Friday, 20 January 2012

(9.30 am)

Conclusion of topics B5 and C5 (continued)

THE CHAIRMAN: Good morning. Yes, Mr Gardiner?

MR GARDINER: Sir, yesterday we were looking at the paper which had been provided by Dr Perry, which is [PEN0180543]. I think you should have a paper copy of that, sir.

THE CHAIRMAN: Yes, I do.

MR GARDINER: If you remember, these were questions which were put to Dr Perry following his appearance during the B5 topic, and if we could go down to the bottom of the page, we will see the first question, which is:

"In SNB0010445 (sic - [SNF0010445]) ... you mention 'package inserts (or other formal product documentation)'. What do you mean by 'other formal product documentation'? What was the purpose of that 'other documentation'?"

Dr Perry answers that over the page, he explains:

"'Other formal product documentation' meant printed information on product vial labels and packaging containers in which the product was supplied. This information would include product name and description, vial content, expressed in international units, and excipients (inactive constituents), storage conditions,

reconstitution instructions, drug status (ie POM -- prescription only medicine) batch number, expiry date, and any warnings such as hepatitis risk."

So he has really answered the question there, sir, and the rest of it is commentary.

The next question is, further down the page, number 2:

"What discussions were there amongst the staff at the PFC of the possibility of including reference to the risk of HIV transmission on package inserts included with their factor concentrates between 1982 and 1985? Who was involved in these discussions? When did these take place?"

His response:

"I cannot recall whether or not in 1982 and 1983 I had any discussions with the PFC director Mr Watt concerning the inclusion of AIDS warnings in PFC products insert leaflets. I do not know if Mr Watt discussed the possibility of including AIDS warnings in PFC leaflets with others, including Dr Cash as national medical director."

But he then goes on to explain that he led a review of packaging systems for PFC Factor VIII and Factor IX products during this period, which resulted in the introduction of new multi-vial packaging:

"Product warnings on both product packaging and leaflets remained unchanged and continued to refer only to a hepatitis risk."

He says apart from that he cannot really recall. He thinks it's possible that discussions such as these took place between Dr Cash, Dr Boulton and the haemophilia directors.

Sir, just to advise you, we did ask Professor Cash and Dr Foster about that and we have brief statements that deal with that. We can look at those next. But the only other important bit of this answer is the final two lines, where Dr Perry says:

"In any event, no action was taken to include any specific reference to AIDS or HIV until HT DEFIX was issued in September 1985."

So really he thinks there was some discussion but nothing was done until September 1985.

This accords broadly with Professor Cash's recollection and he has explained that at [PEN0181145]. So the top half of the page is a repeat of Dr Perry's statement and Professor Cash's responses are in bold, underlined at the bottom. He says:

"I share the recollections of Dr Perry and Dr Foster ..."

We will just look at Dr Foster's in a minute:

"... but am not aware of documents which confirm this. I seem to recall that it arose at the time (early 1980s) when I was a little concerned at the dearth of the reporting of adverse reactions by haemophilia centre staff. That said, I recall, much later, following one of my visits to Australia, I proposed that we ought to consider including in the information on our blood/blood component labels a hepatitis risk warning. This proposal did not enjoy much support from colleagues and in due course a legal opinion was sought from Jim Donald (CSA general manager), a copy of which and associated correspondence should exist in the Inquiry's database. The outcome was no change. No hepatitis warning risk was added to our blood/component labels."

So Professor Cash seems to remember that there were discussions but has been unable to point to any documentary evidence about that.

THE CHAIRMAN: Is this comment about the database just another of Professor Cash's expressions of optimism? Yes.

MR GARDINER: So Dr Foster's recollection is similar. If we could have a look at his response, which is [PEN0181147]. Again, the top half page is a repeat of the extract from Dr Perry's statement and the response from Dr Peter Foster, paragraph 1:

"I clearly remember attending a meeting with haemophilia directors (Scotland) at which Professor Cash proposed that an 'AIDS warning' should be added to the leaflets issued with SNBTS coagulation factor concentrates. The haemophilia directors did not support this proposal as they believed that such a warning would cause 'unnecessary anxiety' to patients. Professor Cash acceded to this view, as he always gave great weight to the views of haemophilia directors."

He says he has not been able to find any records but he believes that Professor Cash made his proposal at the SNBTS haemophilia directors working group that was held on 14 November 1983.

The subsequent paragraphs are an explanation for why he has come to that conclusion. These paragraphs that we see at the top of the next page, 2(iii), 2(iv), 2(v) and 2(vi), are all explanations for why he has come to that conclusion. In paragraph 2 he mentions the fact that the topic of AIDS was considered at the meeting of the working group held on 14 November 1983. He says:

"I believe it must have been during this discussion that Professor Cash proposed that a warning of AIDS should be added ..."

THE CHAIRMAN: A reasonably good analysis of the circumstantial material.

MR GARDINER: Yes. So Dr Foster seems to be corroborating, if you like, Dr Perry's recollection and Professor Cash's one as well.

So if we could go back to the Dr Perry statement on B5, at the bottom of 0545, we see question 3:

"Why and by whom was it decided that there should be no reference to the risk of HIV transmission in PFC factor concentrate package inserts over that period?"

The response to that is:

"The PFC did revise its product leaflets in April 1985 with the introduction of Factor VIII NY (68 degrees/24 hours). The revised leaflet and product label stated that 'the freeze-dried product has been heat-treated but cannot be assumed to be non-infective'. The term 'non-infective' being intended to encompass all potential blood-borne infections, including HIV/AIDS.

"In addition, when the new heat-treated DEFIX product was issued to all centres in October 1985, it did include mention of HIV, as follows: 'in addition, product, plasma pools and individual donations are tested for the presence of antibody to HTLV-III. The product has been heat-treated at 80°C for 72 hours in the freeze-dried state. This treatment is expected to inactivate viruses associated with the Acquired Immune Deficiency Syndrome."

So those were the references that he was able to find but, as he said at the top of the next page:

"... I am unable to find any reference to or evidence of a process which lead any individual(s) to recommend in favour of or against the introduction of AIDS warnings for Factor VIII products."

He then says:

"Prior to 1985, product information supplied by the PFC/SNBTS reflected the background of knowledge and guidance available between 1982 and 1984."

The next bullet points are a list of that background knowledge. We see that he is stressing that prior to 1984, there was no consensus on the causal relationship between AIDS and treatment.

He says:

"The inclusion of such warnings in product literature required some measure of evidence that a genuine risk existed."

At the bottom of the page, just five or six lines up from the bottom, Dr Perry makes a comment, which is:

"The amendment by the SNBTS of its product leaflet to include a specific and unquantifiable risk warning would have done little, if anything, to enhance their knowledge or their communications and discussions with patients, especially as the topic of AIDS was being

widely discussed and considered by haemophilia doctors at the time ..."

If we go over the page, we see the next question, question 4:

"Why was it considered appropriate to include a reference to the risk of hepatitis transmission in the PFC factor concentrate inserts over that period?"

He explains:

"Prior to and during the period 1982-85, hepatitis transmission by coagulation factor concentrates was widely recognised and documented. Accordingly, all manufacturers were required (by regulatory authorities) to include hepatitis warning statements with their product packaging and information leaflets."

Then he refers to the British Pharmacopeia monograph on dried Factor VIII fraction.

The next question 51:

"From whom did the PFC staff take advice about the risks of transmission of HIV via PFC concentrates between 1982 and 1985?"

The response is:

"Various discussions and meetings involved the SNBTS with government health departments ... and other regulatory bodies but I do not recall that this produced any guidance or advice ..."

As he has hinted at in previous answers, he says:

"The PFC maintained an awarenesses of international developments through its network of professional and scientific contacts ... regular discussions with haemophilia directors, SNBTS ... experts (eg Dr Boulton ... Dr Cash)."

He mentions a 1983 application to the Committee on the Safety of Medicines, which included a product insert leaflet which made no mention of HIV or AIDS, and the application was approved.

If we go over the page, at the top he notes:

"The PFC received no subsequent request or advice from the licensing authority ... to include AIDS warnings."

The next question is:

"What advice was given to the PFC over that time period about the risk of HIV transmission from PFC factor concentrates?"

