Friday, 24 June 2011

(9.30 am)

DR ROBERT PERRY (continued)

Questions by MR GARDINER (continued)

MR GARDINER: Good morning, Dr Perry.

A. Good morning.

Q. Dr Perry, you have previously given evidence to the Inquiry in connection with statistics and the C1 topic. This morning you are here to help us with the question of the implicated batch. Just before we start looking at the documents, I wonder if you would mind just reminding us of your qualifications and your present position?

A. My qualifications are, I have a PhD in chemistry. I'm a qualified person under the European Directive, which is a specific professional qualification required in the pharmaceutical industry. My current occupation is participating in the public Inquiry on behalf of SNBTS, but also I'm the executive director of the International Plasma Fractionation Association, which is an organisation based in Amsterdam.

Q. Yes. Thank you.

We are going to be looking at events around about November 1984 and the ensuing years. What was your position at that time?

A. I was acting director of the protein fractionation centre of the Scottish National Blood Transfusion Service.
Q. Right.
A. I had been in post for about ten months.
Q. Sorry?
A. I had been in post for about ten months at that time.
Q. Thank you. You have given us a statement in connection with this topic and that's at [PEN0121331]. You have got a copy of this in front of you?
A. I have, yes.
Q. Is that correct? What you say is:

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

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

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

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

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

A. Okay. Is that better?

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

So if we just read on:

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

Who was Dr Cuthbertson at that time?

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

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

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

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

A. Yes.

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

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

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

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

"The pool from which the batch had been manufactured.

"The identity of the donors contributing to that pool.

"The location of all other plasma from those donors.

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

Is that report an attempt to answer those questions?

A. Yes.

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

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

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

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

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

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

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

Q. Yes.

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

Q. If we could have a look at [SNB00065996], what's that,

Dr Perry?

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

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

A. Indeed, yes.

Q. Do you remember receiving that memorandum?

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

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

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

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

A. Yes.

Q. Is that your recollection?

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

Q. Yes.

A. -- some days after the initial notification.

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

"The review of the batches received ..."

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

A. Yes, indeed.

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

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

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

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

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

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

Then you say:

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

Could we have reference two up, which is the Steel article, which is [LIT0010895]. Is that the article that's referred to?

A. Yes.

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

A. Correct.

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

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

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

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

In the Lancet in 1985.

A. Yes.

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

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

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

Q. Yes. Perhaps we could have a look at [SNB0083434]. Is that the paper that is referred to at reference 2?

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

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

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

A. That's right.

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

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

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

Q. Yes.

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

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

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

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

THE CHAIRMAN: Yes.

MR GARDINER: We will come to the chemical analysis later but if we could go back to the "Actions" document.

Yes, that's great, thank you.

So:

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

A. That's correct.

Q. "It is noteworthy, however, that Steel et al also reported that not all recipients of batch 3-009 developed evidence of HIV infection (14 out of 32 recipients remained uninfected). Although it has never been established conclusively that the batch was infective, the actions taken were made on the basis that this was a justifiable, though unproven, assumption."

Dr Perry, could you just expand on that conclusion about the justifiable, though unproven, assumption?

A. I think this describes -- well, the action that was taken was clearly to recall the batch and to carry out a whole series of subsequent investigations. I think in a sense it's an example of applying a precautionary principle here. We had enough evidence and enough information to allow us to act and act on the basis that -- the conclusion that it was a single batch,

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

Q. Yes.

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

A. Yes.

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

A. Yes.

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

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

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

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

THE CHAIRMAN: Yes.

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

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

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

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

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

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

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

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

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

A. Sure.

Q. It wasn't on the batch?

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

Q. Yes.

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

Q. Yes.

A. Because those assays simply didn't exist.

Q. Yes.

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

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

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

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

Q. Yes.

A. Once the commercial assay was available.

Q. Yes.

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

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

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

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

Q. Yes, thank you.

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

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

Q. Yes.

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

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

Q. Yes.

A. Or indeed antibody to that virus.

Q. Yes. This is between 1985 and 1986?

A. Yes.

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

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

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

Q. It's looking for an antibody?

A. It is looking for antibody.

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

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

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

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

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

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

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

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

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

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

Q. What tests did they carry out?

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

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

A. No, only the antibody test.

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

A. I think that's the report, yes.
Q. Yes. Can you just very briefly talk us through the report, Dr Perry, in terms of what the results were?
A. Okay. If we scroll down -- this is a standard report form that is used by the National Institute of Biological Standards and Control. It's a highly regulated activity. It operates to extremely high standards and they will be very careful in how they respond to enquiries like this.

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

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

looking for antibody, antigen and DNA/RNA fragments.

Q. Yes.

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

Q. Yes.

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

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

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

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

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

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

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

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

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

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

THE CHAIRMAN: Yes.

MR GARDINER: So that's the HCV result.

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

"There is evidence for the detection verified by

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

I'm not sure whether that's helpful to you. Importantly it says:

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

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

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

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

Q. Yes.

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

Q. Yes.

A. It would certainly be consistent with that.

Q. Could we just go back to the --

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

A. Yes.

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

A. Correct.

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

samples down to NISBC?

