blood donations a positive reaction leads to  
5 further detailed confirmatory testing, with the purpose  
6 of identifying true positive results. Unreactive  
7 confirmatory tests define donors regarded as false  
8 positives, ie not carriers of the infection. In the  
9 unwritten contract established with donors in the  
10 mid-1980s we explained the reasons for asking them to  
11 refrain from donating as long as the false reaction  
12 prevents the use of their blood."

13 Over the page:

14 "Most donors accept this without much thought but  
15 some do not. To learn that you may or may not be  
16 carrying a virus which may or may not be sexually  
17 transmissible and may or may not cause serious illness  
18 is, in some donors, a cause of great anxiety. In the  
19 face of such uncertainty, it can be difficult to provide  
20 much in the way of reassurance."

21 In short doctor, is what you were saying there, that  
22 if donors with a history of jaundice had been excluded,  
23 say at any point in the 1980s, before the Hepatitis C  
24 test was available, you wouldn't be able to tell a donor  
25 who had been excluded whether they had the NANBH virus

1 or viruses or not? So donors who had been excluded on  
2 the basis of a history of jaundice would be left in  
3 a state of uncertainty, perhaps, as to their true  
4 positive or negative status?

5 A. Yes, most donors wouldn't enquire further about that but  
6 some would. They would say, "Why are you doing that?  
7 What does it mean? Does that mean I have got a serious  
8 disease? Is it going to make me ill?"

9 Q. It may have been difficult to answer.

10 A. It is difficult because we had no tests. We had no way  
11 of verifying that and it left them uncertain.

12 Q. In paragraph 7 you also explain:

13 "The loss of such a large number of blood donations  
14 could have catastrophic consequences for all patient  
15 groups. Failure to meet the target required for plasma  
16 for fractionation into blood products such as  
17 Factor VIII could have resulted in importation of  
18 products with a much smaller margin of safety than was  
19 assumed for Scottish donor-derived products, and this  
20 was understood even before the onset of AIDS."

21 We may come back in a future topic to consider that  
22 proposition:

23 "Also, until heat treatment of coagulation factors  
24 sufficient to prevent transmission of HCV was  
25 introduced, and due to the pooling of donations,

1 excluding donors with a history of jaundice would have  
2 had no beneficial effect on product safety."

3 In paragraph 7.9 you come to the question of  
4 surrogate testing, which again we will come back to  
5 later. On the final page of this statement, the top of  
6 page 16, you say:

7 "In selecting suitable donors there was and remains  
8 a constant balance to be struck between maintaining  
9 blood supply and ensuring the highest levels of safety  
10 as well as minimising unnecessary rejection of donors  
11 and respecting the principle of duty of care towards  
12 donors."

13 Can you explain that principle a little, doctor; the  
14 principle of duty of care towards donors?

15 A. By that I was really referring fairly specifically to  
16 this situation of effectively surrogate testing. And in  
17 thinking about this whole area since writing that, it  
18 has become clear to me -- and I have not seen this  
19 referred to by other people -- that what we do most of  
20 the time in selecting donors is apply surrogate tests.  
21 And every time you are doing that, you are rejecting  
22 a number of donors who have nothing wrong with them, who  
23 are perfectly well and they have come in to volunteer to  
24 do something for the good of the community and been  
25 turned away, with or without some doubts about their

1 future state of health.

2 By "duty of care" I meant that we should be careful  
3 not to do that unnecessarily, keep it to an absolute  
4 minimum and give the donors as much information about  
5 the situation as we possibly could.

6 To extend the analogy, for instance, if we reject  
7 a donor on the basis of having had a tooth out in the  
8 previous 24 hours, the reason for that is that there is  
9 evidence that something like around 10 per cent of  
10 people who have a tooth out will have bacteria in their  
11 blood stream within the following 24 hours. That means  
12 that 90 per cent of those donors wouldn't have bacteria  
13 in their blood stream and their blood would be perfectly  
14 fine. The trouble is we do not know which because we  
15 don't apply a specific test.

16 So in that sense it is exactly the same as all of  
17 the surrogate testing. You are looking at either  
18 behaviour or characteristics or something else about the  
19 donor that suggests they might have a slightly increased  
20 risk of causing illness in the recipient, which is what  
21 it boils down to. But we mustn't neglect the fact that  
22 these false positives, if you like, the people who get  
23 rejected unnecessarily, can have some impact on them, as  
24 well as the whole process having impact on the blood  
25 supply and impact, therefore, on patients at the other



1 end of the line.

2 Q. So the Blood Transfusion Service, when collecting  
3 donations, has to have regard to the interests of the  
4 donor as well as interests of the recipient?

5 A. Yes. And we have always made it clear -- and we make it  
6 clear in training staff -- that the interests of the  
7 recipient come first but that does sometimes have  
8 a knock-on effect backwards on to the donors.

9 Q. The final paragraph, doctor, paragraph 7.10, you stated:

10 "These considerations lead me to conclude that the  
11 impact on post-transfusion NANBH from an exclusion of  
12 donors with a history of jaundice would have been very  
13 modest, though undoubtedly a small number of HCV  
14 transmissions would have been prevented. The effect on  
15 the blood supply and on individual donors and patients,  
16 on the other hand, would probably have been highly  
17 significant."

18 If we could then compare your conclusion in that  
19 regard, that the effect on the blood supply and on  
20 individual donors and patients would probably have been  
21 highly significant, with Dr McClelland's conclusion,  
22 could we go, please, to his statement, which is  
23 [\[WIT0030072\]](#). Page 0088. The paragraph at the bottom  
24 of this screen commencing:

25 "Assuming that the lower figure ..."

1           In short, Dr McClelland was asked the same question  
2           as you, doctor, in respect of what would have been the  
3           impact on the blood supply if there had been a policy of  
4           excluding all donors with a history of jaundice or  
5           hepatitis.

6           Dr McClelland's conclusion was that he had looked  
7           firstly at what percentage of donors may have had  
8           a history of jaundice and he explained that assuming the  
9           lower figure of around 3 per cent is correct, the  
10          exclusion of donors with a jaundice history would  
11          probably not have had a major impact on supply but this  
12          is essentially speculation.

13          So Dr McClelland's conclusion is that excluding  
14          around 3 per cent of donors would probably not have had  
15          a major impact on supply. Your conclusion is that  
16          a similar exclusion would probably have been highly  
17          significant. Who is right?

18        A. Well, it's speculation, isn't it? But the fact is that  
19          from the period from about 1983 through 1985 and  
20          onwards, there was a significant decline in the number  
21          of donations we took, we think related to the adverse  
22          publicity about AIDS and so on. When that sort of thing  
23          starts to happen, 3 per cent can seem like an awful lot  
24          of donations to be losing.

25          My point is that it could be catastrophic for an

1 individual. Maybe that overall in terms of blood  
2 supply, we could meet targets but for an individual  
3 patient in an emergency situation, if you do not get  
4 blood of the right type at the right time, it can  
5 literally be catastrophic.

6 So I think we always had to bear that in mind and,  
7 yes, you can recover from a 3 per cent loss but it  
8 depends how close to the bone you are.

9 Q. Thank you, doctor. That completes your statement.

10 I won't be much longer but can I go, please, to  
11 another document you have produced, which is number  
12 [\[PEN0100365\]](#). This was the document Professor Cash  
13 referred to yesterday. We can see this document is  
14 entitled "Donor selection policies and procedures"  
15 dated September 2010. Were you the author or principal  
16 author of this document, doctor?

17 A. I was, that's correct.

18 Q. Thank you. I'm not going to go through it in detail for  
19 a number of reasons. Firstly it covers some ground we  
20 have covered previously and I don't want to duplicate  
21 matters. In addition, the question of donor exclusion  
22 for AIDS we will come to tomorrow and also, as I say,  
23 between us we will produce a short note listing the  
24 various guidance documents during the relevant periods.  
25 But there are two pages I would like to go to, please,

1 to pick up something you mentioned earlier. Can we go  
2 to page 12, please, of the document.

3 Under paragraph 5 there is the heading  
4 "Standardisation of donor selection policies within the  
5 SNBTS and across the UK."

6 Could you, please, read that paragraph, doctor  
7 commencing:

8 "It had become clear ..."

9 A. "It had become clear as the response to the challenge of  
10 keeping the blood supplies as safe as possible from the  
11 threat of HIV developed that the differences in approach  
12 between regions and across borders were difficult to  
13 justify. At the request of the SNBTS national medical  
14 director, Dr Gillon was asked to prepare a paper  
15 comparing donor selection policies in the five Scottish  
16 regions. This paper, dated 1 November 1985, was  
17 discussed by the co-ordinating group on 30 April 1986".

18 Q. Can I stop you there, please, doctor, just to look at  
19 each of these documents.

20 Firstly your paper dated 11 November 1985 is  
21 reference [\[SNB0039864\]](#). We can see this document is  
22 headed "Report for the national medical director and the  
23 regional directors of the SNBTS on donor selection  
24 criteria". I think you are the author of this document,  
25 doctor?

1 A. Yes.

2 Q. The background explains that:

3 "The guidelines on the care and selection of blood  
4 donors issued by the NBTS ..."

5 So these are the guidelines by the NBTS of England  
6 and Wales:

7 "... have been felt in the SNBTS to require  
8 adaptation. The national medical director and the  
9 regional directors therefore asked me to prepare  
10 a report comparing donor selection practices in the five  
11 Scottish regions in an attempt to assess the  
12 significance of the existing differences in practice  
13 between the SNBTS centres and the NBTS guidelines."

14 You then explained your method:

15 "By comparing our present selection criteria in the  
16 SEBTS, which are codified by diagnosis and are kept  
17 up-to-date with the NBTS document, I identified a list  
18 of conditions where differences of interpretation  
19 existed and in others where no difference existed, which  
20 might prove contentious in other centres. I then  
21 arranged with the RTDs to discuss these issues with the  
22 most appropriate personnel in each centre and to ask  
23 their views on the NBTS document."

24 It is interesting perhaps, doctor, in the first  
25 sentence there you say that:

1           "By comparing our present selection criteria in the  
2           SEBTS, which are ... kept up-to-date with the NBTS  
3           document."

4           I misunderstood the position. Do you know what  
5           influence, if any, did the NBTS guidelines have in, for  
6           example, the southeast region in Scotland when you were  
7           there in 1983/1984?

8    A. It's hard to be categorical about that. What  
9           I inherited from my predecessor was quite similar to the  
10           document you showed from 1987 in presentation, and  
11           that's where I refer to conditions being listed by  
12           diagnosis. It was an A to Z of conditions built up  
13           through experience, I presume over years, but possibly  
14           influenced by previous guidelines from NBTS. I don't  
15           know that for sure but it was a comprehensive A to Z  
16           listing of conditions with advice for the session staff.

17   Q. I understand. You then explain the result:

18           "There was general agreement that the NBTS  
19           guidelines were unsatisfactory in format. The  
20           information was felt to be badly presented and in  
21           particular there was unanimous criticism of the system  
22           of lists and sublists of conditions, and in addition to  
23           this, every centre criticised particular items in the  
24           NBTS guidelines, although there was no uniformity of  
25           topic criticised. Listed below are the most obvious

1 areas of disagreement in no particular order."

2 Could we then forward, please, to page 4, which is  
3 9867. Before we look at conclusions, just an issue of  
4 tattooing above that. We see that Glasgow would like to  
5 see a more liberal view taken in view of the fact that  
6 most two-ear piercing salons are now accredited to use  
7 sterile techniques:

8 "At present they use the same criteria as other  
9 centres, namely that donors should be deferred for six  
10 months after any tattooing but this is perceived as  
11 a significant and unnecessary source of deferrals. All  
12 other centres use a six-month deferral period."

13 What was the purpose or point of having a six-month  
14 deferral period after having had a tattoo?

15 A. Essentially that sprang from the fear of hepatitis and  
16 six months was chosen as a long enough period to allow  
17 the development of Hepatitis B, which would then be  
18 detected by the routine screening.

19 Q. I understand. We then see your conclusions:

20 "No doubt minor differences exist other than those  
21 discussed above but it can be seen that major  
22 differences of opinion are few. Many of the differences  
23 relate to local factors, eg the call-up interval in  
24 Glasgow, and any guidelines could readily be designed to  
25 accommodate such differences where no scientific

1 principles are thought to be at issue."

2 And the last paragraph. You state:

3 "I formed the impression that all centres were  
4 willing to attempt to reach a consensus. The evidence  
5 obtained suggests that this would be relatively easy to  
6 achieve. While the information in any such document  
7 could be based on the NBTS guidelines with amendments  
8 derived from the above data, it would be important to  
9 strive for a clear and practical way of presenting the  
10 data."

11 So, doctor, when you examined the practices in each  
12 of the Scottish regions in 1985 in respect of their  
13 donor selection policies, did you find a wide variation  
14 of practice or reasonable consistency or what?

15 A. There was a core of consistency, which is almost what's  
16 missing here. We were by then using exactly the same  
17 policies and procedures for hepatitis and HIV and  
18 transmissible conditions such as this. For instance,  
19 the acceptance of jaundice donors and so on. So really  
20 we were working at the margins, largely on issues of  
21 donor safety rather than patient safety. By and large  
22 I think as far as recipient safety was concerned, there  
23 was greater commonality. But for the central core  
24 significant issues of patient safety, I don't think  
25 there was any significant difference.



1 Q. Then to complete this document, over the page at page 5,  
2 which is reference 9868, we see "Recommendations":

3 "1. The NBTS guidelines should not be adopted by  
4 the SNBTS in their present form.

5 "2. If the SNBTS directors are unanimously in  
6 agreement, a comprehensive set of selection criteria  
7 based on the present Edinburgh handbook and taking  
8 account of the various points that have been raised  
9 during this survey should be prepared in draft form for  
10 discussion.

11 "I feel that the differences between the centres are  
12 small enough for this to be undertaken by one person  
13 rather than by a working party or committee. Any such  
14 document would naturally have to be flexible enough to  
15 take account of local factors and also be designed in  
16 a way which allows easy updating."

17 Finally on this point, doctor, could we go to  
18 document [\[SNB0039905\]](#)?

19 Now, these are the minutes of an additional  
20 co-ordinating group meeting of the SNBTS held on  
21 30 April 1986. We can see those present included  
22 Dr McClelland, who chaired the meeting, Dr Brookes,  
23 Dr Mitchell, Dr Perry and Miss Corrie. We can then see  
24 under paragraph 1:

25 "Dr Gillon, Edinburgh, attended for item 2."

1 Under item 2 we can see donor selection criteria.  
2 In short, you introduced the paper we have just looked  
3 at and we can see underlined the words:

4 "Those present agreed that there was a need for  
5 an SNBTS set of criteria to serve as a framework for use  
6 by medical officers and other team staff. It was agreed  
7 that it was for each centre to decide who should take  
8 clinical decisions on donor acceptance."

9 The next words underlined:

10 "The directors at present agreed to recommend to the  
11 full co-ordinating group that the standard guide should  
12 be produced and that the Edinburgh document provided  
13 a basis for this and could be amended in discussion with  
14 the directors. Miss Corrie undertook to send a copy to  
15 each director who had not been present and everywhere  
16 was asked to send comments to Dr Gillon."

17 We can put that to one side, please. I think in  
18 short, doctor, a common set of guidelines were in due  
19 course agreed by the SNBTS transfusion directors?

20 A. Eventually, yes.

21 Q. Could we just complete, doctor, the document  
22 [\[PEN0100365\]](#). This was your donor selection policies  
23 and procedures document. At page 12, please, returning  
24 to paragraph 5 but half way through you say:

25 "It was minuted at the meeting we have just looked

1 at that the directors agreed that a standard set of  
2 criteria should be produced based on the A to Z  
3 guidelines then in use in Edinburgh. The first such  
4 guidelines were finally agreed and issued in 1988.  
5 A formal comparison of how information about AIDS was  
6 provided to prospective donors was carried out at the  
7 request of the NMD in November 1987."

8 Then the next paragraph is to do with AIDS. I'm  
9 going to skip that. Over the page for the final  
10 paragraph in this document. Could you please just read  
11 the paragraph commencing:

12 "At around the same time ..."

13 A. "At around the same time, two UK national developments  
14 were to have major impact on the service. The  
15 introduction of general management to the NHS and the  
16 publication of the first guidelines for the blood  
17 transfusion services in the United Kingdom, to become  
18 known as 'the red book' in 1990. This joint initiative  
19 of the regional transfusion centres and the National  
20 Institute for Biological Standards and Controls had been  
21 set in motion in 1987 with view to complying with the  
22 imminent EU Directive which would bind member states to  
23 introduce strict product liability by July 1988.

24 "Since then seven editions of the red book have  
25 appeared and the expert group devising the guidelines



1 Mr Laing, the question arose as to what guidance had  
2 been in place in respect of accepting donors who had  
3 a history of transfusion. Doctor, I have gone over the  
4 documents we have to try and identify what guidance  
5 there was. Perhaps I could simply take you through  
6 those documents so they are part of the record.

7 It also occurred to me, doctor, that I'm not sure we  
8 have identified all of the guidance which refers to  
9 excluding drug addicts during the last few days of  
10 evidence. So I have also taken the opportunity for  
11 completeness to try and identify all the guidance that  
12 I can find suggesting that drug addicts should not be  
13 accepted as donors.

14 With that background, doctor, could I first please  
15 refer you to document [\[PEN0020462\]](#).

16 I'm taking this short. This is 1971. WHO guidance  
17 on the formation and operation of the transfusion  
18 service. In particular it appeared to be directed to  
19 perhaps developing countries, at least countries which  
20 were starting off in creating such a service.

21 If we could, please, go straight to page 0472, which  
22 is original page 15, a chapter, "Recruitment of blood  
23 donors". Under "Basic systems" it is explained:

24 "There are three basic systems of obtaining blood  
25 donors: (a), paid donation, (b) the bank system and (c),

1 voluntary unpaid donation."

2 Under "Paid donation", midway it states:

3 "Moreover, there is a danger that donors in need of  
4 money will conceal previous illnesses, such as  
5 jaundice."

6 Two sentences on:

7 "This, together with the indisputable fact that such  
8 donors mostly come from the lowest social strata where  
9 alcoholics and drugs addicts are often found, has  
10 brought paid blood donation into disrepute in many  
11 places."

12 I appreciate, doctor, we have never had a paid  
13 system in Scotland. It is simply the reference to drug  
14 addicts I bring out for the record.

15 The next document is [\[DHF0012672\]](#). Again, we have  
16 looked at this document before. It is the 1976 ISBT  
17 criteria for the selection of blood donors. If we can  
18 go, please, to page 2683 --

19 THE CHAIRMAN: Before we go there, you have assented to the  
20 proposition that in Scotland there have never been paid  
21 donors. I understand the position to be that before  
22 1940 some areas did pay donors but it was with the  
23 formation of SNBTA that a general prohibition emerged.  
24 Do you know anything about the history as far back as  
25 that?