He says:

"I do not recall the PFC receiving any specific advice or guidance concerning the risk of transmission of HIV/AIDS by its products, but this does not imply an absence of discussion ..."

He says:

"Even with the benefit of hindsight, it's difficult

to identify what advice could have been given to the PFC, which could ... have been translated into warning statements ..."

Question 7:

"Was there an awarenesses within the PFC of the fact that American products had such warn warnings on their inserts from around October 1983? In relation to this question, Dr Perry's attention is drawn to the following passage from the report of the commission of Inquiry on the blood systems in Canada (the Krever report) which ... provides interesting material as to the international standards referred to by Dr Perry in his letter of 14 March 1988."

There is a quotation from that. Dr Perry's response is:

"It is important to appreciate that the section quote above from the report of Justice Krever concerns concentrates prepared from plasma collected in the USA. Although Cutter Laboratories did include warnings with its products prepared from USA plasma ... it did not provide such warnings in 1984-1985 with products derived from plasma collected in Canada ..."

Dr Perry is making the point that the fact that the same company is adopting different positions in relation to the origin of the plasma suggests that the risk of

AIDS was still considered to be primarily associated at that time with plasma collected in the USA from paid donors.

He refers to product literature from commercial companies which was periodically received at the PFC but he is unable to recollect the extent to which these documents would have been examined at the time by himself or other senior PFC colleagues. He would have been aware that products carried warnings of product infectivity but he can't recall if he was aware of specific AIDS or HTLV-III warnings.

He then talks about a leaflet, dated 1985, for the Cutter heat-treated product Koate HT, but he comes to the conclusion, a little bit further down, after the quotation:

"This information ... [was] intended for healthcare professions rather than an attempt to provide information to patients."

He says he has been unable to find evidence for the precise time when mandatory AIDS warnings were universally required. But his understanding is that different manufacturers adopted them at different times. At the bottom of the page he concludes this answer by saying:

"When it became clear, in October 1984, that there

was a risk from SNBTS products, we quickly issued heated NY product (68 degrees/2 hours) and subsequently modified the leaflet for inclusion with the later Factor VIII product (NY 68 degrees/24 hours) ..."

That's all broadly consistent, sir, with other evidence about the arrival of the viruses in the Scottish donor pool as being of great surprise.

The next question is question 8:

"To what extent did such awareness impact upon the attitudes of PFC staff to include such a warning on their factor concentrate inserts?"

He says:

"I cannot recall any discussions amongst PFC staff, Professor Cash or Dr Boulton concerning the introduction of AIDS warnings in PFC product inserts. I believe the general view held by the PFC, the SNBTS and the haemophilia directors was that the epidemiology of AIDS in the US, and particularly amongst US paid donors, was quite different from that in the UK."

In paragraph 4 he is responding to a suggestion that the Inquiry might wish to consider further investigation relating to the issue of package inserts and he is reminding the questioner that there is in the Inquiry database the document "Hepatitis Risk Warnings" [PEN0120286], which contains examples of product

warnings.

If we look over the page, we see Dr Perry finishing off his comment about a document, commercial leaflets, and he notes:

"Neither I nor other SNBTS staff have been able to locate any further commercial leaflets from the period ..."

I should observe that in the hepatitis risk document there are examples which are in the database, sir.

Sir, that concludes my reference to B5 statements. I think it's appropriate perhaps to give my learned friends an opportunity to make any comments, if they wish, on the documents that I have been referring to.

THE CHAIRMAN: It may be. We will see what they say.

Mr Di Rollo?

MR DI ROLLO: Sir, I have no comment, other than to just thank the Inquiry for the further investigations that it has carried out.

MR ANDERSON: I have nothing to add, sir.

MR JOHNSTON: I have no comment either, sir.

THE CHAIRMAN: Yes, thank you very much.

MR GARDINER: So the next section are C5 documents, so the continuation of the topic that we have been --

THE CHAIRMAN: Is everyone happy with that?

MR DI ROLLO: Yes.

MR GARDINER: Continuation of the topic that we have been hearing evidence about from the turn of the year.

It's convenient to return to Dr Perry, who has kindly provided further information in connection with package inserts relative to non-A non-B Hepatitis, Hepatitis C, and that's at [PEN0180556]. So again Dr Perry is responding to questions from those instructing my learned friend Mr Di Rollo, Messrs Thompsons. The first question:

"Why, prior to March 1987, when Z8 was introduced, did package inserts for SNBTS Factor VIII (presumably also Factor IX) make no reference to non-A non-B Hepatitis?"

Dr Perry's response is:

"The specific wording used in warning statements in product leaflets, product labels and outer packaging was that prescribed by the British Pharmacopeia and approved by the UK licencing authority following the PFC licence application in March 1978:

"Between (at least) 1978 and 1985, the following wording was used in leaflets provided with PFC unheated Factor VIII and Factor IX products."

He gives examples:

"Description -- nevertheless none of these tests are of sufficient sensitively to eliminate the possibility

of transmitting hepatitis.

"Side effects -- 'complications in the use of Factor VIII (or Factor IX) concentrate are rare. Apart from the general complications of hepatitis ...'

"Similarly, the following warnings were used on product labels and product packing respectively. Vial label: this preparation is of human origin and cannot be assumed to be free of hepatitis virus. Packaging: this preparation is of human origin and despite careful screening of donations, cannot be assumed to be free of hepatitis virus."

He tells us again:

"Following the introduction of Factor VIII and Factor IX heat treatment in 1985, the product labels and leaflets were revised to say: the freeze-dried product has been heat-treated but cannot be assumed to be non-infective. This product has been heat-treated at 68°C for 24 hours in the dried state but it cannot be assumed that the product is non-infective'."

Over the page:

"Description:

"The product has been heat-treated at 80°C for 72 hours in the freeze-dried state. This treatment is expected to inactivate viruses associated with the Acquired Immune Deficiency Syndrome.

"Side effects:

"Apart from the general complications of virus transmission, the above statements were designed ...

These are examples that he is giving. There is then some commentary from Dr Perry:

"The above statements were designed to comply with regulatory and pharmacopeial standards and to provide a warning to expert and experienced prescribers of the product (ie haemophilia doctors) of the generally recognised and understood infectivity risks associated with the use of these products. It was reasonable to assume that these expert users would understand that these risks included non-A non-B Hepatitis. Explanation of such risks to patients was exclusively the responsibility of haemophilia doctors."

If we look to the last paragraph on that page he says:

"Examples held by SNBTS from other manufacturers suggest that the statements included with PFC products were typical."

The footnote is to:

"Information provided to Lord Archer by Dr P Foster, September 2007."

Sir, that is in court book. If we look at [PEN0120286], this is the hepatitis risk warning, which

was in court book for B5, and if we go to 0286 --

THE CHAIRMAN: That's where we are, Mr Gardiner.

MR GARDINER: That's right. We see that this is the paper prepared by Dr Foster for the Archer Inquiry, and includes examples of warnings issued with coagulation factor concentrates. So the Inquiry has been provided with examples of the leaflets and inserts that Dr Perry has been giving examples of.

So that is Dr Perry's statement on inserts with regard to Hepatitis C and the Inquiry is grateful to Messrs Thompsons and their counsel for assistance with the questions which have precipitated these answers, for that and for the B5 document as well.

If I could just turn to the next C5 statement, which is [PEN0180874].

Sir, this is a report from Dr Morris, consultant physician in gastroenterology at the Glasgow Royal Infirmary. The purpose of this report was to try to get a picture of the clinical situation with regard to treatment of Hepatitis C. If we could go to the next page, we see there the introduction:

"This report has been prepared by Dr John Morris, consultant physician and gastroenterologist at Glasgow Royal Infirmary, and is offered in assistance to the Penrose Inquiry to offer a perspective on the

development of the Hepatitis C service at Glasgow Royal Infirmary and within the Greater Glasgow Health Board from 1995. In particular this information seeks to address topics C5 and C6 within the terms of reference of the Inquiry, including information given to patients and their families along with information on treatment and impact on patients and their families."

This is a fairly lengthy document. I don't propose to read it all but perhaps I can just notice some things as we go along.