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

THE CHAIRMAN: Yes, Mr Gardiner?

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

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

Q. Yes.

A. But Professor Franklin was obviously closely involved in

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

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

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

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

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

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

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

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

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

A. Yes, that's right.

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

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

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

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

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

Q. Yes, and what is that?

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

Q. Yes.

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

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

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

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

Q. Yes.

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

MR GARDINER: Thank you, sir.

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

A. I'll give you my understanding of what this means. Specificity is the ability of a specific assay system to

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

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

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

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

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

Q. Yes.

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

Q. So it was an infectious batch?

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

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

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

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

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

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

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

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

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

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

A. From NIBSC?

Q. NIBSC, yes?

A. Was it surprising?

Q. Yes.

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

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

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

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

assay sensitivity.

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

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

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

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

A. Absolutely.

Q. -- the batch?
A. Absolutely, indeed. It could have been a window-phase donation where there was no antibody response. So the donor was viremic, was incubating the virus, had yet to develop an antibody response, in which case there would be no antibody or very, very little, diminishingly small quantities. But from the most recent information, we seem to have picked up antibody in the so-called "combi test". So I think to speculate on this is interesting but perhaps not informative, but that certainly -- that could be one -- that could certainly corroborate the initial findings -- the subsequent findings.
Q. So it sounds as though, when you got the testing back in 1985 and 1986, you weren't surprised about the lack of a positive test?
A. I can't remember whether we were surprised. I don't think we were necessarily expecting there to be a positive test. We knew the tests were relatively insensitive. If it was one donation, it would have been diluted by 4,000 other donations in the plasma pool. So there was a massive dilution effect of something like 10 to the 3. During the purification process, we had no idea how HIV antibody partitions through the process.
So I think we probably expected there to be -- there is very little antibody in the Factor VIII product

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Yes.

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

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

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

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

A. Yes.
THE CHAIRMAN: And that results in a ledger entry?
A. Yes.
THE CHAIRMAN: And a batch number for that and storage until they are issued?
A. Yes.
THE CHAIRMAN: And I think I have picked up already that it's 1,020 to Edinburgh and 50 to Aberdeen.
A. Correct.
THE CHAIRMAN: Where is that recorded? Is it recorded somewhere in these papers?
A. That would be recorded on a separate document. All these documents were manual at the time but I think it was a document called a "batch history sheet", which actually signifies the final release, the quality release, of the batch, and then the subsequent distribution record becomes the working ledger for the distribution department.
MR GARDINER: We can see that, sir, at [PEN0121375].
THE CHAIRMAN: Could I see that, please?
A. So this provides the final authority for issue, which again carries my signature. At that time it was the responsibility of the quality manager to determine the quality and the suitability of the product and check that everything had been carried out according to

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

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

A. The plasma?

THE CHAIRMAN: Yes.

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

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

A. Yes.

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

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

A. Yes.

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

A. I was, yes.

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

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

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

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

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

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

Q. Yes.

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

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

A. So there was always a continuous trace.

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

not?

A. Yes.

Q. Yes.

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

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

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

I don't think we have dealt with that?

A. No.

Q. Could you just tell us about that?

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

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

Q. These were the vials that were then tested?

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

Q. And these were early antibody tests?

A. Yes, using the early antibody tests.

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

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

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

A. Yes.

Q. Yes. We have dealt with that.

A. Yes.

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

A. Yes.
Q. Could we go over the page? 4.2 talks about the issue history and we have looked at the batch issue history sheet. The next section is 4.3, "Plasma records", and these are the records that are held locally, I think. Is that right?
A. Plasma records -- I'll just make sure I answer your question correctly. There were two forms of record. Plasma records would be held at the regional transfusion centres, ie the supplying centres, but we would also hold plasma records at PFC. The records at PFC, just to describe this little nuance of the arrangement; at PFC we didn't store information on individual donations, we stored information on groups -- the plasma was supplied in boxes, typically cardboard boxes with barcoded labels and so on. We held those records down to the point of the individual box number, but there was a clear link to the plasma that was contained in those boxes, by the regional transfusion centres. So the regional transfusion centre gave the box its identity.
Q. Yes.
A. It had records in the centre, which identified which plasma donations had gone into that box and PFC held records of the plasma box. So there was a complete trace. But at any point in time PFC wouldn't be able to

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

Q. Using the information from the regional centres?

A. Yes, there was a trace.

Q. Thank you.

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

THE CHAIRMAN: Yes, it would be appropriate.

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

A. Yes.

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

A. Yes, indeed.

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

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

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

circumstances in which there was a need to examine that issue. Anyway, we will see after the break.

(11.02 am)

(Short break)

(11.28 am)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

Can we have a look at [PEN0121376], please? You told us earlier, Dr Perry, that the recall was on 1 November 1984 and I think we see here a letter to Dr McClelland. If we go to the next page, that's from you.

A. That's correct, yes.

Q. If we go back to the previous page, we see paragraph 1:

"Dr Cuthbertson contacted by [yourself] Thursday, 1 November (am) describing HTLV-III seroconversion in three Edinburgh haemophiliacs."

Paragraph 3:

"Dr Cuthbertson contacted Dr Urbaniak (Thursday pm) requesting that the above batch be recalled and quarantined pending documentary confirmation."

