

Friday, 24 June 2011

1

2 (9.30 am)

3

DR ROBERT PERRY (continued)

4

Questions by MR GARDINER (continued)

5

MR GARDINER: Good morning, Dr Perry.

6

A. Good morning.

7

Q. Dr Perry, you have previously given evidence to the

8

Inquiry in connection with statistics and the C1 topic.

9

This morning you are here to help us with the question

10

of the implicated batch. Just before we start looking

11

at the documents, I wonder if you would mind just

12

reminding us of your qualifications and your present

13

position?

14

A. My qualifications are, I have a PhD in chemistry. I'm

15

a qualified person under the European Directive, which

16

is a specific professional qualification required in the

17

pharmaceutical industry. My current occupation is

18

participating in the public Inquiry on behalf of SNBTS,

19

but also I'm the executive director of the International

20

Plasma Fractionation Association, which is an

21

organisation based in Amsterdam.

22

Q. Yes. Thank you.

23

We are going to be looking at events around

24

about November 1984 and the ensuing years. What was

25

your position at that time?

1 A. I was acting director of the protein fractionation  
2 centre of the  
3 Scottish National Blood Transfusion Service.

4 Q. Right.

5 A. I had been in post for about ten months.

6 Q. Sorry?

7 A. I had been in post for about ten months at that time.

8 Q. Thank you. You have given us a statement in connection  
9 with this topic and that's at [\[PEN0121331\]](#). You have  
10 got a copy of this in front of you?

11 A. I have, yes.

12 Q. Is that correct? What you say is:

13 "The Inquiry has requested the SNBTS to provide  
14 a written statement explaining step by step how the  
15 SNBTS came to identify the implicated batch and the  
16 evidence relied on in doing so. The Inquiry has also  
17 sought clarification as to what evidence was considered  
18 by which individuals before the document entitled  
19 "Actions Surrounding Factor VIII batch 023110090" was  
20 prepared. The first question is:

21 "Who carried out the original investigations  
22 concerning the implicated batch in 1984?"

23 Just before we start looking at that, could you just  
24 explain what the document, "Actions Surrounding  
25 Factor VIII Batch 023110090" is?

1 A. This was a document prepared -- I can't recall whether  
2 it was in response to a request by the Inquiry or  
3 a piece of work that we thought was important to do  
4 anyway, but it seeks to put in place a timeline for all  
5 the events following the initial notification through to  
6 the recall, through to the follow-up investigations that  
7 were carried out. So it tries to put the whole process  
8 into some context.

9 Q. Yes. I wonder if you could maybe move your microphone  
10 just a little bit closer to you?

11 A. Okay. Is that better?

12 Q. That's a bit better, I think, thank you.

13 So if we just read on:

14 "Following notification of their findings to the  
15 protein fractionation centre on 1 November 1984,  
16 follow-up actions and investigations were carried out by  
17 Dr B Cuthbertson..."

18 Who was Dr Cuthbertson at that time?

19 A. He was the quality assurance manager of the Protein  
20 Fractionation Centre.

21 Q. "... and subsequently by myself following my return to  
22 PFC on 5 November."

23 Could we just have a look at the "Actions" document,  
24 which is [\[PEN0161258\]](#). We see that this is an SNBTS  
25 document and if we go to the first page we see that

1           there is a glossary of various terms, if we go over to  
2           the next page, a continuation of the glossary and then  
3           over the page we see the contents of the document?

4   A.   Yes.

5   Q.   Which, as you said, is to do with the implicated batch.  
6           Is that right?

7   A.   Yes, indeed, and I'm reminded by seeing the document on  
8           the screen in front of me that this was a document  
9           prepared in response to a specific request from  
10          Mr Tullis.

11   Q.   Yes, thank you.  If we go over the page, we see in  
12          paragraph 1 the question from Mr Tullis, solicitor to  
13          the Inquiry, is repeated and the question was in an  
14          email dated 25 February:

15                 "When it first came to light in the autumn of 1984  
16                 that the group of patients at Edinburgh Royal Infirmary  
17                 had been infected with HIV from a PFC product, a batch  
18                 of Factor VIII concentrate ... was strongly implicated.  
19                 It was decided to identify all donors to the pool of  
20                 plasma from which this batch had been manufactured and  
21                 then quarantine all plasma subsequently donated by those  
22                 donors.  We need a step by step explanation of the  
23                 records and the systems which enabled these steps to be  
24                 taken.  Where and in what form were the records which  
25                 revealed:

1           "The pool from which the batch had been  
2           manufactured.

3           "The identity of the donors contributing to that  
4           pool.

5           "The location of all other plasma from those donors.

6           "Was the infected donation or donations identified?  
7           Was the donor identified? What, physically, happened to  
8           the plasma when it was quarantined?"

9           Is that report an attempt to answer those questions?

10          A.   Yes.

11          Q.   Thank you. If we go to paragraph 2, the first line:

12                 "Information on HIV infection of haemophiliacs in  
13                 Edinburgh first became known to the SNBTS  
14                 in October 1984."

15                 Could you just tell us about that, Dr Perry, from  
16                 the SNBTS perspective?

17          A.   Well, the SNBTS perspective is primarily -- well, this  
18                 particular issue started with a telephone call from  
19                 Dr Ludlam to Dr McClelland, who was then the director of  
20                 the Southeast Scotland Blood Transfusion Service, and so  
21                 I had no personal involvement in this but we have  
22                 records which give this a fairly accurate positioning in  
23                 time. My understanding from the documents, and also  
24                 various discussions with Dr McClelland and others, is  
25                 that Dr Ludlam telephoned Dr McClelland on the evening

1 of 26 October. I think the time has almost been  
2 targeted at about 8 pm, indicating that he, Dr Ludlam,  
3 had just had a call from Dr Tedder indicating that  
4 samples from patients that Dr Ludlam had sent to  
5 Dr Tedder had tested positive for HTLV-III.

6 Q. Yes. What was the next step that SNBTS took in response  
7 to that?

8 A. My understanding is that Dr McClelland telephoned  
9 Dr Cash, who was the national medical director,  
10 discussed the notification. This was quite shocking and  
11 surprising. I don't think anyone was expecting this  
12 information. Discussed the circumstances and concluded  
13 that there was -- on the basis of the preliminary  
14 information that had been provided by Dr Ludlam, there  
15 wasn't a requirement for any specific action to be taken  
16 by SNBTS.

17 Q. Yes.

18 A. I think importantly, Dr Ludlam had also expressed, quite  
19 understandably at that time, that the information be  
20 kept confidential. This was an early report from  
21 a research or experimental assay carried out by  
22 Dr Tedder and he really wanted some confirmation of this  
23 for obvious reasons before this information was more  
24 widely disseminated.

25 Q. If we could have a look at [\[SNB0065996\]](#), what's that,

1 Dr Perry?

2 A. This is a memorandum from Dr McClelland to myself,  
3 copied to Dr Cash, as he was then, describing basically  
4 the events -- well, as the title indicates, the events  
5 leading up to the recall of Factor VIII batch 3-009.  
6 I think Dr McClelland understandably felt it was  
7 important that the various telephone conversations that  
8 had taken place following -- well, from 26 October  
9 onwards, should be recorded. This was a very serious  
10 and important event and I think Dr McClelland is just  
11 simply writing to me to confirm the actions that he had  
12 taken.

13 Q. Yes. So we see in paragraph 4 that at that point, it is  
14 thought that 16 of Dr Ludlam's haemophilia patients had  
15 tested positive for antibodies to HTLV-III?

16 A. Indeed, yes.

17 Q. Do you remember receiving that memorandum?

18 A. I can't honestly remember the circumstances in which  
19 I received it but I certainly have a recollection of the  
20 memorandum. It was an important event and indeed  
21 I responded to it with a letter from myself confirming  
22 that this was indeed my understanding of the events as  
23 well.

24 Q. Yes. Could we go back to the "Actions" document,  
25 please? So again this paragraph is discussing the

1 timeline, and just about five or six lines down this  
2 report says:

3 "On the basis of this initial report, a recall of  
4 batch NY 3-009 was carried out on 1 November 1984."

5 A. Yes.

6 Q. Is that your recollection?

7 A. It's my recollection but I think it's a recollection  
8 based on the letter that unfortunately I don't have with  
9 me, but it was my reply to Dr McClelland's memorandum  
10 when I gave a little more detail about the actions that  
11 SNBTS had taken. But it was certainly very much around  
12 about that time, 1 November, plus or minus a day. It  
13 was --

14 Q. Yes.

15 A. -- some days after the initial notification.

16 Q. Yes. The Inquiry is going to hear from Dr McClelland  
17 next week, so he can perhaps provide some more detail  
18 about this, but if we look at the bottom of that  
19 paragraph, we see that:

20 "The review of the batches received ..."

21 And I presume that's the review by Dr Ludlam and  
22 Dr McClelland?

23 A. Yes, indeed.

24 Q. "... showed that the 16 haemophiliacs had received  
25 a total of 33 batches of SNBTS Factor VIII over a period



1           which could account for the development of their HIV  
2           infection. For each of these 33 batches, an analysis  
3           was performed of the number of the 16 haemophiliacs who  
4           had received each batch. The number of recipients of  
5           each batch varied between two and 15, ie no batch had  
6           been given to all 16 patients. However batch NY 3-009  
7           had been given to 15 of the patients at a time which was  
8           consistent with them developing the infection. In  
9           contrast, two separate batches had been given to 14 of  
10          the 16 patients but following further investigation, it  
11          was found that several of these patients had received  
12          the product after they had become infected."

13                 So those investigations were all carried out by  
14          Dr Ludlam and Dr McClelland. Is that right?

15   A. Yes, indeed. That's right, that's correct.

16   Q. Yes. So just reading on at the bottom of the page:

17                 "On the basis of that, batch NY 3-009 was the most  
18          likely batch to have infected the majority of the  
19          patients, the early decision to recall it on  
20          1 November 1984 was fully justified."

21                 Then you say:

22                 "Steel et al reported in the Lancet in 1988 that  
23          later monitoring revealed that a further three  
24          recipients of the implicated batch developed antibody to  
25          HIV, making a total of 18."

1           Could we have reference two up, which is the Steel  
2           article, which is [\[LIT0010895\]](#). Is that the article  
3           that's referred to?

4   A. Yes.

5   Q. Yes. So we see in the summary of "32 patients exposed  
6           to a single batch of Factor VIII contaminated with HIV",  
7           18 became antibody positive?

8   A. Correct.

9   Q. If we go half way down the introduction passage, it  
10          says:

11                "It was subsequently established that a single batch  
12                of locally-produced Factor VIII had been contaminated  
13                with human immunodeficiency virus (HIV)."

14                The reference to that, if we could go to the last  
15                page, is another article, report, by Ludlam, Tucker,  
16                Steel et al:

17                "HTLV-III infection in seronegative haemophiliacs  
18                after transfusion of Factor VIII."

19                In the Lancet in 1985.

20   A. Yes.

21   Q. Is that where the analysis of the records identifying  
22          the batch is discussed?

23   A. In that particular -- the publication, the 1985  
24          publication to the best of my knowledge was the first  
25          publication which described what we now describe as the

1 "Edinburgh cohort" event. I don't think that paper from  
2 memory carries out a detailed -- I don't think that  
3 paper provides a detailed rationale of how that  
4 conclusion was reached but I think it more or less  
5 accepts that the analysis that was done by Drs Ludlam  
6 and McClelland was correct and it led to identifying  
7 batch 3-009 but, no, the detailed batch analysis isn't  
8 done in that paper.

9 Q. Yes. Perhaps we could have a look at [\[SNB0083434\]](#). Is  
10 that the paper that is referred to at reference 2?

11 A. That's right. It describes 15 patients at that time,  
12 yes.

13 Q. Could we have a look at the second page, please? Under  
14 the top left column, under the heading "Results", we see  
15 that Dr Ludlam et al record that:

16 "Between April and October 1984, anti HTLV-III  
17 developed in 16 patients with Haemophilia A. The  
18 transfusion records of these patients show that all but  
19 one had received a common batch (A) of SNBTS Factor VIII  
20 between March and May 1984. Of all the other batches of  
21 Factor VIII transfused during this period, the next most  
22 likely implicated batch was transfused  
23 during January 1984 and was given to only nine of the 16  
24 patients who seroconverted."

25 A. That's right.

1 Q. "The source of HTLV-III in the one patient with severe  
2 Haemophilia A who did not receive batch A remains  
3 obscure but he did receive batch B ..."

4 And so on. So although that's not a detailed  
5 analysis --

6 A. It's a summary of the analysis that led to the  
7 conclusion.

8 Q. Yes.

9 THE CHAIRMAN: Dr Perry, I'm anxious that we should follow  
10 stage by stage the nature of the analysis that was  
11 carried out. At this stage there is still no chemical  
12 analysis being done. Is that right? One is looking at  
13 the records --

14 A. Yes, this is a pure analysis on the basis of  
15 seroconversions in patients.

16 THE CHAIRMAN: -- and trying to find a pattern.

17 A. And trying to find a common factor in the 15 patients or  
18 the 16 patients who had in fact seroconverted. So it  
19 was a fairly simple analysis, I think in some ways. And  
20 I think even to this day there has been no absolute  
21 chemical proof that this batch was infected, but I think  
22 it is certainly recognised and accepted that this batch  
23 was -- you know, for the purposes of discussion, this  
24 batch was certainly infected.

25 THE CHAIRMAN: Yes.

1 MR GARDINER: We will come to the chemical analysis later

2 but if we could go back to the "Actions" document.

3 Yes, that's great, thank you.

4 So:

5 "Steel et al reported in the Lancet in 1988 that

6 later monitoring revealed that a further three

7 recipients of the implicated batch developed antibodies

8 to HIV, making a total of 18."

9 A. That's correct.

10 Q. "It is noteworthy, however, that Steel et al also

11 reported that not all recipients of batch 3-009

12 developed evidence of HIV infection (14 out of 32

13 recipients remained uninfected). Although it has never

14 been established conclusively that the batch was

15 infective, the actions taken were made on the basis that

16 this was a justifiable, though unproven, assumption."

17 Dr Perry, could you just expand on that conclusion

18 about the justifiable, though unproven, assumption?

19 A. I think this describes -- well, the action that was

20 taken was clearly to recall the batch and to carry out

21 a whole series of subsequent investigations. I think in

22 a sense it's an example of applying a precautionary

23 principle here. We had enough evidence and enough

24 information to allow us to act and act on the basis

25 that -- the conclusion that it was a single batch,

1 3-009 -- was evidence-based, although again not proven,  
2 but there was sufficient information there to allow us  
3 to take the action that we did.

4 Q. Yes.

5 THE CHAIRMAN: Dr Perry, again, I'm anxious that we should  
6 know exactly what's going on. There seems to me to be  
7 a difference between having enough information to take  
8 action. For that a much lower level of proof would be  
9 required --

10 A. Yes.

11 THE CHAIRMAN: -- if one simply applies a common sense  
12 approach. If there is a material risk, then one would  
13 wish to avoid it?

14 A. Yes.

15 THE CHAIRMAN: So I can understand you saying that there was  
16 enough information to take action, but, of course, that  
17 still leaves outstanding the question whether the  
18 information was conclusive in a more general sense, and  
19 for that perhaps a higher degree of probability would  
20 have to be established. I'm not interested in  
21 mathematical certainty. We will never get there.

22 A. Well, the absolute proof, if this is the answer to your  
23 question, would be a clear positive test on the batch in  
24 question, an antibody test, because that's all that  
25 existed at the time, and we didn't have that.

1           The other confusing factor was that not all patients  
2           who received this batch seroconverted, but nonetheless  
3           the compelling evidence was that 15 of the 16 at that  
4           time who had seroconverted, had already received this  
5           batch at a time consistent with it having been the cause  
6           of the infection.

7           So, yes, there are many imponderables in there. At  
8           that time we only had the preliminary assays available  
9           to the research community to establish which patients  
10          had been infected but again, as I say, I think the  
11          pharmaceutical industry, and certainly the biological  
12          pharmaceutical industry, has to take all sorts of  
13          actions based on insufficient information sometimes,  
14          applying what we now describe as the "precautionary  
15          principle".

16 THE CHAIRMAN: Yes.

17 MR GARDINER: We have heard about the "precautionary  
18          principle" quite a lot. Could you just, in a couple of  
19          sentences, explain what you understand by the  
20          "precautionary principle".

21 A. I'm not sure that I will be to enlighten you but my  
22          understanding of the precautionary principle, certainly  
23          in our industry, if there is some evidence that a risk  
24          may exist, then it is incumbent upon the manufacturer  
25          and the supplier of the product to take action to

1 mitigate that risk. Now, clearly there are all sorts of  
2 considerations about how big the risk is and what the  
3 implications of that risk are but for something as  
4 important as this, I think that risk/benefit judgment in  
5 the context of a precautionary principle is not  
6 difficult to take.

7 Q. Yes. At the time of recall, in November 1984, had  
8 a test been done on the batch?

9 A. No, not on the batch. As I say, the commercialised  
10 HTLV-III or HIV antibody test wasn't introduced  
11 until October 1985 and we were relying at that stage on  
12 research assays carried out by, I think at that time,  
13 Dr Tedder and perhaps Dr Mortimer as well from the  
14 Public Health Laboratory Service, and they were the sole  
15 agencies that had access to the early forms of the  
16 HTLV-III test.

17 Q. Yes. The decision to recall, was that not based solely  
18 on an analysis of the transfusion records and  
19 identifying the most likely candidate?

20 A. That's exactly the basis for the recall. We had  
21 information, evidence, that a number of patients had  
22 seroconverted for HTLV-III. They had no other risk  
23 factors and there was no other rational explanation for  
24 their having seroconverted. Therefore, it was a fairly  
25 simple -- once we had confirmation from Dr Tedder and



1 Dr Ludlam that the results that were notified on  
2 26 October were real, ie they had confirmed -- and  
3 I haven't got details of exactly how that was  
4 confirmed -- they would have probably repeated the test,  
5 and I think once we had that information it was a very  
6 straightforward decision that was taken -- I think, in  
7 actual fact by Dr Cuthbertson because I wasn't in the  
8 centre at that time -- to recall the batch and that  
9 would have been on the basis of advice and  
10 a suggestion -- well, certainly advice by Drs Ludlam and  
11 McClelland.

12 Q. Yes. I mean that testing was on patients' samples?

13 A. Sure.

14 Q. It wasn't on the batch?

15 A. At that stage there was no means of testing the batch.

16 Q. Yes.

17 A. So the inference that the batch was implicated was  
18 purely on the basis of the transfusion records and no  
19 more than that. There was no chemical or biological  
20 assay that was done to the material in question.

21 Q. Yes.

22 A. Because those assays simply didn't exist.

23 Q. Yes.

24 A. But just to add to that, that wouldn't be unusual in the  
25 case of things like plasma products, which are complex

1 biologicals. I think there are a number of -- it is  
2 often the case that you can have adverse reactions to  
3 complex biopharmaceuticals without understanding exactly  
4 what has actually caused it, ie without there being  
5 a chemical or a biochemical explanation for it. And  
6 I think you will find that in a number of cases  
7 manufacturers would take action simply on the basis of  
8 observed reactions in patients, without there being any  
9 chemical or biochemical confirmation.

10 Q. Yes. It's jumping forward a little bit in the document  
11 but when was the first testing done on this batch?

12 A. I think this would have been later in 1985.

13 Q. Yes.

14 A. Once the commercial assay was available.

15 Q. Yes.

16 A. And that would have been done on the product itself. To  
17 the best of my recollection, it was done on the plasma  
18 pool as well.

19 Q. Yes. At that time, December 1984, Dr Tedder was testing  
20 blood. Could he not have tested the batch?

21 A. I think he could have tested the batch, although --  
22 again, the assay that he was using wasn't a research  
23 assay. It was by no means validated for patient  
24 samples, let alone as part of a pharmaceutical  
25 evaluation process.

1           He could have done but I think the important point  
2           to understand is that we took action which was to  
3           ensure -- to remove what we suspected to be a risk from  
4           the supply of product, and we did that. Thereafter, the  
5           further examination of whether or not this was a real  
6           effect, in a sense, was secondary. The action that we  
7           had to take first of all was to make safe the supply of  
8           the product, and that we did by recalling it. And once  
9           one has done that, you remove the risk from the supply  
10          and subsequent evaluations and investigations become  
11          secondary to basically maintaining supply of  
12          a replacement product.

13        Q. Yes, thank you.

14                I think if we could go to page 8 of the "Actions"  
15                document, this is jumping forward chronologically but  
16                just because we have been talking about it, paragraph 7,  
17                is that the paragraph that deals with testing of the  
18                batch?

19        A. Yes. Further testing of batch 3-009 and contributing  
20                donors, yes.

21        Q. Yes.

22        A. Again, I don't have the detail in front of me but it  
23                does state quite clearly that the batch was tested over  
24                the period 1985 to 1986, which coincided with the  
25                availability of assays, and it states quite clearly that

1           these were carried out in a number of laboratories,  
2           which would probably, although I would need to confirm  
3           this, include the National Control Laboratory, the  
4           National Institute of Biological Standards and Control,  
5           and to the best of my knowledge, until very, very  
6           recently, none of those assays indicated any chemical or  
7           biochemical indicator that the batch contained an  
8           infectious virus.

9   Q.   Yes.

10  A.   Or indeed antibody to that virus.

11  Q.   Yes.  This is between 1985 and 1986?

12  A.   Yes.

13  Q.   Yes.  Could you talk a little bit about the different  
14       tests that were done on the batch?

15  A.   Well, I'm not an expert virologist, by any stretch of  
16       the imagination, but the tests would have been basically  
17       antibody tests in 1985 and 1986.  That was the original  
18       test that was established by Tedder, and subsequently  
19       commercial organisations, and they would have been  
20       looking for exclusively antibody produced in response to  
21       the infection that latterly became HIV.  I think they  
22       were variants on that.  There was a particular test  
23       which is described as "an enzyme-linked immunosorbent  
24       assay", which basically uses an antigen to capture any  
25       antibodies that exist and then you add various reagents

1           which gives a colour reaction. So there would have been  
2           variations on that particular assay that different  
3           manufacturers would have used.

4   Q.   It's looking for an antibody?

5   A.   It is looking for antibody.

6   Q.   Yes, thank you. So if we look at the third paragraph  
7           there:

8           "When HIV screening was introduced by the SNBTS  
9           in October 1985, all donors found positive were studied  
10          and look-backs were performed on previous donations.  
11          For some of these donations it was possible to find  
12          library samples to test and positive donations were  
13          found which had been included in pools used to make  
14          individual batches. In addition, previous donations  
15          were traced for which no library samples were found but  
16          which were considered to be potentially infective.  
17          These donations (both confirmed positive and potentially  
18          positive) were all traced and the findings are  
19          summarised in an internal report. None of these  
20          donations were used to make batch NY 3-009."

21          The next paragraph deals with further tests in 2008.  
22          Could you just talk us through that, please?