Paragraph 1, Dr Morris gives us the historical perspective, which is:

"Prior to 1995 there was no dedicated liver clinic or Hepatitis C clinic at Glasgow Royal Infirmary."

He explains in the second paragraph:

"In response to requests from Professor Gordon Lowe ... at Glasgow Royal Infirmary, representing the interests of haemophilia patients ... it was determined that a clinician with a dedicated interest in managing patients with liver disease, in particular Hepatitis C, should be appointed."

If we could go over the page, Dr Morris explains at paragraph 2:

"In November 1995 I was appointed as a consultant physician and gastroenterologist ... with a specific

remit to development a dedicated Hepatitis C service ..."

If we go over the page, the second paragraph, he explains:

"Appointments were offered to patients who were Hepatitis C antibody-positive and those who were Hepatitis C antibody and PCR-positive. Genotype testing for Hepatitis C did not become available until a later date. Each patient was identified by the staff of the haemophilia centre. Standard care comprised an initial clinic visit, to which patients were invited to bring relatives or next of kin where appropriate, and thereafter follow-up appointments were arranged as deemed clinically appropriate or necessary. All patients were offered at least two appointments ..."

Then there was follow-up from Professor Lowe. Further down the page he describes the initial clinic visit. Could we go over the page? If we go to the top of the page, he describes the initial discussion:

"... information about the current understanding of the natural history of Hepatitis C as relevant to 1996, the tests that were available to assess the severity ... and to exclude co-existing causes ..."

He sets out the information that was given to the patients. In the next paragraph he notes:

"At the initial consultation, patients and their family members were routinely introduced to Sister Margaret Neilson, viral hepatitis nurse specialist, who was able to offer a point of contact for further information ..."

The Inquiry also has a statement from Sister Neilson, sir.

Could we go over the page? He explains:

"Patients were offered treatment with interferon and if they elected to proceed, received a separate information interview with Sister Neilson ..."

At section 4 in the middle of the page, he explains what happened between 1995 and 1998 in the West of Scotland, that there were three centres established to assess and treat patients with Hepatitis C: Glasgow Royal Infirmary, Gartnavel and Brownlee Centre the regional infectious diseases unit; and it's Dr Morris, Dr Mills and Dr Fox.

On the next page he describes the different groups of doctors who dealt with the condition, which is all very helpful to fill in the picture in the West.

If we could go to the next page, we see at section 5 under the heading of "Assessment of Impact of Diagnosis of Hepatitis C", he sets out the background patient information. He notes:

"A significant proportion of initial consultations with patients reflected the anger or anxiety of the diagnosis of Hepatitis C, the uncertainty about the prognosis and the lack of structured available information from the health service ..."

He says:

"A process of a dedicated Hepatitis C clinic allowed dissemination of agreed information ..."

He then sets out the way that they went about disseminating the information and what it was, placing:

"... specific emphasis on the low risk of transmission to household and personal contacts."

And so on. Over the page, he talks about another way of disseminating information, which was at hospital and medical meetings:

"A particular emphasis was on appropriate counselling, testing and informing patients of positive tests by healthcare professionals ... discouraged random testing ..."

At 5(d) he talks about the establishment of:

"... a nurse-led liver clinic to triage all referrals for patients with Hepatitis C to meet with a specialist nurse rapidly after referral from fellow medical practitioners."

Over the page at 5(e) he refers to:

"Regular liaison and education meetings ..."

And at 5(g) he explains:

"For patients with complex psychological or adjustment problems relating to the diagnosis or impact of Hepatitis C, in collaboration with Dr Roger Wong, clinical psychologist at Gartnavel ... and the network of nurse advisers, we established a method of referring patients for psychological support."

If we just pass to the last page, Dr Morris summarises the document, explaining how a structured and patient-focused approach was established for managing Hepatitis C in Greater Glasgow and Clyde from 1995.

Sir, all of that is extremely useful information for the Inquiry in this topic.

We heard about Nurse Neilson and we have a report from her as well, [PEN0180885]. So that's the report from Margaret Neilson, lead clinical nurse specialist, liver disease, Glasgow Royal Infirmary. If we could go to the next page, we see:

"This report has been prepared by Margaret Neilson ..."

And it outlines the development of a nursing care service for patients with a diagnosis of Hepatitis C, concentrating on points C5 and C6. She was appointed in July 1996 to the position of clinical nurse

specialist, working with Dr John Morris.

Sir, it's a very detailed and full report and I don't propose to go through it line by-line, just to say that it broadly corroborates what we have heard. It's consistent with what we have heard in the Dr Morris report and explains what went on and what information was given to patients from a nurse's perspective.

If we go to 0901, this page, under the heading of "Aims of the Nurse-led Liver Assessment Clinic" and also the next heading, "Mode of Delivery", set out what a nurse would have done with a patient when a consultation was arranged.

If we go over the page, we see there the different headings that the nurse would be expected to discuss with the patient. If we go to the next page, we see the kind of things that were discussed: social history, drug dependency, alcohol history, current medication, harm reduction. And then it would be general lifestyle advice: healthy diet, alcohol reduction, exercise, stress, protecting others and so on.

So again, this is a very helpful document which fills in more of the background to the situation in the West, sir. I don't propose to go into that in any more detail.

Obviously, sir, all of these documents that I'm

referring to will go on to the website and be available to be looked at.

Sir, the next document is [PEN0181225].

This is a statement from June Ward, haemophilia nurse specialist, and we heard from Professor Cachia earlier on this year and he referred to June Ward. Very broadly this statement is consistent with the evidence that you have already heard from him, sir.

If we go to page 2 of [PEN0181225], if we look at paragraph 1.1, just about four lines down, she is talking about providing information to patients. She says:

"I would also offer the same information, particularly in providing information and support to this patient group and patients who were invited to review. If the patient had not been previously tested for HCV, we discussed with the patient the need and value of being tested, gave information to them, so that they could make an informed choice whether they wished to be tested or not. Most patients had been identified as HCV antibody positive but most had not been tested for HCV PCR. This was routinely offered around this time. After discussion, all patients, to my knowledge, consented and took up the offer of testing. If they were previously known to be HCV-positive, they were

fully informed of their HCV status and given both verbal and written information.

"At this time we used a combination of patient information booklets to assist with information provision. These were designed and produced by the Liver Trust and the Haemophilia Society. Our normal practice in the consultation was to offer information on HCV, route of transmission, how it may affect the individual in the future, discuss tests, investigations and treatment options available. In relation to treatment, in 1995 interferon only was available and none of our patients chose to be treated with this."

So again, sir, this is helpful information, filling in the gaps, having already heard Professor Cachia's evidence in this area.

So I propose to leave that statement and we are now about to look at statements from haemophilia clinicians in connection to their practice with giving information to patients. These are the clinicians that we haven't heard evidence from and they are Professor Ludlam and Dr Gibson.

Professor Ludlam's one is at [PEN0180832]. We see at the top of the page the topic, and Professor Ludlam gave evidence in B5 and covered a lot of this area because he talked about discussions with patients about

the risk of hepatitis. So a lot of this, sir, you have already seen.

He starts off, in paragraph 1, by referring to the collective response. If we could just go over the page, paragraph 2, which is a response to C5a, what is contained in this paragraph and what's on the next page is really information that the Inquiry has already heard when Professor Ludlam was here. He talks about:

"... policy to inform patients ... of all the risks of haemophilia as well as its treatment ..."

So I don't propose to repeat that, sir.

If we could go to the next page, the question is:

"The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products."

This is helpful because it's a very particular to the situation in Edinburgh. At the bottom of the page he says:

"In relation to non-A non-B, we initiated treatment, under the supervision of Dr Peter Hayes, with interferon in Edinburgh in 1988 following the ... Hoofnagle (report)."

Then he says:

"Following the publication reporting the identity of HCV ... (Choo et al ...) the initial antibody test was

established at the Central Public Health Laboratory in Colindale."

He says:

"Our initial anonymous testing of stored samples revealed that 85 per cent were antibody-positive ..."

So that seems to suggest that a similar exercise has been gone through as we heard about in Dundee, sir?

He then talks about the studies of Fletcher and Kernoff and he refers to different papers, Watson et al, then he refers to the Professor Simmonds PCR-based assay, which was reported in The Lancet in 1990, which led to work on the characterisation of the genotypes.