Is it this document that leads you to conclude that the recall was 1 November 1984?

A. Yes, that's the best contemporaneous account I have of those specific -- this was a response to Dr McClelland's

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

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

A. The plasma records at PFC?

Q. Yes, please.

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

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

A. Yes, typically, yes.
Q. "... were bound in groups of four for storage purposes and given new identifiers, called 'storage numbers', for each group."
A. Yes.
Q. So each group would be 48 plasma donations?
A. Roughly, yes.
Q. "These new identifiers were also recorded in the plasma traffic sheet along with the weights of the contents in kilogrammes. When required, a suitable weight of plasma was removed from storage."
So what form was the plasma in at that point?
A. Frozen, still in the boxes and still -- well, yes, the plasma would be removed from -- the plasma was stored in the PFC in a minus 40 degrees freezer and it was stored in its boxes. When an instruction to make a batch of product or to process some plasma was made, the plasma boxes would be removed, the plasma donations removed from the boxes, obviously the box numbers recorded on the plasma traffic sheets as described here, and the plasma would then enter process.
Q. So at this stage the 12 individual donations were separate?
A. Yes. Yes.
Q. What were they contained in?

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

Q. This has been sent by the RTCs?

A. Correct, yes.

Q. If we just read on:

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

How do you know that?

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

Q. What was the total weight?

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

Q. Yes.

A. Which is combined plasma plus the plastic container. The actual weight of plasma was 940 kilogrammes.

Q. Yes.

THE CHAIRMAN: You say "plus the plastic container"?
A. Yes, it was a PVC bag.
THE CHAIRMAN: But weren't they weighed originally just in their cardboard boxes?
A. No, they were never weighed inside their cardboard boxes. When they entered process, they would have been weighed -- to the best of my recollection, they would have been weighed as basically frozen lollipops of plasma, but clearly at that stage they were still contained in their plastic outer pack and that plastic outer pack was subsequently removed but we had a standard conversion factor. We knew how much a plastic bag weighed. We could basically calculate the actual amount of plasma.
THE CHAIRMAN: I think then I have not quite got the sequence complete. You say that:

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

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

please, doctor?

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

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

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

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

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

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

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

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

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

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

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

So what was done about those subsequent donations?

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

Q. Yes.

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

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

A. Indeed.
Q. We see that there was a co-ordinating group on 6 November 1984?
A. Yes.
Q. "Where it was decided that the donations used to manufacture the batch should be traced and that relevant information should be provided to each centre to enable them to perform this trace. This allowed each site to trace the constituent donations and therefore the donors. At a further meeting on 20 November it was decided that repeat donations from the donors should be followed up ..."
You have told us that that was done and it was found that none of them were found to be HIV positive?
A. That's correct, yes.
THE CHAIRMAN: Do you have any idea of the number of repeat or return donors?
A. I'm sorry, I don't know how many -- no, I don't, I can't answer that question.
MR GARDINER: Paragraph 6.1 separates this process into plasma donations and then 6.2 is cellular components. Could you tell us what the different approaches were?
A. The PFC simply was required -- well, in some senses they were similar but the plasma from the donations was quarantined. Any plasma that we still had in stock from

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

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

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

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

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

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

A. Yes.

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

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

Was that done?

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

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

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

A. Yes.

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

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

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

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

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

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

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

A. That's correct.

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

A. Yes.

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

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

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

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

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

Then the next paragraph:

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

A. Yes.

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

A. Yes.

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

are listed here?

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

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

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

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

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

Q. Yes.

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

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

Q. Yes. How did they come --

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

the process that went through. So he was excluded.
THE CHAIRMAN: He was mildly reactive for VD according to the records.
A. That's right.
MR GARDINER: Who was it who organised that testing, Dr Perry, of that specific donor?
A. I think if it was a donor in the West of Scotland, it would have been Dr Mitchell or one of his staff.
Q. Yes. So the results would have come back too Dr Mitchell?
A. Indeed.
Q. Thank you.
Then the fourth conclusion over the page.
A. It's really not a conclusion, it's more of a statement of fact, but when the possible infectivity of batch 3-009 was discovered, SNBTS decided to quarantine any further plasma donations pending the investigation, and since the investigation didn't identify an infected donor, the quarantine was ended when heat treatment at 68 degrees for 24 hours -- not two hours -- I think this is an important distinction. At that stage in the process we had already established a process for heating for 24 hours and that coincided with the information that we had received from very reputable, highly well thought of scientists in the US, that indicated that

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

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

THE CHAIRMAN: I think I have one.

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

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

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

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

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

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

A. I don't know but I think --

THE CHAIRMAN: It may not have been your area.

A. It certainly wasn't my area.

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

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

MR GARDINER: Sorry, sir, there was one thing I should put to the witness.

Could we have [PEN0121335] up?

I'm sorry, Dr Perry, I forgot to ask but this. Could you explain what this document is?

A. It's basically a timeline that we assembled really since 2008, when we started on this process of examining the key events and this attempts to record, certainly from a SNBTS perspective, the key steps and actions and discussions that took place between the initial collection of the plasma in October 1983 and the most recent investigation, which was the NIBSC assays on the sole vial that we recovered from the University of Edinburgh. And it attempts to identify what we think are the key pieces of evidence informing the chronology that we now have.