1 A. I am afraid I don't, but it is certainly the case that  
2 since John Copland formed the SNBTA there have been no  
3 paid blood donors in Scotland.

4 THE CHAIRMAN: I think it is safe to take it from then  
5 rather than forever.

6 MR MACKENZIE: Thank you, sir.

7 Dealing with document [\[DHF0012672\]](#), we have gone to  
8 page 2638, under "Viral hepatitis" it states:

9 "Prospective donors should be excluded if it is  
10 known that they too have received a transfusion of blood  
11 or blood products within the last six months."

12 Do you know, doctor, what would have been the reason  
13 for that exclusion?

14 A. I'm sure that at that time that would have been in  
15 relation to the risk of hepatitis.

16 Q. Then over the page, please, under 5, another category of  
17 donors to be excluded are those who are suspected to be  
18 parenteral drug addicts. We can put that document to  
19 one side, please.

20 The next document is [\[SNB0025348\]](#). We can see from  
21 the heading, "The National Blood Transfusion Service of  
22 England and Wales, memorandum on the selection medical  
23 examination and care of blood donors." Can we go,  
24 please, to page 5348, and we can see about half way down  
25 the page, "Conditions which necessitate temporary

1           deferment are as follows", and then subparagraph (v):

2           "If transfused with blood or plasma within the last  
3           six months."

4           There is a temporary deferment of six months. We  
5           can see that, doctor.

6           Can we then, please, go to page 5352? Half way down  
7           the page we can see the sentence:

8           "Elicit drug taking, if admitted or suspected,  
9           should debar."

10          Again, simply for the record, sir, there are similar  
11          provisions in respect of transfusion and drug use in the  
12          subsequent NBTS guidance in 1983, which is [\[SGF0010377\]](#);  
13          in 1985, which is [\[DHF0018931\]](#) and in 1987, which is  
14          [\[SNB0066410\]](#).

15          Could we look at the next document, please, which is  
16          [\[LIT0013627\]](#).

17   THE CHAIRMAN: Pause a minute. I would like to make sure  
18                I have the correct notes of those references. You gave  
19                them quite quickly. Yes. I see that there is one where  
20                I may have transposed. DHF0018391 or 8931?

21   MR MACKENZIE: 8931.

22   THE CHAIRMAN: 8931. Thank you.

23   MR MACKENZIE: I should perhaps read them all again just to  
24                check. The 1983 guidance is reference number  
25                [\[SGF0010377\]](#). The 1985 guidance is [\[DHF0018931\]](#) and the



1 1987 guidance is [\[SNB0066410\]](#).

2 THE CHAIRMAN: Thank you.

3 MR MACKENZIE: The next document, doctor, is WHO guidance in  
4 1978. If we can go, please, to page 3651. Under  
5 "Infectious diseases" we see:

6 "Donors shall have a negative history of viral  
7 hepatitis, of close contact with an individual with  
8 hepatitis within the past six months, or receipt within  
9 six months of human blood or any blood component or  
10 fraction that might be a source of transmission or viral  
11 hepatitis."

12 If one goes over the page as well, at the top, what  
13 is, I think, noteworthy in this document is that there  
14 is no reference to excluding those with a history of  
15 drug use. The document is silent in that regard.

16 The next document, please, is [\[PEN0020249\]](#). This  
17 document is the 1979 DHSS standards for the collection  
18 and processing of blood and blood components, et cetera.  
19 If we can go, please, to page 0253, at the bottom of the  
20 left-hand column, paragraph 1.5.1:

21 "The following illnesses or conditions disqualify  
22 a person from acting as a donor."

23 Then the list includes illicit drug taking. If we  
24 go to paragraph 1.5.3 at the bottom of the right-hand  
25 column, we can see 1.5.3 provides:

1           "The following illnesses, conditions or  
2           circumstances necessitate temporary deferment."

3           Over the page, please, we can see the words  
4           "transfusion within the last six months". Then the  
5           second last document in this regard, please,  
6           [\[PEN0131395\]](#). This is the Glasgow donor selection  
7           leaflet, apparently from June 1983, which we have looked  
8           at before, and I think there is no reference at all,  
9           doctor, in this leaflet to either drug use or previous  
10          blood transfusion. Is that correct?

11        A. That's correct, yes.

12        Q. Then finally can we look, please, at [\[SGF0010397\]](#) if we  
13          look at the top right-hand corner, we see a reference  
14          NBTS 1105 Rev 1983. So I think this bears to be an NBTS  
15          donor leaflet. Does that appear correct, doctor?

16        A. It does, yes.

17        Q. I think two things are noteworthy. Firstly, I think  
18          there is no reference in this leaflet to drug use but in  
19          the second paragraph donors are asked to advise if they  
20          have ever received a blood transfusion.

21        A. Yes.

22        Q. Doctor, these were the only references I could find to  
23          a history of blood transfusion. Have you undertaken  
24          your own researches in the past few days?

25        A. Yes, indeed, and I think it is clear from the historical

1 archive of donor selection materials that in SNBTS we  
2 were excluding donors with a history of transfusion for  
3 a year by the mid 1980s. I'm not sure exactly what  
4 date. I'm pretty sure that was in relation to reports  
5 of occasional late seroconversions in HIV cases, which  
6 turned out not to be substantiated. But I'm sure that's  
7 why it went from six months -- which had certainly been  
8 the case in Scotland prior to that -- to one year, which  
9 remained the case until 2004.

10 Q. Just to clarify that, doctor, there are perhaps two  
11 things. The first matter is how long ago did the donor  
12 receive the transfusion and the second matter is for how  
13 long should they be deferred. So when you say that  
14 there was deferral of donors for one year, does that  
15 relate to the first or the second matter?

16 A. I think it's the same thing, isn't it? We would not  
17 accept a donor who had had a transfusion within the  
18 previous 12 months, from, I think, 1993-ish onwards.  
19 Prior to that, we would not have accepted someone with  
20 a history of transfusion in the previous six months.

21 Q. I see. Sir, I have --

22 THE CHAIRMAN: Could we just pause there? I'm slightly  
23 concerned that the dates don't quite match. If you look  
24 at line 23 on page 57, we were excluding donors with  
25 a history of transfusion for a year by the mid 1980s and

1           then at 58/13 it is from 1993-ish onwards. Now, I may  
2           have got a lot of things mixed up, as often happens.

3   A. 1983.

4   THE CHAIRMAN: 1983 it should be? Fine.

5   MR MACKENZIE: I have no further questions for Dr Gillon.

6           My learned friend Ms Dunlop has, I think, one or two  
7           questions arising from Dr Gillon's evidence last week on  
8           statistics, simply by way of minor clarification.

9                                Questions by MS DUNLOP

10   MS DUNLOP: Sir, you will recall that when Dr Gillon was  
11           here last week and was speaking to his statement,  
12           [\[PEN0010043\]](#), in one of the appendices there was what  
13           looked like a very short interval between the date of  
14           transfusion and the date of reporting. It was six  
15           months. I think you queried, sir, whether that might be  
16           a mistake, whether the 1988, where it appeared as the  
17           date of reporting, might be 1998, and Dr Gillon has  
18           looked into that and in short, Dr Gillon, the answer is  
19           it is not a mistake. Is that right?

20   A. That's correct. I have looked back at the history of  
21           that case, as far as I can, and the patient was  
22           transfused in October 1987. Is that the correct year?

23   Q. Yes.

24   A. And was identified as having hepatitis in December of  
25           that year. This was a patient with chronic renal

1 failure who was under close follow-up.

2 Q. Would you like to see the page? Would that make it  
3 easier? It might make it easier to see the page. It is  
4 [\[PEN0010043\]](#), page 10.

5 THE CHAIRMAN: So this is somebody who is under surveillance  
6 anyway?

7 A. Yes, receiving regular dialysis treatment.

8 MS DUNLOP: And it is patient 9 in this table. There we  
9 have it.

10 Sorry, I interrupted you.

11 THE CHAIRMAN: I think we both did.

12 A. The first we heard of it was March 1998 which would be  
13 a very quick reporting of post-transfusion hepatitis  
14 event, but given that the patient had been identified as  
15 having had a hepatitic illness in December of that year,  
16 it fits perfectly well, and in fact this was when -- I'm  
17 not sure that we could really be sure when there was  
18 going to be a test for Hepatitis C but I do know that  
19 when we were looking at interesting samples to test when  
20 we were working with the prototype test, this was one of  
21 the samples tested and was shown to be Hepatitis C in  
22 fact. So in other words, that was retrospective.

23 Q. Thank you. That was all, sir. We just wanted, while  
24 Dr Gillon was here, to clarify that.

25 THE CHAIRMAN: That's fine. Thank you very much.

1                   Mr Di Rollo?

2                                   Questions by MR DI ROLLO

3 MR DI ROLLO: Just two matters. One is historical and one  
4 is asking about looking back from the perspective of  
5 today.

6                   In terms of the importance of targets, can you just  
7 tell us who was it that would set the targets for the  
8 collection of blood in 1985? How would that actually  
9 happen? Who would actually set the target?

10 A. My recollection is that there were meetings called  
11 supply and demand meetings, which were essentially  
12 regional transfusion directors and the national medical  
13 director, I think with representatives, certainly from  
14 PFC, I think also probably from the blood collection  
15 side, in other words the regional donor organisers. But  
16 primarily these were directors' meetings to set the  
17 requirements for red cells, plasma for fractionation for  
18 the coming year.

19 Q. Would they be set on a regional level or a national  
20 level?

21 A. A lot of work was done prior to the meetings saying, you  
22 know, "How has it gone for the previous year? How do  
23 you see things panning out in the next six months to  
24 a year". At the meeting it would be "Well, fine, but  
25 could you do it bit more" or, "What would you need to do

1 a bit more?" That would be the tenor of the discussions  
2 as I recall.

3 Q. Would each region have its own target or would there  
4 be national Scottish targets?

5 A. As I recall there would be regional targets. There is  
6 an issue which I don't remember seeing mentioned in the  
7 Inquiry before, which is that of hyperimmune plasma,  
8 which was certainly one of the issues that was discussed  
9 at that meeting and took a great deal of effort. And  
10 that was obtaining -- usually by plasma phoresis but not  
11 always -- supplies of plasma from donors who had a high  
12 level of an antibody that could then be manufactured  
13 into a specific immunoglobulin, such as anti-tetanus.

14 These were complicated procedures. Anti-D was  
15 perhaps the major immunoglobulin concerned and there was  
16 a lot of work necessary to ensure regular supplies of  
17 the source materials for that. So that would have been  
18 quite a big part of the discussion at that meeting.

19 Q. So did the regional director then say, "This is what  
20 I need for my region", and he would be responsible for  
21 that or would there be an overarching Scottish view of  
22 it?

23 A. I think the overarching Scottish view would have been  
24 what was needed for patients. The regional director  
25 would be mainly in the position of saying, "This is what

1           we can supply and this is what we will need if we are to  
2           supply more", or whatever it is.

3   THE CHAIRMAN: Can I follow that just a little bit,  
4           Mr Di Rollo?

5   MR DI ROLLO: Yes, of course.

6   THE CHAIRMAN: I do have an interest in the nature of that  
7           exercise and in the exercises generally that were  
8           carried out to forecast the levels of supply that PFC,  
9           for example, might be able to achieve.

10           One of the problems that I might want to look at in  
11           due course is what the focus was. If one looks at their  
12           needs for surgical procedures, I would have thought that  
13           perhaps the level of demand might be fixed by the  
14           clinicians who were likely to be in charge of performing  
15           those procedures. But I'm not sure that I have seen any  
16           input from that quarter being fed through. Rather, the  
17           impression is that what one sees in the documents is  
18           material coming from the regional transfusion directors  
19           as to the levels of material that they will be likely to  
20           be able to provide, and we know, for example, that in  
21           Glasgow, for quite a long period of time, a lot of the  
22           collections went to the production of specific products  
23           and material didn't go to Edinburgh at all. One might  
24           say there was a certain level of tension coming through.

25           But where did the information about the demand for



1 red cells come from, for example? Did it come into this  
2 particular group or was it only plasma that came into  
3 this group? I don't know at the moment.

4 A. I think, in effect, red cells did not come into the  
5 equation for the simple reason that we were clearly, by  
6 the early 1980s, driven by the need for plasma and if we  
7 were to meet the needs of plasma for fractionation,  
8 which was largely driven by Factor VIII production, we  
9 would have an excess of red cells.

10 THE CHAIRMAN: So far as that is concerned, was there  
11 a supply of information about the total demand for the  
12 product or only the demand that PFC would be required to  
13 meet; in other words, did you know about total demand,  
14 including commercial products, at the time of these  
15 planning meetings or did you only know what was likely  
16 to be required for PFC production?

17 A. I'm not sure I can answer that. I would not have  
18 attended the meetings at national level.

19 THE CHAIRMAN: Perhaps someone can take it on later because  
20 there is perhaps quite a big issue around this.

21 Now, Mr Di Rollo, I merely want to widen that.  
22 I don't think that Dr Gillon is the right person to  
23 answer all the questions but if I have flagged up an  
24 area for investigation.

25 MR DI ROLLO: I'm very much obliged.

1           The other matter I wanted to ask about is that you  
2           have obviously conducted an exercise in order to  
3           examine, looking back, the position in relation to not  
4           rejecting donors with a history of jaundice, and I think  
5           you have provided us with a paragraph, paragraph 7.4 in  
6           your statement. You have provided us with an indication  
7           of how it looks in terms of the position. What I would  
8           like to ask you is this: would it be legitimate, knowing  
9           what we know now -- and I appreciate that is an  
10          important qualification -- to say that it's all right to  
11          carry on knowing that you would infect 15 recipients  
12          with HCV?

13        A. Well, I think the point is that nobody knew then.

14        Q. I understand that. I understand that's a very important  
15          qualification. They didn't know. You have made it  
16          clear that that is an important feature of what you say.  
17          What I'm asking you is: would it actually be legitimate,  
18          knowing what we know now, to take that decision?

19        A. Your use of the word "legitimate".

20        Q. Would it be an acceptable clinical decision to make?

21        A. Some people would say "Yes", some people might say "No".

22        Q. What would you say?

23        A. I find it impossible to look back and make a decision  
24          that would have been relevant to what I would have done  
25          at the time. I simply did not know and nobody else knew

1           what the prevalence was in that particular segment of  
2           the donor population. But the evidence we had suggested  
3           that the prevalence was likely to be quite low.

4    Q. I understand all of that. That's not, with respect,  
5           what I'm actually asking you. I'm just asking what you  
6           would say now?

7    A. I'm saying it is a hypothetical question I can't answer.

8    MR DI ROLLO: Thank you, sir.

9    THE CHAIRMAN: Doctor, I suppose if one applied the  
10           protective principle at its extreme, any risk would be  
11           unacceptable, would it?

12   A. Yes. And in fact, if we turned away 10,000 donors in  
13           1986, we would have saved ten transmissions. We would  
14           have prevented ten donors with Hepatitis C from coming  
15           into the system but we would have had no blood on the  
16           shelves.

17   THE CHAIRMAN: When it comes to the final decision on any of  
18           these matters, is there a balance of risk and benefit  
19           that has to be struck?

20   A. There isn't a defined balance of risk and benefit.

21   THE CHAIRMAN: No.

22   A. There is no figure that I'm aware of that anybody has  
23           ever put on it that you could say, "Yes, at this level  
24           this is a risk worth taking".

25   THE CHAIRMAN: I'm not thinking of a figure, I'm thinking of

1 an exercise of judgment that has to be carried out.

2 A. It is just that, sir. But I think the people having to  
3 make the decisions at the time have to exercise judgment  
4 and some of that is intuitive, some of that is based on  
5 experience.

6 THE CHAIRMAN: Mr Di Rollo, is that the sort of area we are  
7 in?

8 MR DI ROLLO: I think so.

9 THE CHAIRMAN: Do you want to follow it in any way?

10 MR DI ROLLO: I'm content. I think the witness has  
11 indicated what his position is, as I understand it.  
12 Sir, I'm content with that.

13 THE CHAIRMAN: Mr Anderson?

14 Questions by MR ANDERSON

15 MR ANDERSON: If I may, sir, thank you.  
16 Dr Gillon, I think you were present yesterday when  
17 Professor Cash was giving evidence. Is that correct?

18 A. Yes, that's correct.

19 Q. You will recall that a large part of his evidence  
20 concerned what appeared to be the unilateral decisions  
21 of the various regional centres in Scotland to stop  
22 taking blood from prisons. Do you remember that?

23 A. Yes.

24 Q. And we hear, for example, that the Southeast first  
25 stopped in December 1981, followed by the Northeast,

1 East and the North in 1983, and then finally by the West  
2 in March 1984. You may recall that Professor Cash was  
3 asked for his views on whether there was information  
4 available from the mid to late 1970s which might suggest  
5 that such decisions could have been taken earlier. Do  
6 you remember that passage?

7 A. Yes.

8 Q. Were you present when the chairman, quite late on in the  
9 afternoon, seemed to suggest that material was available  
10 from which it might be inferred that those who  
11 ultimately took the decisions might have taken them  
12 earlier? Do you remember that?

13 A. Yes, I do.

14 Q. That, I think, was a reference to various papers which  
15 we will come to look at; that is to say the Wallace  
16 paper in 1972, the Prince paper in 1974, the Hoofnagle  
17 paper in 1977 and the Berman paper in 1979. Is that  
18 right?

19 A. Yes.

20 Q. Before we look at those papers, doctor, can you just  
21 tell us a little about the nature of Hepatitis B, for  
22 example in relation to how infectious it is?

23 A. Hepatitis B is a very infectious virus and if we look at  
24 the issues that we are talking about, there is  
25 a gradation from Hepatitis B being highly infectious

1 through HIV being pretty infectious to Hepatitis C, as  
2 it is now known, being not very infectious.

3 It was known by the mid 1970s that Hepatitis B in  
4 any sort of residential setting was likely to spread and  
5 in fact, close family members of people with acute  
6 Hepatitis B or high level carriers of Hepatitis B are at  
7 risk in a way that, for instance, with Hepatitis C  
8 family members are not, just through everyday contacts,  
9 excluding sexual contacts from this discussion.

10 Listening to the discussion yesterday, it struck me  
11 that the assumption that the reference to social and  
12 hygiene issues being code for homosexuality was not  
13 necessarily correct. We also had reference yesterday to  
14 the outbreak in Edinburgh in 1970, when members of staff  
15 were infected with Hepatitis B. They weren't all  
16 sticking needles in themselves. It is a highly  
17 infectious virus.

