Tuesday, 26 July 2022

(10.00 am)

PROFESSOR AILEEN KEEL (continued)

Questioned by MS RICHARDS (continued)

SIR BRIAN LANGSTAFF: Good morning, professor.

THE WITNESS: Good morning.

SIR BRIAN LANGSTAFF: Ms Richards.

MS RICHARDS: Professor Keel, I want to ask you next about the Scottish Executive Inquiry that was undertaken between 1999 and 2000. I want to start in the middle of 1999, so before the decision had been taken to have the Inquiry, at SCGV0000176_118.

This is from Mr Bell in the Health Care Policy Division, 15 July 1999, and we can see it is addressed to the minister and copied to, amongst others, you, and the purpose of the briefing is to brief the minister on The Haemophilia Society's continuing campaign for compensation for haemophiliacs infected with hepatitis C as a result of NHS treatment using blood or blood products.

And if we go over the page, having referred to The Haemophilia Society's campaign, paragraph 4 explains that:

"The previous administration rejected claims for such a no-fault payment scheme on the grounds that ..."

Then before we look at any of those bullet points, we're, here, looking at middle of July 1999, so would it be right to understand that we're now in a devolved government, exercising healthcare powers?

A. Yes.

Q. Then we can see the first bullet point is:

"- the patients concerned received the best treatment available at the time ..."

That's the line which we discussed yesterday.

"... which was essential for their survival and, in the absence of negligence on the part of the NHS there was no basis for making payments."

Now I wanted to ask you about the addition that we see in this document of those words "which was essential for their survival".

That might lead the reader to believe that they were being told that the treatment was invariably life-saving, and that every haemophiliac would have died without it. Would you agree?

A. Well, all severe haemophiliacs are at increased risk of death without coagulation factor treatment. So I think that's what this bullet point is referring to. It doesn't mean that all of them are going to die from their condition, but as I've said yesterday, life-threatening bleeds in severe haemophiliacs are by

no means rare, and particularly intracranial haemorrhage clearly is a severe threat to survival, but I don't think this implies that all of them were at substantial risk of death all the time, but in the event of a bleed, particularly an intracranial bleed, then they definitely would be, and they would need treatment to allow them to come through that bleed.

Q. This is addressed to a minister who is unlikely themselves, for the most part, to have medical qualifications or medical knowledge of their own. Might it not be said that this was putting it too strong, and an overstatement both in terms of an over-generalisation but also an overstatement of the necessity for concentrates?

A. I don't really think it's an overstatement. I mean, it is a generalisation, I agree with you, but I don't believe it's an overstatement.

Q. If we go to the next page, we can see paragraph 7 explains:

"This issue has been treated as a UK-wide matter on which the four territorial Health Departments should adopt a consistent line. Mr Dobson's announcement was therefore endorsed by Mr Galbraith, as Scottish Office Minister for Health."

And that's what we looked at yesterday.

"The issue now comes within the remit of the Scottish Parliament and it appears from the attached correspondence, and a recent enquiry from James Douglas-Hamilton, that the Haemophilia Society is now focusing its efforts on the Parliament."

Then the recommendation in paragraph 9:

"In light of the fact that the Department of Health have rigorously examined this issue twice in recent years and that the Haemophilia Society have not produced fresh evidence to support their claim for financial assistance, we advise that a further examination of this issue would only draw the same conclusions previously reached. We therefore recommend that the Minister endorses the decision taken by her predecessor and signs the attached reply."

If we just go back to the first page, there's some handwriting which says, "I would agree but need SD decision". Do you know whose handwriting that is?

A. No, I don't, but SD is clearly Susan Deacon.

Q. The minister to whom this was addressed?

A. Yes.

Q. And you're the only medical officer -- oh no, there's Dr Woods. Who was Dr Woods?

A. Dr Woods is not a medical doctor. He was chief exec of the Department at that point.

Q. So would it be fair to assume that, in terms of any medical advice within this document, either you're the source of it or effectively you've agreed with it?
A. Yes.
Q. Now that's July 1999. What's your recollection of how it came about that the minister decided to commission an internal investigation?
A. Well, it's a long time ago, but my recollection is that, as the submission indicates, post-devolution there was intense lobbying of MSPs through the Parliamentary process, particularly by The Haemophilia Society, and that the new minister, obviously it was in receipt of all that lobbying, and that, I suspect -- I mean, you are interviewing her, I believe, later this week?
Q. Yes.
A. She's better placed to answer than I. But my impression was that post-devolution, increased lobbying, and she was persuaded that we needed to drill down further into the allegations of The Haemophilia Society that Scottish blood products, principally Factor VIII, were less safe than those coming from England at the time, and she was very keen to get to the bottom of that.
Q. And the ambit of the investigation essentially became the question over Scotland lagging behind England in terms of producing hepatitis-safe heat-treated

concentrate in a period between 1985 and 1987; is that broadly correct?
A. Indeed.
Q. And is it right to understand that ambit is a reflection of the particular focus of The Haemophilia Society's lobbying, is that right?
A. That's correct.
Q. And the investigation was not widened to look, for example, at the position of those should been infected through blood transfusion?
A. No, The Haemophilia Society were very focused on the haemophiliac community, understandably, and the remit of the internal inquiry was framed absolutely around what they wanted to be looked at, and was agreed by them.
Q. And was there any lobby group or other group representing the interests or position of those who had been infected through transfusion at that point in time in Scotland?
A. I can't recall.
Q. If we pick matters up in August 1999, just to establish some of the chronology.

It's SBTS0000379_040, please, Lawrence.

So this is a meeting held on 30 August 1999 to discuss the investigation. We can see that from the Scottish Executive there are four in attendance: you,

Mrs Towers, Mrs Falconer and Mr Palmer. There is also someone attending from the Central Legal Office and then three from SNBTS.

Then if we look at the first paragraph we can see it references to the minister being due to meet The Haemophilia Society on 14 September:

"... to hear their concerns about the infection of haemophiliacs with HCV through treatment with SNBTS products ... explained that the Minister had requested a report analysing what had happened at that time with an assessment of whether SNBTS' position could be said to have been negligent. After the investigation the Minister would brief the Parliament's Health Committee on its findings."

Now, bearing in mind that the focus of the investigation is to determine whether SNBTS had been negligent, is there any particular reason why the investigation process seems to have commenced with a meeting with representatives of SNBTS before even the minister has met with The Haemophilia Society?
A. Well, the meeting was clearly to prepare for that ministerial meeting and make sure that the minister was briefed as accurately as possible in advance of 14 September. So I don't find it surprising in any way that we would want to meet with SNBTS to discuss the

lines of the Inquiry and get preliminary feedback from them on the issues that might arise.
Q. It was presumably never going to be very likely that SNBTS would put their hands up and say, "Yes, we were negligent" or "Yes, we were at fault". To what extent in the course of the investigation was the submissions made by, material provided by SNBTS subjected to any kind of rigorous scrutiny?
A. My recollection is that what was sought from SNBTS was a factual, chronological account of the measures that we had taken in the mid-1980s to ensure that hepatitis C Factor VIII *(sic)* was available.
Q. If we turn then -- so that was 30 August. If we turn to a meeting on 1 September.

That's PRSE0000978.

So this is the second meeting that we see being held, and this is with Professor Ludlam and Professor Lowe, and again you're in attendance, Mrs Falconer and Mr Palmer, also from the Scottish Executive.

The purpose of the meeting in the first paragraph is explained by you as being to clarify the validated information that would be needed from each of the Haemophilia Centres for the planned ministerial briefing on 9 September.

Now, bearing in mind this was looking at -- or this was an investigation which was to look at SNBTS's actions, why had it seemed particularly important to speak to Professor Ludlam and Professor Lowe at the outset, of the investigation?

A. Well, they, each of them, headed up the two biggest Haemophilia Centres in Scotland, so therefore they were the two main prescribers of Factor VIII, so clearly their recollection of events in the mid-1980s was material to the internal investigation.

Q. Can you assist us in understanding why the focus of the investigation was negligence, which would ordinarily be a matter determined by the courts, rather than perhaps a broader question of whether there was fault or things that could or should have been done differently or better?

A. As I said earlier, the remit was that requested by The Haemophilia Society. I imagine that that word -- the use of that word emanated from them.

Q. If we go towards the bottom of the page, please, paragraph 4, this records a further contribution from you:

"Dr Keel pointed out that it would be necessary to fully investigate the circumstances and events during that time and to cost, based on a range of scenarios,

the different types of assistance which might be awarded."

Just pausing there, does that reflect the fact that one of the underlying purposes of the investigation was to inform a decision about whether or not to provide financial support?

A. Not directly. The purpose of the investigation was to understand, as I said earlier, the facts and the chronology of events during the period in question. But it would have been remiss of any Government department not to be anticipating that The Haemophilia Society, which was already lobbying hard for financial redress, would increase those efforts during and after the production of the report.

Q. Then continuing on with paragraph 4:

"It was therefore essential to estimate how many people would be eligible. Any follow-up action taken by the Department would be in consultation with the other territorial departments on a UK-wide basis."

Then this:

"She advised that the chronologies of events provided by BPL and SNBTS were revealing. PFC and BPL had deliberately chosen to pursue different paths in the development of heat treatment methods, in order to cover more than one option and increase the likelihood of at

least one plant coming up with a breakthrough. PFC did so for HIV and BPL then did so (in retrospect unwittingly) for HCV."