Q. Yes. On the right-hand column, are these references to bits of documentary evidence?

A. Yes, indeed.

Q. We see that that starts in June to October 1983, and if we could just go to the last page, it ends up with 31 March 2009?

A. Yes.

Q. Which is the final report?

A. Correct.

Q. Does that cover the span of the things that we have discussed this morning?
A. Absolutely. It covers the span, pre-dating the initial notification from Dr Ludlam, ie the collection of plasma that went into the batch, right through to the very last investigation that has been carried out.
Q. Yes. Thank you very much, Dr Perry.
THE CHAIRMAN: I think if you look at the page before, it may answer one of the question that I asked earlier and wasn't covered. I think if we look down to April 2008, we get the beginning of the final steps in submitting the remaining vial.
A. Yes.
THE CHAIRMAN: Dr Bienek, who contacts Professor Simmonds?
A. That's absolutely right.
THE CHAIRMAN: And that leads to the search that turns up the particular vial. And I think we see that Professor Simmonds sent it.
A. Oh, right, okay.
THE CHAIRMAN: Second bottom entry.
A. That is quite possible. I think -- although I wasn't directly involved in the transmission of this, I can understand that being a very good approach, that SNBTS really didn't want to be seen to be interfering with this really vital piece of information, so it was

directly sent --

THE CHAIRMAN: So Professor Simmonds as the --

A. Yes.

MR GARDINER: Thank you, sir.

THE CHAIRMAN: Mr Di Rollo?

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

Questions by MR DAWSON

MR DAWSON: Could I ask first of all for a document to be put up? The document is [SNF0013624]. You will see that this is a letter which is written by Dr McClelland to Dr Cash.

A. Yes.

Q. Dated 15 November 1984. Have you seen this letter before, Dr Perry?

A. I have.

Q. I think the box to the right of the address indicates that this may in fact be your copy of the letter. Is that right?

A. It is.

Q. You can see there "PFC, received 19 November 1984". "Dr Perry" is ticked, which I presume means that you had seen it?

A. Yes.

Q. In the first paragraph Dr McClelland sets out the reason for the letter. I'll just read that out. It says:

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

Do you remember attending the meeting on 15 November?

A. Yes, but not in detail.

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

A. No, I can't.

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

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

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

Q. Okay, thank you very much.

I would like to come back to this document but could I just jump, at the moment, to your statement? The statement is [PEN0121331].

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

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

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

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

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

Q. I see.

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

"Records of the initial notification to the SNBTS."

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

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

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

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

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

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

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

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

Q. Unfortunately we don't have access --

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

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

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

A. Yes.

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

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

A. Yes.

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

meant by the "relevant period"?

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

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

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

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

A. No.

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

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

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

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

A. Yes, absolutely.

Q. Thank you.

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

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

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

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

I think it says at the bottom, where we have

"Conclusions" under number 4:

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

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

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

Q. Thank you.

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

told, principally in the second column, as I understand it, how many of the 16 seroconverters at that stage had received each batch. Is that a correct interpretation?

A. Yes, that's exact --

Q. We can see at the bottom there the one with the asterisk. That's the implicated batch, isn't it?

A. Yes.

Q. That had been received by 15 of the 16 seroconverters?

A. Yes.

Q. We can see from this that there are various other batches which have been looked at, some of which have 14, some of which have 13, 12, 11, 10 and going down to some have been received by very few?

A. Yes.

Q. And the batches that were referred to in the passage we just looked at are ones, predominantly, with the higher numbers of recipients? Is that correct?

A. Yes.

Q. Thank you very much.

Could we just go back to the previous document, which is [SNF0013624] at 3625, please. You said a moment ago that at this stage you were quite confident that the implicated batch was the batch that had infected at least 15 of the 16 seroconverters. Is that accurate?

A. Yes.
Q. Would it be accurate to describe the exercise that you were carrying out at this meeting as looking at the records to see if you could pin it down to a single batch?
A. No, it was -- I think it was -- it was a specific exercise -- this is my recollection -- and certainly it seems to be borne out by the content of the letter that Dr McClelland wrote to Dr Cash -- it was to make absolutely sure that in our -- if you like, our rushing into a conclusion that 3-009 was the implicated batch, we weren't excluding other batches that could be at risk. It was an attempt to make sure that we were looking at the whole horizon, not just part of the horizon that pointed to 3-009.
Q. So you are looking at a wider number of batches and would it be with an open mind to the possibility there might be more than one infected batch?
A. Absolutely.
Q. Thank you.
Would you be surprised if either of the other individuals who were at the meeting described the exercise as looking at the records to see if you could pin it down to a single batch?
A. No, I think this is a fine judgment, and to a certain

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

Q. Thank very much.

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

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

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

A. Correct.

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

receive it. Is that right?