18 I think that in situations like a prison, like  
19 a residential school, any institutionalised situation  
20 like the armed forces perhaps, Hepatitis B could spread  
21 quite readily.

22 Q. We hear a lot in the press, of course, about the  
23 overcrowding of prisons and we know that prisoners share  
24 cells, washing facilities, eating facilities, toilet  
25 facilities. Presumably on that basis it wouldn't be

1 entirely surprising if Hepatitis B was more prevalent in  
2 such an institution. Would that be fair?

3 A. I think that's exactly right.

4 Q. Yes. If we always keep in mind we are talking about the  
5 period from the mid to the late 1970s, doctor; standing  
6 what was known about non-A non-B hepatitis at that time,  
7 do you think there was any basis for an assumption that  
8 a greater than normal prevalence of Hepatitis B in any  
9 one group, for example prisoners, would necessarily  
10 indicate the presence of non-A non-B hepatitis?

11 A. I don't think it would necessarily imply that but it was  
12 realised and the evidence -- which was very recent;  
13 non-A non-B hepatitis was only described as such in  
14 1974/1975 in the context of transfusion transmission.  
15 Therefore there was, I think, widespread acceptance that  
16 there was probably some other agent or agents which was  
17 blood-borne. Hepatitis B is a blood-borne virus. You  
18 could make that inference but the two don't necessarily  
19 follow, I don't think.

20 THE CHAIRMAN: I'm not quite sure I understand. I'm sure  
21 you will appreciate that when I ask a question it  
22 doesn't imply that I have a pre-conceived answer to it  
23 that Mr Anderson seems afraid about.

24 My interest at this point is that, with the  
25 description of a condition, non-A non-B hepatitis, and

1 the growing appreciation that Hepatitis B didn't  
2 contribute a huge percentage of the overall hepatitis  
3 that was identified -- and Hepatitis A could be excluded  
4 in a whole range of ways -- there was, I think you have  
5 said now, a growing appreciation that there was  
6 something else that was causing hepatitis?

7 A. Yes.

8 THE CHAIRMAN: And one didn't know what that was.

9 A. Absolutely no idea what it was, how much of it there was  
10 around or how dangerous it was.

11 THE CHAIRMAN: But those are different points.

12 A. Yes.

13 THE CHAIRMAN: Not to know about it might have implied  
14 a question as to whether Scotland was doing its bit. To  
15 know about it and form a view about its relevance has to  
16 involve additional factors.

17 A. Yes.

18 THE CHAIRMAN: One would be the geographical question,  
19 whether it was local to Scotland or local just to  
20 America.

21 A. Indeed.

22 THE CHAIRMAN: The next would be whether it was something  
23 that had adverse long-term consequences or not. So  
24 there is a whole number of strata of information that  
25 come into making a judgment.



1           My interest, doctor, is in finding out whether there  
2           was a process of reasoning at the time that led to  
3           a particular view about this unknown percentage of  
4           unidentified hepatitis or not in the first place, and in  
5           the second place, just exactly what the process of  
6           reasoning from time to time was. And I would expect it  
7           to change. So if you can help me with that sort of  
8           approach, I would be very obliged.

9    A. I'm not sure that I can, sir. My impression, listening  
10       to it all and looking at the papers and the evidence and  
11       so on, is that there probably was very little reasoning,  
12       in the sense of thinking, "Oh, two and two makes --

13   THE CHAIRMAN: Five.

14   A. -- five. We must look at prisons." I don't see that  
15       that happens. I think the focus on prisons had been  
16       largely in relation to Hepatitis B, and the feeling was  
17       that testing had reached the level of sensitivity that  
18       took that off the radar to some extent.

19   THE CHAIRMAN: Yes. I know that there is English material  
20       in particular, showing the transfusion directors there  
21       thinking about cutting prisons out in as early as 1973,  
22       which was on the basis of Hepatitis B. But even in that  
23       context the confidence that one might legitimately have  
24       in the testing procedures would change perceptions over  
25       time.

1 A. Yes.

2 THE CHAIRMAN: Mr Anderson, it's that sort of history I'm  
3 interested in and I hope that with other witnesses you  
4 and Mr Mackenzie will be able to help me in due course.  
5 I do have to try to get a picture.

6 MR ANDERSON: I understand that entirely, sir. What  
7 concerned me slightly was the suggestion we would return  
8 to this. If the exercise is to understand the thinking  
9 that went on at the time, it seemed to me that we were  
10 in danger of running out of witnesses who would actually  
11 assist us with that. So the purpose in exploring this  
12 with this particular witness was an attempt to obtain,  
13 I hope, a dispassionate and objective, if possibly  
14 retrospective, view of the thoughts of those involved at  
15 the material time.

16 THE CHAIRMAN: But unless I have got things wrong,  
17 Mr Mackenzie has been focusing on high risk donors at  
18 the moment and we are going to come back later to the  
19 more general history. But I may have got it entirely  
20 wrong, of course.

21 MR MACKENZIE: Sir, I think to some extent, yes, not in this  
22 topic but --

23 THE CHAIRMAN: No, not in this topic, but that's the point,  
24 it is not in this topic we are coming back to it; we are  
25 coming back to look at the topic of hepatitis more

1 generally.

2 MR MACKENZIE: In particular Professor Howard Thomas has  
3 agreed to come along after summer and we can no doubt  
4 explore the relevant history with him.

5 MR ANDERSON: That's encouraging, but, of course, we don't  
6 know that.

7 THE CHAIRMAN: Of course, Mr Anderson, I have set myself  
8 apart from it and I don't really know it all either.  
9 I'm trying to learn as we go, the same as you.

10 MR ANDERSON: We are in the same boat then, sir.

11 Perhaps I can finish this. It won't take long and  
12 it may be of some assistance.

13 I think you may have covered this, Dr Gillon, but  
14 again, always remembering that we are talking about the  
15 period from 1975 to 1979, what was known of the  
16 prevalence of non-A non-B hepatitis at the time?

17 A. In the UK virtually nothing, in fact literally nothing  
18 because, as far as I am aware, the first prevalence data  
19 on transfused patients was published around 1978 by the  
20 Newcastle group. I think that was the first information  
21 we had.

22 Q. It may be obvious from that reply, but what was known  
23 during that period -- that is to say, 1975/1979 -- about  
24 the effect of non-A non-B hepatitis?

25 A. Again very little indeed. The initial feeling -- and of

1 course, by "hepatitis", what we are talking about here  
2 is recognising liver function test abnormalities in  
3 people who were asymptomatic, almost by definition.  
4 Nothing much was known about either the chronicity or  
5 the severity of the disease for several years.  
6 Information came out in a rather piecemeal way,  
7 obviously, as it does.

8 Q. Can we look very briefly at these articles, please. The  
9 first is [\[SGH0029831\]](#). This is the Wallace article in  
10 1972. We see from the summary in the top left:

11 "Men prisoners have a significantly higher incidence  
12 of Australia antigen than non-institutionalised men."

13 Do you see that?

14 A. Yes.

15 Q. If we go over the page to the second column, headed  
16 "Incidence", about one third of the way down it tells  
17 us:

18 "The high incidence of Australia antigen of one in  
19 153 in men prisoners has no obvious explanation. Viral  
20 hepatitis is not a serious clinical problem in the  
21 two institutions concerned and the positive donors are  
22 not drug addicts. What is not known is whether or not  
23 these men were Australia antigen-positive at the time of  
24 their first imprisonment. The high incidence may be  
25 related to social habits and to hygiene."

1           If we just pass from that, we then come to the  
2 Prince article, which is [\[LIT0010363\]](#). We see here in  
3 the summary:

4           "An agent other than Hepatitis B virus seemed to be  
5 the cause of 36 of 51 cases of post-transfusion  
6 hepatitis ..."

7           Do you is see that?

8 A. I do, yes.

9 Q. And then if we turn to the final page -- that's 0368 --  
10 the authors conclude by saying this:

11           "The fact that non-B hepatitis cases are less  
12 frequently associated with serious acute illness does  
13 not imply that such cases are of lesser importance.  
14 Long-term complications of acute Hepatitis B infection,  
15 such as chronic hepatitis, cirrhosis and hepatoma, have  
16 been reported to follow mild anicteric infection more  
17 frequently than severe icteric cases. Consideration  
18 must thus also be given to the possibility that non-B  
19 hepatitis may play a role in the aetiology of some forms  
20 of chronic liver disease."

21           They conclude:

22           "Our findings imply that an substantial proportion  
23 of post-transfusion hepatitis cases is caused neither by  
24 HB virus nor Hepatitis A agent and suggest the existence  
25 of an additional virus(es), hepatitis type C."

1           Is this the first public dissemination, as it were,  
2           of the possibility of a virus other than A or B causing  
3           hepatitis?

4    A.   I think it probably is.  It's certainly the publication  
5           I have in mind in reference to that.  But I have also  
6           seen reference to Harvey Alter having coined the term  
7           "non-A non-B hepatitis".  But it was around exactly the  
8           same time.

9    Q.   It may be axiomatic but this article doesn't mention  
10          prisons at all, does it?

11   A.   Not to my knowledge.  It was based entirely, as far as  
12          I remember, on post-transfusion hepatitis cases, which  
13          were identified by prospective follow-up.

14   Q.   The next that my friend Mr Mackenzie referred to  
15          yesterday is the Hoofnagle paper, and it is  
16          [\[LIT0013657\]](#), if we could have that on the screen,  
17          please.

18                I suppose the first thing one notices about this is  
19                that, unlike the Prince article, this actually makes  
20                reference specifically to non-A non-B hepatitis.  Is  
21                that right?

22   A.   Yes.

23   Q.   We see the title, "Transmission of non-A non-B  
24          hepatitis".

25   A.   Indeed.

1 Q. Whereas Prince simply said there seems to be something  
2 else that isn't B or A. Is that right?

3 A. Yes.

4 THE CHAIRMAN: Could we get the date of that?

5 MR ANDERSON: Yes, sir, it is 1977. We see that in the very  
6 bottom right-hand corner.

7 If we return to the rubric, as it were, we see again  
8 what is said, eight lines up from the heavy type:

9 "Testing of serum samples from these recipients with  
10 hepatitis showed no evidence of Hepatitis B virus or  
11 Hepatitis A virus infection. This study and other  
12 recent evidence suggests that there is a third type of  
13 human viral hepatitis, non-A non-B hepatitis, which is  
14 due to a transmissible agent and may well be associated  
15 with a chronic carrier state."

16 Does that in effect tell us any more, doctor, than  
17 the Prince article did? The language seems to be  
18 remarkably similar.

19 A. It is very similar and, no, it is telling us nothing  
20 that in any way amplifies what the Prince articles tells  
21 us, as far as I can remember.

22 THE CHAIRMAN: What does the language tell us? You see  
23 lawyers tend to think of "may" as indicating a very low  
24 level of probability in any circumstances. Is  
25 scientific language rather different in its intent and

1 effect?

2 A. I think it takes into consideration the overall context,  
3 yes, I think in a different way. It is not purely  
4 hypothetical at this stage. In other words, they have  
5 found people who have evidence --

6 THE CHAIRMAN: That's the point --

7 A. -- of hepatitis.

8 THE CHAIRMAN: I would not want you to be associated with  
9 the thought that, because this says "may", it is an  
10 indication of a very low probability or nothing more  
11 than a possibility. It is not that, is it?

12 A. I would think not, no.

13 MR ANDERSON: I certainly didn't mean to suggest that and in  
14 fairness to the authors of the Hoofnagle article, we see  
15 that they actually say:

16 " ... may well be associated ... "

17 I think that may give an answer to the chairman's  
18 question itself.

19 A. But the statement obviously implies also that we don't  
20 know if it does.

21 Q. Finally, I think in this catalogue we have the Berman  
22 article. It is [\[LIT0010189\]](#). Again there is a specific  
23 reference to non-A non-B hepatitis but this concerns  
24 itself with the chronic sequelae of that hepatitis. Is  
25 that correct?



1 A. Yes.

2 Q. What is said there -- and this is half way through the  
3 rubric, as it were:

4 "Chronic non-A non-B hepatitis was symptomatically  
5 mild and unaccompanied by physical signs or laboratory  
6 evidence of autoimmune disease or severe chronic liver  
7 disease."

8 It concludes:

9 "Thus chronic active hepatitis is a common sequelae  
10 of acute non-A non-B hepatitis but it may have a better  
11 prognosis than chronic active hepatitis of other  
12 causes."

13 Whether the question, Dr Gillon, is whether it was  
14 reasonable to take no action or whether the  
15 investigation is as to the thinking behind it, can you  
16 help us with the impact that these articles cumulatively  
17 had upon the profession, particularly in relation to the  
18 question of the efficacy of continuing to take blood  
19 from prisoners?

20 A. Well, I think this was accumulating evidence that there  
21 was a problem, the magnitude of which was not at all  
22 clear. This is very important evidence in the sense  
23 that it was based on liver biopsies. So when they are  
24 talking about chronic persistent hepatitis and chronic  
25 active hepatitis, they are talking about findings on

1 pathological examination of a biopsy. But this is in  
2 the context of patients who are not experiencing  
3 symptoms to any significant extent and who have no  
4 physical evidence of chronic liver disease. These are  
5 patients who have been followed for quite some time, for  
6 greater than a year at least.

7 So there was evidence that there was something going  
8 on in these patients but it was far from clear what the  
9 ultimate significance of that would be.

10 Q. And these papers would be known or ought to have been  
11 known not only in Scotland but presumably in England,  
12 Europe and indeed the rest of the world. Is that right?

13 A. Indeed, and Professor Sheila Sherlock's textbook in  
14 1983 -- I think this was mentioned in the preliminary  
15 report -- was still describing non-A non-B hepatitis as  
16 essentially benign.

17 Q. Can we look briefly at the final article in this  
18 catalogue? This is the Barr, West of Scotland, one. It  
19 is [\[PEN0140068\]](#). This is 1981. So this, of course, is  
20 very close to the time that the practice began to be  
21 discontinued. We have looked already at the  
22 second paragraph, which says:

23 "Despite the high incidence of HBsAg in male  
24 prisoners, viral hepatitis is not a serious clinical  
25 problem in the institutions surveyed and the positive

1 donors are not drug addicts. This incidence is probably  
2 related to social habits and hygiene."

3 And so that appears to echo the very first of these  
4 articles, the Wallace one. Is that correct?

5 A. Yes, that's correct, yes.

6 Q. But they share a common author, do they not, because we  
7 see the lead author, apparently, or at least the  
8 first-named author, in the one we looked at in 1981 is  
9 A Barr. Is that right?

10 A. Yes.

11 Q. And he is one of the three authors of the Wallace paper  
12 as well. Is that correct?

13 A. Yes, he was one of the senior laboratory personnel.

14 Q. Now, we have heard some evidence about the increase in  
15 drug use, and the chairman in particular has been  
16 interested in the possible accuracy of the assertion  
17 that these donors were not drug addicts. But on the  
18 face of it both the Wallace article and the West of  
19 Scotland article say that the incidence is probably  
20 related to social habits and hygiene. Is that right?

21 A. Speaking about Hepatitis B?

22 Q. Yes.

23 A. Yes.

24 Q. So whether it is right or not, that's what any reader of  
25 the article would take from it, I assume. Is that

1 right?

2 A. Yes, and I think readers interested enough to read this  
3 would know about Hepatitis B and its mode of spread.

4 Q. Finally, doctor, on a quite separate matter -- and this  
5 concerns the cumulative effect of deferrals -- I think  
6 you have produced very recently -- indeed, I think I saw  
7 this for the first time last night -- a chart, which  
8 might assist visually in the understanding of this.

9 I regret this is not in the court book, sir, and  
10 I have a limited number of copies but it may be helpful  
11 and I simply put it up for such assistance as it gives.  
12 I have got copies which I can disseminate.

13 THE CHAIRMAN: If you can let us see it, perhaps you might  
14 actually try to convert it into narrative that will make  
15 sense.

16 MR ANDERSON: I was rather hoping the witness would do that,  
17 sir.

18 THE CHAIRMAN: If you tender it, Mr Anderson, I expect you  
19 to understand it. (Handed)

20 There are quite a few bits. Do you want to leave it  
21 to your witness?

22 MR ANDERSON: Your expectation may be disappointed, that's  
23 all I can say, sir, so I'm going to ask Dr Gillon.

24 We have a very colourful chart here, headed  
25 "Cumulative Effect of PTD Deferrals". Can you --

1 THE CHAIRMAN: I'm sorry, Mr Anderson, before you go any  
2 further, I think that a document like this must be  
3 identified for the future. How shall we do that? Shall  
4 we attribute it to you, "Mr Anderson 1", or would you  
5 prefer it was attributed to SNBTS1 or something like  
6 that?

7 MR ANDERSON: Whatever is easier for the Inquiry team.  
8 I don't mind.

9 THE CHAIRMAN: Is there any nomenclature that would be  
10 confusing. If we do call it "SNBTS1", are we going to  
11 get into a mess or ...?

12 What would be best? I would like consistency once  
13 we start on these things.

14 I'm sorry, Dr Gillon, but getting this right may  
15 seem a matter of no importance but I can assure you,  
16 many months down the line, when we go back over these  
17 things, it takes on a significance that you can't  
18 identify at the time.

19 What should we call it?

20 MR MACKENZIE: Sir, one possibility may be to use the prefix  
21 "HNR", to show that at least it has been produced during  
22 the hearing and it may be that some further details  
23 could be --

24 THE CHAIRMAN: That would be fine. That would mean we  
25 didn't have to distinguish among the various

1 contributors of documents and we just have a numerical  
2 list.

3 Are you quite happy with that, Mr Di Rollo?

4 MR DI ROLLO: Yes, thank you.

5 THE CHAIRMAN: So we will call it "[\[HNR0010001\]](#)".

6 MR ANDERSON: Thank you, sir.

7 Dr Gillon, can you look at the paper [\[HNR0010001\]](#)  
8 and explain to us in language that even lawyers can  
9 understand what it is that we can see here.

10 THE CHAIRMAN: Don't try to cover all lawyers, Dr Gillon.

11 A. This document is a fairly recent document provided to me  
12 by Dr Moira Carter, who is the national donor services  
13 manager for SNBTS.

14 I think I would like to restrict my comments to the  
15 first sheet. I'm not sure what the supplementary  
16 information behind would add to it.

17 The first sheet illustrates the point I made in my  
18 witness statement, sir, in that this derives from the  
19 decision in 2004 to permanently defer any donor  
20 presenting with a history of transfusion since 1980.  
21 This was done in response to the fear -- well, the  
22 knowledge that variant CJD had been transmitted by blood  
23 transfusion and this allowed us to follow prospectively  
24 the effects of banning a cohort of people in the sort of  
25 manner that I described in my witness statement, which

1 would apply to any, in broad terms, surrogate test,  
2 which in effect this is. You can see that  
3 implementation -- and that, I think, was a seventh-month  
4 period -- resulted in the loss of 6,735 donors.