Was it your understanding, therefore, that the different heat treatment strategies adopted by BPL and PFC were in some way coordinated so as to be complementary?

A. I think there was a degree of complementarity. Whether it was serendipitous or -- there definitely was a degree of complementarity, whether that was deliberate or serendipitous evades me at this time. It's so long ago.

Q. We can see, if we then pick it up at paragraph 6, this:

"Professor Lowe and Professor Ludlam confirmed that it was normal practice within their centres to inform patients of the result of a test if they were found to be HCV positive. Dr Keel would confirm that this was the procedure within the other Haemophilia Centres. In particular, she was concerned about the case of a Dundee patient highlighted in the press coverage, who had claimed not to have been informed of his infection for a year after he was tested."

Now, why was it that this issue about informing patients or the failure to inform patients of test results, why was this issue being ventilated in the meeting, given that the ambit of the investigation was

focusing upon the '85-'87 period and SNBTS?

A. The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material.

Q. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"?

A. Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh.

Q. In relation to Glasgow, you were there between 1983 and 1986 and, of course, hepatitis C was not known at that point in time, and there was no test available. So you couldn't, I think, have been familiar with Professor Lowe's practices in relation to hepatitis C, could you?

A. Only insofar as liver enzymes were taken at every visit and discussed at the following visit. So the

non-A, non-B context was discussed in those clinics.

Q. You have, I think, said in response to my question about whether this information was essentially taken at face value -- and I'm paraphrasing your answer, Professor Keel -- what else could be done? The Executive could have asked The Haemophilia Society to provide details of patients who claimed otherwise, could it not? It could have asked to see patient records?

A. Well, it -- The Haemophilia Society and many patients' views were taken into account. Patients wrote in to the Department in the process of the Inquiry, and aired their views. So they were given that opportunity. I'm not sure that going through patients' notes -- well, it would have been a very lengthy and laborious process, particularly going back so far, over 15 years by this point, to try to -- I don't think looking at the notes would have been a very fruitful exercise in trying to determine what the practice was around informing patients of their results.

Q. It might be said, professor, that if you have an investigation, one aspect of which is to look at what patients were told, but if all you're going to do is accept a doctor's assurance that they did tell patients, that's not much of an investigation. If that submission were to be made, what would be your comment?

A. Well, it wasn't -- that element of the investigation wasn't limited to what clinicians had told patients; it was also related to information provided in the form of leaflets, et cetera, and I think we laid hands on a number of those publications in the course of the Inquiry. So it was more of a holistic approach to information provided rather than just practices around informing patients of results.

Q. If we pick matters up next in September, about a week or so later, at SCGV0000043_047. So this is a briefing provided by Mr Palmer, who we saw in attendance at those two meetings, to the Minister, 8 September 1999, copied to you, amongst obviously a number of others. The purpose is described in paragraph 1 as:

"To provide initial briefing to the Minister prior to her meeting with the Haemophilia Society on 14 September ..."

If we go over the page, we can see paragraph 5 sets out what the Government's position has been, essentially if there's no fault there should be no compensation and the assertion is made there again that patients received the best treatment available given the state of knowledge at the time.

Then paragraph 6 says this --

SIR BRIAN LANGSTAFF: That's a slightly different

formulation from the previous one. Previously, there was no reference to the state of knowledge at the time, but the words were, "which was essential for their survival".

MS RICHARDS: Yes, this picks up more the wording of the briefing we looked at yesterday afternoon.

SIR BRIAN LANGSTAFF: Yes, which was, as is set out here.

MS RICHARDS: Yes. Then paragraph 6 says:

"Agreeing no-fault compensation for haemophiliacs with HCV would have major policy implications in that it would promote the elastic concept of 'a moral liability' on government to compensate individuals who have been damaged, however inadvertently, by its actions ..."

Now, this is Mr Palmer's briefing, professor, not yours, but do you recall what your thoughts were at the time about the concept of a moral liability or moral responsibility?

A. Well, at the time, my view was that there had been no fault attributed to SNBTS or the NHS and that that was the justification there had been for many, many years of the Government's position, with the exception of the precedent we discussed yesterday for HIV.

So my view was -- I mean, Mike Palmer's language is slightly difficult to interpret, but I suppose what he's trying to say is that, where patients had been

damaged but no negligence has been proved on the part of the NHS, then for the Government to embark on an open-ended no-fault compensation scheme would be a very major change in policy with major implications further down the route on the amount of money to be spent and, therefore, by definition, the amount of money then available for direct patient care.

I think that's probably what he's trying to get at. Of course, it's his words, as you said, not mine.

Q. Then under the heading "Recent developments" paragraph 7 sets out the background in terms of the Society's campaigning, and then says:

"Their key concerns seemed to be that ..."

And then there were a number, or three subparagraphs. (a) is concerned with the issue that we've already touched on, the difference between Scotland and England in terms of an HCV-safe product. Then (b) and (c), (b) is:

"assurances were given at the time that the SNBTS product was safe from infection, when in fact it was known that it was not safe from hepatitis C;

"(c) some patients who were tested HCV-positive in the early 1990s ... were not told that they were infected until long after the test results were known, during which time they ran a higher risk of infecting

close family members because their ignorance."

So I just draw attention to that so we can make sense of what we see a couple of pages further on. So that's paragraph 7(b) and (c) of the briefing.

If we go to the next page, the bottom of the page has the heading "Current investigations", and paragraph 14 refers to the Department being:

"... engaged in an investigation of events and circumstances surrounding the introduction of heat-treated Factor VIII blood products in the mid-1980s."

Then paragraph 15 refers to paragraph 7(a), so that's the issue about the heat-treated product, and says:

"... we have prepared an initial overview of the events in the mid-1980s, arising from our enquiries so far."

If we go over the page, paragraphs 16 and 17 deal with the charge at paragraph 7(b), so that's the question of the extent to which information about infectivity of the product was provided to patients.

Paragraph 18 refers to the charge at paragraph 7(c), and it's said to be a claim currently investigating, and that's the issue of people not being told of their positive test results.

Then if we go to the heading "Draft agenda for the meeting on 14 September", reference is made to an attached draft agenda at Annex C.

Then paragraph 20 says this:

"With regard to Section 3 of the agenda we will wish to probe the basis for the statements made at the second and third indents of that section."

Now, to understand that, I want to look at the draft agenda with you. So if we could go, please, to page 11. This is the draft agenda, and if we look at paragraph 3, which is the paragraph being referred to in Mr Palmer's briefing:

"Why were Scottish people with haemophilia exposed to the risk of HCV for longer than those treated with English product?"

The second and third indents are:

"Little or no information provided to patients at the time about HCV risks although evidence of non-A, non-B hepatitis transmitted through blood products was being accumulated through the 70s and early 80s."

And:

"By 1985 risks of HIV were very well documented and research well advanced into heat treatment."

So those are the second and third indents. If we

go back to page 4, please, and paragraph 20 of the briefing. Again, I'm conscious this is not a document authored by you, Professor Keel, but the suggestion there, wanting to "probe the basis" for The Haemophilia Society's statement in relation to the second indent, which is about little or no information being provided to patients about HCV, it might be said that the Scottish Executive Health Department was taking an approach towards The Haemophilia Society's assertions, wanting to probe the basis for them, that it wasn't taking towards the Haemophilia Centre Directors, accepting at face value what they told the Health Department.

Do you have any comment on that?

A. I think what we were looking for from The Haemophilia Society was as much intelligence to inform the Inquiry that ultimately took place as possible. I think it was a genuine desire to know what lay behind their allegations rather than subjecting them to a grilling that we weren't subjecting the Haemophilia Directors to.

Q. And then Annex B of the briefing, which Mr Palmer had described as an overview -- an "initial overview arising from our enquiries so far", that starts on page 7.

And if we go over the page to page 8, we've got the heading "Protection from Hepatitis" towards the top

of the page, and then paragraph 8 says this:

"Our consultations suggest that from the late 1970s (when NANBH first surfaced) to the mid-1980s, there was very little evidence that NANBH produced adverse symptoms, and that it was generally regarded as mild and non-progressive. For example, as late as February 1987 Dr Forrester (Medical Adviser at the Scottish Office) reported that: 'Non-A, non-B Hepatitis would appear to be relatively benign, despite some risk of cirrhosis of the liver in the long term, unless the recipient is pregnant when the effects can be very serious'."

Now, again, I appreciate that this is some time ago, but are you able to assist in understanding what's referred to as "our consultations" there? In other words, what was the evidence-gathering exercise that led to the conclusions that are being recorded in paragraph 8? Do you know?

A. No, I don't, but I infer from the mention of Dr Forrester that at least part of that consultation was looking through the files to see -- to gather references to non-A, non-B hepatitis which had been collected by Government. But I don't know what else it means, in terms of consulting.

Q. Was there any form of review of the medical literature

from the '70s and '80s undertaken?
A. That was part of the internal report, yes.
Q. Who would have undertaken that review of the medical literature? Was that you or was that somebody else?
A. Christine Dora was the administrator in the lead drafting the report, so it was principally down to her. But I would -- I can't remember but probably have drawn attention, her attention, to key articles that had appeared in the medical press around about this time.
Q. Do you know whether any consideration was given, whether by Ms Dora or you or by other colleagues within the Health Department, to making any contact with the civil servants in the Scottish Office who'd been dealing with this issue in the course of the 1980s?
A. I've no recollection of that happening.
Q. If we go just then to page 10, paragraph 18 is headed "Initial conclusions", and says:

"Our initial impressions from this outline of events, which has been gathered from our preliminary investigations, are:

"that SNBTS did all they could at the time to develop a Factor VIII product which was safe from HCV, given the state of knowledge at the time and the key objective of combatting HIV."