A. Yes.

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

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

Q. Thank you.

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

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

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

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

Q. Thank you.

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

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

A. Yes.

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

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

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

A. Yes.

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

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

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

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

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

Q. That would have meant that --

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

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

A. Absolutely.

Q. Thank you very much.

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

A. Yes.

Q. Can you just tell me what it is?

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

Q. Is this the antibody testing that you are referring to being done in 1985 and 1986, the results of that?
A. Yes.
Q. If we just skip over to the next page, I think you can see that it's dated 23 June 1986. Do you see that there at the bottom?
A. Yes.
Q. If we just skip back to the first page, I just wanted to ask you really about a couple of things. Your position has been, in light of all of the information including the 2008 testing and all of the circumstances that you have available to you at this date, that the implicated batch was probably what infected the Edinburgh cohort patients. Is that right?
A. Yes, I think --
Q. I'm just trying to summarise what you said --
A. I think that is the most probable and most likely explanation.
Q. The one thing I just want to draw to your attention was when you were making that assessment, you were speculating as to what assay had been used at this stage. If we just scroll down to the bottom, I want to draw your attention to the fact that the batches marked with an asterisk were tested for HTLV antibody using a sensitive variant of the Wellcozyme assay. No trace

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

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

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

A. Yes, it neither means they were infective or

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

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

A. Yes.

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

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

Q. Thank you very much.

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

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

Q. I'm just trying to work out whether any other tests have been done.
A. Have been done?
Q. Yes, indeed. Similar, for example, to the 2008 testing of the implicated batch, have any other tests after this 1985/86 period been done on any of the other broadly implicated batches, if you like, other than the 2008 testing --
A. I would need to check that out. I'm not aware of any. Certainly latterly in 1988 -- in the later 1980s every batch of product manufactured by PFC would have been tested by the NIBSC as part of a batch release process. So towards the end of the 1980s, all batches of product produced by the PFC would have been tested for HIV using a validated assay by the National Control Laboratory.
Q. But focusing specifically on those that were in your list, if you like, from the November 1985 meeting, you are not aware, as things stand today, of any other testing having been done?
A. No, but I perhaps would like the opportunity --
Q. No, indeed.
A. -- just to double-check that they haven't been some research done on any of the batches because, as we know, there are much more searching assays available now.
Q. Would it be right to assume that notwithstanding the

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

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

Q. Thank you very much.

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

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

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

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

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

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

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

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

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

A. Yes.

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

A. That's correct.

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

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

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

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

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

Q. Of course.

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

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

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

A. Yes, I recognise the letter.

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

A. Yes.

Q. Can you tell us?

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

Q. Thank you very much.

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

"At no time during the manufacture of non-heat-treated products did we include a specific warning in our insert leaflets that Factor VIII or Factor IX carried a risk of HIV transmission. Reference to the possibility of hepatitis transmission has always been included, latterly updated to include HIV. I enclose the various texts used for inserts since 1983 and the chronological sequence of their introduction."

A. That's correct.

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

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

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

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

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

agent of AIDS, as you say in number 2?
A. They would look -- generally the industry would look for a very, very good rationale that supported -- and evidence for supporting a statement concerning risk of HIV. I'm not saying that we weren't aware of the emerging risk of AIDS as a causative agent, but at the time you are describing it was far from certain that this was an infectious disease.
Q. Is the position that the text, at least as far as these types of things were concerned, was not controlled by you, it was controlled by the regulatory authority?
A. I think to an extent we control it, we drafted it and we would have checked with the regulatory authorities that the wording was satisfactory. But I think the way we covered it, to the best of my knowledge -- although I would need to look at the specific details and the timelines for the leaflets, was to say that "The product cannot be assumed to be free of the risk of infectious disease" or words to that effect, which covers -- certainly intended to cover hepatitis but, you know, it covers any other infectious disease, which we believe has entered the blood --
THE CHAIRMAN: Dr Perry, could I see if I understand the realities of this? If a product were known to the manufacturer to carry a risk of communication of HIV, is

it likely that a product certificate would have been granted?

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

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

A. Yes, absolutely.

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

A. Yes.

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

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

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

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

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

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

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

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

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

Q. What time was that included?

A. It would have been post-1985.

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

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

the time.
Q. Okay. Thank you very much.
Sir, I don't intend to ask any further questions?
THE CHAIRMAN: Thank you, Mr Dawson.
Mr Anderson?
MR ANDERSON: I have no questions, sir.
THE CHAIRMAN: Mr Johnston?
MR JOHNSTON: I have no questions either.
THE CHAIRMAN: Have you anything to follow on?
Further Questions by MR GARDINER
MR GARDINER: Dr Perry, you have just been asked about package inserts and I think you have given your best recollection of the terms of package inserts.
A. Yes.
Q. But am I right in saying that sitting here today you can't remember exactly what the text of these package inserts might have been in the early 1980s?
A. I think I have a document on my desk here that has some of them described. It's in very small writing but it really is along the lines of "The product cannot be assumed to be free of infectious risk although the plasma has been screened for Hepatitis B" and so on.
Q. Infectious risk from what, though?
A. Any infectious virus or disease or any infection.
THE CHAIRMAN: I don't think this is fair to Dr Perry.