5 Then, following the red columns, these are the  
6 annual total but cumulative numbers of donors deferred.  
7 So, in other words, that's the 635 from the first  
8 seven months and then the additional amount from the  
9 next year and the next year and so on, following the red  
10 columns. So by 2010/2011, based on year-to-date  
11 figures, because obviously we are still in that year,  
12 the loss of donors so far as has been 16,315.

13 The blue columns refer to an assessment -- this is  
14 based on an assumption of the frequency of donation that  
15 would have occurred from those donors -- of the number  
16 of donations lost over that period.

17 MR ANDERSON: But it is based on historical evidence?

18 A. This is based on real evidence of the number of donors  
19 deferred.

20 Q. Yes.

21 A. And it is quite clear, I think, that when you do ban  
22 a large swathe of donors, your loss is cumulative and  
23 that has to be made up for in some way.

24 I might add that the service did successfully make  
25 up for this loss of donors but at the cost of

1 1.3 million, I think, in the first year. So it is not  
2 easy to turn round this particular tank.

3 Q. Thank you very much, doctor, I have no more questions?

4 THE CHAIRMAN: Could I just understand your last answer?

5 The service did make up for the loss of donors at a cost  
6 of £1.3 million. That was the cost of commercial  
7 practices or what?

8 A. No, that was the cost of advertising, primarily, in  
9 various ways and scheduling extra sessions, making sure  
10 that enough donors come through the door to make up for  
11 the loss.

12 THE CHAIRMAN: So it is generating more donations at  
13 domestic level?

14 A. Yes, and a large slice of that was taken up with  
15 television adverts.

16 THE CHAIRMAN: Right. The donor base figures, what are  
17 they?

18 A. One of the ways that Moira Carter and her colleagues  
19 tried to prepare for this was to look at what had been  
20 happening in the donor base; in other words, the number  
21 of donors known to our system who are active, who had  
22 attended within -- I can't remember if it was the last  
23 year or last two years, and that constitutes the base  
24 number of donors that we know are active and can be  
25 called at any given time.



1 THE CHAIRMAN: And we can see a relative increase in the  
2 rate of growth in the numbers in the first period and  
3 then it flattens off a little as time goes on.

4 A. Yes, and that probably reflects the impact of the --

5 THE CHAIRMAN: Of the advertising, yes.

6 Mr Sheldon?

7 MR SHELDON: I have no questions, thank you.

8 THE CHAIRMAN: Thank you very much again. I expect we will  
9 be seeing you yet once more, if not more often than  
10 once, but thank you so far.

11 MR MACKENZIE: Sir, the next witness will be either Dr Perry  
12 or Dr Scott. I wonder, if I may, sir, request a very  
13 short adjournment just to clarify that.

14 THE CHAIRMAN: I think we can't call them both in the hope  
15 that one will turn up, so, yes.

16 (12.34 pm)

17 (Short adjournment)

18 (12.37 pm)

19 MR MACKENZIE: Thank you, sir. The next witness is  
20 Dr Perry.

21 DR ROBERT J PERRY (affirmed)

22 Questions by MR MACKENZIE

23 MR MACKENZIE: Good afternoon, Dr Perry.

24 A. Good afternoon.

25 Q. Could we start, please, by looking at your CV, which

1 will come up on your screen. Our reference number is  
2 WIT0030410.

3 A. Yes.

4 Q. And can we start with the qualifications, please,  
5 doctor? We can see you are obtained a Bachelor of  
6 Science honours degree in chemistry at the University of  
7 London in 1971. In 1975 at Manchester you obtained your  
8 PhD in chemistry. You are a member of the Royal Society  
9 of Chemistry. We also see you are the holder of  
10 "qualified person" status as defined by EEC Directive  
11 75/319/EEC. What does "qualified person" status mean?

12 A. It is a professional qualification, which is an  
13 experience-based qualification, but it is basically part  
14 of the EU regulations on pharmaceutical manufacture.  
15 Manufacturers of pharmaceutical products have to have  
16 people that have the appropriate qualifications for  
17 batch release, distribution of products to the market  
18 and so on. So it is a qualification which is, as I say,  
19 an experience-based qualification, which I actually  
20 received as a result of my experience in previous  
21 employment.

22 Q. I see. When did you become a qualified person?

23 A. I think, from memory, it was in the early 1980s,  
24 probably 1980/1981.

25 Q. Thank you. Turning then, please, to your employment

1 history, I would like to do this in chronological order,  
2 starting at the earliest date. So could we perhaps go  
3 to the next page, please?

4 We see that between 1971 and 1972 you were  
5 a biochemist in the Department of Chemical Pathology in  
6 Hammersmith, London, and then, in particular 1975 to  
7 1977, you were an analytical chemist with  
8 Severn Trent Water Authority. Briefly, doctor, what  
9 were your duties there?

10 A. In the Severn Trent Water Authority?

11 Q. Yes.

12 A. I was a member of a team that did analysis of water  
13 samples and various other materials that the water  
14 authority dealt with. It was an analytical role in  
15 a central regional laboratory.

16 Q. The next job up from that. I think between the years  
17 1977 and 1981 you were chief analyst at the regional  
18 Sterile Supply Unit, the West Midlands Regional Health  
19 Authority. What did that job entail?

20 A. The regional Sterile Supply Unit was  
21 a National Health Service pharmaceutical manufacturing  
22 unit set up by the West Midlands Regional Health  
23 Authority and its purpose was to manufacture sterile  
24 fluids, not blood products but injectable solutions,  
25 topical solutions, for use in the regional health

1 authority in the Midlands of England.

2 I was appointed as part of a team that was appointed  
3 to this new facility and my main role was to set up the  
4 laboratory, to set up the analytical procedures and to  
5 develop quality assurance systems for the manufacture of  
6 the products that the unit was there for. So it was my  
7 introduction to pharmaceutical manufacture. That's  
8 where I became involved in the business of  
9 pharmaceutical manufacture.

10 Q. Thank you. Could we go back to the first page of your  
11 CV, please? We then see at the bottom of the page  
12 between 1981 and 1984 you were quality control inspector  
13 at the protein fractionation centre. Is that correct?

14 A. That's correct.

15 Q. So you joined the SNBTS in 1981?

16 A. Yes, I think it was January or February, yes.

17 Q. Can you give us an indication of your main duties and  
18 responsibilities at that time?

19 A. Yes. This was a new post, that had been developed by  
20 the SNBTS and the protein fractionation centre. My  
21 understanding at the time was that the post had been  
22 created largely in response to the first of the  
23 medicines inspectors' reports of the protein  
24 fractionation centre, where the inspectors identified  
25 deficiencies in some of the procedural aspects,

1 documentation and so on, and the SNBTS and indeed the  
2 PFC felt it wanted to bring on board to its staff  
3 somebody with experience of basically setting up quality  
4 systems and quality procedures in a pharmaceutical  
5 environment. I was effectively employed and appointed  
6 to that role on the basis of my experience with the West  
7 Midlands Regional Health Authority.

8 Q. Thank you.

9 A. But I had no prior experience of blood or plasma  
10 products. This was a completely new area of endeavour  
11 for me.

12 Q. Yes, and then in 1984 I think you became director of the  
13 protein fractionation centre and you held that post  
14 until 2003?

15 A. That's right.

16 Q. Dr Perry, did you succeed Mr Watt in 1984?

17 A. I did. Obviously, I worked very closely with Mr Watt  
18 from 1981, and at the end of 1983 Mr Watt left the  
19 service. He had already indicated his intention to  
20 leave. I had applied for his job. He left slightly  
21 earlier than was anticipated and I was asked to,  
22 technically speaking, become acting director. So I was  
23 appointed as acting director in 1984 and that was made  
24 substantive in 1985.

25 Q. And between, say, 1984 to the end of the 1980s, can you

1        indicate your main duties and responsibilities in that  
2        post?

3        A. My responsibilities were effectively the operational  
4        management of the fractionation centre of the SNBTS, and  
5        my responsibilities covered everything from financial  
6        control, operational management to production, quality  
7        control, not single-handed, obviously -- I had a staff  
8        of about 200/250 people -- and also the research and  
9        development of new plasma products that the service  
10       wanted to bring into use.

11       I think the preoccupation at that time -- and there  
12       was absolutely no doubt in my mind that this was the  
13       case when I joined in 1981 and certainly strengthened as  
14       the 1980s moved forward, that the dominant goal and  
15       target was self-sufficiency. It was very clearly  
16       evident to everyone who worked in it that, in terms of  
17       plasma products, the goal and the aim was to make  
18       Scotland self-sufficient in plasma products and in  
19       particular coagulation factors.

20       Q. Thank you. Then from August 2003 until April 2004 you  
21       were seconded as personnel director of the SNBTS.

22       A. Yes.

23       Q. On the face of it that seems an odd move but perhaps you  
24       can explain that.

25       A. I think the organisation was going through change and

1 I had expressed an interest in this and my previous boss  
2 suggested that I might want to do this on a short-term  
3 basis and I did that. Yes.

4 Q. And presumably as director of the PFC you would have had  
5 organisational responsibilities, including the  
6 management of staff?

7 A. Yes, absolutely.

8 Q. And just to complete the CV, we see that  
9 between May 2004 and May 2005 you were Director of  
10 Pharmaceutical and Technical Projects, National Services  
11 Scotland. Where was that job based?

12 A. Well, National Services Scotland, the office that I was  
13 based at was in The Gyle, which is the headquarters of  
14 the National Services Scotland or the CSA. The role was  
15 to look at the possibility of rationalising throughout  
16 Scotland some of the small-scale NHS manufacturing units  
17 that exist. I think there were three or four of these  
18 small units and the view was that it might be much more  
19 effective, and cost-effective, if they were rationalised  
20 into a single entity. So I did a study on that and  
21 presented it to NSS as a single, discrete project.

22 Q. Thank you. Then between June 2005 and January 2007,  
23 again with NHS Scotland and the SNBTS, you were director  
24 of the Better Blood Transfusion programme. What was  
25 that?

1 A. It was a programme that had a long genesis in SNBTS but  
2 it was effectively a systematic approach to looking at  
3 what some organisations in the world called "optimal use  
4 of blood components". It was about creating good  
5 practice in transfusion, creating training systems for  
6 transfusion. I think a particularly interesting part of  
7 the project was putting in place systems for measuring  
8 specific use of blood components -- red cells and  
9 platelets -- where the blood is actually being used. So  
10 it was a whole range of activities, which were designed  
11 to create, as I say, an optimal use programme for  
12 Scotland.

13 Q. Thank you. I think you left the NHS in January 2007.

14 A. That's correct, yes.

15 Q. And since then and still you are a self-employed  
16 independent consultant. Is that correct?

17 A. Yes.

18 Q. And what matters do you consult on?

19 A. Well, my main role is -- although I am an independent  
20 consultant and employed as an independent consultant, my  
21 main area of activity at the moment is as executive  
22 director of an organisation which rejoices in the title  
23 of "International Plasma Fractionation Association",  
24 which is a trade association representing the interests  
25 of not for profit plasma fractionation organisations



1 throughout the world. It has a fairly modest but  
2 international membership and it's based in Amsterdam.

3 Q. When was that organisation set up?

4 A. It started in about 1991, and indeed the SNBTS was one  
5 of the founder members of that organisation. At that  
6 point it was an European organisation but it has  
7 subsequently expanded to take on board members from  
8 other countries, including Japan, South America,  
9 South Africa and North America and so on.

10 Q. I think at one point I read that it comprised 11 member  
11 organisations from ten countries and is based in  
12 Amsterdam. Is that still correct?

13 A. That's roughly correct, yes.

14 Q. I'm grateful. Thank you, doctor.

15 Turning then to page 2 of your CV, could you please  
16 simply read out the membership of the key committees,  
17 please?

18 A. Sure. Well, going from the top to the bottom, I was  
19 a members of the SNBTS management board and directors'  
20 committee for the Scottish National Blood Transfusion  
21 Service from 1984 to 2004.

22 I was a member of the European Plasma Fractionation  
23 Association, sitting on their board. Each member  
24 organisation had a member on their board and they had  
25 two effective forum for European Plasma Fractionation

1 Association members; that was the general assembly and  
2 the executive board.

3 I was a chairman of the EPFA standing committee on  
4 quality assurance, which was a subcommittee of the  
5 European Plasma Fractionation Association board.

6 I was a member of the UK  
7 Committee on Safety of Medicines -- commonly known as  
8 the CSM -- biological subcommittee from 1986 to 1990.

9 I was a member of the British Pharmacopeia  
10 Commission, specifically its committee K on blood  
11 products. I apologise, I don't have the specific dates  
12 for that. It was a fairly short-lived appointment.

13 I was a member of the UK Government advisory  
14 committee on microbiological safety of blood and  
15 tissues. That has taken two forms really: the Advisory  
16 Committee on Virus Safety of Blood, which I think was  
17 convened in 1991, which then subsequently emerged to  
18 become the Microbiological Safety of Blood and Tissues  
19 Committee.

20 I was a member of the UK BTS and NIBSC working party  
21 on blood and blood products, a member of the SNBTS  
22 medical and scientific committee and a membership of  
23 various ad hoc national and SNBTS committees and working  
24 parties.

25 Q. What is the difference between the EPFA and the IPFA?

1 A. The EPFA was its original manifestation. It was the  
2 European Plasma Fractionation Association. I think  
3 around about 2003 it became the International Plasma  
4 Fractionation Association.

5 Q. Thank you, doctor.

6 You have provided a statement, please, if I can next  
7 go to that. It is [\[WIT0030050\]](#). We can see that you  
8 were asked to provide a statement in respect to the  
9 topic we are looking at today and you were also asked  
10 the matters to be included in the statement and  
11 particularly the question was asked:

12 "Whether in the 1970s or early 1980s Dr Perry or, to  
13 his knowledge, any of his colleagues at the Protein  
14 Fractionation Centre ever (a) considered the practice of  
15 collecting blood from penal institutions and the  
16 increased risks of hepatitis, including non-A non-B  
17 hepatitis, from such donations; (b) considered whether  
18 the practice of collecting blood from penal institutions  
19 should continue; and (c) made any recommendations in  
20 respect of that practice."

21 Can you go to the next page, please? We see:

22 "Introductory comments."

23 Could I ask you, doctor, please, simply to read out  
24 what you have written?

25 A. Under the introductory comment?

1 Q. Please:

2 A. "Prior to my appointment within SNBTS I was employed as  
3 chief analyst in the regional sterile supply unit of the  
4 West Midlands Regional Health Authority. This new NHS  
5 unit was established for the large-scale pharmaceutical  
6 manufacture of sterile injectable preparations for the  
7 region, and my role included the development and  
8 management of quality control systems and procedures  
9 necessary for the commissioning and operation of the  
10 unit within standards of good pharmaceutical  
11 manufacturing practice applicable to the industry in  
12 general."

13 Q. To pause there, doctor, your reference to "good  
14 pharmaceutical manufacturing practice", were these  
15 standards contained in documentary form?

16 A. I was trying to think this morning at what point this --  
17 and I think other colleagues have mentioned the Orange  
18 Guide. I think this was around about 1976/1977 and  
19 these were guidelines really in the course of being  
20 developed by the Medicines Control Agency, the UK  
21 regulator of pharmaceuticals under the Medicines Act.  
22 So I think they did exist but they were very early on in  
23 their development. But I think the principles and  
24 practices of quality management within a pharmaceutical  
25 industry were fairly well understood then and this

1 centre was expected to -- although it was  
2 a National Health Service unit technically, probably  
3 operating under Crown immunity, it was the expectation  
4 that it would operate to current standards of  
5 pharmaceutical manufacture.

6 Q. And these standards would be written down somewhere?

7 A. Yes.

8 Q. Could you read on, please?

9 A. "In March 1981 I was appointed in SNBTS as quality  
10 control inspector in the protein fractionation centre.  
11 This was a new post. Its role inter alia was to develop  
12 and implement quality assurance systems and controls as  
13 part of a programme to bring the centre into compliance  
14 with modern standards of good pharmaceutical  
15 manufacturing practice. I reported to the PFC director,  
16 Mr JG Watt."

17 THE CHAIRMAN: Please carry on.

18 A. "In January 1984 I was appointed acting director of PFC,  
19 following the departure of Mr Watt. This appointment  
20 was made substantive in 1985, reporting formally to the  
21 committee of management of the CSA and responsible for  
22 all activities of the centre -- subject to the  
23 responsibilities and duties of the SNBTS national  
24 medical director."

25 Q. You also said that clearly you had no involvement in or

1 knowledge of discussions, actions or decisions on the  
2 above or other issues prior to March 1981 when you  
3 joined the PFC?

4 A. Absolutely. I had no knowledge of the plasma  
5 fractionation industry or blood establishments or blood  
6 transfusion services prior to my emigration to Scotland.

7 Q. I understand. Then, under the heading "Background  
8 information relevant to the issue", you set out the  
9 organisational framework, accountabilities and  
10 responsibilities in place at that time and you explain  
11 that:

12 "Throughout the period in question, the SNBTS was  
13 (and remains) a centrally financed division of the CSA.  
14 Although widely regarded as a national service providing  
15 blood components, plasma products and services for  
16 Scottish patients, the management arrangements and  
17 accountabilities within the service provided a high  
18 degree of professional autonomy for its constituent  
19 regional centres and the PFC. Effective leadership and  
20 co-ordination of policies and strategy for the service  
21 was provided by the national medical director, although  
22 the ultimate professional responsibility and  
23 independence of regional centres was always respected  
24 and observed. Within this arrangement, which was  
25 typical of the UK and some other European countries, the

1 national medical director exercised managerial control  
2 through persuasion, consultation and ultimately  
3 consensus, when seeking to establish a collective  
4 national position.

5 "It was, therefore, clearly evident and understood  
6 at that time that the responsibility for the  
7 recruitment, selection and testing of donors rested with  
8 the regional transfusion centre directors, who, it was  
9 understood, would take account of appropriate and  
10 contemporaneous UK guidelines. So far as PFC was  
11 concerned, therefore, plasma supplied to the centre for  
12 processing was accepted on the understanding that donors  
13 had been recruited and blood had been collected, tested  
14 and processed according to appropriate UK standards and  
15 under the ultimate supervision and responsibility of the  
16 regional director, and accordingly the donor selection  
17 and epidemiology did not arise as issues for PFC  
18 intervention. However, during this period PFC did have  
19 a pressing interest in plasma quality, but primarily  
20 concerning Factor VIII content, methods for separation  
21 and freezing and transport, and a number of studies were  
22 carried out in an attempt to improve and optimise the  
23 yield of Factor VIII from plasma.

24 "Latterly, during this period ..."