Then, secondly:

"there is no evidence that SNBTS lagged without good reason behind England ..."

Now, those are described as initial impressions and initial conclusions and preliminary investigations, but they're expressed in fairly strong and decided terms at a point in time in which The Haemophilia Society meeting hasn't even taken place yet. It may be submitted to the Inquiry in due course that this was an investigation undertaken essentially with a closed mind or pre-determined position. Do you have any observations in relation to that submission if it were made?
A. I disagree. I think it's absolutely consistent with providing ministers with all the facts that were known at the time and, indeed, the preliminary conclusions that were being drawn from those facts in preparation for a meeting with The Haemophilia Society.
Q. If we turn to SCGV0000170_164, this is a further briefing from Mr Palmer, 10 September 1999, to the Minister, the purpose is said:

"To outline a way forward which the Minister can offer the Haemophilia Society at her meeting with them on 14 September."

Then if we just go down the page, the "Recommendation" is:

"In line with our discussions with the Minister yesterday, we recommend that she closes the meeting on 14 September by outlining the following way forward:

"a) The Department have commenced investigations into Scotland's efforts to make blood products HCV-safe in the mid-1980s, and the concerns articulated by the Society today will be followed up in carrying those investigations forward. I want to emphasise that the Department is at the arm's length from SNBTS and is engaged in an impartial and objective analysis of the events and circumstances surrounding this issue."

Do you consider it's right to say that the Department is at arm's length from SNBTS? Obviously, they are different bodies but we've seen that there was a close -- perfectly understandably -- working relationship between the Department and SNBTS, and there had been regular meetings over the years with SNBTS representatives, again for perfectly proper reasons.

Was the Department really in a position to engage in an impartial and objective analysis of SNBTS's actions?
A. I believe that it was. We had no direct involvement in directing SNBTS's operations, so I think that the Department was in a perfectly reasonable position to conduct this investigation of events that had happened

many years before, based on evidence gathering from SNBTS but also from Haemophilia Directors, as well as The Haemophilia Society.
Q. If we turn to the next page, we can see in paragraph (b) the link being made with the possibility of compensation. Then on paragraph (c) says this:

"The Department aims to report on its investigations within a month ..."

Now, as it happened, it took over a year, it's late October 2000, I think, when the report was published. What's your understanding of why it took that length of time?
A. Well, my recollection of this is hazy, but at least part of it, I think, relates to the fact that I was trying to, from the UKHCDO registry, get accurate figures on how many Scottish patients had been treated with what might be described as at-risk products, during the period in question and that proved a very difficult task, and I can't remember now whether we ever finally got that data that we were seeking. That, at least, was part of the reason that the report took a year rather than month.
Q. I haven't gone to it but I will give a reference for the transcript. It's right to note that you wrote to Dr Colvin, chair of UKHCDO, I don't think the date of

the letter is clear, but it's LOTH0000011_007, and then we will I think see some further documents in early 2000 which report that you've not had a response or that you're chasing for a response.

Can we then just go to SCGV0000170_232. Can we just go to the bottom of the page, please.

I'm sorry, can we take that down. There's something which hasn't been redacted, which I think possibly ought to have been redacted.

I'll come back to that document at a later stage if we need to. That is the note of the meeting. Yes, we do have another version of that document but not at present. My apologies Professor Keel.

In any event, there was a meeting on 14 September with representatives of The Haemophilia Society. The document that we looked at a few minutes ago that was appended to Mr Palmer's briefing that Annex B which set out the initial investigations and initial impressions, do you know whether that document was provided to The Haemophilia Society in the course of the investigation, so that they could see the Department's thinking and comment on and respond to it?

A. I don't remember but I think it's highly unlikely it would have been provided to them. It was internal briefing for ministers, so I think we can conclude it

wouldn't have been shared.

Q. The reason I ask that, professor, in particular is the document I asked to be taken down, I'm just going to read a sentence from it. It's paragraph 10 of that note of the meeting on 14 September and it records the Minister pointing out that she wished the examination to be carried out in an open and transparent manner, and it might be said, again, that conducting the investigation in an open and transparent manner might include providing your initial findings -- when I say "your", the Department's initial findings -- or impressions to the Society for it to be able to respond on an informed basis.

A. Well, again, I beg to differ. I think that when it came to the report, that final report being produced, it was issued in draft form to the main stakeholders, if you like, including The Haemophilia Society, so that they could comment on the more refined conclusions that we'd arrived at, at that point. I don't think that not sharing the ministerial briefing with The Haemophilia Society means that the Inquiry wasn't conducted in an open and transparent way.

Q. Yes, I should say, for the sake of clarity, I wasn't suggesting that the briefing itself was something that ought to be shared with the Haemophilia Society. It was

the annex to the briefing, Annex B, which set out what it was the Department had obtained by way of information and evidence so far.

A. Well, I don't know whether it was shared but, as I said earlier, I think it's highly unlikely.

Q. Can we then just pick up on a point of detail in your witness statement, please. WITN5736003. If we go to page 47, in paragraph (d), if we just -- thank you.

I just want to pick up on a point that's made in the second half of the paragraph. So you're talking here about the different approaches taken by BPL and PFC to viral inactivation and, halfway down the paragraph, you say this:

"In the event, the PFC was ahead of BPL with an HIV-safe product ..."

Then:

"BPL was ahead of the PFC in developing an HCV-safe product in 1985 ..."

Then it's this phrase:

"... (although this was not proven until 1988)."

Now, the Inquiry has seen documents from 1985 and 1986, which suggest that there was a basis for optimism about the BPL product: the initial results and findings were good. That's not something which is referred to here. You use the phrase "although not proven until

1988". Can you help us in understanding why and whether you were aware that there was evidence that the BPL product didn't transmit hepatitis C, that was available in '85/'86?

A. Well, I think having a basis for optimism is not the same as proof that the product was HCV safe and that only emerged in 1988. So that's what I was trying to reflect. There were preliminary, of course, findings along the way, but the nature of hepatitis C is that you have to, in the absence of a test, which was not in existence at that point, you have to let some time elapse to determine whether patients had indeed been infected with non-A, non-B hepatitis.

Q. Do you recall whether you were aware of the preliminary evidence that was available before 1988, which indicated or pointed to the likelihood of this being safe, in terms of transmission of non-A, non-B hepatitis?

A. I don't recall whether I was aware or not. To me, the material point is that it wasn't definitively proved until three years later.

SIR BRIAN LANGSTAFF: May I just ask a question here? By 1988, there wasn't, as yet, a test for the actual virus itself because one hadn't yet been developed; that didn't take place until 1989. So what one is looking for here is a product being administered to recipients

and seeing whether any of them then showed the signs which clinically indicated that they had non-A, non-B. Those signs would be what were repeated liver function tests on more than one occasion which showed elevation, and the absence of any positive test for hepatitis B and hepatitis A. It was really a diagnosis of exclusion, wasn't it?

A. Indeed, yes.

SIR BRIAN LANGSTAFF: So the proof of the pudding is the absence of any infection demonstrated by those tests. You just need one person or two people to say, "Well, I had this product, I have this result, the result is positive, I've got non-A, non-B", and you'd be able to say, well, the product doesn't work.

The proof of the negative is what you have to have to show that the English BPL product actually worked. It's not going to come quickly, but by 1988 you regard it as proven. In other words, there'd been sufficient product out there without any report of any infection.

The steps along the way to that are seeing whether anyone checks at intervals and sees if there's any infection and, progressively, my impression would be with those tests nobody produces a positive result, that goes on, and the groundswell develops to an extent where you can say that yes, this is absolutely proven. Is

that a fair summary of the process?

A. That's absolutely what I was trying to convey but much more fluently, thank you.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: The penultimate sentence in that paragraph makes the point that the BPL product was not produced in sufficient quantities to make England self-sufficient.

Was it your understanding that the cohort of patients who might be particularly at risk in this period that you were looking at, that the Department was looking at, '85 to '87, would be likely to be patients who had been either previously untreated or minimally treated? They were those who were most likely to be at risk from treatment with a product that transmitted hepatitis C; is that correct?

A. Yes, because we know, with hindsight, that prior to an HCV-safe product being produced, that 100 per cent of haemophilia patients would have contracted non-A, non-B hepatitis. So the clinical trials -- and of course this long pre-dates any involvement or any of my involvement through the Government -- the clinical trials that would have been conducted in the mid-1980s would have, I think, exclusively been in previously untreated patients, so that the effects could be determined in them who had never been exposed to any

other products.

Q. Now you observe, as I understand it correctly, that at this point in time, BPL wasn't producing sufficient quantities of product for everybody in England or England and Wales to be treated. Did the Department's investigation look at what might be thought to be the separate but important question of whether BPL might have sufficient quantities of 8Y in order to be able to spare some for that smaller cohort of patients in Scotland who were previously untreated or had been minimally treated? In other words, the very cohort most at risk? Was that something the investigation looked at?

A. I think there is mention in the investigation report, or I've seen it in some document, that a small amount of 8Y, the BPL product, was indeed obtained, I think by Edinburgh, but that was obviously on the basis of clinician-to-clinician approach. I mean, I was working in London during this period in the mid-'80s and I recall that at the Middlesex, where I worked for a bit, that 8Y was often in short supply, even in that major Centre.