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

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

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

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

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

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

Q. Thank you very much.

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

A. Thanks very much.

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

DR JOHN GILLON (continued)

Questions by MR GARDINER (continued)

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

A. That's correct.
Q. -- and other matters. Could you just remind us, please, what your qualifications are and what your position is at the moment?
A. My qualifications are MBChB from Edinburgh in 1973, MRCP (UK) 1975 and MD 1984.
Q. Yes. What's your position at the moment?
A. I'm currently a consultant in the Edinburgh transfusion centre.
Q. Yes. Thank you. We are interested today in HIV look-back and you have kindly provided the Inquiry with a statement about that. Could we just look at that? It's [PEN0120862]. Do you have a copy of this?
A. I have it on the screen.
Q. Yes. The question which you were asked is:

"What steps were taken to identify potentially infectious batches of blood and the individuals who received blood or blood products from those batches?"

Of course, it's implicit in the question that it is after December 1984, when you know that the virus is in the Scottish donor pool. Could you just tell us what your answer to that question was, please?
A. Well, my understanding of this question is that it would relate to the time after the test was introduced in October 1985.

Q. Right.
A. Not December 1984.
Q. Yes.
A. By "infectious batches of blood", I did not take that to refer to batches in the sense in which it has been discussed this morning, which is batches of finished fractionated product, but rather individual donations from donors --
Q. Yes.
A. I hope that's the sense in which it was intended --
Q. Yes.
A. -- because that's the sense in which I have taken it. So what my answer refers to are the discussions that took place in anticipation of that introduction of testing in October 1985 and what we would do in the event of discovering a donor with positive tests for HIV, to try to identify the fate of the previous donations prior to the period of testing.
Q. Yes. And you say that there was a working party established, and this is the working party of the Regional Transfusion Directors' Committee. Is that right?
A. Yes, at UK level, but essentially the English RTDs meeting, which also had representation from Scotland, Wales and Northern Ireland.

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

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

And:

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

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

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

Is that what you are referring to?

A. Yes, that's correct.

Q. So what was the recommendation?

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

Q. Yes. Was that done?

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

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

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

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

So how was that organised?

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

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

first place?

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

Q. Yes.

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

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

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

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

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

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

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

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

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

Q. Yes.

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

Q. Yes. The next question, which is over the page, is:

"Who was responsible for the look-back programme at a national level?"

Could you help us with that question, please?

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

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

A. Yes.

Q. Yes.

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

Q. Yes.

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

A. Yes.

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

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

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

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

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

A. It varied considerably, yes.

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

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

Is that the position?

A. Yes.

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

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

So if you were at the Colinton church session, all

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

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

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

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

What would you do with the mobile vans? How were

the records kept for them?

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

THE CHAIRMAN: Yes. Thank you.

MR GARDINER: Thank you, sir.

(1.05 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Thank you, sir.

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

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

could be.

Q. Yes, thank you.

Could we go back to your statement, please, which is [PEN0120862]? Could we go to the second page? At the bottom of the page the question is about tracing and testing for individuals, and you say:

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

Then the next bit:

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

How would that work, Dr Gillon?

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

What should we do?"

Q. Thank you.

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

"Were any written protocols/procedures created?"

This is about HIV look-back. Can you tell us what the answer to that is?

A. There were protocols and procedures created locally. I haven't been able to find any still in existence but I know that there is documentation of a meeting in the Southeast centre, where we discussed how we would handle the whole introduction of testing, and it's clearly stated then that we would draw up local SOPs and protocols, but I can't find any.

Q. Yes. Just to return to a question that we were discussing before lunch, you have told us about what would be done if a donor was found to be positive. Could you explain to us how you would come to know that a donor had tested positive?

A. We would usually -- the most specific sense in which the term "look-back" is used is called a "targeted look-back", and that means that on the routine testing for a given infectious agent, in this case HIV, which started in October 1985, any donor -- and after October 1985, every single donation was tested --

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

Q. Yes.

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

Q. Yes.

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

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

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

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

Q. When were -- sorry.

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

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

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

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

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

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

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

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

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

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

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

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

THE CHAIRMAN: Thank you Dr Gillon. Mr Dawson?

Questions by MR DAWSON

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

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

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

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

circumstances?

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

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

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

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

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

Q. In the specific sense of a --

A. In the specific case.

Q. Yes.

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

Q. Okay, thank you.

I have nothing further, sir.

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

MR JOHNSTON: No questions, thank you, sir.

THE CHAIRMAN: Thank you very much, doctor.

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

MRS CHRISTINA LEITCH (sworn)

Questions by MR GARDINER

MR GARDINER: Thank you, sir.

Good afternoon, Mrs Leitch.

I think that you have given the Inquiry a statement and if we could have a look at [PEN0121430]? I think you have a copy of that in front of you. Is that right?