25 Which period is this, doctor, you refer to?

1 A. I think this is the early 1980s.

2 Q. Early 80s, I'm grateful:

3 "Latterly, during this period PFC and regional  
4 centres worked more closely on the development of  
5 quality systems and standard operating procedures for  
6 the processing and testing of plasma but this did not  
7 extend to issues of donor selection, which at that time  
8 would have been accepted as the exclusive responsibility  
9 of the regional directors and their medical staff. This  
10 situation remained largely unchanged until  
11 reorganisations of the service in the 1990s. In its  
12 original licence applications to DHSS medicines division  
13 for Factor VIII information on donor selection practice  
14 or policy was neither supplied by PFC/SNBTS or requested  
15 by the UK licensing authority."

16 Do you recall, doctor, when PFC/SNBTS made its  
17 original licence application for Factor VIII?

18 A. I don't personally recall because it was prior to my  
19 joining but I believe it was in 1976 or certainly the  
20 late 1970s the first applications for licences were  
21 submitted to the Department of Health --

22 Q. I'm grateful, doctor.

23 Sir, we next turn to --

24 THE CHAIRMAN: We will be stopping at that point. Before we  
25 leave altogether, in your narrative of the general



1 background, you do point to regional autonomy.

2 A. Yes.

3 THE CHAIRMAN: I can understand regional autonomy where  
4 senior people have to have a great deal of professional  
5 discretion. Did the accountability of regional officers  
6 vary according to their responsibility directly or  
7 inversely?

8 A. I'm not sure I fully understand the question.

9 THE CHAIRMAN: Was there any system of accountability that  
10 was applied to RTDs, for example, for the exercise of  
11 their autonomous powers?

12 A. Certainly in the early 1980s I think it's a fair  
13 statement to make that I think this was a largely  
14 self-regulating activity and I think the individual  
15 directors were held accountable as senior doctors, as  
16 senior consultants, for their activity. I'm not an  
17 expert on the accountability systems within the medical  
18 profession but there was no formal process of audit or  
19 inspection, which is commonplace today.

20 THE CHAIRMAN: Thank you.

21 (1.01 pm)

22 (The short adjournment)

23 (2.00 pm)

24 MR MACKENZIE: Dr Perry, could we return to your statement,  
25 please? We had reached page 0052. In the middle of the

1 page we see you were asked:

2 "Whether in the 1970s or early 1980s Dr Perry, or to  
3 his knowledge any of his colleagues at the PFC, ever  
4 considered the practice of collecting blood from penal  
5 institutions and the increased risks of hepatitis,  
6 including non-A non-B hepatitis, from such donations."

7 You replied:

8 "I have been unable to find any documentary evidence  
9 of any formal (or informal) consideration of this topic  
10 within PFC either before my appointment in March 1981 or  
11 subsequently. However, the letter from Dr Cash to  
12 Mr Watt dated 5 July 1982 clearly seeks his view on the  
13 topic of prison donors."

14 Could we have that letter up on the screen, please?  
15 The reference is [\[SNB0056703\]](#).

16 I think we can see, Dr Perry, that this is a letter  
17 from Dr Cash to Mr Watt, who was the director of the PFC  
18 at that time in July 1982. From the stamp at the top of  
19 the letter we can see that the letter was received on  
20 7 July 1982 and we can see your name, I think, Dr Perry,  
21 there, and I'm coming to that very shortly. Under item  
22 7(a) Professor Cash states:

23 "We need to consider formally in the not too distant  
24 future the question of sessions in prisons et cetera.

25 I would very much welcome your comments as to whether we

1           should abandon this practice."

2           Dr Perry, do you have any recollection of that  
3           letter?

4   A.   No, I don't have any recollection of that letter, which  
5           doesn't mean to say I didn't see it, as evidenced by the  
6           annotation on the top of the letter. But, no, I don't  
7           recall having seen this letter. But clearly I did.

8   Q.   Well, when you say clearly you did, if we can look at  
9           the top of the page again, please, is that your  
10          handwriting, Dr Perry?

11   A.   No, that's Mr Watt's handwriting. The system was that  
12          letters would come into the addressee and then Mr Watt  
13          would annotate them with people that he wanted to see.  
14          He would have copied it to me and scribbled a note on  
15          saying basically, "Bob, we should discuss this". And  
16          there is a tick on it which presumably indicates that he  
17          had either moved on from that or he did actually discuss  
18          it with me, but I have no recollection of that  
19          discussion, I am afraid.

20   Q.   I understand. Do you have any recollection of Mr Watt  
21          having ever expressed any views about the practice of  
22          collecting blood from prisons?

23   A.   No, I don't. I don't.

24   Q.   Thank you. So really you can't help us any further with  
25          that letter?

1 A. No, except to note that it wasn't a letter directly to  
2 Mr Watt. I think, from the content of the letter and  
3 the subject matter, that was a letter that would have  
4 been addressed to all directors of the service at the  
5 time. I think the convention was that the so-called  
6 round-robins, or these letters that should go to all  
7 directors, would have been individually headed with the  
8 recipient's name, but I think, given the content -- much  
9 of which is not related to PFC -- I suspect this was  
10 a general call for comments from regional directors.

11 Q. I understand. Perhaps we can just scroll down --

12 THE CHAIRMAN: Before you do that, can we take anything from  
13 the annotations at the top? There is:  
14 "Bob, we should discuss", and that's you?

15 A. That's me.

16 THE CHAIRMAN: And that's ticked.

17 A. Yes.

18 THE CHAIRMAN: And then if we look at "Action taken", the  
19 only entry is "File".

20 A. Yes.

21 THE CHAIRMAN: Does that help you to guess?

22 A. Not really. This was very commonplace. Most of the  
23 transactions in the SNBTS were carried out by letter and  
24 formal letters between not just directors but staff  
25 generally, and that would have been very commonplace.

1           Mr Watt would have received the letter, referred it  
2           to me, suggested we might talk about it. That could  
3           have taken the form of a very formal discussion or an  
4           incidental conversation in the corridor. So regrettably  
5           I don't recall the discussion but I can't say with any  
6           certainty that I did not have a conversation with  
7           Mr Watt about that particular --

8   THE CHAIRMAN: I'm assuming you did but one can't infer from  
9           the "Action taken" being limited to filing, that Mr Watt  
10          didn't do anything else in response.

11   A. No, I don't think we can assume that. It is quite  
12          possible that he might have asked for something to  
13          happen but I have not found, from any of the research  
14          I've done into my files, any correspondence between  
15          myself and Mr Watt that either suggested a specific  
16          request for me to do something or a specific course of  
17          action that he may or may not wish to take.

18   MR MACKENZIE: Just to finish that point, Dr Perry. If  
19          Mr Watt had written a letter in reply to Professor Cash,  
20          would that fact have been noted on this letter on the  
21          screen?

22   A. Not necessarily. Not necessarily. It wasn't a rigorous  
23          and robust system, I think. Sometimes he might have  
24          noted that he had replied. But there wouldn't be  
25          a chain of evidence, as it were, from the original

1 letter, you know, linking that to a reply and so on.

2 The documentation system wasn't like that.

3 Q. Yes, thank you.

4 You also, I think, indicated that we shouldn't  
5 assume that this letter was only written by  
6 Professor Cash to Mr Watt; in fact you suggested there  
7 were other indications in the letter, that it was  
8 a round-robin-type letter sent by Professor Cash to each  
9 of the transfusion directors. Can you perhaps indicate  
10 briefly the content of the letter which perhaps applied  
11 to PFC and the content which didn't?

12 A. Yes. I think -- firstly, the letter refers to a letter  
13 from Mr Haythornthwaite who was the medicines inspector  
14 at that time, and I think this post-dated his suggestion  
15 that collecting in prisons was not desirable. But that  
16 primarily was targeted at regional transfusion centres.

17 I think item 4, designated QA post, I don't think  
18 that was particularly relevant to PFC. We already had  
19 a designated QA post. That was myself. I was the QA  
20 manager in PFC. That, I think, was an issue surrounding  
21 the suggestion that each regional centre should have  
22 a specific person who was responsible for quality  
23 assurance, because at that time there was no such post  
24 in each individual centre.

25 So I think that was a question that was probably

1 targeted at regional centres rather than PFC. I think  
2 item 7(a) could apply to both regional centres and PFC  
3 obviously. And 7(b) is a specific comment that he has  
4 asked Ewa Brookes to explore that further.

5 Item 10, I think, is really an issue more targeted  
6 at regional centres who were involved in the process of  
7 screening blood. PFC didn't routinely screen individual  
8 donations. That was a responsibility that was very  
9 clearly an operational and management responsibility.  
10 It was very clearly designated to  
11 regional transfusion centres. So item 10, I think, is  
12 certainly targeted at regional transfusion centres.

13 Q. Can we then look over the page?

14 A. Yes, I think that's probably directed at the collegiate  
15 body, as it were. I think individual centres did a lot  
16 of local printing, and there was a suggestion that PFC  
17 as a central national facility could take that up and do  
18 it on behalf of all regional centres.

19 Q. Perhaps the clincher, doctor, if one looks at  
20 Professor Cash's final words:

21 "I look forward to your responses."

22 A. Again, I can't be absolutely certain but, yes, it  
23 certainly indicates to me that he would be expecting  
24 responses from more than one person. Equally he could  
25 be expecting responses to one than one question from one

1 person, so I don't think it is absolutely -- it is not  
2 a clincher for me.

3 Q. I understand. If one then does look back at the  
4 previous page again, finally, in the second paragraph in  
5 the letter, Professor Cash stated that:

6 "There are one or two items which emerge from this  
7 letter which I believe deserves our collective national  
8 attention."

9 A. Yes.

10 Q. Is that perhaps another indicator --

11 A. That's a clear indicator, yes.

12 Q. -- that collective or national attention --

13 A. Yes, the collective national attention would almost  
14 certainly imply to me that Professor Cash at that time  
15 was suggesting that this was something that we  
16 collectively needed to address and come to a position  
17 on.

18 Q. I understand. We can then leave that letter to one  
19 side, thank you, doctor. If I may return to your  
20 statement, please, at page 0052. Picking up the reply  
21 to the specific question about half way down. We have  
22 dealt with that letter. You go on to say that:

23 "I am aware of the references cited in the  
24 preliminary report, which describes the discussions and  
25 actions of SNBTS directors in relation to prison donors



1           which took place during the above period."

2           Could you, please, read on, Dr Perry?

3   A.   "Mr Watt will have participated in these discussions but  
4        I have no recollection or record of having been briefed  
5        or consulted on the content of these directors'  
6        discussions. I have been unable to find any record of  
7        an instruction or request to myself or other PFC staff  
8        to take any action in response to these discussions.  
9        Indeed, since the directorial discussions were, in any  
10       event, inconclusive, it is unlikely that any action  
11       would have been requested."

12   Q.   Please read on?

13   A.   "Finally, following the departure of Mr Watt at the end  
14        of 1983 and my appointment as acting director  
15        in January 1984, I do not recall any further  
16        consideration of collecting blood from penal  
17        institutions, either between directors, which by this  
18        time I would now be party to, or elsewhere. Probably  
19        because the practice ceased in Scotland in March 1984."

20   Q.   Thank you. Could you just then complete that passage  
21        over the page, please?

22   A.   "It is, of course, possible that throughout this period,  
23        PFC staff generally would have been aware of the SNBTS  
24        practice of collecting blood from prison donors as part  
25        of their background knowledge of SNBTS activities. It

1 is equally possible that many would have held personal  
2 views and casual discussions on whether or not this was  
3 appropriate practice. However, I'm not aware of any  
4 substantive or formal consideration of the issue in PFC  
5 between 1981 and 1984."

6 Q. Thank you. Just to complete your statement, at this  
7 point, please, doctor, you were also asked:

8 "Whether in the 1970s or early 1980s you, or to your  
9 knowledge any of your colleagues at PFC, ever considered  
10 whether the practice of collecting blood from penal  
11 institutions should continue."

12 And you replied:

13 "It followed from the above that [you] had found no  
14 record and also have no recollection of any  
15 consideration of whether the practice should continue or  
16 cease. However, again I would expect a number of staff  
17 held personal views and periodic casual discussions on  
18 the subject, although again this is conjecture."

19 Finally you were asked:

20 "Whether in the 1970s or early 1980s you, or to your  
21 knowledge any of your colleagues at the PFC, ever made  
22 any recommendations in respect of that practice of  
23 collecting blood from penal institutions."

24 You replied:

25 "I can find no record and have no recollection of

1 any recommendations from myself, Mr Watt or any other  
2 staff on this practice. I cannot exclude the  
3 possibility that the topic was discussed periodically  
4 between Mr Watt and other SNBTS directors, but I can  
5 find no evidence that such discussions produced  
6 substantive recommendations or proposals."

7 Doctor, that was the end of your statement at that  
8 stage. If we can then, please, go on to the next page.  
9 What I think then happened was that the Inquiry team's  
10 attention was drawn to Dr Wallace's paper in 1972 and  
11 also Mr Barr and others' paper in 1981 in relation to  
12 the higher prevalence of Hepatitis B among prison  
13 donors. I think these papers were sent to all of the  
14 witnesses, including yourself, for any comments you may  
15 have, and in particular you were then asked this  
16 supplementary question. It stated:

17 "Dr Perry should be provided with a copy of the  
18 undernoted papers and asked whether he was aware of  
19 these papers at the time of the publication and what, if  
20 any, conclusion he would draw from them, either at the  
21 time or now, about the appropriateness of collecting  
22 blood from Scottish prisons, including any possible or  
23 likely increased incidence of any non-A non-B hepatitis  
24 from such donations."

25 You provide a full response, doctor, on this page

1 and the following page but I have to say it did then  
2 occur to me when reading this and having now seen your  
3 CV, doctor, I think others are better placed to speak to  
4 what happened in the 1970s and also what should have  
5 happened in the 1970s. In particular those who were  
6 working in transfusion at the time. Professor Cash,  
7 Dr McClelland and Dr Mitchell have all essentially given  
8 evidence on these matters. It did seem to me that they  
9 were better placed to do so. So if you genuinely agree  
10 with that proposition that you would defer to their  
11 views on this question, I don't propose asking you  
12 anything more on it.

13 A. I'm very happy with that proposition.

14 Q. Thank you, doctor. I have no further questions for you.

15 THE CHAIRMAN: Mr Di Rollo?

16 Questions by MR DI ROLLO

17 MR DI ROLLO: Dr Perry, can I just ask, it does appear that  
18 as far as PFC at Liberton was concerned, there was  
19 clearly an importance attached to the drive towards  
20 self-sufficiency in the period that you were there. Is  
21 that correct?

22 A. Oh, yes, indeed. It was a dominant theme from the day  
23 I started, yes. That together with responding to  
24 medicines inspectors' criticisms and so on. So there  
25 was a drive towards improvement of quality systems and

1 developing modern pharmaceutical approach to -- but also  
2 the organisation, I think, as a number of other  
3 witnesses have indicated, the dominant goal in the early  
4 1980s was to make more Factor VIII to meet the  
5 increasing demand for treatment of haemophilia.

6 Q. Who was it that was setting the targets for the  
7 Factor VIII or the amount of blood that was needed to  
8 make the Factor VIII?

9 A. I think the targets primarily came from discussions  
10 between people like Professor Cash, the senior  
11 haemophilia doctors; colleagues from the Scottish Home  
12 and Health Department were involved in this, and I can't  
13 remember exactly the date on which the precise target  
14 evolved but I remember it quite clearly. It was  
15 2.75 million units per million population. That was  
16 considered to be the organisation's goal for  
17 self-sufficiency, judging the increasing demand for  
18 Factor VIII for an increasing haemophilia population,  
19 increased prophylaxis and so on.

20 Q. So presumably the PFC would say, "In order to make so  
21 much Factor VIII we will require so much blood"?

22 A. Absolutely. We would convert that into a volume of  
23 plasma that would be required to meet that demand and  
24 those targets would then be cascaded down to the  
25 regional centres whose job it was to go out and collect

1 the plasma.

2 Q. The drive towards self-sufficiency was motivated by  
3 what? What was the importance, did you understand, in  
4 relation to self-sufficiency?

5 A. My understanding at the time when I joined the service,  
6 as a new person to the blood service, was that this was  
7 a goal or a policy that had been set by the Scottish  
8 executive at the time, that we wanted to meet the WHO  
9 recommendations for self-sufficiency. But I think also  
10 it became very clear that one of the prime  
11 justifications for self-sufficiency was a belief, which  
12 was based on fairly good evidence, that imported  
13 products from the USA, which were the alternative source  
14 of products, were much higher risk products than those  
15 that would be produced from voluntary non-remunerated  
16 blood donors from one's own community. So it was  
17 a target which was aimed at creating a sufficiency of  
18 supply from our own community but also a target which  
19 sought to reduce the risk to haemophilia patients of  
20 transmission of disease from other countries.

21 Q. The risk arises from United States' products because of  
22 the source. If it's a commercial product, if it is  
23 bought from paid donors, then there are certain risks  
24 attached to that, and you understood that?

25 A. At that time, yes, I think that was a well-known part of

1 the SNBTS culture, that locally sourced plasma from  
2 voluntary donors in Scotland was going to be a much  
3 safer raw material than the product made from paid  
4 donors in the US.

5 Q. Concern would arise because the people that were  
6 donating blood, they would be unreliable in relation to  
7 their medical history, for example, or that they would  
8 be at increased risk of infection or that they were from  
9 the lower socio-economic background. That kind of --

10 A. That kind of thing. I think there was also a belief  
11 that there were not rigorous systems for the control of  
12 the raw material, primarily because there was payment  
13 involved and so on.

14 Q. Did it never occur to you that there might be a similar  
15 problem with donors coming from prisons in this country?

16 A. I think I have answered that in either this  
17 supplementary question or another, that from a PFC  
18 perspective, firstly the whole activity of donor  
19 selection was a very clearly demarcated responsibility  
20 for regional centres, and we assumed, rightly or  
21 wrongly, at the time that the senior directors in charge  
22 of the regional transfusion centres would be following  
23 appropriate guidelines to make sure the plasma was as  
24 safe as possible.

25 But even if it were the case that there was a higher

1 risk of infectious disease, particularly non-A non-B --  
2 this is in the early 80s -- from prison donors, removing  
3 that source of plasma from the supply to PFC wouldn't  
4 have made a difference to the safety of the products  
5 that we were manufacturing, and the reason for that is  
6 that the -- our belief at the time was that the  
7 background level of non-A non-B hepatitis in the 1980s  
8 was roughly, I think, from memory, 0.5 per cent or some  
9 figure around that.

10 So even if we removed a few donations by removing  
11 prison donors, each pool of plasma that was used to make  
12 the clotting factor products, the Factor VIII and the  
13 Factor IX, would still have been contaminated from the  
14 infective donations which were in the general blood  
15 donor pool.