He says:

"From these initial investigations it became clear that the first generation of antibody tests did not have sufficient sensitivity to identify all previously or currently HCV-infected individuals."

He culminates this description by saying that it was only really in 1992, when there was reliable and sensitive assays, that he was sufficiently confident to provide the results of tests to patients.

So he didn't give results after testing with the first generation tests. At least that's my reading of what's said there. At (c) he says:

"When reliable tests were available, and although

some of the patients will have been tested from stored samples during initial studies to validate the techniques, in all cases a fresh sample was sought from the patient, after explanation and consent. The patients were told that we considered that we had a sensitive and specific test for both the antibody and virus which was responsible for the majority of cases of non-A non-B Hepatitis. The result would be essential in deciding who might benefit from antiviral therapy ... the patient would be given the result at the next clinic visit (or earlier if specifically requested). In most instances there was no need for urgency."

On the next page he talks about the clinical service that was provided for HCV-positive patients that was developed with Dr Hayes, and in the last paragraph he says:

"For the past 14 years we have been very fortunate to have had the generous commitment and ready availability of Professor Peter Hayes to see our patients ..."

The response to question 4, "Information given to patients". Again, he refers to the collective response and over the page, the top of the second paragraph, he repeats:

"In Edinburgh patients were aware of my concern

about hepatitis and its possible causes because there were frequent discussions ..."

Just going down to the beginning of the next paragraph, he notes:

"The information given to patients with non-A non-B Hepatitis was continually updated with the developments in knowledge and practice."

He says:

"It became clearer in the mid 1980s that it was a potentially serious progressive condition, although it has taken many further years of study to begin to obtain a reasonably reliable estimate ... Once it became clear that it was progressive, and after Hoofnagle's paper in 1986, patients were informed of this and we consequently initiated studies to use interferon treatment. With the advent of HCV testing, it became clearer which patients were most suitable for interferon treatment, so that it could be better targeted and response assessed by quantitative HCV PCR."

So, sir, it seems that the picture at Professor Ludlam's centre was broadly similar to the picture that we are getting of elsewhere in Scotland.

The next document I would like to refer to is also from Professor Ludlam. It's [PEN0181246].

Professor Ludlam was asked to comment on the at that

point perceived difference in opinion between Dr Hay and Professor Nathanson.

I think that things have moved on since then because we have obviously heard their evidence and I think it's fair to say that their positions have been clarified.

THE CHAIRMAN: They have certainly come closer together.

MR GARDINER: Indeed. So I don't propose to take up too much time with this document, other than to notice, if we could go to the fourth page, second paragraph, perhaps unsurprisingly Professor Ludlam is stressing that:

"In my view it is quite inappropriate to equate an anti-HCV test with an HIV test ..."

Sir, I would like to pass to Dr Gibson's statement now, which is [PEN0180824]. This is really the Yorkhill experience, sir. She notes in her first paragraph:

"I was appointed to my post as paediatric haematologist at RHSC, Glasgow, in 1984 but did not assume responsibility for haemophilia care until 1988, when I became the haemophilia director."

She says:

"My recollection is that once referred to the haemophilia centre ... Glasgow, the parents (patients) of boys with haemophilia received information on the best treatment for their son, including all treatment

options if more than one existed. As part of that discussion the benefits and risks of treatment were discussed ... parents (patients) routinely informed of the risk of hepatitis ... patients were managed by a multidisciplinary team with a haemophilia nurse specialist playing a pivotal role in counselling and education."

THE CHAIRMAN: I'm slightly confused by the second line, "parents (patients) of boys". By the time we get to the sixth line, we are clearly talking about patients. Is there any explanation of that apparently odd presentation? Is she saying that parents were treated as patients for information purposes or what? I'm not sure that it matters but it just looks very odd.

MR GARDINER: We think that she is meaning that the information was given to the parents, as opposed to the children, because the children were too young, so yes, she is counting that as information to patients.

THE CHAIRMAN: I would have understood it better if she had missed out the word in parentheses altogether.

MR GARDINER: Well, indeed.

THE CHAIRMAN: I think that's really what ...? Yes, it just looks a very, very odd presentation. Perhaps it doesn't matter.

MR GARDINER: Yes. So that's consistent with what we heard

from Professor Hann and Dr Pettigrew previously.

If we go over the page, paragraph (c), she notes:

"The families were introduced to the haemophilia social worker, who encouraged them to join the Haemophilia Society, which was a useful source of written information on haemophilia, its treatment and complications of treatment ..."

And that there were parent support group meetings where treatments and complications were discussed:

"The Haemophilia Society held and attended meetings ... at least one was focused on hepatitis. They produced written literature and made available a book called "Living With Haemophilia" written by Peter Jones. Most families had a copy and latterly it provided information on hepatitis."

THE CHAIRMAN: The last comment is quite interesting. Do we know how many editions Peter Jones's book went through and when?

MR GARDINER: I don't have that information to hand, sir.

THE CHAIRMAN: It might be worth knowing, since it may well trace the development of material communicated to patients. Whatever else one might think of Peter Jones in some circumstances, this book was clearly an important source of information and it might be helpful to know how it developed over time.

MR GARDINER: Yes. Indeed, sir.

Could we go to the next page? We see at the bottom, the last paragraph, a question about:

"Information given to patients ... on the severity of non-A non-B Hepatitis ...

"Most of the information on the severity of non-A non-B Hepatitis ... came from adult experience. Initially (at least prior to 1985) non-A non-B Hepatitis was generally thought not to be a serious illness. This is the information which would have been given to patients/parents ... later it became apparent that ... it could progress to cirrhosis and liver cancer."

She notes with reference to children it was even less clear because:

".... children had none of the co-morbidities common in adults; for example, alcohol consumption, other drugs, co-infection, which were thought to contribute to liver dysfunction in adults.

"From 1985 onwards, parent/patients would be informed that it was hoped that viral inactivation of clotting factor concentrates ... would reduce, or eliminate, the risk of transmission ..."

Some breaking news on Peter Jones.

THE CHAIRMAN: I had that impression.

MR GARDINER: Which was that the fifth edition was published

in 2002, but we will go and look at the other edition.

THE CHAIRMAN: There should be, in the general publication information then, a track of it down to then.

MR GARDINER: The first edition was 1974, so we can perhaps track through that. Yes.

Could we go to the next page? Under the heading of:

"Tracing and Testing of Patients ..."

Dr Gibson explains:

"Boys were routinely and regularly monitored for complications of haemophilia and its treatment."

The bullet points underneath that paragraph list the tests that were done. She says at the bottom of the page:

"Any patient with a significant abnormality would have been referred to a paediatric gastroenterologist."

On the next paragraph Dr Gibson explains:

"The testing of children followed the same as adult practice ..."

At least the same timeframe:

"... following recommendations from UKHCDO".

In 1991 the Hepatitis C test became part of routine screening and then the RIBA-2 test in 1992. In paragraph 3 she explains:

"Blood samples: during these time periods (1990 to 1995 and 1995 onwards), blood samples were taken from

all patients who had previously received blood or blood products ... either when they attended the haemophilia clinic or were brought by their mother, who had taken the blood when administering factor concentrate at home."

The samples were sent to Ruchill Hospital. If we could go over the page. She explains:

"Parents/Patients were routinely informed that HCV testing was being carried out. They would have been told a virus had been identified, which was thought to be the cause of non-A non-B Hepatitis, and that it was called Hepatitis C. The parents of boys who were Hepatitis C antibody positive were told that their son had been previously exposed to Hepatitis C and that this was the likeliest cause of any abnormal liver function tests. They would also have been told that most patients who received treatment before the introduction of viral inactivation would be Hepatitis C antibody positive. Hepatitis/liver monitoring was considered a routine test and as such, consent was verbal."

Then there is the reference to the medical defence unions, which is something we have heard about from Professor Lowe and also it appears in the collective response.

In the next paragraph Dr Gibson explains:

"The results of Hepatitis C testing was given at the next clinic or the next visit to the department after the result was available ... whether the result was positive or negative."