23   A.   Yes, indeed. I think when the announcement that there  
24          was to be a public Inquiry was made, as you can imagine,  
25          SNBTS began to prepare itself for the Inquiry and

1 I think it wasn't difficult for us to assume that this  
2 particular incident, ie the so-called "implicated  
3 batch", would be an important part of the proceedings  
4 and one of the members of SNBTS, who was involved in  
5 preparing for the public inquiry, made some enquiries  
6 with virology colleagues in Edinburgh, who had been  
7 working with us around that time, to find out -- just to  
8 make absolutely sure that there were no vials of the  
9 original batch 3-009 available.

10 Our belief at the time was that there were none. We  
11 had done an exhaustive search but this was a very last  
12 effort to do it, and the reason for that is because  
13 nowadays, 20 or 25 years later, there are much more  
14 sensitive, much more specific assays to test for both  
15 antibody and the actual virus in the vial and we were  
16 interested in establishing whether or not, using today's  
17 technology, we could establish any indication that the  
18 vial contained infectious material.

19 I think, to a certain extent, to our surprise it was  
20 Professor Peter Simmonds from the  
21 University of Edinburgh had found a vial and it had been  
22 basically laying about in the laboratory as a leftover  
23 from various research that he had been doing, because he  
24 was involved in a number of studies associated with this  
25 batch. It had been stored at room temperature, which is

1 outside its recommended storage, for many years but  
2 nonetheless, this was the only sample that we had of  
3 particularly this batch. I think the action that we  
4 took was to send it to a completely independent  
5 laboratory, to ask them to test for presence of any  
6 indications of HIV antibody or antigen or virus and that  
7 we did.

8 Q. Yes. What was the name of that laboratory?

9 A. The National Institute of Biological Standards and  
10 Control. It's based in Potters Bar and it's the  
11 National Control Laboratory. It carries out a number of  
12 functions on behalf of the UK, including batch release,  
13 specialist testing and so on.

14 Q. What tests did they carry out?

15 A. They carried out a range of antibody tests, antigen  
16 tests and what we now describe as "polymerase chain  
17 reaction", PCR assays, which are assays which detect  
18 infectious virus or fragments of infectious virus or  
19 RNA.

20 Q. Yes. Were the antigen and PCR tests available in 1984  
21 and 1985?

22 A. No, only the antibody test.

23 Q. Only the antibody test. If we have a look at appendix 2  
24 to the report, this is page 23, is that the report of  
25 that testing?

1 A. I think that's the report, yes.

2 Q. Yes. Can you just very briefly talk us through the  
3 report, Dr Perry, in terms of what the results were?

4 A. Okay. If we scroll down -- this is a standard report  
5 form that is used by the National Institute of  
6 Biological Standards and Control. It's a highly  
7 regulated activity. It operates to extremely high  
8 standards and they will be very careful in how they  
9 respond to enquiries like this.

10 My understanding is that the test -- the vial was  
11 tested by nucleic acid amplification technology for HCV,  
12 which is PCR, that's looking for the virus. And the  
13 reason it was looking for HCV was because the vial had  
14 been stored at room temperature for so many years, there  
15 is a view that any virus there may have degraded.

16 In 1983/84/85, we knew products were likely to  
17 contain HCV, so this was a good positive control. If  
18 the result had come back negative for HCV virus, then it  
19 would have led to some doubt over a negative assay for  
20 HIV. So this was a positive control, which is  
21 important, not because we were specifically looking for  
22 HCV. So we were looking for virus or HIV and anti-HIV-1  
23 and 2, which is the antibody test. And the three assays  
24 that -- and as I say, I'm not an expert virologist, this  
25 is not an area of expertise of mine, but they were



1 looking for antibody, antigen and DNA/RNA fragments.

2 Q. Yes.

3 A. And in the report it describes the results -- if we can  
4 scroll up perhaps on to the next page. It describes  
5 basically a very, very brief summary of the test method  
6 and the size of sample taken and so on, and the size of  
7 sample can be important, especially when you are looking  
8 at very low levels of contamination, having a very small  
9 sample may miss a very low level of contamination. So  
10 sample size is actually quite important and they are  
11 describing that methodology here.

12 Q. Yes.

13 A. And the test results -- that's HCV RNA by NAT -- clearly  
14 indicate that the vial was positive for HCV RNA, ie it  
15 had evidence of infectious virus or DNA from the virus  
16 in the vial. So that's the positive control. We know  
17 that the product hadn't degraded to the extent that we  
18 weren't picking up any infectivity at all. So that's  
19 the positive control which subsequently determines that  
20 the subsequent result is a valid one.

21 Q. So that result shows that HCV virus has been found --

22 A. It has been found but importantly it hasn't degraded  
23 over the number of years that the product had been  
24 stored in completely uncontrolled conditions, maybe on  
25 a window ledge in different temperatures, with sunlight

1 and so on. All of these things can have an effect on  
2 the viability of a virus. So this demonstrates that the  
3 subsequent assay for HIV is meaningful.

4 Q. Yes. But would it not make a difference how robust each  
5 virus is?

6 A. Indeed it would, yes. I'm saying "meaningful" rather  
7 than "accurate". I think it's just a surrogate method  
8 of basically answering the question, you know: is it not  
9 the case that the product is negative simply because it  
10 has degraded? And this helps to understand that. Again  
11 it doesn't give -- you are absolutely right, HIV virus  
12 may be much more sensitive to room temperature storage  
13 than HCV. I don't know whether that's the case.

14 THE CHAIRMAN: I think if we look at it as a matter of  
15 logical analysis, had there been no HCV, that would have  
16 led to an inference that there had been a degree of  
17 degradation and therefore if there had been a negative  
18 for HIV, you wouldn't have been able to draw an  
19 inference from that --

20 A. That would have been an inconclusive result, absolutely.

21 THE CHAIRMAN: But once you have a positive for HCV, that  
22 indicates that even if there may have been a degree of  
23 degradation, that has not been sufficient to negative  
24 that aspect and therefore give you more confidence in  
25 the result you get for HIV.

1 A. That's exactly the indication, yes. It's what  
2 virologists call a "positive control". It's a control  
3 that should come up positive if the assay is working.  
4 But you are absolutely right about different  
5 susceptibilities of HIV and HCV to different  
6 temperatures and storage conditions.

7 THE CHAIRMAN: Yes.

8 MR GARDINER: So that's the HCV result.

9 A. Scrolling over to the next page, if my understanding --  
10 so the HIV test -- this is the top of the page. HIV-1  
11 RNA by NAT is a test for virus or RNA from the HIV  
12 virus, using an established assay and that is clearly  
13 HIV negative in a duplicate test. So the conclusion  
14 from that assay is that they could find no HIV RNA in  
15 the sample vial. But then it goes on to say that  
16 additional assays were conducted using basically -- what  
17 they describe as "in-house assays". These are very,  
18 very specialist assays that have been developed by  
19 expert virologists at the National Institute. They are  
20 not used routinely but they can be used in certain  
21 research settings, and I think -- and using those  
22 assays, which are described as, I think -- there is  
23 evidence -- I don't know what "a Magnapure for the HCV  
24 RNA test" means. The statement says quite clearly:  
25 "There is evidence for the detection verified by

1 cloning and sequencing of HIV-1 RNA sequences in the  
2 sample, although at very low levels. The sequence  
3 identity studies indicate the sequences recovered a  
4 close homology with North American HIV circulating at  
5 least in the 1990s in the USA."

6 I'm not sure whether that's helpful to you.

7 Importantly it says:

8 "The conclusion has to be viewed with some caution  
9 given that it is based on only 120 base pairs of  
10 a highly conserved region of the HIV genome."

11 Which basically means that the assay suggests that  
12 there may be a fragment of the HIV RNA there but we  
13 can't be absolutely sure.

14 The anti-HIV-1 and 2 results, which are described  
15 below, demonstrate in the so-called "gen screen  
16 antigen", which is a combi test. It tests for both  
17 antigen, which could be a fragment of the virus, of the  
18 outer coat of the virus, and it also tests for antibody  
19 in what is a combined assay, and they got clearly  
20 reactive, ie positive, results using that assay. Using  
21 other ELISA or EIA tests, these tests came back negative  
22 and the so-called Western Blot, which is another means  
23 of doing an antibody assay, they came back with  
24 indeterminate results for the p24 and p17 antigens.  
25 That's an antigen test looking for a fragment of the

1 virus. And the Innogenetics antibody test was negative.  
2 So, as a result of this study, there were two assays --  
3 the result in the combi test, the so-called combi test  
4 for antibody -- this is my understanding of the  
5 report -- is that that came back positive and there was  
6 an equivocal result with the test for the virus using  
7 the NAT or PCR assays.

8 Q. Yes.

9 A. But this was the first evidence that we, SNBTS, had.  
10 This is 2008. This was the first evidence we had, which  
11 brought the chemical and biochemical evidence in line  
12 with the epidemiological evidence -- if we can call it  
13 that -- of the patients in 1985. And it's consistent,  
14 I think, with it being a very low level contamination,  
15 perhaps from what is described as a window-phase  
16 donation perhaps, but this is speculation.

17 Q. Yes.

18 A. It would certainly be consistent with that.

19 Q. Could we just go back to the --

20 THE CHAIRMAN: Before you go on, can I look at the dates  
21 with you just a little?

22 A. Yes.

23 THE CHAIRMAN: Dr Perry, the tests were carried out in 2008?

24 A. Correct.

25 THE CHAIRMAN: But the report is dated 2009. Who sent the

1 samples down to NISBC?

2 A. I think they were sent down, certainly on the authority  
3 of Professor Ian Franklin. Who actually physically  
4 packaged them up? I think they were sent by a very  
5 secure means. As you can imagine, this was a very  
6 precious sample and we were very anxious that these  
7 samples went to a completely independent laboratory  
8 and -- which is why -- you know, we have some of this  
9 technology within SNBTS but it was, for obvious reasons,  
10 important that we didn't do the assays ourselves. So we  
11 thought the best laboratory to send it to was the  
12 National Institute. I can't explain why the report was  
13 delayed until 31 March 2009. It could well have been  
14 that we had to chase them up for the report. There  
15 could be a whole series of reasons to explain that.

16 THE CHAIRMAN: Yes, Mr Gardiner?

17 MR GARDINER: Could you tell us a little bit about  
18 Ian Franklin's position. What's his position.

19 A. Professor Ian Franklin at the time was national medical  
20 and scientific director of the  
21 Scottish National Blood Transfusion Service, although  
22 importantly he wasn't the national medical director  
23 around 1985. That was Professor Cash, as we know.

24 Q. Yes.

25 A. But Professor Franklin was obviously closely involved in

1           preparations for the Inquiry and took a very clear view  
2           on this.

3   Q.   Could we just expand that page again?  I would just like  
4           to go back and ask you about the difference, if you can  
5           tell us the difference, between the NAT test for HIV and  
6           the in-house test, which you mentioned.  One was  
7           negative and one was weakly positive, I think?

8   A.   Well, I think one has to exercise extreme caution with  
9           anything I have to say on this because this is an area  
10          well outside my expertise.  What I can say is that the  
11          negative NAT test was a test which was a routine --  
12          which is a routine validated assay, ie it's proven to be  
13          effective, sensitive, specific, in the circumstances in  
14          which it is used, which is primarily in the context of  
15          NIBSC.

16                 Most of their work is associated with testing  
17                 product batches, batches of Factor VIII, albumin and so  
18                 on, and various other biopharmaceuticals.  So that test  
19                 is negative but it will be a standard commercial assay.  
20                 The research assay -- and the best analogy I have is in  
21                 forensic science, you hear about things of "low copy  
22                 analysis", "low copy number analysis" and I think that  
23                 it will be similar to that.

24                 I can't describe the specific scientific technical  
25                 differences.  It is not an area of work that I have ever

1           been involved in. But it's to an extent experimental.  
2           It's inconclusive. It hasn't been subjected to the  
3           rigorous sort of analysis that a routine assay would  
4           be -- that would be necessary for a routine assay but  
5           nonetheless it's indicative -- so it provides a  
6           indicative result, a result which may be of interest but  
7           you couldn't use it as conclusive -- you couldn't  
8           conclude from this that the batch was infective from  
9           that assay alone because --

10   THE CHAIRMAN: But taken with other evidence, such as the  
11           original analysis (Overspeaking), I think some of us at  
12           least will know from the criminal area that there is  
13           some controversy over the use of low copy numbers and  
14           whether one can conclude much from them.

15   A. I'm not actually saying this is low copy number  
16           technology, which has a very specific meaning, but there  
17           is an analogy there.

18   THE CHAIRMAN: You have 120 base pairs. You've not got  
19           a significant sequence.

20   A. Yes, that's right.

21   MR GARDINER: Is it indicative of a fragment of RNA of HIV?

22   A. Yes, that's what is being suggested. There is some  
23           evidence, they are saying, although it goes on to  
24           qualify that, saying it's a "highly conserved region".  
25           So that could be a fragment of another virus, is my



1           understanding of what that means, but it's most likely  
2           to be HIV. But it's not -- so it's an indeterminate  
3           result in a formal sense.

4    Q. The other results, the combi tests, comparing them to  
5           the in-house tests, are they more certain, if you like,  
6           or are they as indeterminate?

7    A. I think the combi test results were quite clear. My  
8           understanding is that they were both reactive. I'm not  
9           absolutely sure from this report whether they were  
10           reactive for the antigen or for the antibody, because  
11           that's what the combi test actually does, it tests for  
12           both antigen and antibody. But I think the result is  
13           reactive in both assays and that has a very precise  
14           meaning.

15   Q. Yes, and what is that?

16   A. That there is either antibody or HIV antigen in the  
17           specific sample.

18   Q. Yes.

19   A. Albeit at low levels but it is there, it has been  
20           detected.

21   Q. We heard that the batch was tested between 1985 and  
22           1986. Of the tests that we see here in this report,  
23           which of them, if any, would have been done on the batch  
24           in that period, 1985 to 1986?

25   A. Well, again this is not my area of expertise, the

1 evolution of various generations of assays, but I think  
2 from my general understanding, none of these assays,  
3 which are highly evolved technical procedures that have  
4 been developed over 20/25 years, none of these specific  
5 assays would have been used. They would have been  
6 antibody assays, very early versions characterised  
7 probably by low sensitivity but probably good  
8 specificity but a relatively low sensitivity, ie unable  
9 to pick up low levels of antibody but they would have  
10 been the so-called "first generation" HIV antibody  
11 tests.

12 Q. Yes.

13 THE CHAIRMAN: Mr Gardiner, I have visited Gentech in 1986  
14 when I was in the Crown Office and I also did the first  
15 prosecution in Edinburgh of a trial for rape based on  
16 DNA evidence. I can assure you that the recent tests  
17 are not just a generation but an age away from what was  
18 available in the 1986 to 1990 period, when I became  
19 a judge and gave up knowledge of these things.

20 MR GARDINER: Thank you, sir.

21 Maybe could you just quickly expand about low  
22 sensitivity and good specificity. Could you explain  
23 what you mean --

24 A. I'll give you my understanding of what this means.

25 Specificity is the ability of a specific assay system to

1 target a very specific -- in this case -- virus or  
2 antibody, the HIV -- and excluding the possibility of  
3 so-called "false positives", where other biological  
4 entities in complex mixtures can give a positive signal  
5 in the assays. So specificity for this sort of test has  
6 to be as close to 100 per cent as possible otherwise you  
7 have a problem, not only in terms of giving false  
8 positives in terms of either patient or donor sample.  
9 So that's specificity.

10 Sensitivity is the ability of the assay to detect  
11 low levels, or relatively high levels. So in a perfect  
12 assay you want both specificity and sensitivity.  
13 I think in reality there is probably a trade-off between  
14 the two.

15 Q. Yes. Dr Perry, putting all of these results together  
16 and trying to come to a conclusion about this batch,  
17 could you tell us what your conclusion is about the  
18 batch on the basis of these records?

19 A. On the basis of these records? Well, together with what  
20 I would describe as the "epidemiological evidence" from  
21 the original investigation, I would conclude that there  
22 is a very -- I would regard the batch to be probably  
23 infectious. I think it will always fall short of  
24 absolute proof for reasons that we have talked about,  
25 but I think there is a very strong probability that this

1 batch was the correct batch to have identified as being  
2 the cause of these tragic transmissions, but I can't  
3 really say more than that. I think it's impossible now  
4 to create a burden of scientific proof.

5 Q. Yes.

6 A. But my working assumption, and certainly my personal  
7 conclusion, is that batch 3-009 was implicated and from  
8 subsequent examinations, including the epidemiological  
9 studies, I would conclude that indeed it was an  
10 infectious batch. Although we have never been able to  
11 find the specific donation or donations that caused  
12 that.

13 Q. So it was an infectious batch?

14 A. Well, I have said we have never been able to find the  
15 infectious donation or donations. I think what we  
16 probably can conclude -- but again this is  
17 speculation -- that this was a very low level  
18 contamination, and the obvious evidence for that is that  
19 more than 30 patients received this batch and only 18 of  
20 them seroconverted. That would be consistent with it  
21 having a low level of infectivity.

22 Q. Yes. If we could go back to the "Actions" document,  
23 please, page 9. We see there at the top of the page  
24 a description of the results that we have just looked at  
25 and then the conclusion that the batch was shown to

1 contain low levels of markers of HIV infection and could  
2 have been infective in 1984:

3 "However, due to the ambiguity of the test results,  
4 the infectivity of this batch has never been absolutely  
5 confirmed, nor has a specific infective donor been  
6 identified."

7 You would agree with the first part of that, that  
8 the infectivity of this batch has never been absolutely  
9 confirmed?

10 A. Yes, but I also wouldn't wish that statement to be seen  
11 as an evasive statement. It's not a denial that there  
12 is something about this batch, but I think if one is  
13 being very scientific about it, we don't have absolute  
14 proof that the batch was infective.

15 THE CHAIRMAN: Of course, it may be a decision for me,  
16 Dr Perry, at the end of the day whether there is  
17 a sufficient level of probability to enable the finding  
18 of fact to be made. So the evidence here, you would be  
19 encouraging me to make that finding in fact?

20 A. I think so on the basis of the evidence. Certainly,  
21 I think it would be a brave man or woman that didn't  
22 accept that there was some highly relevant data that  
23 strongly points to --

24 THE CHAIRMAN: There are always brave people around here,  
25 Dr Perry.

1 MR GARDINER: Is it surprising that those results have been  
2 received about this batch?

3 A. From NIBSC?

4 Q. NIBSC, yes?

5 A. Was it surprising?

6 Q. Yes.

7 A. I don't think -- no, I don't think it was surprising.  
8 It wasn't surprising to me because I had already come to  
9 the conclusion that there was a high probability that  
10 this batch was involved in the seroconversion;  
11 therefore, it was only a matter of time arguably before  
12 we found some evidence, using the most sophisticated  
13 sensitive methods that we have got.

14 So, no, I wasn't shocked and surprised. I found it  
15 in some ways reassuring that we were able to find some  
16 chemical or analytical evidence that actually matched  
17 the epidemiological data that we had previously. So,  
18 no, it wasn't a surprise.

19 Q. What, in your view, is the explanation for the negative  
20 results which were on the most recent results?

21 A. On the antibody tests? Just generally, I think that's  
22 simply an issue of sensitivity of the assay. No more  
23 than that. Certainly that's the explanation why we,  
24 SNBTS, in the 1980s, were unable to detect -- or any  
25 other laboratory for that matter. That was an issue of

1 assay sensitivity.

2 Q. Yes, and how can that be explained, given that your  
3 conclusion is that the batch is infective? I think you  
4 mentioned a "window-period as" as a possible  
5 explanation, the window-period of the donor?

6 A. Yes, it's one explanation. It is not the explanation  
7 because I don't think we will ever be able to tie this  
8 down to a specific cause, but one explanation is that  
9 the donation -- or indeed donations because we don't  
10 know that it was one, although we suspect it may only be  
11 one -- that the donor was in the so-called  
12 "window-phase" of the infection, ie had circulating  
13 virus in the blood but had very low levels of antibody  
14 because it was early on in the infection before the  
15 antibody response had kicked in, and this is the  
16 so-called "window-phase" donation, where infections are  
17 very difficult to detect because it's early.

18 So that would be consistent with there either being  
19 a low level of virus contamination or a low level of  
20 antibody. Certainly a low level of antibody  
21 contamination would be consistent with that result.

22 Q. As well as the lack of sensitivity in the early tests,  
23 that might also explain why the tests hadn't picked  
24 up --

25 A. Absolutely.

1 Q. -- the batch?

2 A. Absolutely, indeed. It could have been a window-phase  
3 donation where there was no antibody response. So the  
4 donor was viremic, was incubating the virus, had yet to  
5 develop an antibody response, in which case there would  
6 be no antibody or very, very little, diminishingly small  
7 quantities. But from the most recent information, we  
8 seem to have picked up antibody in the so-called "combi  
9 test". So I think to speculate on this is interesting  
10 but perhaps not informative, but that certainly -- that  
11 could be one -- that could certainly corroborate the  
12 initial findings -- the subsequent findings.

13 Q. So it sounds as though, when you got the testing back in  
14 1985 and 1986, you weren't surprised about the lack of  
15 a positive test?

16 A. I can't remember whether we were surprised. I don't  
17 think we were necessarily expecting there to be  
18 a positive test. We knew the tests were relatively  
19 insensitive. If it was one donation, it would have been  
20 diluted by 4,000 other donations in the plasma pool. So  
21 there was a massive dilution effect of something like 10  
22 to the 3. During the purification process, we had no  
23 idea how HIV antibody partitions through the process.

24 So I think we probably expected there to be -- there  
25 is very little antibody in the Factor VIII product



1           itself, ie there is very little immunoglobulin which --  
2           HIV antibody is immunoglobulin. The process  
3           specifically excludes that from the product. So, no,  
4           no, it wasn't at all surprising that we weren't able to  
5           pick up infectivity.

6   Q. You have mentioned the donations. So perhaps we can  
7       have a look at the history of this batch. Could we go  
8       back to page 5?

9   THE CHAIRMAN: Coming back, Mr Gardiner, to the last part of  
10       the sentence that we looked at, on page 9 --

11   MR GARDINER: Indeed. I have taken things out of order.

12            So paragraph 3 records the history of this batch.  
13       Perhaps you can just talk us through the history,  
14       Dr Perry.

15   A. Indeed, yes. It's a fairly straightforward,  
16       conventional history -- or conventional in our sense.  
17       The plasma was collected from each of the regional  
18       transfusion centres in Scotland. At the time we only  
19       collected plasma from Scotland. The plasma would have  
20       been collected originally as whole blood and then  
21       separated and then supplied to PFC. I think our records  
22       suggest that collection took place around about the  
23       middle of 1983 to October 1983, ie the blood donations  
24       were given around about June to October from memory --  
25       is the dates that we have. A total of 940 kilogrammes,

1           which is about 4,000 donations, was collected and that  
2           was the material that entered the process.