16 Q. Was that a consideration that played a part in the  
17 thinking at the time?

18 A. It was a factor that led PFC not to consider this to be  
19 a major issue.

20 Q. Can you explain because we haven't seen any  
21 documentation to that effect. Nobody so far has given  
22 an indication to that effect, as I understand it, but is  
23 that the reason for carrying on with prison donors,  
24 should we understand, longer than perhaps might have  
25 been appropriate, because it wouldn't have made any



1 difference in relation to PFC?

2 A. Absolutely not, no. Really, for the reasons that I have  
3 described, the FPC wasn't directly involved in  
4 formulating policies and proposals for selection of  
5 donors, either from prisons or elsewhere. But I think  
6 in the informal discussions and views that took place,  
7 we were aware that there was a background level of non-A  
8 non-B hepatitis that couldn't be reduced below the level  
9 that it was at. And removing a small number of  
10 donations, which would have been the effect of ceasing  
11 collections in prisons, wouldn't have made a difference,  
12 but it didn't drive the policy, I think it just led us  
13 to conclude that this wasn't a major issue as far as --

14 Q. You say "us"; who is "us".

15 A. I think the individuals in PFC, in the manufacturing  
16 facility.

17 Q. Did that include the other individuals, the regional  
18 directors and the director of the SNBTS at the time?

19 A. No, I don't think the thinking would have been related  
20 to PFC. I think the thinking in the  
21 regional transfusion centres was usually dominated by  
22 the safety of the red cells and the platelets. I don't  
23 think the fact that it would make no difference at PFC  
24 would have influenced the evolution of discussions on  
25 this topic by regional transfusion centres.

1 Q. You can see obviously that clearly if PFC is setting  
2 targets at a certain level in order to meet a target for  
3 self-sufficiency, then that would obviously put pressure  
4 on the system in order to produce that amount of blood?

5 A. Hm-mm.

6 Q. That's fair, isn't it?

7 A. It is a reasonable proposition. I don't believe it was  
8 true. I think if your question is, did we collect  
9 plasma or blood from any location simply to meet  
10 a quantitative target, I certainly don't think that was  
11 the case. I would argue very strongly against that.  
12 And I think the contribution of prison donations to the  
13 volume of plasma supplied to the PFC at the time was  
14 really quite small.

15 Q. You have mentioned guidelines; you mention that in your  
16 statement. I think you mentioned it in part of your  
17 answers to my questions just now. Do you know what  
18 these guidelines were, or do you have any understanding  
19 of them or do you know which guidelines you are  
20 referring to, or are you just assuming that there were  
21 guidelines which were being followed?

22 A. I think, as I described earlier, my assumption at the  
23 time, and indeed the assumption of the director at the  
24 time, and indeed the operational practices that were in  
25 place and the allocation of responsibilities, were quite

1 clearly that the whole business of selecting appropriate  
2 donors -- both for production of blood components, red  
3 cells and platelets, and also plasma -- to feed the  
4 manufacturing process at the PFC was very clearly the  
5 responsibility of regional transfusion directors and  
6 their expert medical staff.

7 At that time that was a very clear demarcation. PFC  
8 had quite a passionate interest in quality of plasma in  
9 other respects, but that was primarily to do with its  
10 biochemical condition, the level of Factor VIII, the  
11 speed with which the plasma was separated and frozen, so  
12 that we could maximise the amount of Factor VIII that we  
13 could get out of each donation.

14 Q. So you were concerned with yield, I suppose?

15 A. We were, we were concerned with yield.

16 Q. Getting as much material out of the material you had?

17 A. Of course.

18 Q. And that involves an assessment of quality with a view  
19 to producing as much as you can. Is that right?

20 A. We had a number of research projects that sought to  
21 identify the best conditions for separation of plasma,  
22 for freezing it quickly, the way in which you froze, its  
23 storage condition, its transportation and so on, and it  
24 was those elements of plasma procurement that dominated  
25 our activities.

1 Q. Just coming back to the question about guidelines, in  
2 your statement -- this is in background information  
3 relevant to the issue -- you say:

4 "It was therefore clearly evident and understood at  
5 that time that the responsibility for the recruitment,  
6 selection and testing of donors rested with  
7 regional transfusion centre directors who, it was  
8 understood, would take account of appropriate and  
9 contemporaneous UK guidelines."

10 I'm just reading on:

11 "So far as PFC was concerned, therefore, plasma  
12 supplied to the centre for processing was accepted on  
13 the understanding that donors had been recruited and  
14 blood had been collected, tested and processed according  
15 to appropriate UK standards."

16 It is the reference to UK guidelines and appropriate  
17 UK standards. Were you yourself familiar with these or  
18 did you just assume that there were such guidelines and  
19 standards and that those would be followed?

20 A. I knew the existence of such standards but I didn't  
21 spend much time, if any, at that stage in the process of  
22 understanding what they were because I had no locus or  
23 influence in changing them. These were seen as  
24 primarily medical matters for expert transfusionists to  
25 work out the risks associated with certain categories.

1 Q. Presumably it follows from that that whether they said  
2 anything about prison donations or not, it was not  
3 something that you were familiar with?

4 A. No.

5 Q. Thank you, sir. That's all I have to ask.

6 THE CHAIRMAN: Mr Anderson?

7 MR ANDERSON: I have no questions, thank you, sir.

8 THE CHAIRMAN: Mr Sheldon?

9 MR SHELDON: Nor I, sir, thank you.

10 THE CHAIRMAN: Dr Perry, thank you very much.

11 A. Thank you.

12 MR MACKENZIE: Sir, the final witness today is Dr Graham  
13 Alexander Scott.

14 DR GRAHAM ALEXANDER SCOTT (affirmed)

15 Questions by MR MACKENZIE

16 THE CHAIRMAN: Dr Scott, if you have any trouble hearing,  
17 please make sure you mention it right away and we will  
18 try and do what we can for you.

19 MR MACKENZIE: Dr Scott, good afternoon.

20 A. Good afternoon.

21 Q. Dr Scott, you have provided a statement to the Inquiry.  
22 I would like to bring that up on the screen in front of  
23 you, please. The number is [\[WIT0030019\]](#) and if you have  
24 a hard copy, doctor, feel free to use that. I certainly  
25 use the hard copy myself.

1 A. I will use it, yes.

2 Q. I'm grateful. I'll just go through your statement, if I  
3 may, please, doctor.

4 In paragraph 1 you explain your qualifications. You  
5 have a bachelor of medicine, also FRCPE. Is that  
6 perhaps a fellowship of the Royal College of Physicians  
7 in Edinburgh?

8 A. Yes.

9 Q. Also FFPH. I think that is a fellow of the Faculty of  
10 Public Health?

11 A. That's correct.

12 Q. And DPH. When does that stand for?

13 A. Diploma in public health.

14 Q. Thank you. We see that between 1951 and 1956 you did  
15 your national service with the Royal Australian Army  
16 Medical Corp?

17 A. Yes.

18 Q. And you joined Stirling County Council as a senior  
19 assistant medical officer in 1957. In 1962 you were  
20 promoted to deputy county medical officer. Then in 1965  
21 you joined the Scottish Home and Health Department as  
22 a medical officer. That presumably, doctor, was based  
23 here in Edinburgh?

24 A. Yes.

25 Q. Then you were promoted to senior medical officer in

1           1968, and in 1975 you were promoted to deputy chief  
2           medical officer. You explain you had been a principal  
3           medical officer for around a year before being promoted  
4           to DCMO. You explain that between 1965 and 1974 your  
5           work primarily related to medical manpower matters, for  
6           example, control of the number of medical students,  
7           control of training grade and consultant numbers, and  
8           negotiating with the profession in relation to  
9           conditions of service of medical and technical staff.

10           You explain that during that period you did not have  
11           any involvement with either scientific or blood matters.  
12           You also explain that when you became deputy chief  
13           medical officer in 1974, you were one of two deputies.  
14           The other being Dr Ian MacDonald. You explain that the  
15           reason for that was that the chief medical officer at  
16           that time, Sir John Reid, was often absent from the  
17           department as he was much concerned with WHO matters,  
18           which took him out of the office a lot of the time and  
19           that was why it was felt appropriate for there to be two  
20           DCMOs. Was that relatively unusual, doctor, for there  
21           to be two DCMOs?

22           A. That was the first time but at that time, yes, it was  
23           usual.

24           Q. Thank you, doctor. I think the one thing you don't tell  
25           us is when you retired?

1 A. I retired in 1962. I was supposed to retire in 1960 but  
2 Kenneth Calman was made chief medical officer. He had  
3 no experience of departmental matters at all. So I was  
4 asked to stay on for two years to hold his hand.

5 Q. Was that the early 1980s, doctor?

6 A. That was -- well -- I was supposed to retire when I was  
7 60; that would be 1987. I stayed on for two years until  
8 1989.

9 Q. Thank you.

10 Then in paragraph 2 you explain that when you became  
11 the deputy chief medical officer you took over  
12 responsible for all matters relating to the SNBTS.

13 A. Yes.

14 Q. And you spent around 5 per cent of your time on SNBTS  
15 matters. You explain that you used to sit on the  
16 Common Services Agency management committee and in that  
17 capacity was involved in discussions regarding funding  
18 et cetera. The committee had wide membership. There  
19 were health board representatives and the departmental  
20 assistant secretary was also a member. You explain that  
21 you cannot now recollect the level of your input,  
22 although -- over the page -- you suspect your opinion  
23 carried a fair bit of weight and you cannot recollect  
24 the detail of any discussions you had in that capacity.

25 You say:



1            "This is true in relation to all issues covered by  
2            the witness statement request. I stand by my past  
3            actions but cannot now remember why I did what I did or  
4            why I advised in the way that I advised. I should say  
5            that I was heavily reliant on my colleagues, Dr McIntyre  
6            and Dr Forester. I had the highest regard for them  
7            both, particularly Dr McIntyre. He would really only  
8            come to see me if he was in doubt about something."

9            In paragraph 3, doctor, you explain:

10           "This statement relates to a request received by the  
11           Scottish Government legal directorate in October last  
12           year."

13           You remind us that the events and documents  
14           mentioned took place up to 35 years ago, and you say  
15           again:

16           "While I would stand by any actions I took or advice  
17           that I gave, I cannot now recall the specifics of the  
18           reasoning process I employed at the time."

19           The first question you were asked, doctor, was:

20           "The consideration, if any, given by the Scottish  
21           Home and Health Department between 1975 and 1984 to the  
22           practice of collecting blood from penal institutions,  
23           the risk the non-A non-B hepatitis from such donations  
24           and whether the practice of collecting blood from such  
25           institutions should continue."

1           You answered, doctor, that:

2           "I do not know whether SHHD gave any consideration  
3           to this issue; I do not recall being asked to consider  
4           it. In any event, I would not have considered it  
5           appropriate to interfere with SNBTS practices."

6           Can you, doctor, please explain that sentence  
7           a little, where you stated:

8           "In any event, I would not have considered it  
9           appropriate to interfere with SNBTS practices."

10          What do you mean by that?

11        A. Well, I wouldn't have considered it appropriate to  
12        question their decisions about taking donations from  
13        prisons. I considered them to be excellent scientific  
14        individuals and well able to judge what they were doing  
15        in their individual circumstances and their individual  
16        reason. And in their areas, they would know what was  
17        going on. I would not have interfered with that.

18        Q. They, after all, were experts in transfusion medicine.  
19        That, doctor, I take it, isn't your particular  
20        expertise.

21        A. Oh, none. None whatsoever.

22        Q. And you go on in paragraph 4 to say that:

23           "I have been provided with a copy of a minute from  
24           J G Davies to Mr Mackay dated 6 May 1983, which records  
25           that this issue was under constant consideration by

1 SNBTS."

2 I would like now, doctor, to bring that minute up on  
3 the screen, please. The reference is [\[SGH0026764\]](#).  
4 Doctor, in the top left-hand corner we see the reference  
5 "PS/Mr Mackay". Was Mr Mackay the Secretary of State  
6 for Scotland at this time?

7 A. No, I think he was the Minister of Health.

8 Q. I see. What do the letters "PS" stand for?

9 A. Private secretary.

10 Q. I'm grateful. Then there are copies of this minute to  
11 PS/SHHD. What do the letters "PS" stand for there?

12 A. I think they are private secretary to the secretary of  
13 SHHD.

14 Q. Could that perhaps be a reference to permanent secretary  
15 of the SHHD?

16 A. No, it wouldn't be permanent. Permanent secretary was  
17 over -- Scottish officers would be the secretary of the  
18 health department of SHHD.

19 Q. Thank you. Mr Walker, who was that?

20 A. He was the assistant secretary.

21 Q. Dr Scott; is that yourself --

22 A. Yes.

23 Q. -- the reference there. Then a director SIO.

24 A. Scottish information officer.

25 Q. Thank you. We can see the title of the minute is

1 "Acquired immunodeficiency syndrome."

2 If we can go to the very bottom of the minute,  
3 please, we can see the author is J G Davies and the date  
4 is 6 May 1983. Who was J G Davies?

5 A. I'm pretty certain he was an assistant secretary.

6 Q. In the SHHD?

7 A. Yes, division IVD.

8 Q. Thank you. If we go back to the top of the memo,  
9 please, we can see it states:

10 "Mr Mackay may have seen comment recently in the  
11 media about AIDS. He might find it helpful to see some  
12 briefing material on the matter prepared earlier in the  
13 week by DHSS for the Prime Minister. We agree with the  
14 general line in the briefing. There are, however, a few  
15 Scottish points to be made."

16 I should pause, doctor, and ask you: do you have any  
17 recollection of having seen this memo?

18 A. No.

19 Q. I'm grateful. Then if we go down, please, to  
20 paragraph 3, "Donation policy", it states:

21 "The blood transfusion directors in Scotland are  
22 very aware of the problem and have it under constant  
23 consideration."

24 To pause at this point, doctor. The reference to  
25 "the problem which is under constant consideration", do

1           you agree that appears to be a reference to AIDS?

2    A.   Yes.

3    Q.   And we can see then in subparagraph (d) one of the  
4       options being currently considered was:

5           "Avoiding collection in high risk locations such as  
6       prisons or where there is known to be a high proportion  
7       of homosexuals or drug abusers in the population."

8           If I could then, please, doctor, return to your  
9       statement.  In answer 4, paragraph 4, where you say:

10          "I have been provided with a copy of a minute from  
11       J G Davies to Mr Mackay, dated 6 May 1983, which records  
12       that this issue was under constant consideration by  
13       SNBTS."

14          Would you agree -- I think you just have -- that the  
15       issue which was under constant consideration by SNBTS  
16       was the question of AIDS, rather than the question of  
17       collection from prisons?

18   A.   Yes.

19   Q.   I'm grateful.  Sticking with your statement, please,  
20       doctor, the next question you were asked is:

21          "The communications, if any, between the SHHD and  
22       the SNBTS between 1975 and 1984 on the subject of the  
23       collection of blood from penal institutions."

24          You answer that you have no recollection of any  
25       communications which may have passed between SHHD and

1 SNBTS. Doctor, simply to pause here. We have seen  
2 reference in 1983 department and social security  
3 internal minutes to the Home Office in London having  
4 been in favour of collecting blood from prisons from  
5 a rehabilitational aspect of prisoners. Are you aware  
6 whether the SHHD ever held a similar policy; that is of  
7 being in favour of collecting blood from prisons?

8 A. No, I'm not aware that they had expressed any views on  
9 favouring collection from prisons.

10 Q. In short --

11 A. It was a matter for the SNBTS directors.

12 Q. I understand. If I could then, please, return, doctor,  
13 to your statement, to the bottom of page 2. You were  
14 then asked:

15 "The communications, if any, between the SHHD and  
16 the Department of Health between 1975 and 1984 on the  
17 subject of the collection of blood from penal  
18 institutions."

19 At the top of page 3 of your statement in  
20 paragraph 6 you answer:

21 "I have no recollection of any communications which  
22 may have passed between SHHD and DHSS. I do not recall  
23 whether the subject was discussed at meetings of DHSS,  
24 medical staff, which I attended."

25 Doctor, do you have any recollection of having ever

1 discussed with the Department of Health and Social  
2 Security the question of collecting blood from prisons?

3 A. No recollection.

4 Q. The next question, doctor, you were asked was the  
5 extent, if at all, to which the chief medical officer or  
6 the deputy chief medical officer and the permanent  
7 secretary of the SHHD were aware of and were involved in  
8 any consideration by the SHHD between 1975 and 1984 of  
9 the practice of collecting blood from penal  
10 institutions. And the answer:

11 "I cannot recall being involved in any consideration  
12 by SHHD of the practice of collecting blood from penal  
13 institutions. As I mentioned previously, Dr McIntyre  
14 would only refer matters to me if he needed my  
15 assistance."

16 Is it a reasonable inference from that, doctor, that  
17 if the question of collecting blood from prisons in  
18 Scotland did come to the attention of the SHHD, it would  
19 firstly have been considered by Dr McIntyre?

20 A. Probably, but I don't think it ever came to him. Maybe  
21 it's not for me to say that, but I don't think it came  
22 to him. But if he had any doubt, he would come to me,  
23 if he had any doubt.

24 Q. I understand. The next question, doctor, about the  
25 middle of page 3. You were then asked whether yourself

1 or the SHHD were aware of the evidence produced by the  
2 National Blood Transfusion Service for England and Wales  
3 around July 1974, that the incidence of Hepatitis B in  
4 donors from prisons was approximately five times greater  
5 than the incidence in donations from the general public.  
6 And you answered that:

7 "I do not recall being aware of this evidence or of  
8 taking any steps in response to it. I do not recall  
9 whether SHHD took any action."

10 In paragraph 9 you explain that you had been  
11 provided with copies of papers by Dr Wallace and others  
12 in 1972, or rather the paper was published in 1972, and  
13 also you were provided with a paper by Barr and others,  
14 which was published in 1981, and you state:

15 "I do not recall having been aware of these papers.  
16 I do not feel it is appropriate for me to offer any  
17 comments on these papers or their relevance to the  
18 practice of donor selection, as the subject of donor  
19 selection was not within the province of SHHD. SNBTS  
20 directors were in the best position to make informed  
21 decisions based on local circumstances."

22 To pause there, please, doctor. Dr Wallace's paper  
23 in 1972 and also Mr Barr's paper in 1981 reported  
24 a higher prevalence of Hepatitis B in prison donors in  
25 the West of Scotland when compared with non-prison



1 donors. Were you, doctor, aware, or can you recollect,  
2 whether you were aware in the 1970s of there being  
3 evidence that prison donors in the West of Scotland had  
4 a higher prevalence of Hepatitis B compared to  
5 non-prison donors?