No immediate treatment, therefore no immediate urgency to inform them. In the next paragraph she explains what patients were told about the implications of HCV and she explains what she has already said, that their son had probably been previously exposed to the Hepatitis C virus through treatment with concentrates or cryoprecipitates. This was likely to have happened with their earliest treatments. They would be informed that their antibody-positivity did not necessarily mean that they were a chronic carrier.

So that's the Yorkhill picture, sir.

At [PEN0181245] Dr Gibson has also commented on the perceived Dr Hay/Professor Nathanson difference of opinion. What she says is that the practice described in Dr Hay's report was how she remembered local practice in Glasgow. If we could go to [PEN0181240], this is a comment in connection with the Dr Hay/Professor Nathanson point, and this is from Professor Gordon Lowe. Again, he says, if we look at the second paragraph:

"Dr Hay's practice ... is entirely consistent with

the practice ..."

He is correcting the dates but he is saying it is broadly consistent with his own and Dr Walker's practice at Glasgow Royal Infirmary and other centres across Scotland. So aligning more with Dr Hay than Professor Nathanson.

So that concludes the section on the haemophilia clinicians' responses. The next section goes to look-back and we have a statement from Mr Tucker, [PEN0180406]. Sir, if you remember, during Dr Keel's evidence we heard some evidence about Mr Tucker. In paragraph 1 he explains:

"My recollection of events is now rather vague ... some management executive documents are no longer available."

In particular he refers to the note of the meeting between SHHD and SNBTS on 24 May 1994 that we have heard evidence about:

"The minute seeking legal advice on look-back and Scottish Office solicitor's response ..."

And his minute to Lord Fraser. So that's unfortunate.

In the seconds paragraph he explains:

"When routine testing for anti-HCV was introduced in the UK in September 1991, no decision had been taken by

the UK Health Department on whether a look-back programme would be instituted."

He says:

"My understanding was that there were differing opinions on the benefits to patients and that the issue appears to have been put on hold by the UK health departments. I do not recall the issue being raised with SHHD by SNBTS until 1994, when it was discussed at the meeting on 16 May ..."

These are documents that we looked at in some detail, sir.

So just to look at the specific questions that have been put to Mr Tucker:

"What was Mr Tucker's involvement in the look-back exercise?"

He explains:

"I was administrative head of the division, which included Mr Panton's branch, with responsibility for formulating and coordinating policy advice to ministers, based on the views of professional experts. Mr Panton, as branch head, reported to me on the detailed work of liaising with medical and legal advisers as well as with Department of Health administrative staff. I would have put forward the minute to Lord Fraser advising him of the advice received and seeking his decision; the minute

would probably have been drafted in the first instance by Mr Panton."

The next question is:

"Did Mr Tucker attend the meeting on 24 May ...? What was discussed ...? Who made the decision not to commence an HCV look-back in Scotland on 1 June 1994? Why was that decision made?"

He doesn't specifically recall the meeting but he says, unless he was unavailable, he would certainly have been there or Mr Panton would have discussed it with him beforehand. He can't say with certainty what was discussed.

In the next paragraph he refers to the minutes of the meeting. He refers to Dr Keel expressing uncertainty about whether SHHD had a locus in this matter and he says:

"I consider that in issuing his note of 19 May about the commencement date, Mr McIntosh had not been aware that the SNBTS MSC had been asked to await SHHD views. In my view, the meeting of 24 May would have been arranged to explain that SHHD considered that there was a UK dimension to HCV look-back. SHHD would have wished to consult with other health departments before proceeding further. I assume that we would have asked SNBTS at that meeting to delay the proposed announcement

of the commencement of the look-back exercise until further consultations and consideration of advice had been completed. I assume that this was accepted as a reasonable course of action."

That certainly seems to be consistent with ...

THE CHAIRMAN: The assumption that it was accepted as a reasonable course of action perhaps is over-optimistic but it might have been an inevitable course of action, but, yes, it seems to fit in with what had occurred.

MR GARDINER: Yes. The next question is about the unusual events, and he is not sure what Professor Cash was referring to, but:

"It may have related to the postponement."

The next question is about the meeting of the ACMSBT on 29 September 1994:

"Mr Tucker said that approaches to institute HCV look-back in Scotland had been resisted, and that it was important that a UK-wide approach was adopted. Who had resisted? Why? Why was it important that a UK-wide approach be adopted?"

He says over the page:

"As indicated ... we had asked SNBTS to defer taking further action until further information had been obtained regarding the medical, ethical and social implications. It was not a matter of resistance but

rather of caution until this information was available ... I produced a note of this meeting for internal use and I noted that I had expressed the view that 'we (SHHD) had reservations about a look-back unless it was on a UK basis and there were real benefits for patients in treatment'."

He goes on to explain that it would have seemed desirable to obtain views from the ACMSBT because it was an important source of advice to ministers, and in his view, a collaborative and orderly UK approach would have best served the interests of all NHS patients and would have been advantageous in approaching the Treasury if extra funding was required. It was always more difficult to obtain additional money from the Treasury if there was no equivalent request from the Department of Health. So that's his take on the situation.

The next paragraph is in response to question 5, where, at the meeting on 15 December 1994:

"Dr Keel said that the view in Scotland was that the Secretary of State was vulnerable ..."

He is asked to explain the comment. He says:

"I'm not able to expand very much on Dr Keel's comments in the absence of papers relating to the Scottish Office solicitor's advice, but the fact that SNBTS were confident the look-back exercise was feasible

and [practicable] for Scottish patients, together with the prospect of some effective form of treatment becoming available, had led our legal advisers to warn that the Secretary of State would be exposed to a legal liability if SNBTS were not instructed to proceed as quickly as possible."

Again, sir, that's consistent with what Dr Keel told us. Question 6 is about what were the particular Scottish circumstances.

THE CHAIRMAN: It's just repetitive now, isn't it, the questions?

MR GARDINER: Yes, and over the page he says that the particular Scottish circumstances were the evidence from the Dr Gillon pilot scheme, that a Scotland-wide exercise was feasible and practical, and that the cost, excluding drugs, was in the region of £50,000, and could be met from the existing budget. He says he can't recall if any steps were taken by SNBTS between 22 December and before 11 January 1995, but:

"If not, I feel sure that they would have had their reasons ..."

Question 7:

"... 3 April 1995, comprehensive guidance on anti-HCV testing and HCV generally was issued to all doctors in Scotland in the form of a CMO letter.

However, anti-HCV testing had been introduced more than three years earlier ..."

The question is:

"What steps, if any, did the SHHD take to draw doctors' attention to the availability of testing and implications of HCV for patients before April 1995?"

He says:

"SHHD guidance to doctors was undertaken by the CMO and his staff and I would not have expected my division to be directly involved in communicating with GPs or hospital ... staff ..."

He doesn't recall any CMO guidance on HCV after September 1991. He left the Civil Service in mid-March 1995 and was not involved with the guidance issues on 3 April 1995.

I have two more short statements on look-back but I see we are at 11 o'clock ...

THE CHAIRMAN: Okay.

(11.04 am)

(Short break)

(11.30 am)

THE CHAIRMAN: Yes, Mr Gardiner?

MR GARDINER: Sir, still on look-back and only two more statements to go, I can offer that bit of hope.

[PEN0180401]. This is a statement from Dr Young.

The question is:

"What was Dr Young's involvement in the look-back exercise?"

Sir, we are going up the tree from Mr Tucker:

"I was appointed DCMO in 1989 and covered public health responsibilities and hospital services and medical staffing. My first involvement with SNBTS was as a member of the CSA management committee.

"I was periodically involved in consideration of an HCV look-back exercise by virtue of my dual post as Deputy CMO/Medical Director of SHHD management executive.

"1990 Dr McIntyre and, after 1992, Dr Keel had the department's medical lead for Blood Transfusion and related services. They briefed CMO and me at least once a week at our regular meetings with medical staff, and more often if required. The main issue then was HCV testing and look-back."

He now is referring to a meeting in May 1990. It's in a minute that comes after that:

"At its meeting on 23 May 1990, the CSA management committee expressed concern about legal liability issues for CSA should HCV testing of blood donations be implemented or delayed, and asked for a position paper for their June meeting. I briefed them on the

situation; namely that there was as yet no sensitive confirmatory test, false positive tests were a problem and there was no effective treatment. I wrote the memo dated 23 May 1990 to alert Dr McIntyre and Mr Tucker ... to the request for a paper. I do not recall such a paper being produced. I can only assume that things were changing so rapidly that oral updates were given."