So BPL were not hanging on to loads of that product that could have been accessed by Scotland. So I think it highly unlikely that, other than the small

amount that came in, as I said, I think to Edinburgh, there would have been excess product available for north of the border.

Q. It's an issue that this Inquiry has been investigating, Professor Keel, as to whether requests could and should have been made earlier to BPL for a small supply but sufficient to enable the smaller number of Scottish patients most at risk to be treated.

If you don't recall, please say so, and we can obviously look and will look with Mrs Deacon in due course at the final Inquiry report, but do you recall that coming up as an issue in the course of the investigation, whether requests could and should have been made to BPL for a supply earlier than they were?

A. I don't remember that being a subject that was discussed, but I -- as I said a minute ago, I think there is reference in the document that a small amount had found its way north. I imagine that it was understood at the time that BPL were not able to produce enough product to cover England, and therefore that the prospect of them, even if they had been formally approached -- of releasing any for Scotland were low.

Q. If we go to SCGV0000170_152.

This is still in September 1999. If we look at the top of the page, it's an email sent on behalf of the

First Minister, 23 September. And again, it's copied to you, amongst others, and it says this:

"The First Minister has seen your minute of 17 September to the Minister for Health outlining a way forward following the meeting with the Haemophilia Society. He was a little concerned about the possible financial implications and fears that an open mind could be taken to mean an open cheque book. He would be grateful for information on the likely exposure if compensation were to be awarded."

Now, before we look at anything else on this document, do you have any recollection of your thoughts when you saw this email, and the fear about an open mind?

A. No, I don't recall what I thought when I saw the email, but clearly, any administration would want to be able to quantify the amount associated with the compensation if that were to be rewarded -- awarded. And as we've seen from earlier documents, in preparation for this kind of response from ministers, the Department had already begun to try to scope the numbers, so that from -- who might be eligible -- from those numbers we could build scenarios around the possible financial implications of such a scheme if it were adopted.

Q. Could we look at the bottom part of the page, please.

There's a note on the right-hand side which I think says this:

"Ms Deacon's office advises that this is very much a PR exercise and that there is unlikely to be any compensation paid."

Now, this is nine days after the meeting with The Haemophilia Society where the Minister has said to The Haemophilia Society "We're going to be open and transparent". Obviously, this is a matter that Ms Deacon will no doubt be asked about in the course of the week but do you maintain the answer you gave earlier that, from your perspective, this was an independent and impartial investigation in light of, what's said to be here, the advice from the Minister that it was very much a PR exercise?

A. Well, as I said in my written statement, I certainly don't agree with the use of the term "PR exercise". Undoubtedly, ministers were under great pressure to further investigate this area and The Haemophilia Society undoubtedly had in mind compensation at the end of that period. However, I don't think that means that the investigation -- the internal investigation was not conducted in an entirely proper way, as I said, earlier, finding out the facts, detailing the chronology, so that we could really understand what The Haemophilia

Society -- whether what The Haemophilia Society were alleging was true or not. So the use of this term does not tally with my recollection of that period around the investigation.

Q. Moving on, then, through the course of the investigation to November '99, WITN2287019, please.

WITN2280719, we don't have it. Ah, okay, I'll pick that up after the break, in that case.

My apologies, professor, for the document issues this morning.

We'll come back to that, so I'll take the investigation slightly out of chronological order.

If we then move to SCGV0000170_078, this a meeting, 14 January 2000, and I draw attention to this just to see what's set out in paragraph 2, and this, I think, confirms the point you made earlier, Professor Keel. It refers in paragraph 2 to the lack of information received so far from the Haemophilia Directors, and then it sets out that you had written in September, written again in mid-December, and sent another reminder in early January, and that the information received didn't answer all the questions. So I think that reflects what you already told us and put some dates on it.

Can we then pick up ARCH0003312_031. Now, this is

a letter from you dated 17 January 2000, and we can see it's Scottish Haemophilia Directors. Paragraph 1 refers to the meeting that we just briefly looked at. Paragraph 2 of the letter says this:

"You may recall that The Haemophilia Society are also particularly interested in pursuing the issue of what patients were told at the time of Hepatitis C testing, including the clinical implications of a positive diagnosis, in addition, the Society allege that Scottish patients were often completely unaware of possible adverse effects resulting from plasma derived blood products, and of other potential treatment options."

So that's one of the issues that have been flagged up by the Society, and then we can see that, in the third paragraph, you want to discuss these important issues in more depth and so you're inviting the Haemophilia Centre Directors to a meeting.

We can see the meeting itself at ARCH0003312_020. So meeting on 10 February 2000, we can see again the attendees from the Scottish Executive and then on this occasion we have Professor Ludlam and Professor Lowe again but we also have directors from Dundee, Aberdeen, Inverness and Yorkhill.

If we go towards the bottom of the page, we can

see -- and I'm not going to go through the detail of it but we can see reference there to figures of HCV positive patients said to be currently alive.

Then if we go over the page, there's further information about the figures.

If we can pick it up at the bottom of the page, please, paragraph 3:

"Dr Keel reported that a major concern of The Haemophilia Society was that members alleged they were not given a clear explanation of the risks of treatment or the therapeutic options. Patients were tested without their knowledge and were not told of the results for some time and that during that time their partners were exposed to the unnecessary risk of infection."

So you're there recording The Haemophilia Society's complaint from members as to what they were not being told and what was happening without their knowledge.

Then Mrs Towers is then recorded as contributing. Now, Mrs Towers was who?

A. She was a legal adviser to Government.

Q. What she then says is:

"... explained that it was therefore necessary to try to establish whether there was a general policy on

what patients were told and whether there [I think the word 'was' is missing] an assessment of risk and if patients were given a choice."

Now, it might be said that Mrs Towers is there identifying a narrower issue so, rather than looking at what, as a matter of fact, did or didn't happen, looking to see whether there was a general policy about the provision of information to patients. What, if any, comment would you make in relation to that?

A. Not sure I have any comment. She was clearly probing one aspect of this area of the Inquiry.

Q. We can then see a response from Professor Ludlam describing non-A, non-B hepatitis as a mild non-progressive condition -- sorry, in terms of the perceptions until the late 1980s, the first serious study on liver biopsy having been undertaken in 1985. Then this:

"Dr Keel confirmed that this was also her understanding, and Dr Watson advised the only tests for the virus at the time would have been via surrogate markers."

Was your understanding of this important issue, about what was known regarding non-A, non-B hepatitis, essentially based upon what Dr Ludlam was saying to you, or was it based upon your own knowledge and review of

the medical literature? Do you know?

A. The latter.

Q. Then if we go down to paragraph 7, we can see it said:

"Professor Lowe pointed out that there was an awareness of Hepatitis at that time and every patient was treated with great care because of the risks of transmission. He explained that the policy was that patients would be informed they were being tested ... and that the results would be discussed at their next appointment."

Then he refers to a publication in '85 and British Liver Trust leaflets.

Was this information provided by Professor Lowe at this meeting again essentially accepted at face value by the investigation, as far as you can recall?

A. Yes, I think it was.

Q. Then if we go over the page, paragraph 9 says this:

"Professor Lowe pointed out that most patients would have been infected whilst their predecessors were in post and asked whether it was necessary to contact them to make them aware of the situation. Mrs Towers explained that this was a factual information gathering exercise but that it should be borne in mind that the information might be used in future Court actions. Professor Ludlam also sought advice on whether HDs

[Haemophilia Directors] should be looking back to try to identify what had happened to patients whose whereabouts and status were unknown. Mrs Towers confirmed that Central Legal Office was representing the Trusts and SNBTS and that the HDs should therefore follow CLO advice on whether any further investigation or the tracking down of patients was necessary."

Now obviously this paragraph doesn't record any contribution or expression of view from you, Professor Keel. But as a medical practitioner as well, obviously, as medical advisor to the Government, do you have any concerns about the discussion that's recorded here? We have Professor Lowe asking about whether contact should be made with patients who might have been infected, and Mrs Towers saying, "Well, that information might be used in future court actions and you should take legal advice."

A. I don't recollect this part of the discussion. I mean, legal advice is clearly very important. SNBTS were already in touch with CLO, so I think it's probably reasonable that Lynda Towers advised them to speak to CLO before doing anything further.

Q. As a matter -- I'm sorry.

A. If I may. I'm not quite sure what Professor Lowe had in mind in terms of tracking the patients down. I don't

know what was in his mind. I mean, was he going to ask them about what information they'd been given? They would presumably be under the care of another Haemophilia Director or centre somewhere else, who was looking after them from a non-A, non-B infection point of view, and monitoring them. So -- and in due course, the report was going to be produced and indeed, as subsequently happened, there was publicity around awareness raising. So I'm really a bit mystified as to what was in Gordon Lowe's mind.

Q. Yes. Whatever Professor Lowe had in mind, it's I think tolerably clear what Professor Ludlam had in mind, which was the question of whether Haemophilia Directors should be looking back to try to identify what had happened to patients whose whereabouts and status were unknown. The Inquiry has heard evidence, Professor Keel, in particular in relation to mild haemophiliacs who may not be in contact with Haemophilia Centres from one year to the next, and so there may be cohorts of patients not attending regularly at their Haemophilia Centre who might have been infected and were unaware of their infection.