3           The batch manufacturing process was started on  
4           7 November 1983 and that produced over 1,000 vials,  
5           which were cleared for issue on 10 February 1984, and  
6           I think, interestingly, this is a very typical period.  
7           About three months from plasma entering into the  
8           manufacturing process to the batch being released for  
9           use is usually, typically, about three months.

10          I think from a review of -- because we, obviously,  
11          reviewed the batch manufacturing records after the  
12          incident had been reported and there was nothing unusual  
13          or untoward in the batch manufacturing process.

14          Subsequently, 1020 were sent to the Southeast of  
15          Scotland Regional Transfusion Centre and 50 vials were  
16          supplied to the northeast regional transfusion centre in  
17          Aberdeen, where they were held for the treatment of  
18          haemophilia patients.

19   Q.    I think we have the batch records. I think these were  
20          produced recently. Is that right?

21   A.    Yes. Well, they have been available since the batch was  
22          manufactured but, yes, I think they have been  
23          produced -- there's a reference to the paper itself.

24   Q.    Yes. Can we just have a look at [\[PEN0121339\]](#)? If we go  
25          over the page, please, is that the batch record?

1 A. That is indeed what was called the "product clearance  
2 sheet", which is basically the sheet where all the  
3 parameters associated with manufacture, quality control,  
4 are checked by senior managers, and finally, as you can  
5 see at the bottom, batch released for issue by myself.  
6 At that time I was the QC manager.

7 Q. Yes. Could we go to page 1373? This is the second last  
8 page of this 36-page document.

9 A. Yes.

10 Q. If we look at paragraph 7, what does that show?

11 A. It shows the total number of vials that have been placed  
12 at issue. Basically, after quality control samples have  
13 been taken, library samples are taken, they are -- if  
14 I'm reading this correctly -- and it's a long time since  
15 I have seen one of these -- yes, this is the total  
16 number of vials that were entered into stock, which is  
17 1,070.

18 Q. Yes, thank you. If we go to --

19 THE CHAIRMAN: Before you leave, I'm quite interested in the  
20 total recording sequence, Dr Perry. As far as I can  
21 see, what you have got here is the end product, as it  
22 were, of the process. The 1,070 vials have passed all  
23 their checks, quality and other checks, and they are  
24 entered into inventory; in other words, they are put in  
25 stock at PFC?

1 A. Yes.

2 THE CHAIRMAN: And that results in a ledger entry?

3 A. Yes.

4 THE CHAIRMAN: And a batch number for that and storage until  
5 they are issued?

6 A. Yes.

7 THE CHAIRMAN: And I think I have picked up already that  
8 it's 1,020 to Edinburgh and 50 to Aberdeen.

9 A. Correct.

10 THE CHAIRMAN: Where is that recorded? Is it recorded  
11 somewhere in these papers?

12 A. That would be recorded on a separate document. All  
13 these documents were manual at the time but I think it  
14 was a document called a "batch history sheet", which  
15 actually signifies the final release, the quality  
16 release, of the batch, and then the subsequent  
17 distribution record becomes the working ledger for the  
18 distribution department.

19 MR GARDINER: We can see that, sir, at [\[PEN0121375\]](#).

20 THE CHAIRMAN: Could I see that, please?

21 A. So this provides the final authority for issue, which  
22 again carries my signature. At that time it was the  
23 responsibility of the quality manager to determine the  
24 quality and the suitability of the product and check  
25 that everything had been carried out according to

1 instructions and standard operating procedures and so  
2 on. Then, subsequently, this document would be used to  
3 basically stock control and provide a record of the  
4 centres to which the product had been issued.

5 THE CHAIRMAN: I think that's fine at that end. What about  
6 the other end of the process, when the material is  
7 received at PFC? What were the records there?

8 A. The plasma?

9 THE CHAIRMAN: Yes.

10 A. Again it would use various manual documentation. It  
11 wouldn't look like this. We received plasma in  
12 consignments of boxes of 12, which were then combined  
13 into packages of four, and the means of identifying the  
14 plasma -- the PFC only had information on the plasma box  
15 numbers. So we could never identify the specific  
16 identity of a donor. But box numbers related to --

17 THE CHAIRMAN: Mr Gardiner tells me you are coming to it but  
18 it's obvious up to a point that that's the end of the  
19 accounting procedure that's of greatest interest.

20 A. Yes.

21 THE CHAIRMAN: Yes. But if we are coming to it,  
22 Mr Gardiner, I'm happy just to wait.

23 MR GARDINER: Yes. On the batch issue history, is that your  
24 signature there?

25 A. Yes.

1 Q. Yes. So does that mean that you were the relevant QC  
2 inspector effectively --

3 A. I was, yes.

4 Q. Thank you. Could we go back to page 5 of the "Actions"  
5 document? Paragraph 4, which starts, "The recall of  
6 batch NY 3-009 ..." is the next bit in the story of the  
7 history of the batch. Could you just talk us through  
8 that, Dr Perry?

9 A. Well, clearly the PFC, as a pharmaceutical manufacturer,  
10 carried what at the time were comprehensive records for  
11 manufacture. I think over subsequent years the  
12 complexity of the documentation systems have grown  
13 enormously, but at that time it was a fairly  
14 conventional system of records for recording batch  
15 manufacturing activity.

16 All PFC products are manufactured in batches, as we  
17 know, probably typically from 4,000 donations, and each  
18 was labelled with a unique batch number and expiry date.  
19 The batch number allocation would certainly have gone on  
20 at the beginning of the process. Immediately the plasma  
21 entered the process, that would generate a batch -- well  
22 actually, not immediately the plasma goes into the  
23 process, but the plasma goes from plasma to  
24 intermediates and it is the intermediates that are then  
25 used to produce the range of product. It is when the

1 intermediates are selected from stock and then used for  
2 subsequent processing into specific products. That's  
3 when the batch number would be generated.

4 Q. Intermediates. Is that just before they become another  
5 product?

6 A. It's the initial process of splitting the plasma into  
7 what the industry describes as "fractions". So there  
8 would be a fraction that contains Factor VIII, there  
9 would be a fraction that contains Factor IX, there would  
10 be an immunoglobulin-containing fraction, an albumin  
11 fraction. The initial process of fractionation splits  
12 the plasma into those fractions. Those individual  
13 fractions, which are typically stored frozen, would then  
14 be taken out of inventory and entered into a specific  
15 product batch manufacturing process. And at that point  
16 the batch number would be allocated.

17 Q. Yes.

18 A. So there would be a trace-back between the batch number  
19 of the specific product to the intermediate. We would  
20 have a record of the intermediate and how that relates  
21 to the plasma box numbers that were entered into the  
22 process.

23 Q. Yes. Which we are going to come to.

24 A. So there was always a continuous trace.

25 Q. Yes. I think we are dealing with the recall, are we

1 not?

2 A. Yes.

3 Q. Yes.

4 A. Yes, the key stages in the batch manufacturing key  
5 quality test during manufacture and on the finished  
6 product were all recorded in this particular batch  
7 record, and I think there will be then a series of  
8 managerial and supervisory checks controlling a whole  
9 host of parameters that are important for determining  
10 the quality and the safety of the product, and that  
11 ultimately would --

12 Q. I think perhaps could we just move down the page  
13 a little bit to paragraph 3. We have the paragraph that  
14 begins:

15 "The recall of batch NY 3-009 ..."

16 I don't think we have dealt with that?

17 A. No.

18 Q. Could you just tell us about that?

19 A. The recall was to the best of my knowledge -- as I say  
20 I wasn't actually in the centre at the time -- was  
21 initiated by telephone on 1 November. That's what was  
22 reported to me following my return to the centre after  
23 I had been to the Groningen meeting, and this was  
24 followed up with a written recall process on 7 November  
25 and that would be typical.



1           Recalls, when they happen, they are unusual and they  
2           are rare but often it is necessary and important that  
3           you carry these things out quickly. So it was certainly  
4           part of the system then, before days of email and so on,  
5           to initiate important recalls by telephone. So the  
6           telephone recall, which was a very formal process, would  
7           have been carried out on 1 November. And we learned  
8           from that that none of the 1,020 vials were available  
9           for return in Edinburgh. Either they had been used.  
10          But 41 of the 50 sent to Aberdeen were returned unused  
11          and were held in quarantine at the PFC.

12        Q. These were the vials that were then tested?

13        A. Yes, these were the vials that were used for testing as  
14          described here, studies of markers of infectivity, which  
15          is effectively the antibody test, and we would have sent  
16          vials to different laboratories searching for, you know,  
17          any evidence of infectivity. And as we have discussed  
18          at the time, we could find none. These weren't just  
19          tested in our own SNBTS laboratory, I think we went  
20          wider than that to try and get some results but I can't  
21          offhand describe exactly where they were sent but there  
22          would have been a number of laboratories in the UK.

23        Q. And these were early antibody tests?

24        A. Yes, using the early antibody tests.

25                 Unfortunately, we didn't use all of those but all

1 the remaining vials that were held at the PFC of the 41  
2 that were returned from Aberdeen were unfortunately  
3 discarded during a tidy-up of one of the laboratories  
4 and its storeroom in the centre. As you can imagine, we  
5 tended to gather vast numbers of different samples from  
6 different product batches that were used, either for  
7 research purposes or so on, and I think this was in  
8 response to a medicines inspector saying, "You really do  
9 need to sort this cold room out. You are storing far  
10 too much. It is not rational." And I think in response  
11 to that, I think we tidied it up and sadly we tidied  
12 away some of the vials that we had held for research  
13 purposes. There were still, I think, at that stage,  
14 library samples because we did keep very formal library  
15 samples of each batch of product that was manufactured,  
16 but I think they were used in various attempts to  
17 establish if there were any marker of infectivity in the  
18 batch.

19 Q. Then the report talks about the one vial that was  
20 discovered?

21 A. Yes.

22 Q. Yes. We have dealt with that.

23 A. Yes.

24 Q. The next section, section 4, talks about PFC records and  
25 the batch manufacturing record. We have looked at that?

1 A. Yes.

2 Q. Could we go over the page? 4.2 talks about the issue  
3 history and we have looked at the batch issue history  
4 sheet. The next section is 4.3, "Plasma records", and  
5 these are the records that are held locally, I think.  
6 Is that right?

7 A. Plasma records -- I'll just make sure I answer your  
8 question correctly. There were two forms of record.  
9 Plasma records would be held at the regional transfusion  
10 centres, ie the supplying centres, but we would also  
11 hold plasma records at PFC. The records at PFC, just to  
12 describe this little nuance of the arrangement; at PFC  
13 we didn't store information on individual donations, we  
14 stored information on groups -- the plasma was supplied  
15 in boxes, typically cardboard boxes with barcoded labels  
16 and so on. We held those records down to the point of  
17 the individual box number, but there was a clear link to  
18 the plasma that was contained in those boxes, by the  
19 regional transfusion centres. So the  
20 regional transfusion centre gave the box its identity.

21 Q. Yes.

22 A. It had records in the centre, which identified which  
23 plasma donations had gone into that box and PFC held  
24 records of the plasma box. So there was a complete  
25 trace. But at any point in time PFC wouldn't be able to

1 identify individual donations but could do so using its  
2 suppliers, which were the regional centres.

3 Q. Using the information from the regional centres?

4 A. Yes, there was a trace.

5 Q. Thank you.

6 Sir, I'm going to move on to the detail of that and  
7 I think maybe it might be appropriate --

8 THE CHAIRMAN: Yes, it would be appropriate.

9 Because the vulnerable point at that stage is that  
10 there is a physical handling of the frozen plasma --

11 A. Yes.

12 THE CHAIRMAN: -- at the point of filling the box?

13 A. Yes, indeed.

14 THE CHAIRMAN: There is not a linking record there? The  
15 person who fills the box doesn't put in a slip with the  
16 numbers --

17 A. No, there is not a personal identifier, although even in  
18 those days -- well, for those days relatively  
19 sophisticated bar coding systems that could be used to  
20 control any plasma mix-up, but I can't recall -- despite  
21 the fact that by today's standards it was an extremely  
22 manual process and subject to all sorts of opportunities  
23 perhaps for error, I don't recall there being many, if  
24 any, mix-ups in terms of --

25 THE CHAIRMAN: I can't see why you would know except in



1 memorandum to me, where we were just confirming the key  
2 events. And as you can see, the recall process was  
3 started on 1 November.

4 Q. Yes. If we could go back to the "Actions" document,  
5 I think we were just about to look at plasma records, so  
6 paragraph 4.3 is about the records at PFC for the  
7 plasma. If you could just explain to us how they were  
8 organised, please.

9 A. The plasma records at PFC?

10 Q. Yes, please.

11 A. The records of plasma intake at PFC were recorded by box  
12 number, and as I have described, each box would  
13 typically contain about 12 donations. Each box would be  
14 sealed, they were fairly robust boxes and they would be  
15 allocated a specific number by the  
16 regional transfusion centre from which they had been  
17 sent. So the plasma records at PFC would actually only  
18 go down the level of the box number. Clearly, the  
19 Regional Transfusion Centre, who had assembled the box  
20 and placed the donations in it, would have a record in  
21 the centre of the donations that contributed to that.

22 Q. Yes. I think that's the next paragraph. Just reading  
23 here from "Individual boxes of plasma ..." we see that  
24 boxes of plasma -- and that's 12 donations per box,  
25 I think you have told us?

1 A. Yes, typically, yes.

2 Q. "... were bound in groups of four for storage purposes  
3 and given new identifiers, called 'storage numbers', for  
4 each group."

5 A. Yes.

6 Q. So each group would be 48 plasma donations?

7 A. Roughly, yes.

8 Q. "These new identifiers were also recorded in the plasma  
9 traffic sheet along with the weights of the contents in  
10 kilogrammes. When required, a suitable weight of plasma  
11 was removed from storage."

12 So what form was the plasma in at that point?

13 A. Frozen, still in the boxes and still -- well, yes, the  
14 plasma would be removed from -- the plasma was stored in  
15 the PFC in a minus 40 degrees freezer and it was stored  
16 in its boxes. When an instruction to make a batch of  
17 product or to process some plasma was made, the plasma  
18 boxes would be removed, the plasma donations removed  
19 from the boxes, obviously the box numbers recorded on  
20 the plasma traffic sheets as described here, and the  
21 plasma would then enter process.

22 Q. So at this stage the 12 individual donations were  
23 separate?

24 A. Yes. Yes.

25 Q. What were they contained in?

1 A. A plastic bag. For those of us, and you who were blood  
2 donors, you will recognise these plastic bags as the  
3 typical bags that are used in donor sessions, where the  
4 blood is collected in.

5 Q. This has been sent by the RTCs?

6 A. Correct, yes.

7 Q. If we just read on:

8 "The cold storage numbers for each group of four  
9 boxes was recorded in the batch record. A total of 95  
10 cold storage units were used to manufacture the batch of  
11 NY 3-009."

12 How do you know that?

13 A. Because this is recorded in either the plasma traffic  
14 sheets or perhaps the batch record. I haven't been  
15 through it but these data would be recorded. I think,  
16 as we discussed earlier, it was very important that we  
17 had a continuous trace between individual batches of  
18 product and the plasma that contributed to them.

19 Q. What was the total weight?

20 A. Recorded weight as -- reading from the document here --  
21 is 1,043 kilogrammes.

22 Q. Yes.

23 A. Which is combined plasma plus the plastic container.

24 The actual weight of plasma was 940 kilogrammes.

25 Q. Yes.



1 THE CHAIRMAN: You say "plus the plastic container"?

2 A. Yes, it was a PVC bag.

3 THE CHAIRMAN: But weren't they weighed originally just in  
4 their cardboard boxes?

5 A. No, they were never weighed inside their cardboard  
6 boxes. When they entered process, they would have been  
7 weighed -- to the best of my recollection, they would  
8 have been weighed as basically frozen lollipops of  
9 plasma, but clearly at that stage they were still  
10 contained in their plastic outer pack and that plastic  
11 outer pack was subsequently removed but we had  
12 a standard conversion factor. We knew how much  
13 a plastic bag weighed. We could basically calculate the  
14 actual amount of plasma.

15 THE CHAIRMAN: I think then I have not quite got the  
16 sequence complete. You say that:

17 "The new identifiers were recorded in the plasma  
18 traffic sheet along with the weights of the contents in  
19 kilogrammes."

20 I had rather understood that to refer to the groups  
21 of four as they went into storage, which is why I'm  
22 wondering about whether the cardboard was weighed as  
23 well. The alternative is that they weren't weighed  
24 until they were taken out of storage, when they would  
25 only be in plastic bags, just to plug that little gap,

1           please, doctor?

2    A.   I believe that the plasma weight would have been  
3           recorded by the regional transfusion centre, excluding  
4           the cardboard box, but it isn't an important detail and  
5           I'm sorry, I can't give you actually a definite answer.

6    THE CHAIRMAN:  That's all right.  If it is pre-recorded that  
7           answers the question.

8    MR GARDINER:  Yes.  A decision was made to trace the  
9           individual donations used to make this batch.  Could you  
10          explain to us what the process was for tracing the  
11          individual donations?

12   A.   It's really as described here and it was fairly  
13          straightforward.  The system was designed to be  
14          straightforward and to allow a fairly simple,  
15          straightforward identification of individual donations  
16          going into any product batch.  The batch record -- the  
17          formal batch record would have contained the cold  
18          storage numbers, which as we have seen above, gives the  
19          key references for the individual plasma boxes, and that  
20          would have allowed us to identify the specific  
21          individual box numbers.  Those box numbers would have  
22          been compiled, as it says here, for each centre.  Each  
23          centre had its own specific regional or area code and  
24          these lists were supplied to the individual centres  
25          throughout Scotland and they would have then consulted

1           their records, where they would have been able to  
2           identify the individual donations and from the  
3           individual donations, they would be able to identify the  
4           specific donors.

5   Q.   Yes.  I think if we go over the page --

6   A.   I think there was some importance attached to keeping  
7           a separation between PFC, which was basically  
8           a pharmaceutical manufacturing plant, and a relatively  
9           more -- a greater clinical environment at the  
10          regional transfusion centre.  So disabling the ability  
11          of PFC on its own to identify specific donors actually  
12          was quite an important principle, which is why there was  
13          this separation, this punctuation mark in the process.

14  Q.   Yes.  Paragraph 5 details the records that were held at  
15          the transfusion centres.  Could you just describe them  
16          for us?

17  A.   Well, I can't describe them in detail because I have  
18          never worked at a regional transfusion centre but they  
19          would be paper-based at that point in time and I don't  
20          know what form they took.  I apologise.  But they would  
21          have been basically lists of individual box numbers and  
22          associated with the individual box numbers, the  
23          individual donations would be recorded.

24  Q.   In that paragraph, in the second half of it, it says  
25          that:

1           "Since the original donations were collected in  
2           autumn 1983 (entered into production at the PFC on  
3           4 November 1983), it was likely that many of the donors  
4           would have given subsequent donations."

5           So what was done about those subsequent donations?

6   A.   They were subject to a look-back, once we had HIV  
7        results -- HIV assay systems available in October 1985,  
8        the individual donors that contributed to  
9        that particular batch, their donations would have been  
10       tested and any found HIV positive we could have related  
11       that back to a possible inclusion in batch 3-009, but  
12       I think as it described here and elsewhere, none of the  
13       subsequent donations from those donors were found to be  
14       HIV positive. That doesn't mean to say that there were  
15       not infectious donations in the plasma pool because not  
16       all donors return.

17   Q.   Yes.

18   A.   But the plasma was also -- once we had identify the  
19        plasma, both the plasma was quarantined, any subsequent  
20        donations from those individual donors was quarantined  
21        and indeed the red cells and the platelet components  
22        were quarantined, and subsequent donations from those  
23        donors were also subject to -- I don't know what the  
24        technical term was but they would not have been used.

25   Q.   And I think that's set out in the next paragraph?

1 A. Indeed.

2 Q. We see that there was a co-ordinating group on  
3 6 November 1984?

4 A. Yes.

5 Q. "Where it was decided that the donations used to  
6 manufacture the batch should be traced and that relevant  
7 information should be provided to each centre to enable  
8 them to perform this trace. This allowed each site to  
9 trace the constituent donations and therefore the  
10 donors. At a further meeting on 20 November it was  
11 decided that repeat donations from the donors should be  
12 followed up ..."

13 You have told us that that was done and it was found  
14 that none of them were found to be HIV positive?

15 A. That's correct, yes.

16 THE CHAIRMAN: Do you have any idea of the number of repeat  
17 or return donors?

18 A. I'm sorry, I don't know how many -- no, I don't, I can't  
19 answer that question.

20 MR GARDINER: Paragraph 6.1 separates this process into  
21 plasma donations and then 6.2 is cellular components.  
22 Could you tell us what the different approaches were?

23 A. The PFC simply was required -- well, in some senses they  
24 were similar but the plasma from the donations was  
25 quarantined. Any plasma that we still had in stock from

1 those particular donors would be quarantined and any  
2 subsequent donations from those blood donors would also  
3 have been quarantined.

4 The position with cellular products, it was agreed  
5 that, as it says here -- it was agreed that red cell  
6 from donations collected from the donors implicated or  
7 associated with the batch should have been discarded.  
8 Now, I don't think -- I'm not sure that that discard  
9 ever took place. I think that that decision was  
10 reversed subsequently.

11 THE CHAIRMAN: Is it realistic anyway? The red cells would  
12 have been used within three days.

13 A. They had a shelf life of typically maybe five weeks  
14 maximum. But I think this was a period running up to  
15 Christmas and I think, as I think is documented, that  
16 that decision to not quarantine all these donations or  
17 subsequent donations from the donors was subsequently  
18 reversed, and I think there were practical reasons for  
19 that, not least that we were unable to identify any --  
20 the specific donation or donations that had caused the  
21 problem. Therefore, you would have been faced with  
22 a problem of: what do you do with 4,000 donors,  
23 potentially in a suspect category and consistently  
24 unable to use their blood? They would have come back to  
25 donate. So there would have been a problem about

1 notifying these particular donors. So it was not only  
2 the supply of the product that influenced these  
3 decisions but it was the issue of how to manage so many  
4 donors without any clear evidence that any of them were  
5 implicated in 3-009.

6 MR GARDINER: Yes. Of course, as we see later, heat  
7 treatment comes in quite quickly at this stage.

8 A. Yes.

9 Q. So it would be relevant, I imagine. Could we go over  
10 the page to page 8. It's at the top of the page:

11 "Consideration was given to the testing of samples  
12 from all 4,000 donors for evidence of HIV antibody."

13 Was that done?

14 A. I think Dr McClelland and perhaps others discussed the  
15 possibility of this, I think it was with Richard Tedder  
16 and Philip Mortimer from the Public Health Laboratory  
17 Service, and they indicated this was way beyond their  
18 means. Remember at that stage we only had  
19 an experimental research assay which was being carried  
20 out at Middlesex Hospital, and I think the priority  
21 there was screening patients and various other high --  
22 so it certainly wasn't suitable for what for them would  
23 have been very high throughput mass screenings. It was  
24 considered impractical but also -- and I think Dr Tedder  
25 mentioned in his letter that if you can't guarantee to

1 capture all 4,000 donations, the results are not going  
2 to be meaningful, even if you did carry out the assays,  
3 and we certainly were unable to have -- we certainly  
4 didn't have donations or samples from the 4,000  
5 donations that went into the pool because we didn't keep  
6 library samples at that time.