A. Yes.

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

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

Q. Yes. When did you start at Yorkhill?

A. In October 1984, the end of October.

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

A. The consultant in haemophilia was Dr Ian Hann.

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

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

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

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

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

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

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

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

Q. What experience did you have of HIV at that point?
A. Oh, certainly when I took up the post in Yorkhill, none at all. Indeed, I had been there for quite some time when one of the senior managers, in what was then Strathclyde region, came to speak to me about it to say, "We are becoming increasingly aware of this as something we have to respond to as a department and you are the only social worker who is involved in this". So he was coming to learn from me. So essentially at the point I started, I knew nothing about it and gradually this was something I learned about whilst I was learning about haemophilia and other bleeding disorders.
Q. How did you learn about it?
A. Through discussion with -- it would have been Dr Hann, Dr Pettigrew, who was the registrar, who, on a day-to-day basis, did most of the work at clinics with that particular patient group, and Sister Murphy, who was the specialist haemophilia sister in the unit.
Q. Yes.
A. And also Dr Hann did make me aware that there was a social work special interest group, although that was largely to do with haemophilia, and I did meet with that. It was under the banner of the British Association of Social Workers. So we did have meetings from time to time, information sharing, and through

a variety of sources then, I became knowledgeable.

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

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

What would you discuss at those meetings?

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

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

they were under pressure.

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

Q. How often would you have these meetings?

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

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

A. No.

Q. Do you have any knowledge of that process?

A. No, none at all.

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

A. Yes.

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

A. The parent group?

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

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

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

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

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

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

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

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

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

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

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

Q. Yes. How often did the group meet?

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

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

Q. The parents were concerned about being overheard by

their children?

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

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

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

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

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

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

Q. Yes.
A. Ultimately there was a terrible sense of betrayal by the NHS and there were a lot of feelings about that.
Q. Could we go to page 4, please? At paragraph 9 you talk about the isolation and stigma related to HIV that had left people feeling powerless. I wonder if you could expand on that, please, Mrs Leitch?
A. Yes. As I was saying earlier, the level of fear and anxiety in society at the time was very, very high. Scarcely an evening seemed to go by without there being some reference on television, and working with families affected by that, I was acutely aware of it. It was a time in which children would be hearing cruel and sometimes quite vicious jokes in playgrounds. Parents knew, particularly after the early situation in which a young child had to hear something about himself on the news, that if they did not maintain absolute secrecy, their lives could be spread across newspapers or whatever, and there were situations in which people were being persecuted in one part of the country or another because they were seen to have HIV.

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

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

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

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

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

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

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

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

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

Could you tell us about this example?

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

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

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

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

Suddenly there we were in the hospital being told

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

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

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

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

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

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

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

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

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

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

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

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

about there?

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

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

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

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

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

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

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

Q. Yes. I understand.

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

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

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

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

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

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

A. Give me a second. (Pause)

Five.

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

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

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

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

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

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

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

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

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

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

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

A. No.

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

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

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

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

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

Q. Yes.

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

THE CHAIRMAN: Mr Di Rollo?

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

Questions by MR DAWSON

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

A. No.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR DAWSON: Of course.

THE CHAIRMAN: I think to be fair to everybody, we might all

need a little time to think about what you have been bringing out, so we will have a break.

(3.12 pm)

(Short break)

(3.30 pm)

THE CHAIRMAN: Mrs Leitch, before the break you painted a picture of a fairly stark contrast between the practice, in the way of protective clothing and other matters, that seems to have stopped at the hospital door, contrasting the freedom of association that was advised for people outside. Do you have any idea where the ideas developed within the hospital that resulted in that sort of behaviour?

A. All I know is that there was -- there was an infection control senior nurse, and I presumed that she didn't develop the policy on her own but it certainly came from --

THE CHAIRMAN: From her?

A. Within the hospital. But I wouldn't know anything about the mechanics of how that policy was developed.

MR DAWSON: Thank you, sir.

Mrs Leitch, from your contact with the parents, did you get the impression that they had any insight into how it was that their boys had become infected?

A. Well, as time went on, they understood the discussions

that were certainly going on about the source of the infected blood products and -- I mean, there was a lot of discussion at the time about imported blood products and so on, and there was certainly the view that more ought to have been done to ensure that blood products were safe and were produced within the UK.

There were various conflicting views at the time. But certainly it seemed -- well, my recollection of the discussions with the parents were that they believed it was due to changes that were taking place in the provision of blood products and they felt that some of those changes related to the situation in England, where I think blood products were sourced differently, or produced differently. And my feeling was that there was a view that Scotland could have essentially avoided that problem.

I can't recall the technicalities of it but the parents -- they certainly had an understanding at the time, from the information that was available, about how this had come about, and I think it would be reasonable to say there was a view that this could have been avoided. And certainly amongst other people that I spoke with from the haemophilia world and adults who had also been infected by HIV, because I did have contact with a number of people through my role in the

Macfarlane Trust, that was a view that some people held. So the accuracy or reasonableness of that view I can't comment on. I can only say that that seemed to be part of the feeling that was around.

Q. So these were the views that were being expressed by the parents at the time? Was there any attempts on the part of the medical staff to try and give some clear information, perhaps, as to the source of infection?

A. Not that I am aware of. I can't think of any particular discussions that were taking place about those issues and I think that -- yes, it was a very difficult one, I suppose on both sides. Parents were feeling very angry, very, very distressed about things and I think that the medical staff are feeling very anxious and nervous about the whole situation. They were also in a difficult position.

Q. Thank you.

I would just like to ask you a question about one of the comments you make in your statement. It's at paragraph 14.

Could we have that up, please?