6 A. I don't think I was aware of it. I don't recall but  
7 I don't think I was aware of it.

8 Q. Thank you.

9 THE CHAIRMAN: Before we leave paragraph 9, could you help  
10 me, please, Dr Scott, with the statement that the  
11 subject of donor selection was not within the province  
12 of SHHD? Had a question arisen in Parliament at that  
13 time about collection of blood from prison, who would  
14 have answered the question?

15 A. Probably SHHD.

16 THE CHAIRMAN: It would have been the Minister of State in  
17 the Scottish Home and Health Department, responsible for  
18 SHHD?

19 A. Yes.

20 THE CHAIRMAN: Well, what do you mean by saying that the  
21 subject of donor selection was not within the province  
22 of SHHD, please?

23 A. It is a loose phrase. The subject of donor selection  
24 was being left to the directors.

25 THE CHAIRMAN: But you do appreciate that's a very different

1 matter?

2 A. I think that is loosely worded, yes.

3 THE CHAIRMAN: Thank you.

4 MR MACKENZIE: Thank you, sir.

5 So, doctor, I think you would accept that the  
6 question of donor selection was within the province of  
7 SHHD to the extent that SHHD, or at least the relevant  
8 minister, was ultimately responsible for the health  
9 service.

10 A. Yes.

11 Q. But is your position that essentially the question of  
12 donor selection was something which was delegated, at  
13 least on a de facto basis, to the SNBTS directors?

14 A. I don't know about the word "delegate". It was their  
15 responsibility and whether it is delegated to them,  
16 I don't know, but it was left to them as their  
17 responsibility, which they accepted.

18 Q. If, doctor, in the 1970s you or your department had  
19 tried to suggest to the SNBTS directors which donors  
20 they should or should not take blood from, what do you  
21 think the response would have been?

22 A. To mind their own business, to an extent, whatever you  
23 want. They would have said, "We are doing it. It is  
24 our responsibility as consultants to do this and we are  
25 doing it."

1 Q. I understand. At the bottom of page 3, doctor, the next  
2 question you were asked is whether you or the SHHD were  
3 aware of a letter, dated 6 January 1975, by Dr Garrot  
4 Allan of Stanford to Dr William Maycock of the blood  
5 products laboratory warning of the increased risk of  
6 hepatitis, including non-A non-B hepatitis from blood  
7 collected from prisoners. Over the page, doctor, you  
8 say:

9 "I do not recall being aware of this particular  
10 piece of correspondence or of taking any steps in  
11 response to it. I do not recall whether SHHD took any  
12 action."

13 To pause there, doctor. Did you have any knowledge  
14 in the 1970s of the work of Dr Garrot Allan in America?

15 A. No.

16 Q. I think we have also heard reference to Dr Garrot Allan  
17 having published a book of his studies in perhaps the  
18 early 1970s, where the point, I think, essentially he  
19 was making was that blood collected from commercial  
20 donors in the United States had a far higher incidence  
21 of either post-transfusion hepatitis or perhaps  
22 Hepatitis B -- I think it was probably the former --  
23 than blood collected from non-commercial donors. Do you  
24 have any recollection of that book or that point?

25 A. No.

1 Q. Moving on to a different matter, doctor, you were also  
2 asked whether you or the SHHD were aware of a letter  
3 dated 1 May 1975 by Dr Yellowlees, the chief medical  
4 officer for England and Wales to all region medical  
5 officers on the subject of blood donation and hepatitis.

6 We will come to some documents in this regard  
7 shortly, doctor, but, firstly to read your answer in  
8 paragraph 11, you replied:

9 "[You] have been provided with certain papers and  
10 that it is clear from these papers that the letter from  
11 Dr Yellowlees was copied to me and that I gave some  
12 consideration to the issue of whether SHHD should  
13 endorse the introduction of a more specific test for  
14 Hepatitis B. The reverse passive haemagglutination  
15 test, RPH. My handwritten notes from Dr McIntyre's  
16 minute of 13 May 1975 record that SHHD had no objection  
17 to the introduction of RPH testing. The question of  
18 donor selection is a separate issue and one which was  
19 dealt with by SNBTS."

20 I would like, doctor, to pause at this stage and  
21 take you to a number of documents around this period,  
22 which I think help provide the context for  
23 Dr Yellowlees's letter. In particular, doctor, I think  
24 you may be able to help us with interpreting some of the  
25 handwriting on the minutes at the time.

1 A. I'll do my best.

2 Q. The first document, doctor, is [\[SGH0030186\]](#). Doctor, we  
3 can see this is a minute dated 2 May 1975 by  
4 Dr E M Warwick, addressed to you, Dr Scott. Who was  
5 Dr Warwick?

6 A. She was a senior medical officer involved in infectious  
7 diseases.

8 Q. We see the minute is addressed to yourself, doctor, and  
9 also copied to the DCMO. At this point would this be  
10 the other DCMO as well?

11 A. No, that would be Dr Smith, I think, at that time.

12 Q. Dr MacDonald and Dr Gordon, the heading is "Blood  
13 donation and hepatitis". It stated:  
14 "Dr MacDonald left the attached teleprint ..."  
15 What's a teleprint, doctor?

16 A. It was a kind of fax.

17 Q. I wondered, yes:  
18 "... with me this morning and Dr Gordon and  
19 I subsequently had a word with Dr McIntyre who had  
20 already received the copy (also attached) of the actual  
21 letter sent out by DHSS to all the regional medical  
22 officers. It seems that this is primarily a blood  
23 transfusion matter, though we should be glad to be kept  
24 informed of any action that you may be arranging to  
25 take."

1           What did Dr Warwick mean by saying:

2           "It seems that this is primarily a blood transfusion  
3           matter."

4    A.   As I say, she was a senior medical officer with  
5           responsibility for other things, infectious disease, and  
6           any question relating to infectious she should be kept  
7           informed. That was my understanding of her minute.

8    Q.   When she said "this seems primarily a blood transfusion  
9           matter", did she mean by that it was a matter for you  
10          and your particular part of the department?

11   A.   Yes.

12   Q.   I understand. The next document, please, is  
13          [\[SGH0030185\]](#). We can see, doctor, this is a minute  
14          written by yourself, I think, if we scroll down the page  
15          a little. Is that your signature and name there,  
16          Dr Scott?

17   A.   Yes.

18   Q.   To the left of that we can see the date is 8 May 1975?

19   A.   Yes.

20   Q.   If we go back up to the top, please, doctor, we can see  
21          this minute is addressed to Dr MacDonald and Dr Smith  
22          and also a copy to doctors Warwick, Gordon and McIntyre.  
23          The heading is "Blood donation and hepatitis, DHSS/CMO  
24          letter of 1 May."

25          I think that's a reference to Dr Yellowlees's letter

1 of 1 May 1975. Does that appear correct, sir?

2 A. Yes.

3 Q. I should pause, doctor. Do you have any recollection of  
4 this memo at all?

5 A. No, I don't have any mental recollection of it. As  
6 I say, I obviously saw it.

7 Q. You set out in this minute that:

8 "The position, as I understand it, is that the  
9 Maycock advisory group set up a small working group to  
10 consider geographical and racial factors and they  
11 produced recommendations in the form of an appendix  
12 which appeared in an early draft. It was our view as  
13 soon as we saw it, and indeed finally the view of the  
14 whole advisory group, that the inclusion of such an  
15 appendix could be inflammatory and the appendix was  
16 therefore dropped."

17 I should pause, doctor, and ask: what was your  
18 involvement with the Maycock advisory group in the mid  
19 1970s? I don't think you were a member, were you?

20 A. No, I wasn't.

21 Q. But obviously you were aware of the work of the group,  
22 given your position in SHHD?

23 A. Yes.

24 Q. And then in the second paragraph, the minute provides:

25 "DHSS seemed to have interpreted the decision of the

1           Maycock group as being that although the appendix had  
2           been dropped, it had been agreed that a letter should be  
3           sent out drawing the attention of RMOs and regional  
4           directors to the recommendations of the small working  
5           group."

6           The next paragraph:

7           "All I intend to do at present is to ask Dr McIntyre  
8           to discuss the recommendations with the national medical  
9           director ..."

10          That will be the national medical director of the  
11          SNBTS?

12         A. Yes.

13         Q. "... and establish the practice in Scotland now and when  
14           the more sensitive methods of antigen screening have  
15           been instituted, I would have little doubt that the  
16           practices recommended is what Scottish centres are doing  
17           or are intending to do."

18          Finally you say:

19          "If they are not, then all that would require to be  
20           done would be to send a letter from the department,  
21           drawing the attention of the NMD to the recommendations  
22           of the small group and asking him to take it up with  
23           regional directors."

24          I think we have seen, earlier in the Inquiry, that's  
25          in fact what happened. I don't think the various



1 handwriting on this minute matters much, apart from  
2 perhaps at the very bottom where we can see, I think,  
3 your initials again, in the bottom right-hand corner.  
4 I think those are your initials, doctor?

5 A. Yes.

6 Q. And the date, 13 May?

7 A. Yes.

8 Q. And I think you say:

9 "Dr McIntyre, you may now proceed as outlined at X."

10 And we can see the second last paragraph of that  
11 minute, you have marked a "X"?

12 A. Yes.

13 Q. The next document --

14 THE CHAIRMAN: Before you go on.

15 Dr Scott, who would have been responsible within the  
16 Scottish Home and Health Department for the health of  
17 prisoners at this period? Not necessarily the  
18 individuals but first of all the officer?

19 A. I don't think SHHD was involved in the health of  
20 prisoners.

21 THE CHAIRMAN: Well, there would be a prisons division, I  
22 take it, even then, but I'm looking for information  
23 about the medical aspects of prisoners. You don't think  
24 SHHD would have been involved at all?

25 A. The question of the -- I'm sorry, if I'm thinking. The

1 question of the prison medical service -- I'm not sure  
2 it was within the SHHD. I think it was in the  
3 department as a whole but I don't think it was  
4 specifically within SHHD. I may be wrong. I just have  
5 no recollection.

6 THE CHAIRMAN: You have no recollection. If we look up to  
7 the top, to the list of people who received copies of  
8 this document, we now have six names including your own.

9 A. Yes.

10 THE CHAIRMAN: None of them would have been involved with  
11 this topic so far as you can recollect?

12 A. With ...?

13 Q. With health of prisoners?

14 A. No, none of them.

15 THE CHAIRMAN: Thank you.

16 MR MACKENZIE: Yes, doctor, the Scottish Home and Health  
17 Department, presumably the home part of the department,  
18 would have been responsible for the running of prisons  
19 generally.

20 A. Yes.

21 Q. But in particular the health of prisoners, you can't  
22 recollect which part of the SHHD would have been  
23 responsible for that?

24 A. The home side.

25 Q. The home side?

1 A. Yes.

2 Q. The next document, please, doctor, is [\[SGH0030184\]](#). If  
3 we scroll done the page, please, we can see this is  
4 a typed minute by Dr McIntyre dated 13 May 1975. Then  
5 if we go to the top of the page again, please, we can  
6 see this minute was sent to yourself, Dr Scott, with  
7 a copy to Mr Roberts. Is that correct?

8 A. Yes.

9 Q. Who was Mr Robertson?

10 A. He was either a principal or an SEO. I don't remember  
11 his exact grade, but he was on the administrative side  
12 involved with such matters.

13 Q. Again, the minute is still on the subject of the  
14 advisory group on the testing for HBsAg. There is  
15 a discussion of the particular type of test. Dr McIntyre  
16 writes:

17 "There is now no doubt that the advisory group will  
18 recommend RPH for routine screening of blood for HBsAg.  
19 It is also likely that following representation from  
20 this department, the passive inhibition agglutination  
21 test will be accepted as being perfectly satisfactory  
22 for the detection of antigen. From a the draft text of  
23 the report it would appear that they are approximately  
24 equally sensitive. There would seem therefore to be no  
25 reason why a gradual change should not be made at an

1 earlier date to one or other of the more sensitive  
2 methods."

3 Then the next paragraph states:

4 "This subject will be sure to come up at the  
5 Scottish transfusion directors' meeting on 11 June, and  
6 if the NMD knew in advance that we were agreeable in  
7 principle to the introduction of a more sensitive test,  
8 they could perhaps ask the directors to come prepared to  
9 discuss at that meeting the test they were likely to  
10 adopt and the financial implications thereof. I agree  
11 that the question of money will be up to the NMD but  
12 I feel sure that he will eventually come to us for  
13 additional money for this purpose. It is just possible,  
14 however, that some of the centres, eg in the West, have  
15 already built in some additional staff, part of whose  
16 duties will be to carry out these new tests. I doubt if  
17 all Scotland will use the inhibition agglutination test.  
18 While Dr Wallace has no reason to doubt its sensitivity,  
19 he is still to be convinced by a large reported  
20 comparison."

21 I think, doctor, you have previously been sent  
22 a copy of this document and asked to help us with the  
23 handwriting?

24 A. Yes.

25 Q. If one goes to the handwritten passage, just under the

1 date, 13 May 1975, I think firstly there is  
2 a handwritten note by yourself, doctor, dated perhaps  
3 13 May?

4 A. Yes.

5 Q. You have previously advised that the handwritten note  
6 said as follows:

7 "Mr Roberts, NMD was at me again today on giving  
8 Wallace go ahead. Could we at least say the department  
9 has no objection to Wallace using RPH? As I said in my  
10 minute (and NMD has also made the point) the tests to be  
11 used are largely a question of clinical practice. If we  
12 say we have no objection, it is easier than saying we  
13 recommend -- this can only ..."

14 I think the final words, Dr Scott, you weren't  
15 entirely clear what they said but you suggested they  
16 appear to say:

17 "This can only further publication and  
18 consideration."

19 But you appreciate that may not be the correct  
20 interpretation of the final words.

21 A. I can't read my own writing. That word beginning with  
22 an "F", I don't know what it is. Maybe -- probably  
23 "follow". "This can only [probably follow] publication  
24 and consideration. Sorry, I can't make out my own  
25 writing.

1 Q. To be fair, we are asking you some time after the event,  
2 to be fair to you.

3 Then simply to complete the handwriting, the  
4 interpretation thereof. I think underneath that  
5 Mr Roberts has written a note to you, Dr Scott, which  
6 I think states:

7 "I agree what you say. I think that having no  
8 objection puts us less at risk to appeals for financial  
9 assistance, which would be unlikely to go [or be]  
10 forthcoming anyway than 'recommending'."

11 Or "recommendations."

12 Finally to complete the next note, I think you,  
13 Dr Scott, then write a note to Mr Roberts saying:

14 "I told NMD that we had no objection to Dr Wallace  
15 going ahead and using RPH. I drew attention to the form  
16 of words. As the request was verbal, no letter seemed  
17 to be indicated."

18 But I think, just to complete this line, we will  
19 see, doctor, in the event, it wasn't RPHA which  
20 Dr Wallace sought additional funding for, rather it was  
21 an RIA test?

22 A. Yes.

23 Q. In particular, if we can, please, go to document  
24 [\[SGF0012836\]](#). It's a letter dated 22 June 1976 by  
25 Dr Wallace to Dr McIntyre. We don't have to look at the

1 content of this letter, doctor, but in short Dr Wallace  
2 explained that RIA testing was more sensitive for  
3 Hepatitis B antigen than RPHA testing, and Dr Wallace  
4 sought funding for RIA testing. Have you had a chance  
5 to look at this letter previously, doctor?

6 Perhaps I should just take you through the main  
7 parts, doctor?

8 A. I think there is more of it.

9 Q. Yes.

10 A. Where it came to, as it were, the crunch.

11 Q. If we look, doctor, in perhaps in the middle paragraph  
12 commencing:

13 "You attended meetings ..."

14 In that paragraph we see:

15 "It was acknowledged that radioimmunoassay was the  
16 most sensitive method available for the detection of  
17 HBsAg but in practical terms, both expert groups  
18 recommended that reversed passive haemagglutination,  
19 RPHA, should be introduced as the method of total  
20 screening because RPHA could be introduced much more  
21 rapidly than a more sophisticated RIA technique."

22 If we can go over the page, please. Dr Wallace, who  
23 I think, it would be fair to say, was at the forefront  
24 of the issue of screening of Hepatitis B in the UK in  
25 much of the 1970s, had been carrying on using RIA and

1 had found it to be more sensitive, rather than RPHA.

2 And in the final paragraph on page 2 he states:

3 "There is, in my opinion, substantial evidence in  
4 favour of total screening by RIA rather than by RPHA."

5 Then over the page, please, at page 3. In the first  
6 paragraph Dr Wallace stated:

7 "The cost of RIA screening at the commercial rate  
8 would be £50,000 per annum. This sum allowed for HBsAg  
9 testing in the current year as £24,000 which would allow  
10 us to undertake total screening by RPHA. Since we are  
11 already in danger of overspending under the head of  
12 medical supplies, there is insufficient money in our  
13 present allocation to allow us to undertake total  
14 screening by RIA after the middle of August 1976."

15 Then in the final paragraph, Dr Wallace states:

16 "As I have indicated above, copies of this letter  
17 are being sent to Miss Corrie and to Mr McPhee. I have  
18 not, at this stage, informed either the Scottish legal  
19 office or my own Defence Society of the position because  
20 I am hoping that something can still be done to maintain  
21 a sensitive method of testing donations."

22 I think in short, doctor, Dr Wallace wished to  
23 continue screening with RIA rather than RPHA because it  
24 was more sensitive and he wished extra funding to enable  
25 him to do so. Does that seem a fair summary of the



1 letter?

2 A. That's what he says in that letter, yes.

3 Q. Yes. That really, doctor, is a precursor to looking at  
4 the next document, which is [\[SGF0012834\]](#). Doctor, this  
5 is the typed minute by Dr McIntyre, dated 28 June 1976,  
6 addressed to yourself; do you see that?

7 A. Yes.

8 Q. The passage I'm interested in, doctor, is about half way  
9 down, the paragraph beginning:

10 "Dr Wallace has been involved in the problems of  
11 hepatitis right from the beginning and knows that the  
12 problem is complex and that Hepatitis B is only the tip  
13 of the iceberg."

14 Do you see that sentence, doctor?

15 A. Yes.

16 Q. What do you think Dr McIntyre meant by saying that  
17 "Hepatitis B is only the tip of the iceberg"?

18 A. Well, we knew that there were other hepatitis agents  
19 involved that hadn't emerged then. Non-A non-B. Nobody  
20 had developed a test for the other forms of hepatitis.

21 Q. I understand. Then simply for completeness with this  
22 minute, the handwritten passage beneath Dr McIntyre's  
23 typed minute, is this in your handwriting, doctor?

24 A. Yes.

25 Q. I think it is dated 29 June, addressed to Dr McIntyre

1 and I think you say that:

2 "I have suggested a few minor amendments leaving out  
3 ..."