7 Q. Could we look at [\[PEN0121423\]](#)? I think that's a letter  
8 to Dr Tedder from Dr McClelland, dated 28 November 1984?

9 A. Yes.

10 Q. If we look in the first paragraph, he says:

11 "We have now identified all the donors who  
12 contributed to the batch of Factor VIII under  
13 discussion. There are approximately 4,000. Donation  
14 samples are available from approximately half of these  
15 at present and the remainder will take some considerable  
16 chasing up."

17 I think, as you have just said, Dr Tedder advised  
18 that that probably was not enough to make the exercise  
19 worthwhile because if we look at [\[PEN0121424\]](#), that's  
20 a letter to Dr McClelland from Dr Tedder, says that he  
21 is not enthusiastic about the process although he would  
22 be enthusiastic if Dr McClelland could guarantee to get  
23 99.5 per cent of the donors, then it might be worth  
24 trying. But am I right in thinking that that was never  
25 done and therefore the testing never took place?



1 A. To the best of my knowledge, the testing never took  
2 place.

3 Q. Well, Dr McClelland is going to be here next week. So  
4 he can tell us about that. Okay, if we could go back to  
5 the "Actions" document, please, we see at the top of  
6 page 8 that:

7 "The decision to discard the red cells was reversed  
8 ..."

9 That was for the operational requirements of the  
10 service. Is that right?

11 A. That's correct.

12 Q. Yes. As you said, it was decided that the 4,000 donors  
13 should remain on service.

14 A. Yes.

15 Q. Could we now go over to page 9, please. Paragraph 8  
16 deals with the introduction of heat treatment. Was the  
17 introduction of heat treatment a factor which was taken  
18 into account in deciding whether or not to continue  
19 these investigations?

20 A. The introduction of heat treatment was certainly  
21 a factor in deciding ultimately -- well, ultimately it  
22 wasn't that long after the October notification but it  
23 was a factor in deciding that the plasma collected from  
24 these donors and associated with these donations would  
25 be acceptable for subsequent manufacture because, you

1 know, our understanding and a leaf from the reports from  
2 the CDC in America was that the heat treatment protocol  
3 that we were using then was more than adequate to deal  
4 with any potential contamination that may have resulted  
5 from that. So, yes, it was a factor, certainly in terms  
6 of placing the plasma back into process -- or the  
7 donations from the donors that were implicated in the  
8 first batch.

9 Q. Yes. Just the first bullet point there in that  
10 paragraph:

11 "It's noted that no cases of HIV have ever been  
12 reported in recipients of SNBTS heat-treated  
13 Factor VIII."

14 Then the next paragraph:

15 "All plasma in stock in October 1984 when the first  
16 evidence of infection came to light was used in the  
17 manufacture of heat-treated Factor VIII, which was  
18 issued from 1985 onwards."

19 A. Yes.

20 Q. "This provided the basis for releasing the quarantined  
21 donations from the donors who had contributed to batch  
22 NY 3-009."

23 A. Yes.

24 Q. If we just move to the conclusions of this report,  
25 Dr Perry, could you just talk about the conclusions that

1 are listed here?

2 A. Yes, indeed. The first conclusion that I think we have  
3 drawn from this, not only the investigation then but our  
4 subsequent, more recent, investigations, are that, as  
5 it's described here, the infectivity -- I think these  
6 words are chosen quite carefully but:

7 "The infectivity of the batch was deduced from  
8 epidemiological data available in 1984."

9 That is the evidence of transmission to individual  
10 patients in the Edinburgh cohort. That's I think what  
11 we mean by "epidemiological data". I think we are  
12 saying it seems likely -- I think we can debate whether  
13 it is likely, probable, highly likely but it's certainly  
14 likely in my mind, and indeed probable, that this  
15 assumption was correct, but as we say, it has never been  
16 proven but that's a simple fact, it is not an attempt to  
17 evade the possibility that the batch of SNBTS product  
18 transmitted virus. I think the whole of the SNBTS  
19 is very happy to accept that that is the situation and  
20 the position.

21 The actions at the time were all well documented and  
22 most of the documentation is available and described in  
23 the paper. Again, that's perhaps a subjective view from  
24 the SNBTS but we believe that we have a good -- even in  
25 those days we had a fairly good record-keeping system

1 for these specific types of data and we think it's  
2 fairly comprehensive and we are not aware of any  
3 information or data that is perhaps significant but  
4 missing.

5 Q. Yes.

6 A. None of the donors whose plasma was used to make batch  
7 3-009 was ever identified as being HIV positive, which  
8 is perhaps an important, though in a sense unfortunate,  
9 conclusion. But the SNBTS has never been able to find  
10 an individual donor or donation that contributed to  
11 that.

12 I think there were some suspicions around the end of  
13 1984 that a donor from the West of Scotland may have  
14 been the implicated donor but subsequent follow-up  
15 proved that not to be the case. There was a very short  
16 period of time where I think the West of Scotland had  
17 identified a donor who they believed to be a homosexual  
18 and had a marginally possible transmissible disease that  
19 was picked up but I think their -- "expectation" is  
20 probably too strong a word, but they thought that that  
21 might be the donor that had contributed but it turned  
22 out not to be the case.

23 Q. Yes. How did they come --

24 A. He was tested, I believe, by Dr Tedder because he was  
25 a specific donor and we had a sample. I think that's

1 the process that went through. So he was excluded.

2 THE CHAIRMAN: He was mildly reactive for VD according to  
3 the records.

4 A. That's right.

5 MR GARDINER: Who was it who organised that testing,  
6 Dr Perry, of that specific donor?

7 A. I think if it was a donor in the West of Scotland, it  
8 would have been Dr Mitchell or one of his staff.

9 Q. Yes. So the results would have come back too  
10 Dr Mitchell?

11 A. Indeed.

12 Q. Thank you.

13 Then the fourth conclusion over the page.

14 A. It's really not a conclusion, it's more of a statement  
15 of fact, but when the possible infectivity of batch  
16 3-009 was discovered, SNBTS decided to quarantine any  
17 further plasma donations pending the investigation, and  
18 since the investigation didn't identify an infected  
19 donor, the quarantine was ended when heat treatment at  
20 68 degrees for 24 hours -- not two hours -- I think this  
21 is an important distinction. At that stage in the  
22 process we had already established a process for heating  
23 for 24 hours and that coincided with the information  
24 that we had received from very reputable, highly well  
25 thought of scientists in the US, that indicated that

1           that temperature and time were highly effective against  
2           HIV. So it was partly on that basis that the quarantine  
3           was lifted on the plasma.

4   Q.   Sir, I don't have any more questions.

5   THE CHAIRMAN: I think I have one.

6           Dr Perry, in your last answer but one I think you  
7           said that SNBTS has never been able to find out the  
8           individual donor or donors whose blood may have been  
9           infected. Is it not rather the case that, having failed  
10          to persuade Dr Tedder and others to take up the issue,  
11          the whole question just fell? It wasn't pursued?

12   A.   I think the question did fall. As far as the plasma  
13          fractionation centre was concerned, this became an  
14          interesting topic but not highest on our agenda because  
15          at that stage we had taken action to ensure the safety  
16          of the product. So I think for a number of reasons, you  
17          are absolutely right, there was -- (a), I think it was  
18          considered impossible that we would ever find the source  
19          of the donation. We had tested the plasma pool and the  
20          product by the most searching methods available, and by  
21          the end of 1985 -- and at that stage I think you are  
22          absolutely right, I think our view was that we would  
23          never be able to get to the bottom of this specific  
24          incident.

25   THE CHAIRMAN: Of course, one possible response to that is

1           that, as return donors came along, the constituency  
2           began to narrow.

3    A.   Yes, I think the hope may have been also -- but this is  
4           again speculation -- that as the donors came back and  
5           an HIV test was introduced, we would ultimately get  
6           a donor that came in that was HIV positive that we would  
7           then be able to relate back to 3-009, but we were never  
8           able to. We certainly were able, as has been indicated,  
9           to identify HIV positive donations whose donations we  
10          now know were included in batches of Factor VIII.  
11          Thankfully heated batches of Factor VIII. And we now  
12          know that they didn't transmit HIV. But we were never  
13          able to -- using the look-back process that was put in  
14          place -- identify the specific donor or donors that  
15          contributed to batch 3-009.

16   THE CHAIRMAN: One possibility is that the donor  
17          subsequently died of AIDS? Was there ever any attempt  
18          to correlate those who had died of AIDS with those who  
19          had been blood donors over the critical period?

20   A.   I don't know but I think --

21   THE CHAIRMAN: It may not have been your area.

22   A.   It certainly wasn't my area.

23   THE CHAIRMAN: I asked the question merely to raise the  
24          point for others to look at, Dr Perry.

25   A.   The answer is I can't answer, I am afraid.

1 MR GARDINER: Sorry, sir, there was one thing I should put  
2 to the witness.  
3 Could we have [\[PEN0121335\]](#) up?  
4 I'm sorry, Dr Perry, I forgot to ask but this.  
5 Could you explain what this document is?  
6 A. It's basically a timeline that we assembled really since  
7 2008, when we started on this process of examining the  
8 key events and this attempts to record, certainly from  
9 a SNBTS perspective, the key steps and actions and  
10 discussions that took place between the initial  
11 collection of the plasma in October 1983 and the most  
12 recent investigation, which was the NIBSC assays on the  
13 sole vial that we recovered from the  
14 University of Edinburgh. And it attempts to identify  
15 what we think are the key pieces of evidence informing  
16 the chronology that we now have.  
17 Q. Yes. On the right-hand column, are these references to  
18 bits of documentary evidence?  
19 A. Yes, indeed.  
20 Q. We see that that starts in June to October 1983, and if  
21 we could just go to the last page, it ends up with  
22 31 March 2009?  
23 A. Yes.  
24 Q. Which is the final report?  
25 A. Correct.



1 Q. Does that cover the span of the things that we have  
2 discussed this morning?

3 A. Absolutely. It covers the span, pre-dating the initial  
4 notification from Dr Ludlam, ie the collection of plasma  
5 that went into the batch, right through to the very last  
6 investigation that has been carried out.

7 Q. Yes. Thank you very much, Dr Perry.

8 THE CHAIRMAN: I think if you look at the page before, it  
9 may answer one of the question that I asked earlier and  
10 wasn't covered. I think if we look down to April 2008,  
11 we get the beginning of the final steps in submitting  
12 the remaining vial.

13 A. Yes.

14 THE CHAIRMAN: Dr Bienek, who contacts Professor Simmonds?

15 A. That's absolutely right.

16 THE CHAIRMAN: And that leads to the search that turns up  
17 the particular vial. And I think we see that  
18 Professor Simmonds sent it.

19 A. Oh, right, okay.

20 THE CHAIRMAN: Second bottom entry.

21 A. That is quite possible. I think -- although I wasn't  
22 directly involved in the transmission of this, I can  
23 understand that being a very good approach, that SNBTS  
24 really didn't want to be seen to be interfering with  
25 this really vital piece of information, so it was

1 directly sent --

2 THE CHAIRMAN: So Professor Simmonds as the --

3 A. Yes.

4 MR GARDINER: Thank you, sir.

5 THE CHAIRMAN: Mr Di Rollo?

6 MR DI ROLLO: Sir, Mr Dawson will ask the questions.

7 Questions by MR DAWSON

8 MR DAWSON: Could I ask first of all for a document to be

9 put up? The document is [\[SNF0013624\]](#). You will see

10 that this is a letter which is written by Dr McClelland

11 to Dr Cash.

12 A. Yes.

13 Q. Dated 15 November 1984. Have you seen this letter

14 before, Dr Perry?

15 A. I have.

16 Q. I think the box to the right of the address indicates

17 that this may in fact be your copy of the letter. Is

18 that right?

19 A. It is.

20 Q. You can see there "PFC, received 19 November 1984".

21 "Dr Perry" is ticked, which I presume means that you had

22 seen it?

23 A. Yes.

24 Q. In the first paragraph Dr McClelland sets out the reason

25 for the letter. I'll just read that out. It says:

1            "I have had several discussions with  
2            Dr Christopher Ludlam following the discovery that some  
3            recipients of PFC Factor VIII have developed antibodies  
4            to HTLV-III during 1984 which must at present be  
5            attributed to infusions of PFC product. I spent severe  
6            hours this morning with Dr Ludlam and Dr Perry, acting  
7            director of PFC, reviewing the data and write now to  
8            report to you, as national medical director, on our  
9            conclusions."

10           Do you remember attending the meeting on  
11           15 November?

12           A. Yes, but not in detail.

13           Q. Right. I have a few questions for you about it. Can  
14           you remember who called the meeting?

15           A. No, I can't.

16           Q. There is a reference there to you, Dr Ludlam and  
17           Dr McClelland having spent several hours reviewing the  
18           data. Can you give me some indication as to what  
19           "reviewing the data" actually involved at the meeting?

20           A. It was looking at -- I think Dr Ludlam at that stage had  
21           identified -- basically presented an early version of  
22           a spreadsheet, which included the patients that had been  
23           infected. Those that had received the product, those  
24           that had been infected, this matrix of how many  
25           individual patients had received different batches of

1 product over the critical period, and the critical  
2 period being the period during which the transmissions  
3 of HTLV-III were thought to have occurred, and it was  
4 basically those data -- it certainly wasn't  
5 individual -- we didn't look at individual clinical,  
6 medical records or anything of that nature. It was data  
7 that had already been preassembled by Dr Ludlam based on  
8 his records but also backed up by whatever blood  
9 transfusion records were available at the time.

10 Q. Okay, thank you very much.

11 I would like to come back to this document but could  
12 I just jump, at the moment, to your statement? The  
13 statement is [\[PEN0121331\]](#).

14 You were asked there in question 3, if we could just  
15 scroll down to the bottom, what evidence was used in the  
16 compilation of the lengthy SNBTS document, which we have  
17 gone through very carefully this morning. One of the  
18 references you have at the bottom there, to records that  
19 might have been available, is the first bullet point:

20 "The evidence and information gathered included  
21 records of the initial notification to the SNBTS,  
22 Dr McClelland by Dr Ludlam on 26 October 1984."

23 Were you aware at the time of the meeting of such  
24 records existing -- the November meeting?

25 A. I was aware at the November meeting that Dr Ludlam had

1 done an analysis on patients and batches infused,  
2 looking at transfusion records, clinical records and so  
3 on, but I think at that stage -- the bullet point  
4 referred to here actually refers to Dr McClelland's  
5 original written notification, his memorandum on  
6 20 November.

7 Q. I see.

8 A. That's primarily what I had in mind when I wrote:

9 "Records of the initial notification to the SNBTS."

10 Because it was in that document that it states quite  
11 clearly -- and I have no reason to suggest that it was  
12 wrong -- that it was on the evening of 26 October.

13 Q. Thank you. If we could just go over the page, there is  
14 another question about the documentary evidence  
15 available to us. You say in the first main paragraph  
16 there, after having listed documents that might have  
17 been of assistance:

18 "Unfortunately neither the SNBTS nor, it is  
19 understood, Professor Ludlam, have been able to locate  
20 the original data analysis and rationale which led to  
21 the conclusion that NY 3-009 was implicated in a  
22 transmission of HTLV-III. Some of the data was included  
23 in the report prepared by Dr Cuthbertson."

24 And this attaches an appendix that they were  
25 submitted to the Inquiry in 2010.

1           Just in relation to that first data, the original  
2           data analysis and rationale, is that the document or  
3           documents you referred to a moment ago, being the sum  
4           total of Dr Ludlam's researches before the November  
5           meeting or were there other documents available --

6    A. I think the only document that I'm aware of -- and this  
7           is the document that sadly we haven't been able to trace  
8           either in SNBTS, but then that wouldn't be unusual  
9           because this was a document that I recall maybe  
10          contained clinical details and so on that Dr Ludlam  
11          wouldn't have wished to be used outside of his  
12          particular jurisdiction. But the specific document  
13          I think I'm referring to is the original matrix that  
14          Dr Ludlam put together to inform his initial discussions  
15          with Dr McClelland and Dr Tedder.

16   Q. Right. So those documents existed but those weren't  
17          documents that were available to you at the November --

18   A. Yes, they would have been available at the November  
19          meeting, yes. I think they would have been, absolutely.

20   Q. Unfortunately we don't have access --

21   A. Unfortunately I can't remember the content. I have  
22          a very vague recollection of them. They were certainly  
23          likely more detailed than the subsequent reports which  
24          were included in Dr Cuthbertson's report. But summaries  
25          of them -- the only summary that we have of these

1 particular analyses is the summary that was prepared by  
2 Dr Cuthbertson in his report but also in Dr McClelland's  
3 letter to Dr Cash of 15 November, where he basically  
4 describes the rationale for excluding other batches as  
5 being suspect.

6 Q. If we could go back to that letter now, that was the  
7 original one we were looking at, which is [\[SNF0013624\]](#).  
8 Just to put this in a bit of context, by this stage  
9 there had been the recall of the implicated batch --

10 A. Yes.

11 Q. -- that you were talking about earlier. Could I just  
12 ask you: there are a number of numbered paragraphs at  
13 the bottom, three of those on the first page and in the  
14 first paragraph -- this is the first paragraph, I think,  
15 of the explanation of the way in which the data was  
16 being reviewed, written by Dr McClelland, he says:

17 "Using his own records, confirmed where appropriate  
18 by BTS records, Dr Ludlam prepared lists of all  
19 recipients of the implicated batch. All the batches  
20 received by the [blank] patients who were seroconverted  
21 and all the batches used in his patients during the  
22 relevant period."

23 A. Yes.

24 Q. I just wondered whether you might be able to help us  
25 with the time period you were looking at, ie what is

1           meant by the "relevant period"?

2    A.   I think the "relevant period" is the period from the  
3           data on HTLV transmissions, the Richard Tedder, the  
4           Dr Tedder data reported on specific samples provided by  
5           Dr Ludlam, which had time references to them.  I think  
6           Dr Ludlam and Dr Tedder knew when those samples had been  
7           taken from the patients.  So the specific time period is  
8           presumably before that date.  So it's the period in  
9           which the infectivity using this batch could have  
10          occurred.

11   Q.   So would that be the period between a patient's last  
12          negative test and first positive test.  Is that right?

13   A.   Yes.  But also -- yes, that's absolutely right, yes.

14   Q.   Would you have been looking at data before the date of  
15          the last negative test?

16   A.   No.

17   Q.   Right, so it was simply looking at the data available  
18          about transfusion for each individual patient, although  
19          taken together, between the date of the last negative  
20          test and the first positive test?

21   A.   And identifying whether the specific batch or batches  
22          that that patient got and the dates that they got them  
23          was consistent with their seroconversion date as  
24          estimated by the samples that had been taken.

25   Q.   I think you said earlier that that analysis showed you



1           that the seroconversions of the patients were at a time  
2           consistent with infection by the implicated batch?

3    A.   Yes, absolutely.

4    Q.   Thank you.

5    A.   This -- I should point out that that letter was -- and  
6           this meeting was specifically called not to -- well, it  
7           was to review the decisions on 3-009, but by that time  
8           I think we were fairly confident that we had taken the  
9           appropriate action and so on.  But it was also to  
10          subsequently confirm that there were no other batches of  
11          product that we should be placing in a suspect category  
12          and take action on.

13                 So this was to review not only the initial decision  
14                 but to make sure that there weren't other batches that  
15                 we should be acting upon and recalling and doing further  
16                 investigations with.

17  Q.   Indeed.  As far as the other batches are concerned, if  
18          we can just look over the page, please, there is  
19          a reference at the numbered paragraph 6 to a number of  
20          other possible batches there, where Dr McClelland says:

21                 "There are several earlier batches, eg 768, 784,  
22                 773, 791, which are not available for issue.  These  
23                 could merit a similar investigation but time is  
24                 insufficient to do this on the present occasion."

25                 I think it says at the bottom, where we have

1 "Conclusions" under number 4:

2 "There may be a need for further confirmatory  
3 examination of the patient exposure to selected earlier  
4 batches, although stocks are exhausted."

5 So was the position that, given the pressures of  
6 time on you at that stage, although there were other  
7 batches which might have been of interest to you because  
8 these were not available for issue -- and could not  
9 affect or infect anybody else -- you didn't look at  
10 these as carefully as you looked at other batches?

11 A. I think that's a reasonable interpretation but I think  
12 it also reflects the fact that we were fairly confident  
13 about the original identification of batch 3-009 and the  
14 next two most suspect batches being excluded, because  
15 the timeframes in which the seroconversions took place  
16 were not consistent with the dates on which these  
17 batches were administered to the patients.

18 Q. Thank you.

19 There is a table which is attached to this letter.  
20 I think my understanding is that it has a separate  
21 reference. So we will have to get that up. It's  
22 [\[SNB0065994\]](#). Our understanding is that this is the  
23 table that was attached to the letter, although the date  
24 is 14th, rather than the date of the 15th. But here we  
25 have some information about various batches. We are

1 told, principally in the second column, as I understand  
2 it, how many of the 16 seroconverters at that stage had  
3 received each batch. Is that a correct interpretation?  
4 A. Yes, that's exact --  
5 Q. We can see at the bottom there the one with the  
6 asterisk. That's the implicated batch, isn't it?  
7 A. Yes.  
8 Q. That had been received by 15 of the 16 seroconverters?  
9 A. Yes.  
10 Q. We can see from this that there are various other  
11 batches which have been looked at, some of which have  
12 14, some of which have 13, 12, 11, 10 and going down to  
13 some have been received by very few?  
14 A. Yes.  
15 Q. And the batches that were referred to in the passage we  
16 just looked at are ones, predominantly, with the higher  
17 numbers of recipients? Is that correct?  
18 A. Yes.  
19 Q. Thank you very much.  
20 Could we just go back to the previous document,  
21 which is [\[SNF0013624\]](#) at 3625, please. You said  
22 a moment ago that at this stage you were quite confident  
23 that the implicated batch was the batch that had  
24 infected at least 15 of the 16 seroconverters. Is that  
25 accurate?

1 A. Yes.

2 Q. Would it be accurate to describe the exercise that you  
3 were carrying out at this meeting as looking at the  
4 records to see if you could pin it down to a single  
5 batch?

6 A. No, it was -- I think it was -- it was a specific  
7 exercise -- this is my recollection -- and certainly it  
8 seems to be borne out by the content of the letter that  
9 Dr McClelland wrote to Dr Cash -- it was to make  
10 absolutely sure that in our -- if you like, our rushing  
11 into a conclusion that 3-009 was the implicated batch,  
12 we weren't excluding other batches that could be at  
13 risk. It was an attempt to make sure that we were  
14 looking at the whole horizon, not just part of the  
15 horizon that pointed to 3-009.