It might be worth having a quick look at that, [SGH0027939]. I think the Inquiry has looked at this in the context of introduction of screening.

It's dated 23 May 1990. He is noting a concern about the legal liability aspect and wishing to take a firmer grip on how this issue is handled. "Conclusion":

"Would you please brief me and discuss what kind of paper should go, who would draft it and would it be necessary to involve Professor Cash?"

What he is saying in this statement is that he doesn't recall any paper ever being produced. I think when Ms Dunlop comes to address you on C4, we will see that the text here is very similar to what's in his statement for C4 as well.

So could we go back to this statement? Dr Young's statement. He says in the paragraph before question 2:

"I was not directly involved in the work up to the introduction of screening donors for HCV and

subsequently the introduction of look-back. I was part of the system generating the Scottish version of CMO letters to all doctors, including CMO 95/1 and 95/7, but this was more of a proofreading function."

Question 2, the question is:

"Why was a look-back exercise not commenced ... in September 1991?"

He gives the reasons as being the gaps in the scientific and medical knowledge, the natural history of the disease was not fully known, no cure available, no feasibility study had been completed. These are things that we have all heard about before.

Question 3:

"On 3 April 1995 comprehensive guidance on anti-HCV testing and HCV generally was issued to all doctors in Scotland in the form of a CMO letter. However, anti-HCV testing had been introduced more than thee years earlier ..."

The question is:

"What steps, if any, did the SHHD take to draw doctors' attention to the availability of testing ..."

He says he doesn't know of any prior notification to doctors. So he doesn't know.

Question 4. There is a long preamble and then the question:

"Was the availability of testing publicised to the general public? If so, what arrangements were made for any such individuals who wished to be tested?"

That's individuals who had been recipients of blood or blood products:

"If not, why not?"

His response is:

"My understanding of the decision to concentrate on post-1991 donors and recipients was that donors were a known set who were alive and in touch with the service and recipients' hospital records were liable to be available. A pilot study had confirmed feasibility. Tracing all pre-1991 recipients could prove difficult but some might read about the look-back in the press. Anyone in that category who sought advice from their doctor or the SNBTS would of course be counselled and, if they wished, tested."

The last question is about the working party. He does not remember when viral inactivation procedures were introduced. That is the end of Dr Young's statement.

So could we just move to the last one? [PEN0180404]. This is from Sir Kenneth Calman. Sir Kenneth notes at the top of his statement:

"The preliminary report of the Inquiry is an

excellent and detailed account of the process of identification and implementation of screening for HCV and HIV.

"I joined the civil service as CMO ... in January 1989 with no previous contact with SHHD ..."

We see later on that he left in 1991. So that's the span, 1989 to 1991.

Question 1 is:

"Was Sir Kenneth ... involved in the discussions between SNBTS and the DOH?"

He says:

"... by 1989 much of the knowledge base had been established ... and I do not recall being personally involved with discussions, though SHHD medical staff were part of the process."

He says:

"The key issue is the question of look-back for HCV."

He refers to the documents. He is able to tell us that he had regular informal meetings while he was CMO Scotland with the other UK CMOs, but he has no rememberance of this being raised. He did not attend, as far as he is aware, any SNBTS or DOH meetings. He took over the CMO England post on 17 September 1991.

Question 2:

"What steps, if any, did the health departments (and specifically SHHD) take to draw doctors' attention to the availability of testing and implications of HCV for patients before April 1995?"

His answer is that in 1995 he was CMO England and unfortunately he cannot comment on how things developed in Scotland.

THE CHAIRMAN: A very good defensive position for him to take up.

MR GARDINER: Sir, that's the end of his statement and that's the end of the additional items of evidence for the C5 topic. Again, perhaps it would be appropriate to ask my learned friends whether they would wish to comment or say anything about these statements.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: Thank you, sir. I have no comment to make.

MR ANDERSON: Nor I, sir.

MR JOHNSTON: I have no comment either, sir, thank you.

THE CHAIRMAN: Thank you all for cooperating in this matter. I know that the lack of comment now doesn't reflect a failure to take part in discussions before. Thank you very much.

MR GARDINER: Ms Dunlop will now address C4.

Conclusion of topic C4

MS DUNLOP: Sir, just to try and round off one or two points

in relation to C4, the first comment I wanted to make is not actually to do with C4, it's just a small point about yesterday's events.

The difficulty that was experienced because Mr Watters wasn't able to comment at first questioning about the evidence from Dr Boulton. If I can just say that Mr Watters was emailed on Monday and specifically asked to look at page 38 of Dr Boulton's evidence.

I say that really for the record and for the benefit of the people who sit behind us and who tee all these things up for the hearings. I just want the record to be clear that there wasn't any failing in intimating that that was the intention in advance.

THE CHAIRMAN: Well, it's always difficult to persuade people who are not intimately connected with it to --

MS DUNLOP: I don't want to make any criticism at all of Mr Watters, and he did extremely well in attending voluntarily in Plymouth and giving evidence. I think there were always going to be logistic issues doing that sort of exercise over the videolink, and there was a lot of hard copy material couriered to him and no doubt it was quite short notice for him to take on board everything he was being asked to do.

THE CHAIRMAN: I think it's a great pity that he wasn't able to come here but I rather feel that we would have

benefited from having him here and perhaps taking a bit longer with him, but sometimes one cannot have everything.

MS DUNLOP: Yes, indeed, sir. That was really logistics as well. I think in the end it boiled down to flights and transport arrangements to get him home again.

Just to make a very short point, which has been drawn to my attention, and again it's not a major issue at all, but on Day 69, which was 24 November 2011, Dr McClelland was questioned about when screening of donated blood for Hepatitis C began in Edinburgh and Southeast Scotland, and there was a little bit of dubiety about the date. I have now seen an email which informs us that testing began on 30 July 1991, that that was done so that all products on the shelf on 1 September 1991 could be said to have been tested, and records have been checked with the lab manager to obtain that information.

Next, sir, just some outstanding statements from people who didn't attend to give evidence in person. The first is Dr Follett. His statement is [PEN0171860]. That will appear. It's very short.

In relation to C4, Dr Follett simply says that he wasn't involved in any discussions concerning the introduction of testing and he can't usefully reply to

1 our questions.
2 THE CHAIRMAN: Is Dr Follett male?
3 MS DUNLOP: Yes, Eddie. He did provide some information on
4 the Microbiology Reference Laboratory but, as we
5 established with Professor Cash, this doesn't actually
6 directly bear on the topic, although at one point we
7 were under the impression that it did.
8 The next statement is from Dr Gillon. It's
9 [PEN0172069]. Again, extremely short. Not really
10 a statement. It's more in the nature of a letter. He
11 didn't feel he could provide answers to any of the
12 questions based on personal experience. He says his
13 only contribution to the work described in our narrative
14 was to lead a small working party, and obviously we know
15 about that now.
16 Then Scottish Government witnesses, a number of
17 those whose names have cropped up regularly.
18 Dr McIntyre, [PEN0172073]. A longer statement. He was
19 sent the same schedule of questions in relation to this
20 topic as the other witnesses and he has answered some of
21 them.
22 He was obviously an observer at the ACVSB meetings.
23 He says he doesn't remember the particular meeting of
24 24 April 1990. In answer number 3 he says:
25 "Both the committees comprised experts in various

relevant fields. They advised both SHHD and DHSS. For convenience they were serviced by DHSS."

Simply to say, sir, that that's not, I suspect, completely accurate. They were not both serviced by DHSS. The person who provided the secretarial services to ACTTD looks to me to have been somebody who worked with Dr Gunson within NBTS. So actually potentially quite a significant point also in relation to the role of ACTTD in providing advice, and actually we have examined that in some detail and we understand, I hope, that the role, as it eventually resolved itself, was not one of direct access to the Department of Health.

Then on to the next page. I don't think there is anything I need to highlight here. That's paragraph 13. Similar sorts of remarks made about the interrelationship between SHHD and DHSS. He talks about, if we go on to the next page, problems of semantics, which may be this whole issue of what does it actually mean to say "DHSS are taking the lead," and so on.