As a medical professional, whatever this particular paragraph does or doesn't mean, as a medical professional, would it have been, in your view,

important that -- bearing in mind we're now in 2000 and there's a possibility of patients infected through blood products not knowing of their infection, would it be important for those patients to be identified and tested and informed?

A. Well, it would be, but I suspect that even the mild haemophiliacs who, as you say, would probably have little contact with the Centre, would have been aware, in the preceding decade, of the existence of a hepatitis C test, and there certainly were great efforts -- and we discussed some of these yesterday -- in raising awareness of the availability of an HCV test for anybody who'd received blood transfusion or blood products.

Q. Just one further document before we break, and this now moves to March 2000. It's SCGV0000171_052.

This is an email from Christine Dora, dated 28 March 2000, and I'm looking not at the very top of the page but at the -- which is I think forwarding the email on -- but to the next -- thank you -- to what is now on top of the screen.

So it's from Christine Dora to you and to Mrs Towers, subject "help! haemophilia and hepatitis C".

Just to understand, Mrs Dora or Ms Dora was the person who was primarily charged with undertaking the

investigation, and it's her fact-finding exercise and her conclusions that we see in the investigation report, is it not?

A. Yes.

Q. Then we see her saying this:

"Dr Keel, Mrs Towers

"I have now waded through the papers you got from Prof Cash, relating to SNBTS, and the only things I can say are:

"a) I don't understand half of them!

"b) as far as I can make out, 'we' (in Scotland) were only getting around to seriously thinking about ALT testing of donations in March 1988 -- after the period in question. I suppose we could try to emphasise about how unreliable it was -- but that in itself is a big dollop of hindsight."

"The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give me any advice in relation to the sequence of events as they might relate to our investigation? Even something demonstrating that by the time adequate testing of donations was available, heat treatment was already protecting people? Or something demonstrating that the testing available at the time was inadequate?"

Now, again, it may be submitted to the Inquiry in

due course that this is not a reassuring email to read, in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in relation to that?

A. Well, first of all, I don't think we know the content of Professor Cash's papers. In my experience of his *modus operandi*, many of them possibly didn't relate to the subject of the Inquiry, so I don't think it's surprising that Christine Dora and the administrator would not be able to understand medical communications. But what I think we do not know, as I said a minute ago, is what was in those papers from Professor Cash, they may not even have been about hepatitis C, they may have covered other areas.

And the other element, of course, is that anything that Christine Dora was going to put in the report relating to the medical facts, then I was there to cross-check them.

Q. Now, we can see there being identified a concern arising from Professor Cash's papers about ALT testing, and that not having been considered, the inference may be, sufficiently timelessly. We see Ms Dora commenting that:

"The Haemophilia Society are not going to ... rest if we put nothing in about testing."

Then if we can just go to the top of the page there's a handwritten note, is that your handwriting, where it says, "X is a balance between"?

A. I can't actually be sure. It may be, but I don't think it is.

Q. In any event, it says:

"X [and that's the paragraph about The Haemophilia Society not resting 'if we put nothing in about testing'] is a balance between sticking to what we were asked to do & anticipating further demands. I am still inclined not to cover testing in the body of the report."

Regardless of what the remit of the report was, and whether testing fell within the existing remit or not, was the concern about what Scotland had or hadn't done in relation to ALT testing, something that was identified and flagged up as an issue for the minister to consider, as far as you can recall?

A. I can't recall, and we spent some time on ALT testing yesterday, and I gave you my views on its lack of sensitivity and specificity, in particular, in terms of picking up non-A, non-B hepatitis. So I think we probably regarded ALT testing as an irrelevance in the

context of tying to understand what efforts were made by SNBTS to produce a non-A, non-B safe product in the mid-1980s.

MS RICHARDS: Sir, I trespassed into break territory, so perhaps we could take our morning break now.

SIR BRIAN LANGSTAFF: Yes, well, we'll take a break until 11.50. 11.50.

(11.19 am)

(A short break)

(11.50 am)

MS RICHARDS: Professor Keel, I'm going to go back to a document which I had wanted to look at earlier, and we didn't have it and it's entirely my fault because I gave the wrong reference. So the correct reference is WITN2287021.

And if we go to the second page, top half of the page, we can see these are the notes of a meeting between The Haemophilia Society and the Scottish National Blood Transfusion Service, 25 November 1999, and then we can see a number of attendees on behalf of The Haemophilia Society, and then on behalf of SNBTS, and then you and Thea Teale there on behalf of the Scottish Office.

This was taking place in the course of the investigation and, as I understand it, the suggestion of

a meeting between SNBTS and the Haemophilia Society was something which arose out of one of the earlier meetings as an idea that this might be a good thing to do.

A. Yes.

Q. If we go to the third page, there's just a couple of points I wanted to pick up. So the bottom half of the page refers to a presentation by PF, so that's Peter Foster, and then paragraph 3.1 we see PD, that's Philip Dolan, for The Haemophilia Society, raising the question of who determined the operating policies for haemophilia provision.

I just wanted to ask you about what you say here and on the following page. In the third bullet point it's:

"AK [that's you] also advised that national policy in matters relating to donor testing were the responsibility of UK ministers. They took advice from a UK advisory committee the Advisory Committee for the Virological Safety of Blood, ACVSB."

Then there's reference to the membership of ACVSB.

Then if we go over the page, if we look again at the bottom half of the page, about halfway through the paragraph that's on the screen it says:

"Several questions were asked on why ALT testing was not introduced in the UK."

There's a response from BMcC [that's Brian McClelland] and then you're recorded as saying:

"AK advice that the ACVSB had considered this issue over a number of years. On each occasion, they agreed that ALT testing should not be introduced because of the poor specificity of this test."

Now, Professor Keel, the ACVSB only met for the first time in 1989, in April 1989. So it would appear that what you're setting out at the bottom of that page may not be correct. What was the basis of your understanding that the issue of ALT testing had been considered over a number of years by ACVSB?

A. Well, if they met for the first time in 1989, then 1999 we're talking about ten years later. So I think my statement could be considered accurate.

Q. Do you know or did you know in 1999 what consideration had been given and by whom to the question of surrogate testing in Scotland in the 1980s? It wasn't the ACVSB in the '80s, because it -- unless you're just talking about 1989. Did you have any knowledge of what other bodies or organisations or individuals had considered that issue?

A. No, I can't recall having any knowledge of them.

Q. And this deals with ALT testing, and of course that may be the specific issue that had been raised by those

present. But another aspect of surrogate testing is HBc testing. Was that something which was thought about in the course of the investigation at all as far as you can recall?

A. Well, it had been -- the remit of the investigation agreed by The Haemophilia Society didn't cover surrogate testing. So I think the answer to your question is no.

Q. I don't know what independent recollection you have of this meeting at this distance of time, Professor Keel, but if we go back to the second page --

SIR BRIAN LANGSTAFF: Just before we do, can we come back to that, the page we were on, please? And let me ask you just a couple of questions, Professor, about the last bullet point on the page.

ACVSB, having met for the first time in 1989, by which time a test was being promoted by the Chiron Corporation in the United States, and rapidly was becoming available in the UK, albeit a second generation, ultimately, can you help at all with why the ACVSB might have been considering ALT testing in the first place? After all, if there was a specific -- a test specific to the virus in question, why would you want a surrogate test?

That's the first question.

A. Yes, well, you'll forgive me because, of course, this

comment, and ACVSB's first meeting of course pre-date my Government employment, so I have no direct knowledge of what exactly discussions were in ACVSB. You're absolutely right, there must have been other bodies. There would have been other bodies in the departments of health which preceded ACVSB who considered issues of surrogate testing, and I guess that my comment here was not as precise as it might have been. I should have said ACVSB and predecessor committees, have considered this issue over a number of years.

SIR BRIAN LANGSTAFF: I see. That explains that, thank you.

The second question is that what is being envisaged for ALT testing here, I think, is use as a form of screening test. That would be right, would it?

A. Yes.

SIR BRIAN LANGSTAFF: If one's having a screening test, the object of the test is to screen out anything which might be the infection in question, am I right about that?

A. You are.

SIR BRIAN LANGSTAFF: So why does the poor specificity of the test, rather than the poor sensitivity, matter directly?

A. Well, if the test is positive, not because of non-A, non-B hepatitis or whatever organism, then you could

consider it a false positive. It's elevated for other reasons, and I've already referred to them on a number of occasions, you know, other hepatitis viruses, other affections, alcohol, obesity, et cetera.

So that would be considered a false positive in the context of a screening test aimed at identifying non-A, non-B hepatitis.

SIR BRIAN LANGSTAFF: I understand. So what you are summarising here, or at least -- it's a minute, of course, so may not represent everything that you said, but what you are summarising here was the problem of confirming, as it were, a positive test, of eliminating false positives --

A. Yes.

SIR BRIAN LANGSTAFF: -- albeit they'd been screened out, the -- you're left with the donor who is told they're positive when they're not, and that may cause problems. I understand. Right, thank you very much.

MS RICHARDS: If we go back to the second page, please, and the list of attendees. You'll see, Professor Keel, that the list of attendees for the Haemophilia Society includes B Wright, Bill Wright, and Mr Wright has told the Inquiry of his recollection of this meeting, of surprise being expressed by SNBTS representatives that someone could be infected as late as 1986, and with the

response being, "Well, he's sitting here". Because that was Mr Wright's own situation.