4 A. Present financial situation.

5 Q. Thank you:

6 "We should rest on the Maycock report advice, which  
7 took into account sensitivity and cost."

8 A. Yes.

9 Q. Could you perhaps read on, doctor.

10 A. "They knew that RIA was marginally more sensitive but  
11 did not recommend as a routine."

12 Dr Wallace, (inaudible) he was a member and  
13 a signatory to the report, Dr Wallace was.

14 Q. Thank you. I think we know that in the event,  
15 Dr Wallace was unable to continue using RIA screening,  
16 at least for a period, and we have previously seen  
17 a letter Dr Wallace then wrote to his medical colleagues  
18 in the West explaining that fact and that he was going  
19 to have to use a less sensitive screening test. I don't  
20 think we have to take you to that letter, doctor.

21 THE CHAIRMAN: Is that a letter of 26 July?

22 MR MACKENZIE: It is indeed, sir, yes.

23 Doctor, can I now, please, return to your statement  
24 and complete that? At page 4 of your statement, about  
25 half way down the page, the question is asked:

1           "Whether the witness or SHHD were aware of the  
2           internal correspondence within the DHSS in July  
3           and August 1983 on the practice of collecting blood from  
4           prisons."

5           I take it, doctor, you were shown a copy of these  
6           DHSS minutes when you prepared this statement?

7    A. I was not aware of the correspondence.

8    Q. Yes. Doctor, when you prepared this statement we are  
9           looking at, I take it you were shown a copy of the DHSS  
10           minutes?

11   A. I believe I was, yes.

12   Q. I'm sorry, doctor?

13   A. I believe I was, yes.

14   Q. Maybe I should take you to them again for completeness.

15           The first one is reference number [\[SGH0010575\]](#). We  
16           can see, doctor, this is a minute from J B Brown to  
17           a Mr Parker, dated 27 July 1983, entitled "The use of  
18           blood from prisons". So were you shown a copy of this  
19           minute when compiling your statement?

20   A. Yes.

21   Q. And you say you don't recall being aware of this minute.

22           And for completeness, can we please have [\[SGH0010574\]](#)?

23           Again, doctor, this is a DHSS minute. The author of  
24           this minute is a P A Winstanley, dated 23 August 1983,  
25           and it is addressed at the top of the page to

1 Mr J B Brown again, and headed "Use of blood from  
2 prisons". So you had an opportunity, doctor, to read  
3 that minute when compiling your statement?

4 A. Yes.

5 Q. Again, I think your position is that you don't recall  
6 having seen that previously?

7 A. No.

8 Q. Thank you. Finally, please, doctor, to complete your  
9 statement. At page 4, just above paragraph 12, you were  
10 asked. You were then asked:

11 "In the 1970s and early 1980s, did the Scottish Home  
12 and Health Department or ministers encourage donations  
13 in prisons ..."

14 You reply:

15 "Neither SHHD nor ministers encouraged donations  
16 from prisons."

17 Then the final question you were asked, doctor, was:

18 "What was the view, if any, of yourself or SHHD  
19 between 1975 and 1984 on the practice of the collection  
20 of blood from penal institutions?"

21 And you say:

22 "I don't have a view on this. In my opinion, this  
23 was a matter for SNBTS."

24 Doctor, looking at matters today and with the  
25 benefit of hindsight and all that we know, do you have

1           any view today on the question of collecting blood from  
2           prisons in Scotland from the 1970s and 1980s?

3    A.   I don't believe in answering questions with the perfect  
4           vision of hindsight. I just don't believe in it. If  
5           you had the perfect vision of hindsight about the whole  
6           of your life, would you have done anything any  
7           different? I don't accept the premise of the perfect  
8           vision of hindsight. I'm sorry, that's the way I feel  
9           about it.

10   Q.   Thank you.

11                 Sir, I have no further questions for Dr Scott.

12   THE CHAIRMAN: Mr Di Rollo?

13                         Questions by MR DI ROLLO

14   MR DI ROLLO: Dr Scott, we heard yesterday from  
15           Professor Cash, who was, as I'm sure you are aware --

16   A.   I was.

17   Q.   -- the director of the  
18           Scottish National Blood Transfusion Service, I think, at  
19           the time where you were at the Home and Health  
20           Department.

21   A.   Yes.

22   Q.   It is unavoidable for me to summarise his position but  
23           I do want to ask you one or two questions. It seems  
24           that there is a contrast in relation to what you have  
25           said today, perhaps, and what he told us yesterday, in

1           that it appears that his position was that it was really  
2           a matter for the Scottish Home and Health Department or  
3           beyond, the DHSS in London, to direct the transfusion  
4           service in Scotland as to what should happen in terms of  
5           whether blood should be taken from prisoners or not.

6   A.   Did he say that?

7   Q.   He perhaps didn't put it quite in that way but what he  
8       did say -- I can quote.  He was asked:

9           "Who had the power to tell the directors what to  
10          do?"

11          He said:

12          "I would have to say in the environment we worked,  
13          it would be none other than the Scottish Home and Health  
14          Department, and in terms of individuals, I would have to  
15          nail poor old Dr Graham Scott, deputy chief medical  
16          officer, because it was one of his many responsibilities  
17          at the Blood Transfusion Service."

18          So that's what he said yesterday.  Do you have  
19          anything you want to say about that?

20   A.   I would have said if I had told the SNBTS directors what  
21       to do with regard to the donors selection, I would have  
22       been told to mind my own business.

23   Q.   Would it have been put in those terms or would it have  
24       been put more colourfully?

25   A.   Probably more colourfully in private, yes.

1 Q. So your position is that it was a matter for him and  
2 them to decide what to do in relation to from whom they  
3 took blood?

4 A. Yes.

5 Q. The other thing, I think it is fair to say, that  
6 Professor Cash indicated to us was that he certainly  
7 thought -- or gave the impression of thinking -- that  
8 they were waiting for a lead from somewhere else, ie  
9 either from Edinburgh or perhaps from London. In other  
10 words, there should have been a UK policy in relation to  
11 these matters; that it was a UK issue whether to collect  
12 blood from prisoners or not. It would have been part of  
13 a UK policy. Are you aware of whether there was a UK  
14 policy in relation to that or was it something just for  
15 the Scottish National Blood Transfusion Service to  
16 decide upon?

17 A. As far as I was aware, it was for the national blood  
18 transfusion directors to decide individually, in light  
19 of their own experience and in the light of the region  
20 they were operating in, what they should do and they  
21 did -- they didn't do it altogether, they were spread  
22 out in time as to when they stopped taking it in prison.

23 Q. I take it, if they were waiting for a lead from you or  
24 from beyond you, they weren't going to get that lead  
25 from there?

1 A. I considered it to be their responsibility individually.

2 Q. So they wouldn't get a lead from the Scottish Home and  
3 Health Department?

4 A. No.

5 Q. And they wouldn't get a lead from London either?

6 A. No.

7 Q. Thank you.

8 THE CHAIRMAN: Dr Scott, do you appreciate that if I were to  
9 accept as reliable the evidence of Professor Cash that  
10 has just been read to you and at the same time accept as  
11 reliable your recollection of affairs, one inference  
12 might be that no one in Scotland had any input into the  
13 decision as to whether or not to take blood from  
14 prisoners? Do you appreciate that?

15 A. The only people in Scotland, as I saw it, was the SNBTS,  
16 the directors individually or collectively.

17 THE CHAIRMAN: That was not my question.

18 A. Sorry.

19 THE CHAIRMAN: I'll repeat it. Do you appreciate that if  
20 I accept as reliable the evidence of Professor Cash as  
21 to his attitude towards your role and SHHD's role and at  
22 the same time I accept your evidence as to your  
23 understanding of the position, one inference could be  
24 that no one in the governmental structures in Scotland  
25 had any particular interest or influence over the



1 collection of blood in prisons?

2 A. I was not aware of the collection of blood from  
3 prisoners.

4 THE CHAIRMAN: If I formed that view, it might suggest that  
5 there was rather a big gap in the governance of this  
6 issue, mightn't it?

7 A. I don't think so. I think when you take the view that  
8 it was up to the SNBTS directors to make the decision on  
9 their own and they would not have appreciated any  
10 interference from anybody else as consultants in the  
11 NHS, they were in the position to make their own  
12 decisions.

13 THE CHAIRMAN: Mr Anderson?

14 Questions by MR ANDERSON

15 MR ANDERSON: Dr Scott, good afternoon to you. You don't  
16 appear to accept the proposition that the SNBTS  
17 directors were waiting for some sort of guidance from  
18 either the Scottish Home and Health Department or the  
19 DHSS in London. Is that correct?

20 A. That's correct.

21 Q. Can we look together, please, at this letter of  
22 1 May 1975 that Mr Mackenzie referred you to. It is  
23 [\[SGH0030187\]](#). Do you see that?

24 A. Yes.

25 Q. I think this is a letter that forms the basis of one of

1 the questions that was put to you and you deal with this  
2 in your statement, but you see there that this is  
3 a letter from the chief medical officer from the  
4 Department of Health and Social Security?

5 A. Yes.

6 Q. And it is addressed to all regional medical officers.  
7 Do you see that?

8 A. Yes.

9 Q. And if we go over to page 2 of that document, do you see  
10 under the heading of "Prisons" it states:

11 "There is a relatively high risk of Hepatitis B  
12 being transmitted by the blood of prisoners. But there  
13 is probably an equally high risk in other groups of the  
14 population, eg drug addicts, who are not so easily  
15 identified in advance as prisoners, if they can be  
16 identified at all. The advice we have received is that  
17 it is not necessary to discontinue the collection of  
18 blood at prisons and similar institutions provided all  
19 donations are subjected to one of the more sensitive  
20 tests referred to above."

21 Do you see that?

22 A. Yes.

23 Q. What do you think the purpose of that paragraph is  
24 within that letter? It is a letter from the chief  
25 medical officer to all regional medical officers.

1           What's the purpose of it?

2    A.   The advice we have received -- where did we receive it?

3           Who was it from?

4    Q.   Would you agree with the fairly straightforward

5           proposition, Dr Scott, that the purpose of this letter

6           is essentially the dissemination of advice, isn't it, to

7           the regional medical officers?

8    A.   Yes, that's essentially what it's doing.  Yes,

9           undeniable.

10   Q.   We know that that letter or a copy of that letter was

11          sent by your colleague, Dr McIntyre, to

12          Major General Jeffrey, the national medical director of

13          the SNBTS.  Do you know that?

14   A.   Yes.

15   Q.   Why do you think your colleague Dr McIntyre was sending

16          copy of that letter to the SNBTS?

17   A.   Presumably for their information.

18   Q.   It is not just for their information, is it; it is the

19          advice that is contained within that letter this is

20          being specifically forwarded to the SNBTS, is it not?

21   A.   Yes, I suppose that's correct.  I have never seen this

22          letter.

23   Q.   Members of the Scottish Home and Health Department

24          attended the meetings of the directors of the SNBTS from

25          time to time.  Is that not correct?

1 A. There was usually somebody there in attendance, yes.

2 Q. Yes. And did you ever attend any of these meetings?

3 A. No.

4 Q. Was that largely your colleagues, Dr McIntyre and

5 Dr Forrester?

6 A. Yes.

7 Q. Dr McIntyre, I think, is currently recovering from an

8 operation. Is that right?

9 A. I haven't seen him for years.

10 Q. What about Dr Forrester; is he still alive?

11 A. No idea.

12 Q. But in any event, any representative, whether it be

13 Dr McIntyre or Dr Forrester, that attended the meetings

14 of the directors of the SNBTS would be aware of the

15 discussions at those meetings and would consequently be

16 aware of any discussion that there had been in relation

17 to the question of collecting donations from prisoners.

18 Is that not right?

19 A. Should be, yes.

20 Q. Thank you very much, sir.

21 THE CHAIRMAN: Mr Sheldon?

22 MR SHELDON: Thank you, sir.

23 Questions by MR SHELDON

24 MR SHELDON: Doctor, the chair asked you some questions

25 about whether the question of donor selection was within

1 the province of the Scottish Home and Health Department;  
2 do you recall that a little bit earlier today?

3 A. Yes.

4 Q. And I think it is clear that in terms of political  
5 accountability, all matters relating to the health  
6 service in Scotland were within the province of the  
7 Scottish Home and Health Department and the relevant  
8 Scottish minister; would you accept that, in terms of  
9 accountability to Parliament?

10 A. Well, there is this question of the status of  
11 a consultant, which is rather unique. A consultant --  
12 and the SNBTS directors were consultants -- you  
13 interfere with them at your peril. They are, in terms,  
14 responsible to their patients and at the end of the day  
15 through the MDA(?) to the courts.

16 Q. You perhaps anticipated where my line of questioning was  
17 going but in terms of political accountability, I think  
18 you would accept that politically, in terms of  
19 Parliamentary accountability, health matters in Scotland  
20 were within the province of SHHD?

21 A. Yes, generally.

22 Q. I just want to explore a little what you meant when you  
23 said that the selection of blood donors wasn't within  
24 the province, or what you saw as the province of SHHD.  
25 I think we have some evidence from Dr McClelland of

1 SNBTS that in the 1970s and early 1980s, the concept of  
2 clinical freedom was sacrosanct?

3 A. Yes.

4 Q. And I really just wanted to ask you how, if at all, that  
5 concept or that idea informed your view of the province  
6 of SHHD at that time?

7 A. It was always there, in terms of consultants. Their  
8 decisions were their decisions. I was involved in that  
9 side with the rest of my job. And consultants made  
10 their decisions and were responsible for them. And in  
11 the end only to the GMC, or, if there was negligence, to  
12 the courts.

13 Q. So would you distinguish then between matters of policy  
14 and matters of clinical judgment?

15 THE CHAIRMAN: I'm sure he will now, Mr Sheldon. Please.

16 A. I don't know how clinical consultants would take it if  
17 they were informed of anything that limited their  
18 ability to make decisions they wanted to. It would be  
19 in terms of what money was available to them and all the  
20 rest but not the actual decision they made on an  
21 individual patient.

22 MR SHELDON: Just to put that in a more general context,  
23 would you regard the question of whether it would be  
24 appropriate to continue to accept blood donations from  
25 prisoners as a matter of clinical judgment or a matter

1 of policy?

2 A. Clinical judgment.

3 Q. We also heard evidence from Professor Cash yesterday.

4 Well he was asked by Inquiry counsel: would it be fair

5 to say that medical and scientific matters relating to

6 transfusion were primarily for the SNBTS, whereas wider

7 policy matters may involve government? And he agreed

8 with that proposition or that characterisation of

9 matters. Would you also agree with it? That medical

10 and scientific matters relating to transfusion were

11 primarily for the SNBTS, whereas wider policy matters

12 may involve government?

13 A. Yes.

14 Q. You would agree with that?

15 A. Yes.

16 Q. We understand, of course, that the Scottish Home and

17 Health Department combined certain functions, really the

18 functions of the Home Office and the Department of

19 Health in England. I really just wondered if you can

20 help us a little bit with the extent to which the DHSS

21 was involved at that time in informing and guiding

22 health issues in Scotland. We have seen numerous

23 references to the DHSS in the correspondence and so on.

24 How did that fit in with the Scottish Office and the

25 SHHD?

1 A. Well, we would listen to what they had to say.

2 THE CHAIRMAN: I didn't hear that.

3 A. Sorry.

4 THE CHAIRMAN: I didn't hear that, doctor.

5 A. We would listen to what they had to say, of course, but  
6 not necessarily take it fully. We regarded ourselves as  
7 separate from DHSS on certain matters.

8 MR SHELDON: But you would look to them for guidance and  
9 assistance on certain occasions; is that fair to say?

10 A. We would look at what they said.

11 Q. If I can ask you a hypothetical question -- I understand  
12 that you are perhaps not a fan of those -- but if the  
13 transfusion directors had asked SHHD for guidance on an  
14 issue related to the selection of blood donors --  
15 I think there is no suggestion that actually was done --  
16 but if they had done so, how would that have been  
17 handled? How would you have handled it?

18 A. We would just discuss -- if DHSS had made any statements  
19 on it, we would have looked at what they had said or we  
20 would have discussed it internally within the department  
21 with our administrative colleagues. Our official  
22 position is we advise the administrators and they take  
23 the action. It doesn't always just follow through as  
24 simply as that, but that's the official position.

25 Q. Would you also look to the question of whether there



1           were any groups, advisory groups, working on the matter?

2    A.   Yes, if we had an advisory group in Scotland that was

3           looking at a thing, we would refer it to them.

4    Q.   What about DHSS advisory groups or UK advisory groups?

5    A.   If they had given advice which they had sent to us, we

6           would look at it.

7    Q.   Perhaps we could look again, please, at the letter

8           [\[SGH0030187\]](#). Perhaps just see the first page, please.

9           We have seen this letter already briefly. This is the

10           letter from Dr Yellowlees to all regional medical

11           officers. We see that the first paragraph reads:

12                   "The department has recently received advice from

13                   a group of experts on the use of blood donations from

14                   certain categories of donors."

15                   There is a little asterisk and if we look to the

16                   foot we see that the experts in that context is the

17                   subgroup of the advisory group on testing for Australia

18                   antigen.

19    A.   Yes.

20    Q.   Do you see all that? So can we take it that the letter

21           from Dr Yellowlees proceeds on the basis of advice

22           received from a working party or an advisory group?

23    A.   Yes.

24    Q.   Would that be your understanding of it?

25    A.   Yes.

1 Q. All right. Just thinking more generally then about this  
2 type of advice, or this type of circular from a medical  
3 officer, what would the basis of such advice generally  
4 be if and when the chief medical officer sent out  
5 advice?

6 A. In the light of all information available from whatever  
7 source.

8 Q. Which might include, of course, a working party, a group  
9 of experts or whatever?

10 A. Yes, whether from the DHSS or within our own orbit.

11 Q. Thank you, sir. Nothing further.

12 THE CHAIRMAN: Dr Scott, thank you very much indeed.

13 MR MACKENZIE: Sir, there are no further witnesses today.

14 In fact tomorrow, a different topic of B1 with  
15 Dr McClelland, the question of donor exclusion in AIDS,  
16 and then revert finally on Tuesday next week to C1 with  
17 Professor Leikola.

18 THE CHAIRMAN: Mr Sheldon, I make it clear that I have no  
19 objection generally to leading questions. This Inquiry  
20 will never finish if we don't have them. Just  
21 occasionally I have to be sensitive to the position of  
22 the witness and I don't want to be put in a position of  
23 making adverse comments if it is unnecessary.

24 MR SHELDON: I appreciate that, sir.

25 THE CHAIRMAN: Until tomorrow, ladies and gentlemen.

1 (3.49 pm)

2 (The Inquiry adjourned until 9.30 am the following day)

3

4

I N D E X

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