Then some further answers, which I think don't particularly add to the other information we have been able to obtain, just to look at them perhaps in passing.

Not at the meeting in Rome. Then on to the next page, the hornet's nest. I think we have progressed

a bit on the topic of the hornet's nest.

Then some questions about the reaction to the CSA meeting on 23 May 1990, to which Mr Gardiner was just referring, and then some questions about funding. Actually I'm going to mention some documents which bear on funding shortly. The answers, I think, from now on get rather shorter, and many of them are that Dr McIntyre isn't able to comment.

So that's Dr McIntyre's statement. There is also Dr Young. His statement is [PEN0172071]. One of the questions in our schedule referred specifically to Dr Young and it was about this period in May/June 1990, when the CSA management committee were obviously concerned -- rightly, as it turned out -- about the potential for litigation, and Dr Young provided a short response concerning the memo of 23 May 1990 and its aftermath. The text of this, I think, is actually the same. Yes, I think the wording is the same as in the section of the statement to which Mr Gardiner was referring and so this doesn't really add anything.

I should say, we did ask Dr Young again if he had any further information on any of the other questions but Dr Young is not in the best of health, so it would, I think, have been inappropriate to have pressed him any further on these matters.

Mrs Sandra Falconer, [PEN0172120]. Mrs Falconer explains her own career in the Civil Service and fast forwards, really, to paragraph 32, because that section of questions relate to the period after she joined the relevant branch. She gives some narrative. If we go on to the next page, we can see she gives some narrative of the various memos and their preparation.

I'm not convinced, sir -- even after we have looked at all the statements in this little group from people who used to work in SHHD -- that we have got to the bottom of why this submission couldn't go to the minister until the start date was known. That remains a bit of a puzzle. But that certainly seems to have been a consistent theme. It seems to have been a view that the submission couldn't go the minister until the start date was clear.

THE CHAIRMAN: It is a slightly odd notion. It anticipates that you can't ask for consent to something unless you are already set up to implement it on a specified date, but that may be again the Civil Service way.

MS DUNLOP: Or it may have related to the particular likes and dislikes of the occupant of the post at the moment. One doesn't know.

THE CHAIRMAN: Indeed.

MS DUNLOP: Then on to the next page. Mrs Falconer just

sets out very clearly all her contributions to the various memos.

THE CHAIRMAN: And some procedural aspects that look quite novel.

MS DUNLOP: Yes.

THE CHAIRMAN: I'm not sure it's necessary to know about an MEL.

MS DUNLOP: No. It's a new term, "executive letters" and "management executive letters".

Paragraph 10 -- and with apologies because I'm not convinced this is on my document list. I think it is quite useful just to look briefly at a pair of documents at this point, which are being covered in paragraph 10.

The background to this is that Dr McIntyre, having learned that there was now information, I think, principally contained in an article by Professor Tedder and others about sexual transmission of Hepatitis C --

THE CHAIRMAN: I have seen reference to that.

MS DUNLOP: Yes -- had written to the Department of Health asking if this factor was going to affect the introduction of screening in any way, and the correspondence is perhaps slightly revealing.

Can we look first, please, at [SGH0027835]. That's Dr McIntyre writing to Dr Metters. He is mentioning the anticipated introduction date of 1 September 1991 and

posing the question whether there is a need for a change in the policy decision, and then Dr Metters writes back -- [SGH0027834] -- in a nutshell saying no, but Mrs Falconer has highlighted the sentence in this letter from Dr Metters, which is about half way down the third paragraph:

"We do not anticipate advice from this committee will influence the date of the introduction of routine hepatitis screening."

This committee appears to be the TTD committee, not the VSB committee.

THE CHAIRMAN: Yes.

MS DUNLOP: I wouldn't want to read too much into that comment but it does perhaps again fit with other evidence about the respective roles of the different committees.

THE CHAIRMAN: Certainly about attitudes of one to another.

MS DUNLOP: Yes.

THE CHAIRMAN: Could we look up at the manuscript at the top:

"We must get it up this week before recess."

So that's a different --

MS DUNLOP: I think Mr Panton took this correspondence as being the news he had been waiting for, that finally a date was clear, and Dr McIntyre, having written and

said, "Is 1 September still the date?" and Dr Metters effectively writing back and saying "Yes", was enough --

THE CHAIRMAN: Nothing was going to affect it.

MS DUNLOP: Yes -- enough in Mr Panton's mind to trigger the commencement, or at least the sending of the submission to the minister. And obviously by this point he is concerned to get it in before the Parliamentary recess as well.

Could we go back to Mrs Falconer's statement, please?

Just on to the next page. It may be that Mrs Falconer has provided an answer to another question that seems slightly puzzling, which is why SNBTS were not to be told that there was an unofficial start date of 1 July 1991, which at first blush seems slightly strange since they would have to know because they were the ones responsible for implementation. Mrs Falconer is suggesting in her answer, or her paragraph 13, that it may have been effectively a matter of form. She suggests:

"The Department of Health colleagues may have requested that the start date should not be shared because it would not be appropriate to suggest that a possible date had been set before the advisory committee had had an opportunity to discuss the matter

at its meeting, and agree a recommendation."

THE CHAIRMAN: The cynics among us might think that that is likely to be the case and very typical of the realities, that the department would be taking its decisions and perhaps not giving full weight to the advice it might anticipate, just getting on with it.

MS DUNLOP: Certainly the conversation in which Mrs Falconer is asked not to pass on the information takes place shortly before another meeting of ACVSB. So it would fit with that chronology, that she is being asked not to share the information until the committee has endorsed the 1 July as the start date.

THE CHAIRMAN: Perhaps it's not right to be too cynical about it all. I suppose the way the VSB committee approached it might have depended in part on whether there was a practicable framework for implementing whatever its advice might be.

MS DUNLOP: This is all interesting territory and obviously is going to have to be studied at length.

THE CHAIRMAN: Yes.

MS DUNLOP: Then on to the next page. There is just a question about whether there could have been earlier commencement in Scotland.

Then we have Mr Roddy Angus. He is [PEN0172084]. Again, he gives a little bit of background. He doesn't

have any information about how the membership of the two committees was decided. On the next page, paragraph 5, it refers to it always having been the understanding that any new test would be introduced simultaneously throughout the UK.

Then on to the next page, another reference to the Department of Health taking the lead, and then in paragraph 8 I think another contribution on the whole hornet's nest question, which seems to be more or less exactly right, as far as we have been able to establish in oral evidence.

Perhaps it means that the hornets were surprised rather than angry. I think that's what he is saying.

THE CHAIRMAN: I thought the two things usually went together.

MS DUNLOP: Well, not necessarily, I suppose.

Then on to the next page. He has a useful ready-reckoner about who was who within the branch set out for us there and on to next page, and then some answers to do with funding. I think, with this information and also information from Mr Tucker, we do, I think, now have a reasonably complete understanding of the funding position. That really is all that Mr Angus has to say:

"The matters addressed in paragraph 31 onwards took

place after I had moved to another post."

I think he may have been replaced by Mrs Falconer. That's my hunch.

THE CHAIRMAN: I think, if you go back a page, you will see that it shows that he did a sort of standard three-year stint in that position before being moved on to something else of which he had no prior knowledge.

MS DUNLOP: Right.

THE CHAIRMAN: He was replaced by Sandra Falconer on 10 December 1990.

MS DUNLOP: Thank you, sir, I had lost that.

THE CHAIRMAN: Nearly four years.

MS DUNLOP: Yes. Then he has a record of his own employment in an appendix at the back. He is currently a civil servant in the Scotland Office elections and boundaries team, which is no doubt a lively post, offering a lot of topical interest.

THE CHAIRMAN: Yes, a lot of topical interest even as recently as yesterday.

MS DUNLOP: Mr David Hogg provided a statement. It's [PEN0172146]. He gives again a bit of background and he tells us at the foot of the first page that he has had access to the relevant SHHD file.

Then he has answered question 13. He tells us at the end of his answer:

"It was often the case that the Scottish Office would be provided with a copy of a proposal which had been drafted in the Department of Health and would 'Scottify' it."

THE CHAIRMAN: That's a new expression. Put a kilt on it was what I had understood there.