16 Q. So you are looking at a wider number of batches and  
17 would it be with an open mind to the possibility there  
18 might be more than one infected batch?

19 A. Absolutely.

20 Q. Thank you.

21 Would you be surprised if either of the other  
22 individuals who were at the meeting described the  
23 exercise as looking at the records to see if you could  
24 pin it down to a single batch?

25 A. No, I think this is a fine judgment, and to a certain

1 extent that could be -- that description could describe  
2 what I have just described, that by eliminating all  
3 other batches, you are focusing on one batch, but  
4 I don't think -- we are playing with words here, but my  
5 understanding was that we came together to make  
6 absolutely sure that we had covered all the risks that  
7 were prevalent at the time.

8 Q. Thank very much.

9 Could I just ask you about one further paragraph?  
10 That's on this page after the number 6 paragraph. There  
11 is a paragraph there which says "1", then we have  
12 a blank:

13 "... requires further serological investigation  
14 urgently. This patient did not receive the implicated  
15 batch and is not known to have other risk factors.  
16 Retesting of the first positive sampling is in progress  
17 but will not exclude an identification error. Should  
18 the testing of a new sample confirm positivity, it will  
19 be necessary to review the data in light of this  
20 finding."

21 I think as we know from the table, the implicated  
22 batch had only been received by 15 of the 16  
23 seroconverters?

24 A. Correct.

25 Q. This passage is talking about that one who didn't

1 receive it. Is that right?

2 A. Yes.

3 Q. What was the thinking at the meeting as to the  
4 explanation as to how that patient had become infected?

5 A. I can't honestly recall what the discussion was and  
6 perhaps, you know, any recollection I have now might be  
7 just a reconstruction, but the obvious conclusion is  
8 that there could be more than one batch, the patient  
9 could have other risk factors that haven't been  
10 identified. It could be the result of treatment outside  
11 the Edinburgh centre that wasn't recorded. And I think  
12 around that time -- although Dr Ludlam will confirm or  
13 deny that this is the case, but the transfusion records  
14 of individual patients may not always be complete.

15 Q. Thank you.

16 A. Particularly if they are travelling and so on and so  
17 forth. There are a number of theories that I imagine  
18 were put forward at that time why the 16th patient  
19 hadn't received batch 3-009. But included in that would  
20 be the possibility of another batch having transmitted.

21 Q. I think the process that you were going through at this  
22 stage, you have described was one of deductive reasoning  
23 based on the information; it wasn't a scientific  
24 examination. We have looked at the testing from later.  
25 Are you aware of any process, at a later stage than

1 this, to take account of any developments in the  
2 knowledge which was available to review the conclusions  
3 that were reached in the deductive process which had  
4 been carried out at this stage?

5 A. I think Dr Ludlam -- there are certainly a number of  
6 publications that have been published. But I think the  
7 direct answer to your question from my perspective is  
8 that I wasn't personally -- or the PFC wasn't involved  
9 in any other more detailed analysis. I think by this  
10 stage we had taken the necessary action, as the  
11 pharmaceutical provider of the product, and in a sense  
12 moved on. I think Dr Ludlam may well -- and probably  
13 did -- carry out all sorts of further investigations to  
14 try and better understand the events around this time.

15 Q. Thank you.

16 A. But as far as we were concerned, we had as much  
17 information as we needed to ensure that we had taken the  
18 appropriate action.

19 Q. Indeed. Could we just move on to a separate document  
20 and a slightly separate topic. This is the document  
21 [\[SNB0039205\]](#). I just wanted to ask you a couple of  
22 brief questions about this. This is a letter written by  
23 you a little bit later in time period, on  
24 8 January 1985, to Dr Cash?

25 A. Yes.

1 Q. This is related to something you have told us about  
2 already, which I think is a request by you, if I could  
3 put it that way, for the plasma which had been  
4 quarantined in the aftermath of the Edinburgh  
5 seroconverters -- the knowledge of them having  
6 seroconverted, and you are requesting here that the  
7 plasma be released for use. Is that accurate?

8 A. It's a proposal with a rationale for that proposal.

9 Q. Right. And the rationale that you put forward to the  
10 proposal is really in two parts. The first, which  
11 I think you have referred to already, is the fact that  
12 heat treatment was coming in and you could be quite  
13 confident by January 1985 the heat treatment was going  
14 to do what it intended to do. Is that right?

15 A. Yes.

16 Q. I just really wanted to ask you about the second part of  
17 that, to which you have made reference already. You  
18 appear to be justifying your proposal also by reference  
19 to the fact that:

20 "The HTLV-III status of the potential suspect donor  
21 in the West of Scotland is or will be known in the very  
22 near future."

23 My question is: why did you consider that to be  
24 supportive of your proposal?

25 A. Well, it would have helped only in the event that that



1 donor turned out to be positive because then we could  
2 have identified that donation, but it was perhaps  
3 journeying in the hope that that donor would have proven  
4 to have been positive.

5 Q. That would have meant that --

6 A. That would have meant that they had identified the  
7 infective donation that had contributed to the pool and  
8 all other 3,999 donors could have been released -- or  
9 the plasma from those donors could have been released  
10 into use --

11 Q. But that would be working on an assumption that there  
12 was only one infected donor?

13 A. Absolutely.

14 Q. Thank you very much.

15 I just wanted to ask you another brief question  
16 about a topic you have covered in great detail. That's  
17 the various testing that has been done on the implicated  
18 batch. As I say, it has been covered in great detail  
19 but I want to take to you one document, which is  
20 [\[SNB0086427\]](#). Have you seen this before?

21 A. Yes.

22 Q. Can you just tell me what it is?

23 A. It's the interim report, I think, written by  
24 Dr Cuthbertson, who is the quality assurance manager at  
25 the protein fractionation centre --

1 Q. Is this the antibody testing that you are referring to  
2 being done in 1985 and 1986, the results of that?

3 A. Yes.

4 Q. If we just skip over to the next page, I think you can  
5 see that it's dated 23 June 1986. Do you see that there  
6 at the bottom?

7 A. Yes.

8 Q. If we just skip back to the first page, I just wanted to  
9 ask you really about a couple of things. Your position  
10 has been, in light of all of the information including  
11 the 2008 testing and all of the circumstances that you  
12 have available to you at this date, that the implicated  
13 batch was probably what infected the Edinburgh cohort  
14 patients. Is that right?

15 A. Yes, I think --

16 Q. I'm just trying to summarise what you said --

17 A. I think that is the most probable and most likely  
18 explanation.

19 Q. The one thing I just want to draw to your attention was  
20 when you were making that assessment, you were  
21 speculating as to what assay had been used at this  
22 stage. If we just scroll down to the bottom, I want to  
23 draw your attention to the fact that the batches marked  
24 with an asterisk were tested for HTLV antibody using  
25 a sensitive variant of the Wellcozyme assay. No trace

1 of antibody was found in any of these batches. We know  
2 the results already but does the specific reference to  
3 the test alter your general view in any way about the  
4 sensitivity of that testing?

5 A. Absolutely not. I think the Wellcozyme assay was an  
6 earlier version, a perfectly workable version of one of  
7 the first HIV antibody assays that were used in the UK.  
8 So again I emphasise I'm no expert in this area but at  
9 that stage these assays would have been relatively  
10 insensitive compared to modern day standards. As  
11 I think I have explained before, these batches, these  
12 are testing product batches which themselves have very  
13 low levels of immunoglobulin and therefore by definition  
14 you have removed the target -- you know, the target  
15 antibodies that you are trying to detect have been  
16 already reduced to a fairly low level. So I wouldn't  
17 expect -- this is not a surprise and it certainly wasn't  
18 a surprise at the time.

19 Q. I think, if I understand the totality of your evidence,  
20 the position is that this testing, which suggests that  
21 there is no antibody in these tested batches, has to be  
22 viewed with some scepticism, given the reliability of  
23 the testing available and the various other factors you  
24 pointed out?

25 A. Yes, it neither means they were infective or

1 non-infective. It demonstrates that there is not  
2 a very, very high level of antibody in the plasma pool,  
3 otherwise one might have surmised that this would  
4 breakthrough into the product and be tested by  
5 a relatively insensitive test.

6 Q. You see there that the batches marked with the asterisk  
7 were the ones that were tested, and there have obviously  
8 been four batches tested, including the one at the  
9 bottom, which is the implicated batch, and the other  
10 three are some of the ones that you had been looking at  
11 in the November meeting, I think. Is that correct?

12 A. Yes.

13 Q. I think obviously your conclusions about the reliability  
14 of the testing would apply to the results in respect of  
15 all four?

16 A. Yes. I think our conclusions at the time were: it was  
17 a useful exercise but we can't draw any conclusions in  
18 terms of the infectivity of the product from these  
19 assays.

20 Q. Thank you very much.

21 Are you aware of any other testing having been done  
22 on batches other than the implicated batch from amongst  
23 those that you were looking at at the November meeting,  
24 other than these tests?

25 A. No, the only tests that would -- sorry --

1 Q. I'm just trying to work out whether any other tests have  
2 been done.

3 A. Have been done?

4 Q. Yes, indeed. Similar, for example, to the 2008 testing  
5 of the implicated batch, have any other tests after this  
6 1985/86 period been done on any of the other broadly  
7 implicated batches, if you like, other than the 2008  
8 testing --

9 A. I would need to check that out. I'm not aware of any.  
10 Certainly latterly in 1988 -- in the later 1980s every  
11 batch of product manufactured by PFC would have been  
12 tested by the NIBSC as part of a batch release process.  
13 So towards the end of the 1980s, all batches of product  
14 produced by the PFC would have been tested for HIV using  
15 a validated assay by the National Control Laboratory.

16 Q. But focusing specifically on those that were in your  
17 list, if you like, from the November 1985 meeting, you  
18 are not aware, as things stand today, of any other  
19 testing having been done?

20 A. No, but I perhaps would like the opportunity --

21 Q. No, indeed.

22 A. -- just to double-check that they haven't been some  
23 research done on any of the batches because, as we know,  
24 there are much more searching assays available now.

25 Q. Would it be right to assume that notwithstanding the

1 unusual circumstances in which the 2008 vial of the  
2 implicated batch was found, there would not be likely to  
3 be any samples of any other of these batches available  
4 for testing to date?

5 A. I think it's highly unlikely that there would be but  
6 again I would need to check.

7 Q. Thank you very much.

8 I would just like to move on to ask you a few  
9 questions about a totally separate topic.

10 THE CHAIRMAN: Just to help me to understand where we are  
11 going. Is it to be suggested that some other batch did  
12 have a significant impact on patients?

13 MR DAWSON: Well, sir, I'm simply seeking to explore --

14 THE CHAIRMAN: Well, it takes a great deal of time unless we  
15 know where we are going, Mr Dawson, and if it is not to  
16 be suggested that there is another batch implicated or  
17 potentially implicated, it is not going to help me  
18 terribly much. I do have to know what it's about,  
19 please.

20 MR DAWSON: The position is that I'm exploring whether or  
21 not testing has been done on other batches so as to  
22 enable such a proposition to be made, and I think  
23 Dr Perry has provided, certainly from our point of view,  
24 some useful information in that regard.

25 THE CHAIRMAN: Not to my point of view. I think, with

1           respect, you have to persuade me that it's worthwhile.

2   MR DAWSON: I'm moving on from that topic at this stage,  
3           sir. I take that on board.

4           The topic that I was going to ask you some questions  
5           about, Dr Perry, is something which you may know about  
6           as well, and that's the topic of package inserts in the  
7           product coming out of PFC.

8   A. Yes.

9   Q. Could I just ask you in broad terms, in the early to mid  
10          1980s, am I correct in understanding that inserts were  
11          put in products coming out of the PFC giving a number of  
12          different kinds of information about those products?

13   A. That's correct.

14   Q. Who were those pack inserts designed for? Were they  
15          designed for the doctors that would be getting these  
16          produces into their centres or were they designed for  
17          the patients or who?

18   A. It's a good question. Certainly nowadays you have  
19          a thing called a "product information leaflet" and  
20          a "technical information leaflet" and they have  
21          different target audiences, and they are written in  
22          completely different ways. At that time, I think the  
23          answer to your question is they were targeted, in the  
24          way they were written, certainly at prescribing doctors.  
25          They gave some basic characteristic but also some of the

1 information was very accessible to lay people in terms  
2 of how you reconstituted the product, how you used it  
3 and so on.

4 Q. Was part of the purpose of the package insert to give  
5 information about the possibility of there being risks  
6 of viruses being transmitted through the product?

7 A. The package inserts that we had in common with the rest  
8 of the industry certainly included warnings that --  
9 I think we were very general in our warnings saying,  
10 "This product, although the plasma is tested for  
11 Hepatitis B, it cannot be assumed to be free of  
12 infectious risk", or words to that effect. So, yes, it  
13 was designed to give a warning to both patients and  
14 certainly to doctors, but doctors already knew this --

15 Q. Of course.

16 A. -- that these products carried a risk associated with  
17 them. So the document that was included with each vial  
18 was really part of that process but also to satisfy our  
19 essentially legal obligations within the pharmaceutical  
20 industry, and even then the industry was required for  
21 prescription medicines to have some sort of information  
22 leaflet associated with them.

23 Q. Could I just take you to a document which might provide  
24 some more information to assist on this. It's  
25 [\[SNF0010445\]](#). We see that that is a letter written by



1           you to Professor Cash on 14 March 1988. You may not  
2           have seen this. Have you seen this one recently,  
3           Dr Perry?

4   A. Yes, I recognise the letter.

5   Q. Do you remember what this letter was all about?

6   A. Yes.

7   Q. Can you tell us?

8   A. I think this was a request from Professor Cash to myself  
9           to provide him, and perhaps the wider SNBTS, with  
10           a summary document describing the SNBTS actions that  
11           were taken generally around the emergence of HIV,  
12           HTLV-III and AIDS.

13   Q. Thank you very much.

14           If we could go over to page 0448, please, we see  
15           there under paragraph 4 you address the subject of  
16           package inserts AIDS warnings. You say that:

17           "At no time during the manufacture of  
18           non-heat-treated products did we include a specific  
19           warning in our insert leaflets that Factor VIII or  
20           Factor IX carried a risk of HIV transmission. Reference  
21           to the possibility of hepatitis transmission has always  
22           been included, latterly updated to include HIV.

23           I enclose the various texts used for inserts since 1983  
24           and the chronological sequence of their introduction."

25   A. That's correct.

1 Q. You then say under "General Conclusions" at number 2:

2 "HIV was not established unequivocally as the  
3 causative agent of AIDS until at least mid-1984."

4 I just wanted to ask you whether consideration had  
5 been given within PFC to include in the text information  
6 about the risks of AIDS or HIV from the products at any  
7 stage in 1983 or 1984?

8 A. No, for perhaps a very good reason. I think at that  
9 stage, with the state of scientific knowledge, it would  
10 have been highly improper for any manufacturer of  
11 a pharmaceutical product without good reason and without  
12 good evidence that the product may present a risk of  
13 HIV -- The sort of information that is provided in these  
14 package insert leaflets is highly controlled and highly  
15 regulated and I think in the absence of any information,  
16 the control authorities would have taken grave exception  
17 to us intimating without any evidence on -- that this  
18 was the case. I'm not suggesting that there was no  
19 evidence. I know there was a body of evidence growing  
20 and so on but not to the extent that allowed one to  
21 place this as a standard warning in a pharmaceutical  
22 product.

23 Q. So is the position that the regulatory authorities would  
24 only allow that to happen at a point where it had been  
25 established unequivocally that HIV was the causative

1 agent of AIDS, as you say in number 2?

2 A. They would look -- generally the industry would look for  
3 a very, very good rationale that supported -- and  
4 evidence for supporting a statement concerning risk of  
5 HIV. I'm not saying that we weren't aware of the  
6 emerging risk of AIDS as a causative agent, but at the  
7 time you are describing it was far from certain that  
8 this was an infectious disease.

9 Q. Is the position that the text, at least as far as these  
10 types of things were concerned, was not controlled by  
11 you, it was controlled by the regulatory authority?

12 A. I think to an extent we control it, we drafted it and we  
13 would have checked with the regulatory authorities that  
14 the wording was satisfactory. But I think the way we  
15 covered it, to the best of my knowledge -- although  
16 I would need to look at the specific details and the  
17 timelines for the leaflets, was to say that "The product  
18 cannot be assumed to be free of the risk of infectious  
19 disease" or words to that effect, which covers --  
20 certainly intended to cover hepatitis but, you know, it  
21 covers any other infectious disease, which we believe  
22 has entered the blood --

23 THE CHAIRMAN: Dr Perry, could I see if I understand the  
24 realities of this? If a product were known to the  
25 manufacturer to carry a risk of communication of HIV, is

1           it likely that a product certificate would have been  
2           granted?

3    A.   Probably not, although the parallel -- it was certainly  
4           known that these products carried the risk of  
5           transmitting non-A non-B hepatitis and they were fully  
6           licensed, but that's perhaps for another day.  But  
7           I think if there was certain knowledge that there was  
8           a risk of HIV transmission from a product, then it would  
9           have been very difficult for a licensing authority to  
10          say this is an acceptable product to place on the  
11          market.

12   THE CHAIRMAN:  Particularly since the one thing that was  
13          known or believed about HIV -- well, it wasn't about  
14          AIDS infection at this stage -- was that it was likely  
15          to be fatal.

16   A.   Yes, absolutely.

17   THE CHAIRMAN:  Yes.  So what Mr Dawson must be talking about  
18          is a situation in which it is not known that there is  
19          a high risk of transmission of HIV.

20   A.   Yes.

21   THE CHAIRMAN:  Is it in that context that you would  
22          anticipate that the regulatory authority would say it  
23          would be irresponsible to highlight a risk that was not  
24          known?

25   A.   I can't speak on behalf of the regulatory authorities

1 but I can certainly say from my experience that the sort  
2 of words and the sort of warnings that you include in  
3 these documents is very, very highly controlled and very  
4 highly scrutinised, and I think they would want some  
5 fairly good evidence that this was an actual, measurable  
6 risk on an evidence base before they would allow that  
7 sort of warning, because, you know, it would be  
8 distressing and perhaps considered inappropriate to  
9 include those things without good evidence.

10 THE CHAIRMAN: Again, Mr Dawson, I would benefit from  
11 knowing the point, with respect. I understand why you  
12 are interested in product leaflets and that there are  
13 many issues here, but the HIV one worries me a little.  
14 If it is to advertise a risk I think I have to know what  
15 the suggestion is as to the level of risk that's  
16 involved and how it might be put over at this very early  
17 period.

18 MR DAWSON: Indeed. I think it may become apparent. I have  
19 literally a couple more questions on it. It may become  
20 apparent what I'm trying to suggest.

21 The first question is whether you were aware of any  
22 references in commercial product leaflets on the market  
23 in the early to mid 1980s about the specific risk of  
24 HIV?

25 A. I can't, without notice, but I would certainly be very

1 happy to go and look at those. My best guess at this  
2 point is that like ourselves, commercial organisations,  
3 including those in the US, would not have included  
4 specific AIDS or HIV -- well, it wouldn't have been HIV  
5 in 1983, but specific AIDS warnings in their products at  
6 that time.

7 Certainly, subsequently to the virus being  
8 discovered and it being proven as being the causative  
9 Factor VIII then it would have been highly appropriate,  
10 and I think manufacturers did include HTLV-III or HIV  
11 warnings in their leaflets, basically saying, "We cannot  
12 guarantee that this product will not transmit" even  
13 though --

14 Q. What time was that included?

15 A. It would have been post-1985.

16 Q. The regulatory standards that you have talked about in  
17 connection with the inclusion of this type of  
18 information in product leaflets, in 1983, 1984 and 1985,  
19 were the same standards being applied to PFC product as  
20 to the commercial products by those authorities?

21 A. The PFC was -- as we discovered from other  
22 conversations -- was subject to Crown immunity but as  
23 a manufacturer we certainly took the position that our  
24 products, certainly in terms of leaflets and information  
25 to patients, should comply with the general standards at

1 the time.

2 Q. Okay. Thank you very much.

3 Sir, I don't intend to ask any further questions?

4 THE CHAIRMAN: Thank you, Mr Dawson.

5 Mr Anderson?

6 MR ANDERSON: I have no questions, sir.

7 THE CHAIRMAN: Mr Johnston?

8 MR JOHNSTON: I have no questions either.

9 THE CHAIRMAN: Have you anything to follow on?

10 Further Questions by MR GARDINER

11 MR GARDINER: Dr Perry, you have just been asked about

12 package inserts and I think you have given your best

13 recollection of the terms of package inserts.

14 A. Yes.

15 Q. But am I right in saying that sitting here today you

16 can't remember exactly what the text of these package

17 inserts might have been in the early 1980s?

18 A. I think I have a document on my desk here that has some

19 of them described. It's in very small writing but it

20 really is along the lines of "The product cannot be

21 assumed to be free of infectious risk although the

22 plasma has been screened for Hepatitis B" and so on.

23 Q. Infectious risk from what, though?

24 A. Any infectious virus or disease or any infection.

25 THE CHAIRMAN: I don't think this is fair to Dr Perry.

1           Mr Dawson, I'm in danger of having to tighten up on  
2           advance notice of the points to be taken. So far I have  
3           tried to be very lax about it but we must be fair to  
4           a witness. Asking points of detail after a very long  
5           period of time -- a necessary elapse in this case -- is  
6           not fair, and I think that if there are particular  
7           points to be put to Dr Perry over this, I'm sure he will  
8           accommodate us, as he said he would, by looking at any  
9           material you care to put to him, and let us have a note  
10          about it, Dr Perry. But I'm not anxious to see any  
11          witnesses to this Inquiry be pilloried in effect by  
12          being --

13       MR DAWSON: Sir, just on the issue of tightening up the  
14          rules, this is a matter which I raised with the Inquiry  
15          counsel. I was actually going to look at some specific  
16          text but I rather realised that Dr Perry would not be in  
17          a position to comment on it --

18       THE CHAIRMAN: Well, I have allowed it to be raised with  
19          Inquiry counsel as a shortcut but really I do have to  
20          know, and if you leave me in doubt in a passage of  
21          evidence as to where we are going, it is not helpful to  
22          me. I want to follow what's going on. In the meantime  
23          just take it as a shot across the bows. I have no  
24          intention of tightening up before it is absolutely  
25          essential, but if necessary, gentlemen, I will. Just



1 deal with it informally. So long as we can deal with it  
2 informally to the satisfaction of parties, it is by far  
3 the best solution. It means that there is no need for  
4 conflict of any kind. But if you would sort this one  
5 out, I would be very much obliged.

6 MR GARDINER: Perhaps, Dr Perry, we can just leave it on the  
7 basis that we can sort out the exact text of these  
8 inserts at some later date.

9 A. I think the SNBTS, and certainly myself, would be more  
10 than happy to come forward with a sort of measured and  
11 as comprehensive overview of the information that we  
12 provided in our product leaflets at an appropriate time.  
13 That wouldn't be a problem. I know these information  
14 leaflets exist. I know we have records of them and we  
15 can discuss them.