Do you have any recollection of that, or of being aware that somebody infected in the very period that you were investigating was there?

A. I've no recollection, and I may point out this is Mr Wright's recollection of the meeting. I don't recall that being discussed.

Q. Can we turn, then, to March 2000 just to complete a chronology of events in relation to the investigation. SCGV0000171_053.

This a minute from you, 23 March 2000 to Ms Dora, and you're providing your comments on the draft report that she's produced.

If we could just go down the page to paragraph 4. You say in paragraph 4:

"As far as the Conclusion is concerned, I agree with John that this should be made for definite."

"John" I think is Mr John Aldridge; is that right?

A. Yes.

Q. What was his role?

A. I think he was director offer finance at that point.

Q. Then you suggest that the paragraph could "refer to the fact that comparable developments in the commercial sector usually take significantly longer than SNBTS's

development".

I'll come back to that in a moment but if we just go over the page, you then say this:

"Finally, as far as financial help is concerned, you will need no reminding that DH are very nervous about this. Mike McGovern made a point of bringing the issue up with me during a recent unrelated telephone conversation, during which I reassured him that we recognised that compensation in this area would set a very difficult precedent for the Government, given the many claims for compensation that it receives."

Now, bearing in mind Ms Dora's role was to investigate whether there had been fault on the part of SNBTS or negligence on the part of SNBTS, and to reach conclusions, why was it relevant for you to remind her that the Department of Health was very nervous about the possibility of financial help?

A. Well, because it was a material issue that was discussed -- being discussed at that time. I mean, it's not directly relevant to the investigation but clearly from previous documents we have seen that the Scottish Office, Scottish Executive subsequently, had over the years already done some pre-planning around the impact that setting up a compensation scheme would have. Not expecting that that would be the case, but in

preparation for that, should it be an eventuality.

Q. If we turn to the draft report, it starts on page 3., we can see that there are -- and this continues through the draft -- a number of -- if we go to the bottom of the page, please, Lawrence -- a number of handwritten comments and then there are deletions and additions that have been suggested in typewritten form, and we see an example of that in paragraph 4.

Just so that we can understand who's providing what comments, were your comments the handwritten ones or the typed ones, do you know? We can go over the page if it might help.

A. Yes, please.

Q. Yes, so if we go over the page, there's some -- and can we have a look at the next page as well? Can we put this page and the following one on screen at the same time? It might help Professor Keel.

So I don't know whether that assists in working out which comments you authored or not.

A. Could you show me page 3 in large, please. I can't really see it clearly.

Q. Yes, of course.

It's page 3 internally, so if you go to page 5 electronically, Lawrence.

Does that assist at all, Professor Keel?

A. I think -- I think the retyped text probably came from me.

Q. I'm not going to go through the detail of the suggested amendments. It was just to try to understand who was amending what.

In terms of the conclusion that you'd wanted strengthening, if we go to page 11, bottom of the page, so the "Conclusion":

"The episode of HCV infection of haemophiliacs is devastating for the individuals infected and their families, and is a matter of public distress and regret. While ..."

And I'm just going to read out the amended text:

"While the facts suggest that those involved in the manufacture of blood products made every effort to develop products free of viral risk, it is undeniable that these efforts took some time to come to fruition. However, to talk in terms of people being exposed 'longer than they should have been' is not accurate."

Then there's a reference to that being "expanded in the light of comment in covering minute". And then at the bottom of the page there's a reference to:

"Scientific knowledge ... developing rapidly during the period in question. From the available evidence, SNBTS appear to have acted ..."

And then there's text "as quickly as possible", somebody else has crossed that out and suggested "reasonably":

"... under the circumstances."

And then I think the suggestion is the words "as quickly as they could" go in there:

"... to develop a Factor VIII product free of the risk of Hepatitis C."

Can you recall why it was you wanted that paragraph strengthened?

A. Well, the context in which this investigation was taking place, the period that it was looking at was one of fairly frenetic activity in the protein -- in the fractionation of blood products world. You know, there is evidence which is cited in the report from the US and other European countries of fractionators really struggling to understand what processes could be safely applied to factor concentrates to render them virus free, without making them unsafe or reducing the active ingredient by such an amount that, you know, there wouldn't be enough product to go round.

So I wanted this paragraph in, to make sure that everybody knew that it wasn't just the UK that was struggling to achieve safety, viral safety, in blood and blood products at this point; it was a worldwide issue.

Q. Then if we turn to SCGV0000171_077, this is a minute from Christine Dora, 4 April 2000 -- that appears on page 4 but we don't need to go to that -- to the Minister for Health and Community Care. We can see, if we just look at the purpose of the minutes, so if we go a little further down the page, it's to "let the Minister see and comment on a draft report", and then various matters in which the minister's approval was sought in terms of the process of publishing the report, and so on.

I just want to ask you about something that's on page 2 of the minute, which was copied to you. It's paragraph 7., so towards the bottom of the page, where Ms Dora says this:

"The second part of our remit was:

'"to examine evidence about the information given to patients with haemophilia in the 1980s about the risks of contracting HCV from blood products'."

Then Ms Dora says this:

"This was much more difficult to research than the first part, since we could not find many papers from so long ago. However, Haemophilia Centre directors told us verbally that what they could remember, and we have detailed this in the report. I believe some of them are worried about possible litigation, and we have been

unable to obtain some of the papers they have mentioned. I am willing however to accept that there was no evidence that clinicians had a policy to deliberately mislead their patients about the risks of using Factor VIII."

Now, Professor Keel, would you accept that the issue that Ms Dora addresses in that final sentence of paragraph 7, whether there's a policy of deliberately misleading patients, is a narrower issue than the broader question contained within the remit, which was to look at what information was given to patients; it's a significantly narrower issue, isn't it?

A. Yes, I agree.

Q. Why was it, do you know, that the remit having been that this broader issue, reflecting what The Haemophilia Society was saying to the Department, that only the narrower issue was answered?

A. Well, I think that the broader issue is perhaps better addressed in the report but, in relation to this paragraph, I think Christine Dora is reflecting the difficulty that we had in obtaining the papers that the Haemophilia Directors said were available during the period in question, and it's not surprising that there was that difficulty, given the gap between the activity we're talking about and the report in 2000.

Q. You've told us already that the Department essentially accepted at face value what the Haemophilia Centre Directors said about their approach to providing information to patients. We have here Ms Dora setting out her belief that some of them were worried about possible litigation. Would that not ring alarm bells as to whether the Department could safely simply rely upon what the directors were saying on this particular issue?

A. Why would it ring alarm bells?

Q. Because if they're worried about possible litigation they may be less than forthcoming about what information was or wasn't provided to patients.

A. Well, that may or may not be the case, but I think they could be worried about possible litigation and still disclose all of the information available to them. The two are not mutually exclusive.

Q. The report itself, in final form, was published in October 2000 but I'm not going to take time going through that with you, Professor Keel, and we can pick that up with Ms Deacon later in the week.

I want, then, to look at some documentation and decision making from 2000 onwards on the issue of financial support for hepatitis C. Some of it overlaps with the time period of the investigation. So if we start with DHSC0032292_045.

This is an email chain in April 2000, so it's after the first draft of the report has been produced and it's while the report is being finalised. If we go to the second page, we can pick up the email chain. So the bottom half of the page we have, if we go just up a few lines, please, Lawrence, further up, so I can see who the email -- thank you, perfect.

So we can see Ms Dora is sending an email on 19 April to you and to a number of others and she says in the body of the email:

"Thanks to those of you who have commented up to now on my attempts to draft a report. Please find attached what I hope is now a pretty final draft Ministerial submission with recommendations on handling."

Then if we go to the top of the page, we've got an email from John Aldridge, and we can pick it up in the third paragraph of the email, where he says this:

"I note the issues on which you are seeking the Minister's views. I think she should be pointed very firmly in the direction of not agreeing to compensation or special priority treatment for Hep C sufferers who may have been infected by NHS treatment. That would have huge implications for other areas of NHS activity, and would, I am sure be resisted strongly by colleagues

in the other parts of the UK and the Treasury as well as by me!"

Then if we go to the first page, we can see there's a name there about a third of the way down the page, Francis Gibb. What was the role of Francis Gibb within the Department?

A. He wasn't in the Department, he was chief exec of the Common Services Agency.

Q. We can see, if we just look -- I'm sorry.

A. Sorry, I was just going to add: within which SNBTS was situated.

Q. Then we can see the comment from Mr Gibb, so just below the list of attendees, is this:

"I agree with these sentiments as they are in tune with the advice we gave at the meeting. Beware of going down a path which could have serious repercussions for the future. We could open the floodgates if we are not careful."

Do the views there expressed by Mr Gibb and Mr Aldridge reflect the general thinking in the Department in Scotland at the time, which was, essentially, fundamentally opposed to financial support or compensation for those infected with hepatitis C?

A. Yes, for the reasons that we discussed in some detail yesterday, setting yet another precedent, which would

mean that other groups -- and I mentioned some of them yesterday -- who felt that they would be entitled to compensation would not being allowed access to it. So, yes, this was the general feeling in the Department at that point.

Q. If we go to your statement, WITN5736003, page 44, you were referred to that email exchange and then we can see your answer at A76. You say:

"These views were held in SE [so Scottish Executive] and the health department around this time ..."

Then in paragraph (b) you set out your view:

"I agreed that the establishment of a scheme for compensation of HCV infected patients would set a dangerous precedent."