MS DUNLOP: They may be synonymous.

Then he jumps to paragraph 22. He is really just explaining the different communications, I think. Then, similarly, in answer 24 he is helping to clarify the hieroglyphics, and some further comments in answer 25 on funding.

Funding continues on the next page. Actually, I'm not sure about the £700,000 figure, or at least that £700,000 was the figure that went in in the bid. But I think that's a detail that probably doesn't matter at all.

Then on the next page he clarifies what I think was a misapprehension on my part. It's to do with the handwritten instruction about the Scottish submission based on the English one but shorter. I had read that as a description but I think it was more of the nature of an instruction. So it wasn't that the submission had already been written, it was that it was to be written and it was to be based on the English submission, but

shorter.

Then at the bottom he offers some thoughts on continued delays and why they occurred and goes on to conclude, on the final page, that:

"The submission went forward to ministers at the only appropriate stage in Scotland; otherwise, it would have been out of line with the unified approach for implementing of Hep C testing in the UK."

He has quite an interesting observation at the very end, and this is back to the question about why the date wasn't to be openly discussed. He observes:

"This ..."

That is, the date:

"... must have been subsequently confirmed at the aforementioned ACVSB meeting, as in D McIntosh's (SNBTS) letter to Dr McIntyre dated 12 March 1991 (page 143). He clearly states 1 July 1991 as the agreed introduction date."

No doubt he is right about that but it is, of course, true that the minutes of the ACVSB meeting don't themselves refer to a date. Anyway ...

Those are the statements from former civil servants in the SHHD.

We have a further statement, which was provided in response to a set of questions, and this is from

Lord Forsyth. Perhaps we could have both the questions and the answers open because it's difficult to read the answers without the questions.

The questions are [PEN0172799]; then the answers are [PEN0172801]. So if we keep them both open perhaps. I don't know, maybe we can even juxtapose them. We haven't done that for a while; it's perhaps time to try it again.

Thank you.

So we asked a set of general questions and then some specific questions. Lord Forsyth, in the first paragraph, narrates the background to the preparation of the statement.

THE CHAIRMAN: It suggests he has been given very little time to deal with this, Ms Dunlop:

"I have been asked to give a written statement within 14 days to the Inquiry."

MS DUNLOP: Well, there had been a bit of correspondence before the beginning of November in connection with trying to sort out a date for him perhaps to come, and that proved quite tricky. There was then a decision taken to begin by at least getting a statement. Then, of course, to get the statement, some questions had to be sent, and the idea was that, once the statement came in, a final decision could be taken on attendance and

really, given the limited nature of the statement, it didn't seem necessary to arrange for Lord Forsyth to attend. I'm sorry if he felt rushed in his preparations.

The first question was about the distinguishing characteristics of issues of which he was made aware. He says he would have expected officials to keep him informed on any issues which had been important public policy considerations or which would require additional resources.

In relation to how issues would be brought to his attention, he identifies one or two mechanisms: the sending of submissions, and he says he received a couple of red boxes every night and had meetings during the day.

He doesn't, I think, say in terms whether he himself identified issues and said that he wanted to be kept informed on those issues. I think, perhaps by implication, he is telling us that there weren't regular scheduled meetings involving medical civil servants, but more meetings of the nature of as and when, so if an issue cropped up that seemed to need a meeting, a meeting would be organised.

On the specific questions, he says that the issues concerning screening would have been drawn to his

attention by submissions from officials, and I think we have all of those.

If we look at the second page of the questions, please, again I'm not sure that he has specifically characterised his perception of the issue but he goes on to respond to the further questions. He does so by reference to the correspondence that he had with Roger Freeman. We did look at that, I think, in November.

If we look at the second page of the answers, please, he isn't really able to shed much light on why the submission didn't go to the minister until July 1991. We know that, of course, the first level explanation for that is that the submission couldn't go until there was a date agreed, which takes us back to previous discussions.

As far as the question of why a submission was required at all is concerned, he says that officials were right to conclude that the matter required ministerial approval.

Those are all the statements from witnesses who didn't attend in person.

Insofar as funding is concerned, it is a little bit bitty but I think the most important point is that no witness has suggested that any part of the interval

between the availability of a test and the introduction of screening was attributable to funding issues.

But just to look at how funding was arranged, can we start with the July 1991 submission, which is [SGH0027828], and could we go, please, to paragraph 7, which is on page 2?

The second sentence of paragraph 7 reads:

"In anticipation that testing would be introduced in 1991/92, a PES bid was lodged and this was successful. SNBTS are in a position to commence testing from the same date of 1 September as the rest of the UK. The costs for 1991/92 will be in the region of £700,000 and, as indicated above this, has been already included in the CSA allocation."

That, I think, may be where the £700,000 figure comes from but that wasn't the figure that was originally included in the bid and it may be -- this is speculation on my part, I hasten to add but it may be that the figure has dropped to £700,000 because of the interval between the beginning of the financial year and September. So it's only going to be roughly a half year's screening that's going to be required.

Anyway, the second document in relation to funding is [SNB0027404]. This is an agenda for a management board meeting on 12 February 1991. The second item on

that relates to PES90, so Public Expenditure Survey 1990. Whoever composed this agenda -- it may or may not have been Mr McIntosh -- said:

"This year sees a welcome first in that the service's total allocation is already known. The figure for 1991-92 is £24.456 million, which represents an uplift of £4.1 million on last year's spending power. After making due allowance for inflation, a figure of approximately £2.5 million is available for new developments, of which £1.1 million will be needed for anti-HCV testing."

A document which I think goes with this document is [SNB0027426], which is 111 pages relating to PES. We can see that this is going to be an item at the meeting, the management board meeting, of 12 February 1991. It's narrated that:

"This section of the agenda provides a summary comparing the original bids against the revised costings and an agenda listing setting out the bids and who will speak to them. Detailed bids are also included, set out in the same order as in PES90."

If we look to page 2, looking at paragraph 2.1, it's listed as "Microbiological Screening, Anti-HCV."

That's going to be introduced by Mr Francis. If we go to the next page, we can see that 1.2, under the

heading "Inescapable Bids", is:

"Microbiological screening of blood donations."

There has been an original costing at 1.7 million and that's now 1.1, and then, if we look to page 5, we can find even more detail. This is material relating specifically to anti-HCV screening and setting out estimated costs, both in terms of capital and revenue, and then the revised bid, which is, roughly speaking, 106,000 of capital and 1.117 million of revenue. And there is more detail about different costs per centre, which is on the succeeding pages.

In fact what seems to have happened is that the meeting in February 1991 didn't get as far as talking through the detail of this and it was continued to a further board meeting in April 1991, but I would suggest that, on the general question of the mechanics of obtaining funding for the screening, it is clear that the bid was included in PES90, that that was successful and that the funding was available and indeed the board was in a position to discuss the detailed allocation within the overall funding by February 1991.

I have no other documents to tender in relation to this topic, sir. I should say, however, that, not only in relation to this topic, in relation to one or two other topics as well, documents are still trickling in.

It's not a flood but there is a bit of a trickle. In some instances they are new and unanticipated documents, sometimes from the 1980s, and in other instances they are documents that we are awaiting. There are one or two statements and other responses to further questions which are still to come in.

We will, of course, tell the legal representatives of core participants about any such documents we receive bearing on the topics which have been examined in evidence and about answers we get to outstanding questions.

We have a new section on our website, which sets out supplementary evidence that we have received, and I would anticipate that we will be adding to that as some of this additional material comes in.

I should at this point ask you, sir, to offer to the core participants an opportunity to comment on all the C4 material, in case there is anything they want to raise.

THE CHAIRMAN: Mr Di Rollo?

MR DI ROLLO: Again, thank you, but I have no comment to make at this time.

MR ANDERSON: The same, sir.

MR JOHNSTON: I'm in the same position, thank you.

MS DUNLOP: Right.

THE CHAIRMAN: Is that us now until 30 March?

MS DUNLOP: Yes, until 30 March, yes.

THE CHAIRMAN: Well, if anyone else has anything to bring to our attention in the interval, I have no doubt that will be done.

(12.24 pm)

(The Inquiry adjourned until Friday,

30 March 2012 at 9.30 am)

I N D E X