16 Q. Thank you very much.

17 THE CHAIRMAN: Thank you very much, Dr Perry. I'm afraid  
18 that means you are not finished yet but perhaps we can  
19 get to the answers in another way.

20 A. Thanks very much.

21 MR GARDINER: Sir, Dr Gillon, is the next witness.

22 DR JOHN GILLON (continued)

23 Questions by MR GARDINER (continued)

24 MR GARDINER: I think you have previously appeared at the  
25 Inquiry and given evidence before about statistics --

1 A. That's correct.

2 Q. -- and other matters. Could you just remind us, please,  
3 what your qualifications are and what your position is  
4 at the moment?

5 A. My qualifications are MBChB from Edinburgh in 1973, MRCP  
6 (UK) 1975 and MD 1984.

7 Q. Yes. What's your position at the moment?

8 A. I'm currently a consultant in the Edinburgh transfusion  
9 centre.

10 Q. Yes. Thank you. We are interested today in HIV  
11 look-back and you have kindly provided the Inquiry with  
12 a statement about that. Could we just look at that?  
13 It's [\[PEN0120862\]](#). Do you have a copy of this?

14 A. I have it on the screen.

15 Q. Yes. The question which you were asked is:  
16 "What steps were taken to identify potentially  
17 infectious batches of blood and the individuals who  
18 received blood or blood products from those batches?"  
19 Of course, it's implicit in the question that it is  
20 after December 1984, when you know that the virus is in  
21 the Scottish donor pool. Could you just tell us what  
22 your answer to that question was, please?

23 A. Well, my understanding of this question is that it would  
24 relate to the time after the test was introduced  
25 in October 1985.

1 Q. Right.

2 A. Not December 1984.

3 Q. Yes.

4 A. By "infectious batches of blood", I did not take that to  
5 refer to batches in the sense in which it has been  
6 discussed this morning, which is batches of finished  
7 fractionated product, but rather individual donations  
8 from donors --

9 Q. Yes.

10 A. I hope that's the sense in which it was intended --

11 Q. Yes.

12 A. -- because that's the sense in which I have taken it.  
13 So what my answer refers to are the discussions that  
14 took place in anticipation of that introduction of  
15 testing in October 1985 and what we would do in the  
16 event of discovering a donor with positive tests for  
17 HIV, to try to identify the fate of the previous  
18 donations prior to the period of testing.

19 Q. Yes. And you say that there was a working party  
20 established, and this is the working party of the  
21 Regional Transfusion Directors' Committee. Is that  
22 right?

23 A. Yes, at UK level, but essentially the English RTDs  
24 meeting, which also had representation from Scotland,  
25 Wales and Northern Ireland.

1 Q. Yes. I am looking for appendix 1 of this statement,  
2 [\[SNB0049046\]](#). You said in your statement that the  
3 working party presented its recommendations in the form  
4 of a report. Is this the report that you referred to?  
5 A. Yes, the date is at the bottom of the report, I think,  
6 of 11 July 1985. Would that be correct?  
7 Q. Yes.  
8 A. I'm sure that's it.  
9 Q. If we go to the last page, it shows the date  
10 11 July 1985.  
11 A. Yes.  
12 Q. If we go back to the first page, is that where we see  
13 the recommendation, in paragraph 3?  
14 A. This document was -- and indeed the working party was --  
15 to look globally at the implications of the introduction  
16 of anti HTLV-III screening tests, and so the body of  
17 this report is about how we handled test results and  
18 what we did about donors, and it's only, I think, in the  
19 last two paragraphs that it addresses the question of  
20 what should happen about previous donations and the  
21 recipients.  
22 Q. Yes. So on the first page it's recognising that there  
23 is a degree of urgency for the introduction of routine  
24 anti-HTLV-III screening of blood donations. Then over  
25 the page we see:

1           "By this means it may be possible to commence  
2 screening of blood donations by October 1985."

3           And:

4           "It was agreed that the introduction of the tests  
5 should take place throughout the UK."

6           But I think the bit that you are referring to is on  
7 page 4 at paragraph 7, which says:

8           "Follow-up of recipients of previous donations given  
9 by donors found to be HTLV-III positive."

10          Is that what you are referring to?

11 A. Yes, that's correct.

12 Q. So what was the recommendation?

13 A. The recommendation was that in the case of an HIV  
14 positive donor being identified, if they had donated  
15 previously, the recipients of the blood components from  
16 that donation would be traced and considered for testing  
17 and counselling, as appropriate, if they were still  
18 found to be alive.

19 Q. Yes. Was that done?

20 A. That was indeed done. It was accepted by all the UK  
21 transfusion services that that recommendation was  
22 entirely appropriate. I think it derived from the  
23 recommendation which was agreed in the United States in  
24 the previous year, towards the end of 1984, where the  
25 joint blood services there made a joint recommendation

1 that this should happen. I wasn't a member of this  
2 working party but obviously there would have been  
3 discussion of that and the importance of doing this.

4 Q. Yes. Could we go back to your statement? If we look at  
5 page 2, at the top of the page we see:

6 "SNBTS directors accepted the recommendation ... In  
7 addition, the SNBTS regional transfusion centres  
8 informed PFC of any confirmed cases of donors with  
9 anti-HTLV-III whose plasma had been shipped to PFC for  
10 blood product manufacture."

11 So how was that organised?

12 A. What happened when a positive donor was identified would  
13 be that in the case where previous donations existed the  
14 local QA manager would notify the consultant -- and in  
15 the case of Edinburgh that would be me -- in writing  
16 with a list of the previous donation numbers and  
17 probably also the donor's registration number. I can't  
18 remember exactly the amount of detail we got on that.  
19 But from that donation number the consultant would  
20 obtain the relevant data on each donation: when it was  
21 donated, what components were manufactured and where  
22 they went. Also, in the case where we were told that  
23 a donation had been included in a box of plasma, we  
24 would notify PFC by letter.

25 Q. Yes. How would the donor have been identified in the

1 first place?

2 A. By the donor office, by reference through the individual  
3 donation number, which links it to the individual  
4 donor's registration number, and the office then relate  
5 that back to the donor record --

6 Q. Yes.

7 A. -- which in those days was entirely manual, so it's  
8 analogous to what we were hearing about PFC records  
9 today, and there would be an individual donor record  
10 card of some sort: different cards from different  
11 centres but essentially the same system.

12 Q. Yes. You explained further down the page, question 2,  
13 in terms -- the context is:

14 " ... steps taken to trace and arrange testing for  
15 any such individuals."

16 You make a distinction between where components were  
17 issued to SNBTS-administered blood banks and non-SNBTS  
18 blood banks. Could you explain the different processes?

19 A. Yes. In, mainly, the east coast centres -- Edinburgh,  
20 Aberdeen, Dundee and also Inverness in fact -- we, as  
21 SNBTS, would have responsibility for the hospital blood  
22 bank in the hospital in which the SNBTS centre was  
23 located, so the Royal Infirmary of Edinburgh, Ninewells  
24 in Dundee, Aberdeen Royal Infirmary and so on. In that  
25 case we would have direct access to the blood bank

1 records of what happened to a given unit of blood. We  
2 would be able to identify the patient directly and use  
3 that information to directly communicate with the  
4 clinician responsible for that patient's treatment,  
5 which would usually be done by letter.

6 In the case of hospital blood banks outwith the  
7 SNBTS jurisdiction, so, for instance, the Western  
8 General in Edinburgh or Perth Royal Infirmary, for  
9 instance, in the Tayside region, the identity of the  
10 patient would not be established by us but by the  
11 haematologist in charge of the blood bank. So we would,  
12 as consultants, write to the consultant in charge of the  
13 blood bank in the outlying hospital -- and indeed this  
14 would apply to all of the hospitals in the west outside  
15 Law Hospital and many of the district general hospitals  
16 throughout Scotland. We would write directly to the  
17 haematologist in charge of the blood bank saying that  
18 this particular unit of blood, which was sent to them on  
19 a given date had been found to be HIV positive and that  
20 we would recommend that the patient be identified and  
21 the clinician notified.

22 Q. Yes. Who would deal with the process after that?

23 A. In general terms the process would have been dealt with  
24 by the clinician.

25 Q. Yes.



1 A. In fact the numbers, as you can see in the statement,  
2 for HIV were really quite small and in my recollection  
3 I don't think SNBTS were responsible for any of the  
4 direct counselling and testing of patients, certainly  
5 not in the Edinburgh centre.

6 Q. Yes. The next question, which is over the page, is:  
7 "Who was responsible for the look-back programme at  
8 a national level?"  
9 Could you help us with that question, please?

10 A. There was no co-ordination or management of this process  
11 at a national level, and that was largely in keeping  
12 with matters generally at that time. The management of  
13 any individual action or project was usually taken at  
14 local level, if you like, at SNBTS regional centre  
15 level, and each centre would have had its own procedures  
16 and paperwork and would have worked essentially to the  
17 same ends and the same way but using different  
18 documentation.

19 Q. Yes. So it was organised on a regional basis?

20 A. Yes.

21 Q. Yes.

22 A. So effectively policy came back to the centres through  
23 the regional director, who, in discussion with  
24 colleagues, would put in place the appropriate measures.

25 Q. Yes.

1 THE CHAIRMAN: Dr Gillon, as you probably know, I have heard  
2 quite a lot about regional autonomy but here we have got  
3 a policy adopted nationally in rather particular  
4 circumstances.

5 A. Yes.

6 THE CHAIRMAN: Am I to understand that even in those  
7 circumstances there was not direction as to how it  
8 should be implemented locally?

9 A. I think in those circumstances at that time there were  
10 few, if any, written national policies issued in the way  
11 that they are now and have been for many years. If  
12 a decision like that was taken now, there would be an  
13 agreed national policy, signed off by the national  
14 medical and scientific director and issued formally  
15 through the QA systems with appropriate document  
16 control. That simply didn't exist in those days.

17 There would in many circumstances be a letter from  
18 the national medical director to the directors, which  
19 would be cascaded down. I'm not sure in this  
20 circumstance that that even existed for look-back but it  
21 was promulgated. I'm not entirely sure in what form  
22 that promulgation came to us but I'm sure it was  
23 implemented in all five regions.

24 THE CHAIRMAN: But if other circumstances are any guide, the  
25 means of implementation, the recording of implementation

1 and the accounting for or feedback of information and  
2 implementation would be likely to vary.

3 A. It varied considerably, yes.

4 MR GARDINER: We see that at the bottom of that page that we  
5 are on, in response to question 4, which is about how  
6 the look-back programme was put into effect, which is  
7 what we are talking about, you say:

8 "In essence, it was the responsibility of the  
9 regional transfusion director and the consultant in  
10 donor care and selection in each region to ensure that  
11 appropriate arrangements were made for look-back."

12 Is that the position?

13 A. Yes.

14 Q. And you go on to talk about the fact that there was no  
15 national donor administration system. Could you tell us  
16 a little bit about the national donor database and so  
17 on?

18 A. Well, there wasn't one at that stage at all. They were  
19 entirely separate, with, as I have said, different  
20 systems of keeping the basic information on a donor,  
21 even to the extent that the way in which donors were  
22 catalogued was different. For instance, in the  
23 Edinburgh centre it was done by what's known as  
24 a session.

25 So if you were at the Colinton church session, all

1 of the records pertaining to that were in a single  
2 drawer and there were little yellow cards with all of  
3 the donations written by hand and I think that other  
4 centres had completely different steps for tracing back  
5 to find out where and when a donation was given.

6 So they were very different and it was only in 1987  
7 that we started to build what was known as Dobbin, the  
8 initial national computer system, and that initially was  
9 very segregated in terms of region, but at least the  
10 donor record was then agreed and with an agreed format  
11 in terms of the amount of information that went on and  
12 the amount of information that went on to the individual  
13 donor's record in relation to a given donation, so in  
14 terms of test results and other relevant information,  
15 for instance, like donor medical facts and so on.

16 So that became standardised, I think, around 1987  
17 and basically that system was in place even after we  
18 introduced a much more sophisticated computer system in  
19 1998, which was -- the Dobbin system was in-house built,  
20 it was built by our own IT people, based on a prototype  
21 system in Edinburgh. I think in 1985/1986 it was  
22 developed.

23 THE CHAIRMAN: We are going to have to stop, if that's all  
24 right, Mr Gardiner?

25 What would you do with the mobile vans? How were

1 the records kept for them?

2 A. Very much the same. They would take a box with the  
3 cards relating to that particular place, which would  
4 usually be a workplace in the case of a mobile van.  
5 But, of course, you were always getting new donors,  
6 unexpected donors, so there would to be a system for  
7 registration and documentation relating to that, as  
8 there still does.

9 THE CHAIRMAN: Yes. Thank you.

10 MR GARDINER: Thank you, sir.

11 (1.05 pm)

12 (The short adjournment)

13 (2.00 pm)

14 THE CHAIRMAN: Yes, Mr Gardiner?

15 MR GARDINER: Thank you, sir.

16 Dr Gillon, before lunch you told us that if you  
17 became aware that a donor had tested positive, then the  
18 PFC would be notified by letter about that fact. What  
19 would the PFC do once they had been notified?

20 A. That's a good question. I'm sure that Bruce Cuthbertson  
21 must have answered it in another context but essentially  
22 they would find out what was made from that particular  
23 donation or box of plasma, as it would have appeared to  
24 them, and then if necessary, they would recall that and  
25 ensure that everything was quarantined or recalled that

1           could be.

2    Q.   Yes, thank you.

3           Could we go back to your statement, please, which is  
4    [\[PEN0120862\]](#)? Could we go to the second page? At the  
5    bottom of the page the question is about tracing and  
6    testing for individuals, and you say:

7           "Where the component was issued to a non SNBTS blood  
8    bank, the information was passed to the consultant  
9    haematologist in charge of the blood bank who would  
10   normally communicate directly with the consultant in  
11   charge of the patient."

12          Then the next bit:

13          "Often SNBTS advice would be sought as part of the  
14   process of informing and counselling the patient."

15          How would that work, Dr Gillon?

16   A.   In those early days of HIV, very few of the clinicians  
17   would have had to deal with a case or had to have  
18   a patient tested. So they would be looking for advice  
19   about how to go about that, what to tell the patient,  
20   how to handle the test results. It may even be  
21   necessary to go through the GP initially to make sure  
22   that we know for sure that the patient is still alive.  
23   So given that we had had fairly extensive discussions  
24   about that whole process, it would be natural to ask us,  
25   usually in a telephone call, "How should we handle this?"

1           What should we do?"

2    Q.   Thank you.

3           Could we now go to question 5, which is on page 4?

4           The question is:

5           "Were any written protocols/procedures created?"

6           This is about HIV look-back. Can you tell us what

7           the answer to that is?

8    A.   There were protocols and procedures created locally.

9           I haven't been able to find any still in existence but

10          I know that there is documentation of a meeting in the

11          Southeast centre, where we discussed how we would handle

12          the whole introduction of testing, and it's clearly

13          stated then that we would draw up local SOPs and

14          protocols, but I can't find any.

15   Q.   Yes. Just to return to a question that we were

16          discussing before lunch, you have told us about what

17          would be done if a donor was found to be positive.

18          Could you explain to us how you would come to know that

19          a donor had tested positive?

20   A.   We would usually -- the most specific sense in which the

21          term "look-back" is used is called a "targeted

22          look-back", and that means that on the routine testing

23          for a given infectious agent, in this case HIV, which

24          started in October 1985, any donor -- and

25          after October 1985, every single donation was tested --

1 and has been -- so if we found a donor who was positive,  
2 who had given previously prior to the introduction of  
3 testing, we would do what is called a "targeted  
4 look-back"; in other words, we would know that there was  
5 that donation or those donations which were potentially  
6 infectious. At the time there was no way of identifying  
7 them as such. So we would go back to try to ascertain  
8 whether any patient had been infected as a result of any  
9 of those previous donations being transfused.

10 Q. Yes.

11 A. There are various other ways in which a look-back can be  
12 triggered and, for instance, it might depend on either  
13 the donor or a patient being identified as having HIV --

14 Q. Yes.

15 A. -- at a later date. So even although the donor had  
16 never come back post-1985 and been tested by us, we  
17 could be informed, for instance, by another clinician  
18 that a patient had shown up with HIV and said they had  
19 had a transfusion, let's say, in 1984. Could we check  
20 that out. And we would do that and potentially find an  
21 infectious donor.

22 Q. Yes. So we would be wrong to think that look-back would  
23 involve analysing a library of blood samples from donors  
24 that has been kept or something like that?

25 A. There have been proposals -- there was a proposal later



1 in the context of HCV, that we should take out all the  
2 stored library samples in the UK and test them for HCV.  
3 That was not done, largely for logistical reasons.  
4 There were millions of samples by that time. But when  
5 HIV testing started in 1985 there were virtually no  
6 archived samples within SNBTS, or anywhere else for that  
7 matter. It simply hadn't been done up until then.

8 Q. When were -- sorry.

9 A. I was just going to say: so we couldn't do that as far  
10 as donors were concerned but there have also been  
11 proposals to do a general testing of people who received  
12 a transfusion and indeed, again in the context of the  
13 HCV look-back, the chief medical officer wrote to all  
14 doctors in the UK saying, "Patients with a history of  
15 transfusion might reasonably want to be tested for HCV,  
16 even although they have got no reason to suspect they  
17 have been at risk". And I know that in San Francisco,  
18 they issued notices to everybody who had had  
19 a transfusion in the five years prior to HIV testing  
20 coming on, saying they should go and get tested and  
21 almost no one did. It was really not very productive.

22 Q. But in Scotland HIV look-back has not involved analysing  
23 library samples simply because you didn't have them?

24 A. We didn't have them at that time.

25 Q. Yes. You have told us that since October 1985 blood

1 donations have been tested for HIV. Since that period,  
2 is it possible for blood that has been infected with HIV  
3 to get into the system, if you like?

4 A. There remains a tiny but finite risk that an infected  
5 donation could be missed by testing. As testing has  
6 become better and more sophisticated and more sensitive  
7 over the years, that risk becomes less but what we are  
8 talking about is the possibility of a donation or  
9 a donor being in the so-called "window-period". As the  
10 period between being exposed to the virus by high risk  
11 activity or transfusion, use of drugs, whatever, and  
12 then developing the antibody to the virus. So there is  
13 a period after exposure to the virus when the virus is  
14 propagating itself in the person's system, and after  
15 a certain period antibodies arise to combat the virus.

16 Now, that takes time and the length of that time  
17 before antibodies becoming detectable relates to the  
18 sensitivity of the test. And in the early days of HIV,  
19 we were talking probably of around three months before  
20 the test then in place could identify the virus.

21 It is now down to something like ten or 11 days. So  
22 the window-period has shortened, but even in the early  
23 days this was a very, very rare event because it needs  
24 a certain conjunction of circumstances between the  
25 donor's behaviour and the donation and the test

1 configuration. But it has happened but it's a very rare  
2 event.

3 Q. In your personal experience, how rare is this  
4 phenomenon?

5 A. We know of only one transmission by a window-period  
6 donor in Scotland in all the time we have been testing,  
7 and that was shortly after testing. That was in the  
8 middle of 1986 and that is a case which has been  
9 recorded in the literature, published, I think, in the  
10 Lancet.

11 Q. Sir, I have no further questions for Dr Gillon.

12 THE CHAIRMAN: Thank you Dr Gillon. Mr Dawson?

13 Questions by MR DAWSON

14 MR DAWSON: Dr Gillon I want to ask you a couple of  
15 questions about the passage that you were referred to at  
16 the bottom of page 2 of your report. Could we just have  
17 that up?

18 Thank you very much. It was just that last  
19 sentence. You have given a comment on this already  
20 where you say:

21 "Often SNBTS advice shall be sought as part of the  
22 process of informing and counselling the patient."

23 Can you assist us with what the advice from SNBTS  
24 would have been if the local doctor responsible for the  
25 care of the patient had asked for such advice in these

1           circumstances?

2   A.   Well, I think essentially we would be recommending that  
3       there would be a very high likelihood of a unit in that  
4       kind of circumstance being infectious, and that it would  
5       be in the patient's best interests, probably, to offer  
6       them counselling and testing.

7   Q.   Right.  So would there be a need for testing in those  
8       circumstances on the basis that there was such a high  
9       likelihood?

10  A.   There would certainly be a need for testing because  
11       otherwise how would you know if the patient was  
12       infected?

13  Q.   Right.  Who is responsible for the dissemination of that  
14       advice to local doctors within SNBTS?

15  A.   Dissemination in a general sense, do you mean or in the  
16       specific sense of an individual case?

17  Q.   In the specific sense of a --

18  A.   In the specific case.

19  Q.   Yes.

20  A.   It would usually be the consultant in charge of donor  
21       health in the local centre.

22  Q.   Okay, thank you.

23           I have nothing further, sir.

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

25  MR JOHNSTON:  No questions, thank you, sir.

1 THE CHAIRMAN: Thank you very much, doctor.

2 MR GARDINER: The next witness is Christina Leitch, sir.

3 MRS CHRISTINA LEITCH (sworn)

4 Questions by MR GARDINER

5 MR GARDINER: Thank you, sir.

6 Good afternoon, Mrs Leitch.

7 I think that you have given the Inquiry a statement  
8 and if we could have a look at [\[PEN0121430\]](#)? I think  
9 you have a copy of that in front of you. Is that right?

10 A. Yes.

11 Q. Yes. I think in the first paragraph you talk about your  
12 role at Yorkhill. Could you just tell us a little bit  
13 about that, please?

14 A. Yes. I moved to Yorkhill as senior social worker, which  
15 meant that my role was part managerial. There was  
16 a team -- a small team of social workers in the  
17 hospital. So I managed directly some of those and had  
18 overall responsible for the work of the team and in  
19 addition to that, part of my role was to carry certain  
20 case loads.

21 Q. Yes. When did you start at Yorkhill?

22 A. In October 1984, the end of October.

23 Q. Yes. Who was the consultant that you dealt with at that  
24 time?

25 A. The consultant in haemophilia was Dr Ian Hann.

1 Q. What was your responsibility at the hospital as far as  
2 the haemophilia patients were concerned?

3 A. Well, what we agreed would be my role was that I would  
4 provide a social work service to the entire patient  
5 group. So there would be a number of things that would  
6 have to be considered, basic practicalities for some  
7 families, applying for benefits that they were entitled  
8 to, to assist with the care of their children, and  
9 I would make people aware of those things and assist  
10 them around those. But it was also to be a part of the  
11 haemophilia team. So that rather than refer families  
12 when a problem might arise, I was seen as someone who  
13 would routinely speak with families. So I would meet  
14 people at the clinic. The medical staff were very keen,  
15 as was I, to ensure that people saw it as a reasonable  
16 thing that from time to time they might have problem in  
17 meeting their children's needs and would look for some  
18 support rather than stigmatise someone by saying you are  
19 being referred to social work.

20 So it was a routine part of the team to provide  
21 ongoing support to the families, recognising that caring  
22 for a child with a serious bleeding disorder was  
23 a particularly stressful and challenging thing for  
24 parents at times. So that was the initial role that  
25 I considered would be important to take on and then, as

1 time went on, my role changed in relation to the  
2 children who were diagnosed as having HIV.