Then you go on to explain about other possible categories of patients, and (c) says your:

"... advice to Ministers would have been along the lines outlined above ..."

Now "dangerous precedent" is, it might be said, quite a strong way of putting it. Does that reflect your own strength of feeling at the time?

A. Yes.

Q. Then if we could go, please, to SCGV0000171_031.

If we look at the second page, we'll see -- we

don't need to look at the detail of it, but this is part of the same email chain, so we've got Christine Dora's email at the bottom, John Aldridge's response at the top.

If we go back to the first page, we can see, at the bottom half of the page, Ms Dora's response to Mr Aldridge. She says this:

"I note what you say about pointing the Minister away from compensation. I'm intending to leave the arguments about compensation and other possible action to a future minute, for the sake of digestibility. I agree that the arguments tend against the award of compensation (or hardship payments). The Macfarlane Trust for people infected with HIV is an uncomfortable precedent in this respect, so we'll need to marshal the arguments carefully. I also understand that Lord Hunt at the Dept of Health has been reflecting on the idea of a possible hardship fund for Hepatitis C victims ..."

Then this:

"... I really think it would be wise to have both Ministers discuss and at least decide whether to operate in step with each other (although I am hoping they will decide the same thing and it won't be compensation)."

Now this is the author of the investigation

report. Why is it part of the role -- or is it part of the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself?

A. No, I can't say I'm concerned by it. You have to remember, compensation was not part of the remit of this internal investigation. However, it was foreseen, and had been for many years, that compensation was an issue, and could become an even bigger issue following the publication of the report. I think Christine Dora was merely sharing in the general sentiment around the Departments of Health up until that point that going down the route of a compensation scheme, where no negligence had been demonstrated, would be ill advised.

Q. If we move forward from April 2000 to February 2001, and go to SCGV0000174_068, this is an email from Christine Dora, again 19 February 2001, to a number of recipients, including you, and it says -- records a conversation she's had with Charles Lister from the Department of Health in London, and then the first paragraph says this:

"Lord Hunt has apparently agreed to meet Lord Morris (President of the Haemophilia Society) and others tomorrow ... to revisit the idea of compensation

for Hep C positive haemophiliacs. I understand this may be prompted by political considerations; I also however understand that Lord Hunt inclines naturally towards sympathy for the plight of the affected haemophiliacs. Officials' advice has not changed, but they have been asked to put together costings for various options and to offer an assessment of the extent of any precedent which might be created."

Then this:

"Charles and I acknowledged that if one of the 4 administrations should crack, it becomes presentationally much more difficult for the others not to, and he said he would keep us informed."

Now, of course, this is two years into -- or more -- into devolution by this point in time, and Scotland has responsibility for its own health issues and is free to take its own course. What, if anything, do you recall about the concern of holding a common line between the four administrations and the presentational difficulty referred to there? Do you recall that being discussed?

A. Well, I can't specifically recall the discussions, but reading this and other papers has reminded me that it was indeed a matter of concern as to whether Lord Hunt was going to deviate from the previously agreed position

across the UK that there would not be a compensation scheme. So I recall that element of it, but specific discussions, no.

Q. Then just for the sake of completeness in relation to this document, the bottom -- we can see some handwriting there, and then the bottom half of the page includes some other that handwriting:

"This gives me enormous concern. Please arrange for urgent contact to be made with Philip Hunt's office ... emphasising that we have withstood enormous pressure on this issue -- not least after discussions directly with him -- any movement from the previous position, without discussion with other administrations, would, in my view be quite unacceptable.

"Happy to have conversation directly if [necessary]."

I think there's another email from this time which might suggest that's coming from the minister or the minister's office. In any event, that is not your handwriting?

A. No.

Q. If we go to SCGV0000174_066, we can pick it up in the middle of the page with an email addressed to Christine from Karen which summarises those handwritten comments:

"The Minister was grateful for this -- although

she commented that it gave her enormous concern", et cetera.

Which is why I inferred that that handwriting is by or on behalf of the minister.

If we just go to the top of this email, just to see where we get to within February 2001, we can see Sandra, presumably Sandra Falconer, to Karen saying:

"I have been informed by colleagues in DH(E) that Lord Hunt made it clear to Lord Morris and Eddie O'Hara MP that the Government had decided against compensating haemophiliacs with HCV when Frank Dobson held his review ..."

Which we know was 1998.

"... and that the subject is now closed."

Then the response at the top of the page:

"The Minister will be vvv relieved!"

Would it be right to understand that as at February 2001, the position in Scotland is still set firmly against financial support for those infected with hepatitis C from their treatment?

A. Yes.

Q. Now as you'll recall, Professor, the Health and Community Care Committee of the Scottish Parliament undertook their own inquiry of forms and produced a report into 2001.

That's at MACK0001929_001.

I don't propose to go through the detail of it. We can see the title of the report there.

If we just go to page 23, we can pick up what the Committee said about financial assistance. So you'll see, Professor, the heading "Targeted financial and other assistance regardless of negligence". Then the report reads, in paragraph 83:

"The more that we as a Committee have investigated the issues raised in the two petitions, the more our conviction has grown that what lies behind both is a fundamental question of fairness and consistency.

"84. The individuals who petitioned us contracted a serious and incurable virus many years ago as a result of medical treatment, or are relatives of those people. Understandably, they feel wronged, and have campaigned over many years for recognition and redress. To these individuals the relatively narrow question of whether or not any particular agency or individual within the NHS has been legally negligent, while important and worthy of exploration, is of secondary importance. What it they consider more important is that the Executive recognise what they would classify as the moral case for providing support, and that it provides the concrete practical assistance that they consider would be fair

and appropriate."

Then the paragraphs go on to set out in 85 and 86 the general principle about not paying out unless there's negligence and then referring to exceptions within that, the Consumer Protection Act, and then in paragraph 86 the Macfarlane Trust.

If we go over the page, and pick it up at the bottom half of the page -- no, in fact, I'm sorry, could we pick it up at paragraph 88, first of all, towards the top of the page:

"The example cited by [and the name is redacted but it's someone on behalf of The Haemophilia Society] is a simple and striking one. It is difficult to disagree that it highlights the inconsistency of the current position, especially given that the effects of hepatitis C can, when severe, be practically as devastating as those of HIV."

Then paragraph 90 says this:

"Having considered the issues raised in the petitions, the Committee has become persuaded by what we classified as the 'moral' case for providing financial assistance to those individuals infected with hepatitis C through blood transfusions."

Then the Committee goes on to say that they're not advocating a transition to a complete no-fault

compensation scheme.

At paragraph 91, they say this:

"The Committee therefore wishes to stress the narrowness of the view to which it has come. We are not advocating the principle that all injury caused through NHS treatment should be compensated. Nor are we asking the Executive to establish any new, wide-ranging precedent on the management of risk in clinical decision-making. Instead we simply seek to correct an inconsistency in the operation of an already created and narrow precedent; namely the precedent create when the Macfarlane Trust was set up. We do not envisage that any ad hoc decision to provide financial or other help to individuals infected with hepatitis C through NHS treatment, would necessarily require the NHS to change any of its current medical policies and practices on risk arising from treatment."

So, professor, it's right, isn't it, that the Committee did not share your view and the Department's view that this would establish a dangerous precedent?

A. Yes, I think you can certainly conclude that from their report.

Q. Then if we just go to the "Recommendations" on page 26, we can pick it up at the bottom of the page:

"We recommend that the Executive set up

a mechanism for providing financial and other appropriate practical support to all hepatitis C sufferers who have contracted the virus as a result of blood transfusions provided by the NHS in Scotland, or which involve blood or blood products produced by the SNBTS."

Then if we go to the next page, I won't read the recommendations in full, but paragraphs 2, 3 and 4 provide as follows:

"2. We recommend that this mechanism for providing financial and other support comes into operation within a period of twelve months.

"3. The level of financial assistance awarded to any claimant should be determined on the basis of need, having regard to the physical or psychological loss individually suffered, and should include redress for practical difficulties such as the inability to obtain an affordable mortgage or life insurance."

Then:

"4. In determining an appropriate package of assistance, and in particular in clarifying what practical help can be offered, the Executive should consult hepatitis C sufferers -- both haemophiliac and non-haemophiliac."

Now, before I ask you about that, can I just show

you an email you sent in response. It's at SCGV0000247_094. This is from you, 3 October 2001, to Mrs Falconer, copied to others. Paragraph 1:

"You were right to emphasise in our initial response to this that we will require time to consider its recommendations! No surprises in the sense that we were expecting the Committee to recommend compensation for those who have contracted Hep C through blood transfusion and fall outside the terms of the Burton Judgment."

Then you go on to make number of points. I don't think I need to take you through those. You suggest in paragraph 2 that the Committee has underestimated the difficulty in determining levels of compensation based on need.

What do you recall of your response to and your thoughts about the Committee's report? I don't mean some of the finer points of detail, but the broad thrust of it, which is the Executive should set up a scheme for compensation and recommending something which went directly against the policy which the Executive and its predecessor had maintained for a number of years?

A. Well, a number of observations if I may. First of all, going back to the report, it talks about haemophiliacs and probably recipients of blood transfusion feeling

wronged. As I pointed out yesterday and again today: those groups were not unique. There were other groups which we were aware of, and doubtless others that we're not aware of, who were interested in pursuing compensation. So the report, in using that phase, doesn't acknowledge the wider context and possibility -- nay, reality -- that others would come forward if a compensation scheme was set up for this group of individuals.