This is the paragraph in which you are describing a paper that you presented to a conference and that you had obtained the parents' permission on before doing that. The response from the parents was, as you set out

there, that they were happy for you to do that but agreed after discussion as to the purpose and value of the paper. You say that one parent said that they felt that some people were making a career out of working with HIV and publishing papers. Can you give us a bit more explanation about what you think that parent meant by that comment?

A. At that particular time there were a number of people speaking as experts on the subject, whether that was at conferences or whatever, a variety of pieces of research that seemed to be taking place in different parts of the country, looking at the impacts on families, looking at a variety of aspects, and parents had fairly strong feelings about that.

I mean, the paper itself in some respects was one that was probably controversial at the time, as far as my social work colleagues were concerned, in that there was a very strong view that many people held that all of these boys all have to know everything about what's happening and their condition, and I had spent quite a lot of time working with this particular group of parents who, I have to say, were, in my opinion, quite exceptional really. They were all extremely good parents, very, very capable, very sensitive, caring, nurturing individuals, but we had spent a lot of time

talking about the pros and cons of sharing information with their sons and about the rights of young people to have information, but the rights of people in general to sometimes not have information too. We all use denial quite effectively at different times in our lives, and these parents certainly wouldn't have prescribed to the view that everybody should be told everything straight away all at one time, kind of thing, and there were different views about things hike that.

So the parents knew -- I had spoken with parents about the fact that I felt it was important to share some of their experiences and their thoughts and mine in working with them on these issues with other people, and they were all happy about that. But certainly one particular mum was very clear about the number of people that she felt had limited experience in working with families affected by HIV, and she felt that some people had limited experience of working with parents whose children had HIV but who were nonetheless speaking at conferences or whatever and publishing things and she was -- as I say, they were all very capable parents, they were very aware that in some professions it is good for your career to publish things and there was a great deal of feeling about that, and I was straight with them about why I felt it would be important to share my work

and their views with other people but that beyond that it wasn't something we were seeking to publish, and they were all satisfied with that really.

Q. You point out that you had obviously gone out of your way to explain to the parents the purpose and value of your paper. Do you think that there had been any attempt on the part of these other people who were giving such papers to explain the purpose and value of their papers to the parents?

A. Other papers would be from other people, not professionals directly involved with the group I was working with. They were thinking in general terms about other people's points of view. I think there was certainly -- there was some awareness that -- for example, there were different points of view. They knew that other people would have been saying that, "Oh, you should all have been telling your children the minute they got to ..." whatever age. They felt that there were a lot of people that were setting themselves up perhaps as experts, without really having direct contact with them and listening to them.

THE CHAIRMAN: Was this purely in the social services side?

A. No, not -- I was aware of the -- my social work colleagues having in many instances very different views from me but the parents were also aware that were there

were lots of other people within health, social work or whatever working in this field but presenting points of view in different venues as experts, and the parents were questioning their expertise, shall we say.

THE CHAIRMAN: I really wouldn't like you to go too far round a speculative route that might end up as a criticism of people you don't even know about, and Mr Dawson will no doubt be careful not to ask a question of such generality again that the answer might be misused, Mrs Leitch.

MR DAWSON: Could I just ask you one final question, Mrs Leitch. I wanted to ask you, if you can, to describe for us how in your opinion the parents of the haemophiliac boys who were infected with HIV dealt with that tragic situation?

A. In my experience of working with parents at that particular time and in the many years since I would have to say that I have never come across parents who would have been able to deal with it more effectively than this group. They were quite exceptional. It seemed to me at the time and since it was quite remarkable that it did happen that they were such extremely good parents. At the time that this happened these were boys who were all functioning extremely well in school. They were all doing well academically, emotionally well balanced,

healthy children. None of them had any behavioural problems. They were the kinds of families that I would not have expected to ever have to be particularly involved with in my role as a social worker other than perhaps giving information and advice.

It was an exceptionally painful experience for them but they were all able to focus first and foremost on the needs of their children. Everything they did was with their children at the absolute centre of all their thinking. I couldn't overstate that. They were extremely good, caring, nurturing parents. They were worried, anxious, fearful, all of the things that you would imagine parents would feel in those situations, but at all times their focus was very much on their children's needs and -- yes, I couldn't praise them highly enough in that regard.

Q. Thank you very much indeed, Mrs Leitch. Thank you, sir?

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: I have no questions.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: I have no questions.

THE CHAIRMAN: Anything else you wish to follow?

MR GARDINER: The next day will be Tuesday, with Dr Ludlam in the morning and Professor Lowe in the afternoon.

THE CHAIRMAN: Mrs Leitch, thank you very much. It's very

helpful to have a different perspective on these things.

A. Thank you.

THE CHAIRMAN: Next week's programme, if we manage to stick to it, will be what, that apart?

MR GARDINER: Dr Ludlam on Tuesday and Professor Lowe on Tuesday afternoon and then Dr McClelland on Thursday morning, we hope. We hope that it will be done in the morning but you never know.

THE CHAIRMAN: Yes, that's the sort of forecast that's just a challenge to others.

(3.43 pm)

(The Inquiry adjourned until Tuesday 28 June 2011 at 9.30 am)