3 Q. Yes. How long were you working at the hospital before  
4 your role changed?

5 A. I cannot say with absolute certainty. I do recall one  
6 particular incident, and again I can't really put a time  
7 on it. My sense of it was that it wasn't a huge long  
8 time but it was a situation in which one of the children  
9 was admitted to hospital and the boy, who was around  
10 ten, I think, at the time, discovered, from watching the  
11 evening news, that he had HIV because it had been leaked  
12 to the press that a child with haemophilia was in  
13 Yorkhill for a particular procedure and it not being  
14 a very large patient group, the boy knew that it was him  
15 that was being talked about, and at that particular time  
16 I spoke with the haemophilia sister about it and then  
17 I recall going to introduce myself to the mother and  
18 just to try and see if I could offer some support at  
19 that time. My feeling is that I wasn't there a very  
20 long period of time before that happened but I really  
21 can't put a precise date on it.

22 Q. So would you say that would be around about the end of  
23 1984, perhaps?

24 A. I'm thinking probably into 1985 but I honestly -- I'm  
25 only guessing.

1 Q. What experience did you have of HIV at that point?

2 A. Oh, certainly when I took up the post in Yorkhill, none  
3 at all. Indeed, I had been there for quite some time  
4 when one of the senior managers, in what was then  
5 Strathclyde region, came to speak to me about it to say,  
6 "We are becoming increasingly aware of this as something  
7 we have to respond to as a department and you are the  
8 only social worker who is involved in this". So he was  
9 coming to learn from me. So essentially at the point  
10 I started, I knew nothing about it and gradually this  
11 was something I learned about whilst I was learning  
12 about haemophilia and other bleeding disorders.

13 Q. How did you learn about it?

14 A. Through discussion with -- it would have been Dr Hann,  
15 Dr Pettigrew, who was the registrar, who, on  
16 a day-to-day basis, did most of the work at clinics with  
17 that particular patient group, and Sister Murphy, who  
18 was the specialist haemophilia sister in the unit.

19 Q. Yes.

20 A. And also Dr Hann did make me aware that there was  
21 a social work special interest group, although that was  
22 largely to do with haemophilia, and I did meet with  
23 that. It was under the banner of the British  
24 Association of Social Workers. So we did have meetings  
25 from time to time, information sharing, and through



1 a variety of sources then, I became knowledgeable.

2 Q. Yes. Could we have a look at page 2 of your statement,  
3 please? In paragraph 5 you say:

4 "Dr Hann, Dr Anna Pettigrew and the haemophilia  
5 sister, Chris Murphy, and I met occasionally."

6 What would you discuss at those meetings?

7 A. For the most part we would be having a discussion about  
8 children or families that we had met with in the week.  
9 Dr Pettigrew, Sister Murphy and I met very frequently  
10 throughout the week as really part of a team seeing the  
11 children. So if anyone brought a child up to the  
12 hospital for emergency treatment, they would always let  
13 me know and we always met at the clinic itself. And we  
14 would have a discussion, sharing information.

15 In addition to that, we did sit down, the four of  
16 us -- that is to say the three of us plus Dr Hann --  
17 from time to time to discuss how things were going with  
18 the patient group, was certainly my memory of it in the  
19 earlier days. So it might be that they had a concern  
20 about how a particular family were managing or I might  
21 have a concern. Perhaps a family had approached me.  
22 Sometimes families would be very happy for me to share  
23 information about family circumstances if a family were  
24 under particular pressure, say, if they realised that it  
25 would help the medical or nursing staff to know that

1           they were under pressure.

2           Other times I would say, "I'm not at liberty to tell  
3           you the details but this particular family could do with  
4           a wee bit extra understanding" -- or whatever -- "right  
5           now". We share information as appropriate so that we  
6           were all aware how particular boys in the families were  
7           doing, essentially.

8   Q.   How often would you have these meetings?

9   A.   I can't recall with any certainty. It was not --  
10       I don't believe it was on a weekly basis, the meetings  
11       with the consultant. I think we perhaps met with him  
12       every few weeks. But other than that, Dr Pettigrew and  
13       Sister Murphy and I met frequently.

14   Q.   Yes. Were you involved at all in communicating the  
15       results of antibody testing to parents or to patients?

16   A.   No.

17   Q.   Do you have any knowledge of that process?

18   A.   No, none at all.

19   Q.   Okay. I think you mentioned the patient group?

20   A.   Yes.

21   Q.   Could you tell us how that came to be set up?

22   A.   The parent group?

23   Q.   Parent group? Yes, I'm sorry.

24   A.   As time had gone on and I was working with the families  
25       whose sons had HIV, I became increasingly aware that the

1 parents were -- well, they were in a nightmare  
2 situation. They had each been told the news and  
3 understood that there was a massive risk that they might  
4 lose their child. Unlike parents from other parts of  
5 the hospital, who were perhaps given dreadful news,  
6 "Your child has leukaemia" or cancer or whatever, these  
7 parents were going away with some terrible knowledge,  
8 and at that time, the fear in the world at large around  
9 HIV was horrific. Some of the adverts on television  
10 would have struck fear into most people's hearts. It  
11 was a time when there was almost a hysteria. I think  
12 that would be fair to say. People were terrified that  
13 anyone would find out the child had HIV because of the  
14 impact that would have on the child and themselves.

15 So we are talking about parents who were living with  
16 an incredibly painful situation as parents and as  
17 families, but were also having to deal with this  
18 incredible fear of other people finding out, worried  
19 sick about how their children and they would be treated  
20 if it did. There were some schools that were anxious  
21 about having children with haemophilia and looking for  
22 reassurance around those things. It seemed to me that  
23 those parents were in an exceptionally difficult  
24 situation and unable to talk to anyone very much about  
25 it.

1           There was also a tension that had built up between  
2           the families and the hospital. Parents spoke about  
3           feeling angry. Sometimes that could be openly expressed  
4           and sometimes not, but expressed in different ways.  
5           There was a tension at times between the families and  
6           the hospital, and I think that was natural and  
7           understandable when parents felt that the hospital, the  
8           NHS, that was there to treat and care for their children  
9           had let them down, was how it was perceived.

10           So parents were feeling isolated from the rest of  
11           the haemophilia patient group in many respects. There  
12           was a painful distance growing up between parents and  
13           key staff in the hospital and those parents could talk  
14           to no one else about it. And for some of those parents,  
15           there were the added difficulties in that if there were  
16           other people within their family who had haemophilia,  
17           they might be worried that they had relatives who were  
18           also affected. So it was something that people couldn't  
19           really talk about.

20           It seemed to me that the only other people that they  
21           could share some of that feeling with would be other  
22           parents in the same situation. It seemed like  
23           a desperate need to try and tackle some of the awful  
24           feelings of isolation that people had and help them to  
25           find a support network for themselves. So I spoke with

1 each of the parents individually and said to them that  
2 I was thinking that this might be something that would  
3 be helpful to them. So I consulted them to see what  
4 they felt about it. I explained to each of them very  
5 carefully that if other parents agreed to do this, that  
6 being part of that group would mean that from the moment  
7 you walked into that room, your confidentiality was gone  
8 as far as the other people in that room were concerned,  
9 but that people who would be invited to be part of that  
10 were all people that I believed I could trust to respect  
11 one another's privacy, and on that basis the parents  
12 seemed very keen to participate.

13 What I did, for various reasons, partly because of  
14 the feelings around the hospital at the time and partly  
15 to be absolutely tight about privacy, was that I spoke  
16 to my own social work manager, who agreed to locate  
17 premises, social work premises, that we could use, where  
18 no one would know who we were. We were simply  
19 a patients' group, meeting on a Friday evening. So that  
20 was some of my thinking behind setting it up and that  
21 was the basis on which the group met.

22 Q. Yes. Was that in late 1987 that you set the group up?

23 A. I think so. It is difficult to be precise about times  
24 but I think it was around that time.

25 Q. Yes. How often did the group meet?

1 A. Again, it is so very long ago. I can't say with  
2 absolute certainty. I think initially we met weekly.  
3 Part of establishing the group and because the need was  
4 really very high. And then as time went on, we agreed  
5 that the group didn't need to meet as frequently as  
6 that, and the parents then getting to know one another  
7 were making informal contacts with one another, which  
8 was also one of the benefits I would hope they would get  
9 out of it. So I believe that we gradually reduced the  
10 frequency of meetings. It was something I felt was  
11 important for the parents to lead.

12 And we arrived at a point at which I think we all  
13 agreed we didn't need to meet on that basis any more;  
14 they were able to talk with me and they could talk with  
15 one another. But it also had allowed couples to talk  
16 with one another. I think that was one of the other  
17 things even that sometimes would be easy to overlook,  
18 that parents couldn't talk about something like that  
19 when they had children about the house. There was that  
20 awful fear that they couldn't even have a conversation  
21 within their own homes at the time. So I think the  
22 importance of giving them a safe place to talk was quite  
23 important and I think the need for that gradually came  
24 to an end.

25 Q. The parents were concerned about being overheard by

1           their children?

2    A.   At times, yes, and some of the parents had other  
3           children at home and might have other family members  
4           around in a whole variety of ways.

5    Q.   Yes.  Can we have a look at paragraph 7 of your  
6           statement?  You say that you met many parents from other  
7           parts of the country and some mothers felt guilt.  What  
8           did they feel guilt about?

9    A.   I think it was the sort of guilt that people at one  
10           level knew was irrational, they had nothing to feel  
11           guilty about, but emotions and logic don't always marry  
12           very well in these situations.  I think for parents, the  
13           feeling that -- and belief almost that you should be  
14           able to protect your children from harm is such a very  
15           deep rooted one, particularly for very caring parents,  
16           and all of the parents that I came across were very much  
17           very caring and attentive parents, but when this  
18           situation unfolded, I think some mothers felt incredibly  
19           guilty because they knew that this is an inherited  
20           disorder and in that they had something in common with  
21           other parents whose children inherit disorders.  And it  
22           doesn't matter how many times you tell yourself there is  
23           no need to feel guilty about it, I think sometimes it is  
24           just part and parcel of being a parent.  But for many of  
25           the parents that was greatly exacerbated by the fact

1           that they were treating their children at home, and  
2           although they had not chosen the treatment, had no sense  
3           of -- had no real responsibility for what that treatment  
4           had done, I think for many of them it was an incredibly  
5           painful thing to look back and consider that, whilst  
6           they had been giving their children treatment and  
7           believing that that was for the best, in reality that's  
8           what had made them ill and which might ultimately cost  
9           them their lives. And I think that that was a terrible  
10          burden for people to have to live with.

11        Q.   Yes. In that paragraph you mention parents being  
12          intensely angry. Could you talk a bit more about that?

13        A.   There were certainly times that parents within  
14          Yorkhill -- I mean, I'm speaking just now about parents  
15          that I met from different locations, but some of the  
16          parents in Yorkhill certainly felt very, very angry  
17          about what had happened and at times the name of the  
18          previous consultant, Dr Willoughby, came up in  
19          discussion. I had not met him. He had left Yorkhill  
20          before I arrived there. But parents certainly made the  
21          point at times that they did wonder had his sudden  
22          departure -- that was how it was described to me.  
23          I don't know whether it was sudden or not -- but they  
24          felt that his decision to go and live and work in  
25          Australia somehow related to what later unfolded.



1 Q. Yes.

2 A. Ultimately there was a terrible sense of betrayal by the  
3 NHS and there were a lot of feelings about that.

4 Q. Could we go to page 4, please? At paragraph 9 you talk  
5 about the isolation and stigma related to HIV that had  
6 left people feeling powerless. I wonder if you could  
7 expand on that, please, Mrs Leitch?

8 A. Yes. As I was saying earlier, the level of fear and  
9 anxiety in society at the time was very, very high.  
10 Scarcely an evening seemed to go by without there being  
11 some reference on television, and working with families  
12 affected by that, I was acutely aware of it. It was  
13 a time in which children would be hearing cruel and  
14 sometimes quite vicious jokes in playgrounds. Parents  
15 knew, particularly after the early situation in which  
16 a young child had to hear something about himself on the  
17 news, that if they did not maintain absolute secrecy,  
18 their lives could be spread across newspapers or  
19 whatever, and there were situations in which people were  
20 being persecuted in one part of the country or another  
21 because they were seen to have HIV.

22 So at a time in which there was a campaign, for  
23 example, for compensation, parents were saying, "We  
24 can't even take part in that. We cannot express our  
25 view to anyone within the NHS. We cannot exercise our

1 right to contact our MPs or other people that might act  
2 on our behalf" because of this feeling that they had to  
3 maintain absolute secrecy. Because it was secrecy more  
4 than confidentiality.

5 The fact that they simply couldn't speak openly  
6 about it was incredibly difficult. I think that being  
7 able to come together and at least speak with one  
8 another was helpful in that regard, but at one point  
9 I remember parents talking in particular about this view  
10 that I would like to be able to speak to my MP. I would  
11 like to write a letter, I cannot even do that. And we  
12 talked about a way in which that could be done. And  
13 I remember making the offer, and I can't remember how  
14 many parents took up the offer but I know that some did.  
15 I said, for example, "You could write a letter and keep  
16 it completely and utterly anonymous, make sure that  
17 there are no identifying details about yourself and your  
18 child. You could give a letter like that to me in  
19 a sealed envelope and I will put it in another envelope  
20 with a covering letter to whatever MP or whoever you  
21 want to write to, to say that I know who you are, I am  
22 very clearly saying to them that it's a genuine letter  
23 but they will not know who you are. And they can reply  
24 to me and the letter will again be forwarded to you in  
25 a sealed envelope", that kind of they think.

1           So that at least people felt that in one way or  
2           another they had a voice. And I think that was one of  
3           the very difficult things for people, feeling they had  
4           no voice, they were not in a position to speak up  
5           because it was their child's right to privacy as well as  
6           their own, that they had to consider.

7    Q.   Yes. If we go down the page a bit to paragraph 11, you  
8           say that you were a founding member of the  
9           Macfarlane Trust, which was set up in 1988 and began  
10          making payments in 1989. Was that because of your  
11          knowledge of working with people with HIV?

12   A.   Yes. The Haemophilia Society were asked to appoint  
13          a number of people but also to advise the government on  
14          other appointments to the trust. And what the  
15          Haemophilia Society advised me at that time was that  
16          they had had a number of letters from parents saying  
17          "There needs to be someone from Scotland on the Trust  
18          and we would like it to be a social worker".

19                 And I think by that time -- I think there were also  
20                 some people in the adult hospital, who were perhaps  
21                 relatives or friends, who had also been writing and  
22                 saying, "We want someone from Scotland". So I think the  
23                 Haemophilia Society recommended me for that because of  
24                 those letters. But also, prior to that, the Society had  
25                 contacted me at one point to say I was the only social

1 worker who was working with parents in the way that  
2 I was, with the parents group. So certainly they had  
3 asked me to speak about that at one of the conferences  
4 which were for professionals and families. And also  
5 I had presented a paper on the work I was doing with the  
6 parents but with the parents' consent.

7 Q. Yes. If we go down to paragraph 12, we see that you  
8 describe there an example of stigma that you saw  
9 yourself. Before I ask you to tell us about that,  
10 Mrs Leitch, if I can just politely remind you that we  
11 are being very careful not to mention any specific names  
12 of people.

13 Could you tell us about this example?

14 A. Yes. This was a situation in which one of the boys with  
15 HIV was in hospital. Whenever any of the children with  
16 haemophilia were admitted to hospital, whether they came  
17 up on an outpatient basis or they were admitted, I would  
18 get a call from the haemophilia nurse or from the doctor  
19 to say, "So and so is in", so that I would go and see  
20 the child, see the family and so on.

21 On this particular occasion I had had a phone call  
22 to say that this young lad was admitted to one of the  
23 wards. Sister Murphy and Dr Pettigrew were going up to  
24 see him and I had said I would pop round and join them,  
25 and I remember meeting them at the lift and I think it

1 was Dr Pettigrew explained to me that there was an  
2 expectation that when we went upstairs we would have to  
3 go into the room wearing gowns, disposable gowns.

4 I can't remember if we were expected to wear masks  
5 and gloves as well, but I think that was the case. It  
6 was certainly a case of having to be very covered up and  
7 I was absolutely appalled. There was absolutely no need  
8 for it in my opinion and there was no need for it based  
9 on everything that I had learned about HIV, and there  
10 was no need for it based on what we were consistently  
11 telling parents and others. Sister Murphy and I, for  
12 example, would go out to schools -- as a matter of  
13 course. If a child with haemophilia was starting a  
14 school or changing school or sometimes schools would ask  
15 or there might be an issue that a parent would raise.  
16 And some schools, for example, were saying, "We will  
17 need to know if a child in our school has HIV", and we  
18 would always say to them, "No, you absolutely don't.  
19 You have very clear guidelines that tell you how you  
20 should deal with blood in any circumstance, no matter  
21 whose it is. And you use a weak bleach solution to  
22 clean things up. You wear gloves, it's simple good  
23 practice and nothing beyond that is an issue  
24 essentially."

25 Suddenly there we were in the hospital being told

1           that we had to be covered from top to toe and I said,  
2           "Well, I am not going to do that". And my two  
3           colleagues explained to me that this was a policy that  
4           had been introduced as part of the infection control  
5           policy for the hospital. I said, "Well, I am simply not  
6           going to do that", because it just felt wrong. And  
7           I said, "Anyway, I don't work for the hospital. So what  
8           are they going to do? Sack me? They can make a  
9           complaint to my department. I'll fight my corner when  
10          we get there but I'm not going to do this."

11                 At which point both Dr Pettigrew and Dr Murphy said,  
12           "Right, the three of us will go together, you walk in  
13           first and we'll go behind you". And despite the fact  
14           that their position was perhaps a bit more precarious  
15           than mine, they were very clear that we would do the  
16           same. We went into the room. And the parents were  
17           there at the time and they had been given the exact same  
18           instruction. We said, "We are not going on follow it",  
19           and there was immense relief on the part of the parents.

20                 The boy had gone in the hospital the night before  
21           and they had found this very, very upsetting, obviously.  
22           And they felt that their son was being treated as though  
23           he was the carrier of the plague. And he was sitting in  
24           bed and a nurse came in completely gowned and she had  
25           his lunch on a plate, one of the normal hospital plates,

1 but with a paper plate on top of it, and she told him to  
2 hold out his hands and she slid the paper plate onto his  
3 hands. And I looked at the paper plate and there  
4 were -- it was baked beans and mince and mashed  
5 potatoes. And I remember looking and thinking, "How do  
6 you eat that from a paper plate?" And he looked and  
7 sort of laughed and said, "This is what it has been  
8 like". And while he was laughing, it was so obvious  
9 that he was deeply hurt by it. It was absolutely  
10 horrible and that incident has -- it has remained very  
11 clearly in my mind for a very long time.

12 Q. Can we just go on to the next page of the statement,  
13 please? At the bottom. In paragraph 17 you talk about  
14 discussions with parents. Perhaps you could tell us  
15 a little bit about that.

16 A. Yes. Certainly. I am guessing around the percentages  
17 but my understanding was that -- and my recollection is  
18 that in the early days, when I had learned about HIV, we  
19 were talking about a situation in which not everyone who  
20 had been exposed to the virus would go on to have -- so  
21 many people would not have any health problems at all;  
22 that a large number would have some health problems  
23 related to HIV, and it seemed that a small percentage  
24 would die. Although small percentage don't really mean  
25 anything if it is you or your child. But as time went

1 on, those figures changed and it became very quickly  
2 clear that more and more children were -- and more  
3 people with HIV were going to become seriously ill. And  
4 there was a point at which information about that was  
5 extremely negative, while there was nothing in  
6 a treatment perspective that was really holding out any  
7 hope.

8 And I do remember one particular mum looking at me  
9 and saying, "Things are so bad now, they really are all  
10 going to die, aren't they?" And we had a discussion  
11 about her feelings at that point but it was certainly  
12 looking very bad indeed. And, of course, as time had  
13 gone on and some of the boys were beginning to present  
14 with different illnesses, then parental anxiety was  
15 extremely high and their fears were enormous.

16 Q. Did you receive any advice from medical staff about  
17 prognosis as time went on?

18 A. As time went on, yes. The information generally that  
19 was becoming available to all of us seemed to be that  
20 really there wasn't much hope that children would  
21 survive really, in the longer term. And as time was  
22 going on, and certainly once the Macfarlane Trust was  
23 meeting -- there was a situation in which, when the  
24 Macfarlane Trust set up, for example, one of the first  
25 tasks we had was to find out who is out there, who is



1 infected by this and what is their health. No one knew.  
2 And clearly people were not going to be writing in and  
3 saying, "Hello, it's me", because they didn't know who  
4 was getting that information and how it would be held.  
5 And a basic exercise in finding out the numbers and what  
6 people's health was like had to be undertaken, and that  
7 was something that we did through the medical staff and  
8 social work staff in all the hospitals up and down the  
9 country, who were treating people with haemophilia. So  
10 that initially we would get an understanding of how many  
11 people are affected and what has been happening to them,  
12 so that we simply had the figures. And then, of course,  
13 you were hearing about the numbers of people who had in  
14 fact become very ill and we were hearing about people  
15 who had died and partners who had become ill. And so  
16 I think that was really the first time that there was  
17 a picture, because there was no source of information  
18 made available to us as trustees. No one could give us  
19 that information until that exercise was undertaken. So  
20 certainly there was a point at which it did seem to me,  
21 and my impression could only have come from my  
22 professional colleagues in health, that the situation  
23 looked extremely poor, that the prognosis for each of  
24 the children we were working was extremely poor.

25 Q. What sort of time would that be that you are talking

1 about there?

2 A. I think, given that the Macfarlane Trust began to meet  
3 in 1988, I think certainly by that time things were  
4 looking very, very bad.

5 Q. Yes. In your discussions with parents, did you pass on  
6 information that you had learned from medical colleagues  
7 about prognosis and the disease and so on?

8 A. No, that would not have been my responsibility to be  
9 sharing medical or nursing information with families and  
10 I wouldn't have done that in any situation other than in  
11 a circumstance in which perhaps I might have been  
12 requested to do so, and certainly not with that  
13 particular patient group.

14 There would be times when thinking about haemophilia  
15 in general, not HIV, I would, for example, work with  
16 parents to help them to learn more about their child's  
17 condition once they had been given information by  
18 medical or nursing staff. I would work to try and  
19 reinforce that and talk with them about what they had  
20 already been told and help them to learn. Some parents  
21 were more able than others sometimes in learning about  
22 management of haemophilia, but I would never be the  
23 first person to be sharing information with people.

24 I would discuss things that parents might raise with  
25 me but it would not be for me to take information and

1 give it to people as a social worker. I was always very  
2 conscious of the fact that sometimes information is  
3 given to social workers in order that it be passed to  
4 other people, whether the social work department or  
5 families. Sometimes you gain information because you  
6 are also part of the trusted team on a ward and that  
7 information rests there.

8 Sometimes you get information just because you  
9 happen to be there. You have to be -- well, I was  
10 always very conscious and always very particular with  
11 the workers that I managed, that it was important to  
12 differentiate between information that comes to you in  
13 that way and information that you are at liberty to  
14 share with others.

15 Q. Yes. I understand.

16 Could we go over the page to page 7? We see from  
17 paragraph 19 that you left Yorkhill at the end  
18 of March 1992 and by that stage another social worker  
19 had been allocated to the haemophilia unit. Why was  
20 that?

21 A. Prior to that there was a point at which, as I said  
22 earlier, I did have a role as manager within the team,  
23 and in addition to supervising workers and giving them  
24 support, advice and guidance around their own case load,  
25 I would also manage such situations as child protection

1 investigations that would be presented within the  
2 hospital. And it seemed to me that the only way that  
3 I could undertake my responsibilities as manager and  
4 also work with families in the haemophilia unit would be  
5 to share that responsibility with another social worker.

6 The families whose sons had HIV were people that  
7 I had by then been working with for quite some time and  
8 I did not feel that I could -- I just didn't have the  
9 time to give to other families. I wanted to be able to  
10 focus on them and not others. So a social worker within  
11 the team was directed to work with the haemophilia unit,  
12 as well as myself. So that families coming in with  
13 younger children. She gradually picked up that  
14 responsibility and so basically she worked with other  
15 haemophilia patients. I focused on the ones with HIV  
16 and continued to do that until the boys went to adult  
17 hospitals and then, as I say, I left.

18 So there was a gradual handing over but it was a  
19 sharing of responsibility so that I had the freedom to  
20 give those families the time I felt they needed.

21 Q. How many families living with HIV were you dealing with  
22 at that time?

23 A. Give me a second. (Pause)

24 Five.

25 Q. How much of your time was taken up with that work?

1 A. It was variable. Really quite difficult to quantify.  
2 Families who were working, which in fact each of them  
3 were, tended to need time outwith my normal working  
4 hours. So there was a great deal of time that, for  
5 example, the parents group. That was on a Friday  
6 evening. So I wouldn't normally have worked on a Friday  
7 evening.

8 So there would be a certain amount of time during my  
9 normal week, depending on what was happening with  
10 families. It was very variable. It is not something  
11 you could really describe. It was dictated by the needs  
12 of families.

13 Q. Yes. Just looking a bit further down the page, at  
14 paragraph 20, you say that you thought that children  
15 with bleeding disorders were not regarded in the same  
16 way as the oncology patients and they were treated  
17 differently. Could you explain what you mean by that,  
18 please?

19 A. Yes. Initially it was something that I became aware of  
20 it and did wonder if I was perhaps being over sensitive  
21 on behalf of the children that I worked with. Then I do  
22 remember one of the social workers who was working  
23 within my own team obviously, but whose specific  
24 responsibility was working with oncology patients,  
25 coming downstairs one day and saying to me that she was

1           acutely aware that the children who had haemophilia  
2           seemed to be treated differently in the wards. And her  
3           phrase was "They are second-class citizens there".

4           And Sister Murphy and I also discussed it. To some  
5           degree we felt that it was -- and perhaps it was  
6           entirely because often they were children who were on  
7           the ward because of a bleed. A child might come in --  
8           I'm thinking of one particular boy, a good example,  
9           a skinny wee lad with the thinnest possible legs who  
10          could come in sometimes with a knee that was almost the  
11          size of a football, for example.

12          So they would come in with a bleeding problem, a  
13          knee, a very badly swollen knee, ankle or something or  
14          other, and the joint would be immobilised. They were  
15          told, "You don't get out of bed", or if they were out of  
16          bed, they would be in a wheelchair, but other children  
17          in that ward would be very, very sick and sometimes the  
18          children with haemophilia -- I'm not thinking about the  
19          ones with HIV at this point -- but they might, apart  
20          from that one mechanical-type problem, be otherwise  
21          quite well. And I do remember one ward sister  
22          complaining to me one day that -- I think how she put it  
23          was, "Two of your boys have been racing up and down the  
24          ward in wheelchairs". And I could see that that was not  
25          exactly desirable but they were just lively boys who

1           were in hospital and otherwise feeling quite well, but  
2           sometimes I think that staff were a bit impatient with  
3           them. They were after all just children and they were  
4           there with a very serious problem, they just didn't  
5           necessarily feel very sick and want to lie in their beds  
6           all of the time.

7           But it did mean that things were -- they did feel  
8           quite different. There were one or two other children  
9           with different types of blood disorders that I felt were  
10          in a similar situation. Perhaps, I think, it might to  
11          put it in context, sometimes it did seem, looking at the  
12          hospital as a whole, that, for example, when  
13          organisations in the community would want to do  
14          fundraising for a children's hospital, lots of money  
15          would be raised for the wards where children were  
16          treated who had cancers or who had kidney disease but  
17          never for the units where children had disabling and  
18          unattractive conditions. There seemed to be some  
19          conditions that elicit a greater level of sympathy in  
20          society as a whole, I think, than others.

21        Q. Yes. In paragraph 21, if we just go down a bit further  
22          on, you talk about the first child to die in Yorkhill  
23          being a baby that was infected with HIV. But this is  
24          a child that didn't have haemophilia --

25        A. No.

1 Q. -- as such. That's right. You say that some of your  
2 colleagues felt deeply upset at how this was managed.  
3 I wonder if you could talk a bit about that and also  
4 whether that continued subsequently.

5 A. It was a situation in which I was not directly involved.  
6 It was one that was really well known throughout the  
7 hospital, and certainly at least two of the social  
8 workers that I managed came to me and expressed their  
9 concerns about what they described as "hysteria" that  
10 they were witnessing in some parts of the hospital. And  
11 there was tremendous anxiety about how this situation  
12 should be managed and who was going to do this, that,  
13 and the other. And certainly one worker spoke with  
14 great feeling about the parents seeming to be lost in  
15 the middle of it all. And it seemed to me quite strange  
16 that given the policies that were introduced before and  
17 the fact that we had known that sooner or later such  
18 a situation would arise, there seemed to be such tension  
19 and such discussion actually. It was not a situation  
20 that I felt should have been the subject of so much  
21 discussion around the hospital in fact. It did not feel  
22 at all appropriate or right.

23 Q. Yes. The families that you were working with, did you  
24 find that they were affected by this episode?

25 A. I believe that they were. There was certainly -- there



1           were a number of things that families spoke about and  
2           had high anxiety about in a period thereafter. People  
3           worried about things like, "If my son dies, how will his  
4           body be treated, how will we be treated, will we be  
5           allowed to do this or that. Will we be allowed to have  
6           a normal funeral. Will there be an undertaker that will  
7           be prepared to provide any kind of service." There were  
8           tremendous anxieties around things like that for  
9           parents.

10        Q. Yes.

11                 Sir, I don't have any more questions for Mrs Leitch.  
12                 Thank you very much.

13        THE CHAIRMAN: Mr Di Rollo?

14        MR DI ROLLO: Again, Mr Dawson is dealing with this.

15                                 Questions by MR DAWSON

16        MR DAWSON: Good afternoon, Mrs Leitch. You say in your  
17                 statement, and I think you have repeated again today,  
18                 that the task of breaking the news of infection to the  
19                 parents was not your role. What I wanted to ask you  
20                 about that was: did the medical staff who were  
21                 responsible for that task seek your advice as to how  
22                 they should go about it?

23        A. No.

24        Q. Was that something that you had any experience or  
25                 training with, breaking bad news to people?

1 A. Yes. In general terms it would have been part and  
2 parcel of my social work training and also I had worked  
3 in an adult hospital before going to the children's  
4 hospital. And whilst in an adult hospital it was not my  
5 job to give that sort of news to people, I did have  
6 a great deal of experience, sometimes in -- yes,  
7 speaking with medical staff who were sometimes  
8 reluctant. Sometimes people were desperate for  
9 information about what was happening to them and it was  
10 a situation in which I took a very active role  
11 sometimes, having to speak to medical staff and saying  
12 "This particular patient desperately needs to know  
13 what's happening and you need to tell them".

14 There were certainly -- I can think of one or two  
15 situations in which consultants within the adult  
16 hospital were actually refusing to share information  
17 with people but then saying, "If you really feel that  
18 they are desperate to know, you can tell them". And  
19 there were one or two situations in which I did that  
20 because people asked, and I had certainly worked with  
21 children whose parents were dying in an adult hospital.

22 So I did have quite bit of experience in a whole  
23 variety of ways, yes. And also there was an established  
24 role in the hospital in as much as within the oncology  
25 unit, for example, there was always a social worker

1           there -- or certainly had been for a long time before I  
2           arrived -- where there was a social worker who worked  
3           very closely with medical staff and who continued to be  
4           part and parcel of the discussions when parents were  
5           given that news. So there was an established practice  
6           within the children's hospital.

7    Q. I just wanted to ask you a few questions about the  
8           parents group that you have spoken about already that  
9           you were responsible for setting up in 1987.

10            Could we have paragraph 6, please, of the statement  
11           up on the screen. If we just skip over the next page,  
12           please.

13            This is the passage where I think you are describing  
14           the circumstances in which the parents group came to be  
15           set up by you. You see about five lines down there you  
16           have mentioned the fact that the parents group proposal  
17           was not well received by your health colleagues as it  
18           seemed to heighten fears regarding litigation. I just  
19           wondered if you could explain a little bit more about  
20           how it was expressed to you by health colleagues that  
21           they had such fears about the setting up of this group  
22           at that time?

23    A. It was a discussion that I had -- which I explained  
24           that -- what my thinking was, that I felt it would be  
25           helpful to the parents to set up this group. And this

1 was at the point at which I had already spoken with each  
2 of the parents and they were all more than willing, very  
3 happy, in fact, to be part of it. And I shared that  
4 information with my colleagues and I was taken aback by  
5 the response. And one of the comments was, "Well, we  
6 need to be a part of that". And I said "No, that was  
7 not going" -- at that particular time there was  
8 certainly a feeling that the parents had been distancing  
9 themselves from the hospital, not coming as often as  
10 they might to clinics or -- to hand in blood samples or  
11 whatever. There was a clear tension that was difficult,  
12 I think, for staff who had been working closely with  
13 parent for a very long time to deal with. And I think  
14 it was understandable that they would feel uncomfortable  
15 about the fact that people with whom they had had an  
16 good working relationships and parents that they had  
17 been supportive to, seemed to be rejecting them to some  
18 degree. And we had been having discussions about the  
19 fact that it was about all of these feelings and  
20 emotions that parents had, rather than about the  
21 individuals that maybe felt they were on the receiving  
22 end of it.

23 However, the response was, "We need to be a part of  
24 that then," I said, no, this was something that was very  
25 much about the parent. It was about their needs. And

1 explained what my thinking was and why it was important  
2 to be the parents group and work with just me there.  
3 And the comment was made about, "Well, if it's happening  
4 in the hospital, folk had a right to be there". And  
5 again I explained that I wasn't planning to have it  
6 within the hospital and that confidentiality within the  
7 group was going to be absolutely non-negotiable. It was  
8 certainly put to me that, "We need to know what's  
9 discussed and what's happening". And I was very clear  
10 that was not going to happen but went on to explain that  
11 whilst I was continuing to have positive contact with  
12 the parents and a positive working relationship with  
13 them, I understood that it was difficult for others that  
14 that was feeling damaged at that point, that because  
15 I was, in a sense, a part of the parents group and not  
16 a part of it in the sense that they were, but I was  
17 acceptable, as it were, to the parents group, whilst  
18 being a part of the ward team, it seemed to me that  
19 I would be able -- I was hoping over a period of time  
20 that I would be able to build some kind of bridge again  
21 between the parents and the hospital team, that I didn't  
22 see it as widening the gulf. And there was concern  
23 expressed to me that it would widen the gulf. And I was  
24 explaining, "No I don't believe it will", and why  
25 I thought that gradually by helping people to deal with

1 all of the feelings that were around, the feelings of  
2 anger and resentment that were perhaps a barrier to them  
3 working with health staff in the way that they had  
4 previously done, that we would be able to overcome those  
5 things.

6 But it was a very tense discussion and I certainly  
7 was very -- yes, I was very concerned about it and I do  
8 remember very clearly speaking with one or two of my  
9 social work colleagues about it just because I felt  
10 I needed to talk to someone else about it. And the  
11 tensions between my health colleagues and myself were  
12 overcome fairly quickly but there was a comment about  
13 people coming together and what the impact of that might  
14 be. And, you know, a comment was made about people  
15 being sued or whatever, but the comments had been made  
16 from time to time.

17 There was an anxiety about what action parents might  
18 take and against whom they might take that action.  
19 I think that, given the types of discussions that were  
20 going on and the campaign beginning about compensation  
21 and so on, it was bound to give rise to some anxiety all  
22 round.

23 Q. Had there been a parents group at Yorkhill for the  
24 parents of the haemophilia patients before that?

25 A. Yes, there was a parents meeting that took place. It

1 was more a parents meeting, rather than a parents group,  
2 in that it was a gathering of parents that took place  
3 from time to time. It would be attended by the medical  
4 staff. I began to attend when I went there. It was an  
5 opportunity for information to be shared about a variety  
6 of things. They did a little bit of fundraising and  
7 I remember taking a role in that, helping them.

8 So there would be things like discussion around  
9 benefits issues, or particular things that were coming  
10 up in general terms, but it was a meeting of parents and  
11 sometimes the agenda would be influenced by the medical  
12 staff. "There is something we want to tell you about  
13 this or that," you know, something about what might be  
14 happening at a clinic or it might be issues that parents  
15 were bringing up around children being excluded from  
16 school trips. A variety of things. But it wasn't about  
17 the more personal aspects of parents' lives. It wasn't  
18 the situation in which you would worry about  
19 confidential things being discussed, for example.

20 THE CHAIRMAN: Mr Dawson, we will have a short break at that  
21 stage.

22 MR DAWSON: I have only a couple more questions, sir.

23 THE CHAIRMAN: We have to consider the impact on others.

24 MR DAWSON: Of course.

25 THE CHAIRMAN: I think to be fair to everybody, we might all





1 that were certainly going on about the source of the  
2 infected blood products and -- I mean, there was a lot  
3 of discussion at the time about imported blood products  
4 and so on, and there was certainly the view that more  
5 ought to have been done to ensure that blood products  
6 were safe and were produced within the UK.

7           There were various conflicting views at the time.  
8 But certainly it seemed -- well, my recollection of the  
9 discussions with the parents were that they believed it  
10 was due to changes that were taking place in the  
11 provision of blood products and they felt that some of  
12 those changes related to the situation in England, where  
13 I think blood products were sourced differently, or  
14 produced differently. And my feeling was that there was  
15 a view that Scotland could have essentially avoided that  
16 problem.

17           I can't recall the technicalities of it but the  
18 parents -- they certainly had an understanding at the  
19 time, from the information that was available, about how  
20 this had come about, and I think it would be reasonable  
21 to say there was a view that this could have been  
22 avoided. And certainly amongst other people that  
23 I spoke with from the haemophilia world and adults who  
24 had also been infected by HIV, because I did have  
25 contact with a number of people through my role in the

1 Macfarlane Trust, that was a view that some people held.  
2 So the accuracy or reasonableness of that view I can't  
3 comment on. I can only say that that seemed to be part  
4 of the feeling that was around.

5 Q. So these were the views that were being expressed by the  
6 parents at the time? Was there any attempts on the part  
7 of the medical staff to try and give some clear  
8 information, perhaps, as to the source of infection?

9 A. Not that I am aware of. I can't think of any particular  
10 discussions that were taking place about those issues  
11 and I think that -- yes, it was a very difficult one,  
12 I suppose on both sides. Parents were feeling very  
13 angry, very, very distressed about things and I think  
14 that the medical staff are feeling very anxious and  
15 nervous about the whole situation. They were also in  
16 a difficult position.

17 Q. Thank you.

18 I would just like to ask you a question about one of  
19 the comments you make in your statement. It's at  
20 paragraph 14.

21 Could we have that up, please?

22 This is the paragraph in which you are describing  
23 a paper that you presented to a conference and that you  
24 had obtained the parents' permission on before doing  
25 that. The response from the parents was, as you set out

1           there, that they were happy for you to do that but  
2           agreed after discussion as to the purpose and value of  
3           the paper. You say that one parent said that they felt  
4           that some people were making a career out of working  
5           with HIV and publishing papers. Can you give us a bit  
6           more explanation about what you think that parent meant  
7           by that comment?

8    A. At that particular time there were a number of people  
9           speaking as experts on the subject, whether that was at  
10           conferences or whatever, a variety of pieces of research  
11           that seemed to be taking place in different parts of the  
12           country, looking at the impacts on families, looking at  
13           a variety of aspects, and parents had fairly strong  
14           feelings about that.

15                 I mean, the paper itself in some respects was one  
16           that was probably controversial at the time, as far as  
17           my social work colleagues were concerned, in that there  
18           was a very strong view that many people held that all of  
19           these boys all have to know everything about what's  
20           happening and their condition, and I had spent quite  
21           a lot of time working with this particular group of  
22           parents who, I have to say, were, in my opinion, quite  
23           exceptional really. They were all extremely good  
24           parents, very, very capable, very sensitive, caring,  
25           nurturing individuals, but we had spent a lot of time

1 talking about the pros and cons of sharing information  
2 with their sons and about the rights of young people to  
3 have information, but the rights of people in general to  
4 sometimes not have information too. We all use denial  
5 quite effectively at different times in our lives, and  
6 these parents certainly wouldn't have prescribed to the  
7 view that everybody should be told everything straight  
8 away all at one time, kind of thing, and there were  
9 different views about things like that.

10 So the parents knew -- I had spoken with parents  
11 about the fact that I felt it was important to share  
12 some of their experiences and their thoughts and mine in  
13 working with them on these issues with other people, and  
14 they were all happy about that. But certainly one  
15 particular mum was very clear about the number of people  
16 that she felt had limited experience in working with  
17 families affected by HIV, and she felt that some people  
18 had limited experience of working with parents whose  
19 children had HIV but who were nonetheless speaking at  
20 conferences or whatever and publishing things and she  
21 was -- as I say, they were all very capable parents,  
22 they were very aware that in some professions it is good  
23 for your career to publish things and there was a great  
24 deal of feeling about that, and I was straight with them  
25 about why I felt it would be important to share my work

1 and their views with other people but that beyond that  
2 it wasn't something we were seeking to publish, and they  
3 were all satisfied with that really.

4 Q. You point out that you had obviously gone out of your  
5 way to explain to the parents the purpose and value of  
6 your paper. Do you think that there had been any  
7 attempt on the part of these other people who were  
8 giving such papers to explain the purpose and value of  
9 their papers to the parents?

10 A. Other papers would be from other people, not  
11 professionals directly involved with the group I was  
12 working with. They were thinking in general terms about  
13 other people's points of view. I think there was  
14 certainly -- there was some awareness that -- for  
15 example, there were different points of view. They knew  
16 that other people would have been saying that, "Oh, you  
17 should all have been telling your children the minute  
18 they got to ..." whatever age. They felt that there  
19 were a lot of people that were setting themselves up  
20 perhaps as experts, without really having direct contact  
21 with them and listening to them.

22 THE CHAIRMAN: Was this purely in the social services side?

23 A. No, not -- I was aware of the -- my social work  
24 colleagues having in many instances very different views  
25 from me but the parents were also aware that were there

1           were lots of other people within health, social work or  
2           whatever working in this field but presenting points of  
3           view in different venues as experts, and the parents  
4           were questioning their expertise, shall we say.

5   THE CHAIRMAN: I really wouldn't like you to go too far  
6           round a speculative route that might end up as  
7           a criticism of people you don't even know about, and  
8           Mr Dawson will no doubt be careful not to ask a question  
9           of such generality again that the answer might be  
10          misused, Mrs Leitch.

11   MR DAWSON: Could I just ask you one final question,  
12          Mrs Leitch. I wanted to ask you, if you can, to  
13          describe for us how in your opinion the parents of the  
14          haemophiliac boys who were infected with HIV dealt with  
15          that tragic situation?

16   A. In my experience of working with parents at that  
17          particular time and in the many years since I would have  
18          to say that I have never come across parents who would  
19          have been able to deal with it more effectively than  
20          this group. They were quite exceptional. It seemed to  
21          me at the time and since it was quite remarkable that it  
22          did happen that they were such extremely good parents.  
23          At the time that this happened these were boys who were  
24          all functioning extremely well in school. They were all  
25          doing well academically, emotionally well balanced,

1 healthy children. None of them had any behavioural  
2 problems. They were the kinds of families that I would  
3 not have expected to ever have to be particularly  
4 involved with in my role as a social worker other than  
5 perhaps giving information and advice.

6 It was an exceptionally painful experience for them  
7 but they were all able to focus first and foremost on  
8 the needs of their children. Everything they did was  
9 with their children at the absolute centre of all their  
10 thinking. I couldn't overstate that. They were  
11 extremely good, caring, nurturing parents. They were  
12 worried, anxious, fearful, all of the things that you  
13 would imagine parents would feel in those situations,  
14 but at all times their focus was very much on their  
15 children's needs and -- yes, I couldn't praise them  
16 highly enough in that regard.

17 Q. Thank you very much indeed, Mrs Leitch. Thank you, sir?

18 THE CHAIRMAN: Mr Anderson?

19 MR ANDERSON: I have no questions.

20 THE CHAIRMAN: Mr Johnston?

21 MR JOHNSTON: I have no questions.

22 THE CHAIRMAN: Anything else you wish to follow?

23 MR GARDINER: The next day will be Tuesday, with Dr Ludlam

24 in the morning and Professor Lowe in the afternoon.

25 THE CHAIRMAN: Mrs Leitch, thank you very much. It's very

1 helpful to have a different perspective on these things.  
 2 A. Thank you.  
 3 THE CHAIRMAN: Next week's programme, if we manage to stick  
 4 to it, will be what, that apart?  
 5 MR GARDINER: Dr Ludlam on Tuesday and Professor Lowe on  
 6 Tuesday afternoon and then Dr McClelland on Thursday  
 7 morning, we hope. We hope that it will be done in the  
 8 morning but you never know.  
 9 THE CHAIRMAN: Yes, that's the sort of forecast that's just  
 10 a challenge to others.

11 (3.43 pm)

12 (The Inquiry adjourned until Tuesday 28 June 2011  
 13 at 9.30 am)

14  
 15 DR ROBERT PERRY (continued) .....1  
 16 Questions by MR GARDINER (continued) .....1  
 17 Questions by MR DAWSON .....74  
 18 Further Questions by MR GARDINER .....103  
 19 DR JOHN GILLON (continued) .....105  
 20 Questions by MR GARDINER (continued) .....105  
 21 Questions by MR DAWSON .....123  
 22 MRS CHRISTINA LEITCH (sworn) .....125  
 23 Questions by MR GARDINER .....125  
 24 Questions by MR DAWSON .....153  
 25