I've commented in my -- in paragraph 2 here on how you would go about setting up the difficulties in going about setting up such a scheme based on need. How would you define physical or psychological loss at individual level? I could already envisage real difficulties in defining categories of patients and the level of their suffering to be compensated.

So I guess my reading of the report was that it was slightly naive in its assumption that you could just set up a scheme and that would be very straightforward.

And I also think that their conclusion that they didn't want to compensate everybody who had been injured at the hands of the NHS, in their view -- they didn't want a compensation scheme that covered everybody, and that seemed to me rather illogical in singling out hepatitis C infected individuals as a special category

for compensation when there were other groups of patients out there who would feel equally wronged and equally eligible for such compensation.

Q. And as far as you can recall, were your views about the Committee's report shared by your colleagues within the Scottish Executive and in particular within the Health Department?

A. As far as I can recollect, yes.

Q. Now the Government, as we know, the Scottish Government, didn't proceed to implementation of the Committee's recommendations. Instead, it set up what's been referred to in the Inquiry's hearings as the Ross Group or the Ross Committee. So the expert group under the chairmanship of Lord Ross.

Do you know why the Government went down that route rather than simply proceeding to implement the recommendations of the Health and Community Care Committee? And in particular, are you able to comment on a submission that may be made to the Inquiry that that was a delaying tactic?

A. My recollection of the setting up of the Lord Ross expert group is I really had very little to do with it. This was a matter for officials and legal advisers to be fully involved in. You would need to ask ministers what was in their minds in terms of setting up the expert

group. Part of it certainly was, as far as I could recollect, to get a better handle on the difficulties I've already mentioned, and are covered in paragraph 2 here, of defining levels of compensation and I think at least part of the expert group's task was to try to better understand those difficulties.

Q. Can I ask you then to look at something you say in your witness statement more broadly on the question of compensation.

It's WITN5736003, and if we could go to page 60 and it's the bottom half of the page.

You were asked in question 105 about some emails regarding the costs of a scheme. I'm not going to ask you about that. But you say in paragraph A105, third line:

"I regretted that the Burton judgment had forced a move away from the previous principal *[sic]* that no compensation was due where there was no negligence proven on the part of NHS."

Now the expression of regret about the Burton judgment is not, I think, a view that the Inquiry has heard from others so far in the course of its hearings. Why did you feel that way about a judgment of the High Court?

A. Because it seemed logical to me that the previous

principle, that no compensation was due if there had been no negligence proven, was a sound one. And the Burton judgment clearly opened -- or exposed the NHS to much wider, a much wider range of liabilities ie, providing compensation where no negligence had been proven.

Q. Now, the Ross Committee or the Ross Group produced its preliminary report in, I think, September 2002 and it's HSOC00033499. I'm not going to take you through the detail of either the preliminary or the final reports, Professor Keel, but is it likely that you would have read these reports at the time?

A. Yes.

Q. What was, as far as you can recall, your view about what was being recommended by the Expert Group, in terms of compensation/financial support?

A. Well, I have no direct memory from that time. I mean, I've obviously read papers referring to the Expert Group and, certainly, the levels of compensation being proposed were perceived as rather high and therefore unaffordable. But I can't say that was my original thought. It's been derived from reading the papers.

Q. If we look at SCGV0000251_018, and we go to the second page, this is from Bob Stock, 29 January 2003, to the Minister who, by now, is, I think, Malcolm Chisholm.

It's copied to you, your name is on a long list of recipients on fourth page. We can see what it records in paragraph 1 is:

"To record and confirm the decision taken today to inform the Health and Community Care Committee that the Executive would be prepared to fund a scheme that would make lump sum payments to those who now have Hepatitis C as the result of receiving blood, blood products or tissue from the NHS in Scotland."

Then reference is made in paragraph 3 and 4 to there having been a brief discussion at Cabinet, and the costing of a scheme, this is paragraph 4:

"On the basis of making lump sum payments of £20,000 to all those who now have Hepatitis C -- with a further £25,000 to those who have cirrhosis, liver cancer or liver failure."

It's said:

"This was put forward, with the agreement of the First Minister, to the Committee today."

So in terms of the chronology of events, Professor Keel, we have the preliminary report in September 2002 and then, whilst the final report is awaited -- and it was published in, I think, March 2003 -- the Minister makes an announcement along the lines that we see referred here of a willingness to

fund a scheme that would make payments along these lines.

Do you have any recollection of what your involvement in that decision-making process was and in what was obviously a change of position on the part of the Scottish Executive?

A. I think my involvement was minimal. Clearly this was a political decision made in Cabinet, and I don't recollect being involved in any of the discussions around it.

Q. Can I ask you to look at a document at DHSC0020742_071, please. I think that's the right reference, Lawrence.

This is to take you back in time to 2001. If we go to page 3, this picks up on the Burton judgment, and we can see the first paragraph reads:

"In March 2001, the High Court in [England] awarded damages", et cetera.

That's a reflection of Mr Justice Burton's judgment. Then the second paragraph says this:

"Following the CPA High Court ruling, the Scottish Executive announced in August [August 2001] a decision to settle outstanding legal actions brought under the Act by Scottish blood recipients infected with hepatitis C."

Then there's a reference to the Health and

Community Care Committee report.

So bearing in mind that decision to settle outstanding legal actions brought under the Consumer Protection Act, can I now ask you to look at a different document which I hope you were provided with overnight, Professor Keel. It's a very short document.

SBTS0000357_059.

This is from Bob Stock to Susan Murray, you, Steve Lindsay, Brian McClelland, copied to Lynda Towers and Angus Macmillan Douglas. The date is 29 June 2001, and it's then headed "Scrutiny of Outstanding claims", and it says:

"I propose primary recipients of this message [which would include you] meet on Monday [2 July] to go through the list of court actions which has been prepared by CLO/SNBTS. The main purpose will be to endorse the proposed categorisation into those where CLO will enter into discussions with the legal representatives of claimants -- and those where they will not.

"Hopefully this will be a straightforward matter but the Minister was anxious that the list is thoroughly scrutinised (particularly by [Scottish Executive] solicitors) before any letters are sent out."

It's a limited piece of material upon which to

prompt your memory, Professor Keel, but do you have any recollection of your involvement with the process referred to here of deciding how outstanding claims should be dealt with?

A. No, I don't and clearly I was only going to be at the meeting for half an hour. So I think I infer from that that my involvement was minimal, and not particularly material to the discussion around eligibility of these litigants under CPA to have a claim settled.

Q. Leaving aside this particular document, do you know whether you had any broader involvement with providing advice from a medical perspective about how individual claims should be assessed and what approach should be taken to the payment of compensation or otherwise?

A. No, I suspect that this discussion around whether they should be settled or not was entirely on legal grounds and not medical.

Q. We can take that down, thank you.

Now, in relation to events in 2003, Professor Keel, we've looked at that document that refers to the announcement in January 2003 of two levels of financial support, the payment of £20,000 and the payment of £25,000. I'm not going to take you through lots of documents relating to 2003 but if I just give you a very brief chronology and then I'll ask you about

it.

The Inquiry knows from other evidence that there were discussions between Mr Chisholm and the Secretary of State for Health within the UK Government, at that point Alan Milburn. Advice was sought from Law Officers as to whether Scotland could set up a financial support scheme using its devolved powers or whether this was a reserved matter.

Then in June 2003, Mr Milburn was succeeded by Dr Reid, John Reid, as Secretary of State for Health in the UK Government, and he took a different view in relation to what the position should be in England, resulting in a press announcement at the end of August 2003 that England would be setting up a scheme.

Did you, as far as you can recall, have any involvement with that process, so the process of going to the Law Officers for advice, or discussions as to what might be the position in England and the effect that might have upon the schemes or a scheme in Scotland?

A. I'm afraid I've no recollection of being involved in those -- in that particular part of the chronology.

Q. Did you have any understanding in 2003 as to whether that announcement we looked at, in January 2003 of the 20,000 and the 25,000, was it your understanding that

that was -- fixed the parameters of a scheme in Scotland, or was the position about what the payments might be still -- still flexible and open for the further consideration?

A. I don't recall. I mean, I imagine I thought that that was broadly the framework with which we were going to proceed. But with John Reid's change of direction south of the border, I suspect the figures were further discussed and refined.

Q. But you don't recall being party to those discussions?

A. I don't recall being part of that.

Q. You did, however, I think, have some involvement in discussions about the medical trigger for the second stage payment. We can look at two or three documents in that regard, but before we do so, what do you recall about the decision-making process in relation to that?

A. Well, clearly the second payment of £25,000 on the diagnosis of cirrhosis was a key point in determining the level of payment.

Now, the gold standard -- there is no other test other than liver biopsy that really meets the criteria for a definitive test to diagnose liver cirrhosis. And I think I say in my written statement -- or highlight the issues that that would have given rise to for the haemophilia patients in particular. Liver biopsy is

a highly invasive medical procedure, which carries with it the risk of haemorrhage, which clearly in haemophilia patients would be extremely serious. So it was -- would not be a routine -- or an investigation routinely embarked on in that group of patients.

So I had discussions with, I recall, Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any other non-invasive test that might act as the trigger for that second payment.

My recollection is that discussions with Peter Hayes and more widely failed to yield any real substitute for liver biopsy. So I think ultimately the conclusion was that any diagnosis of cirrhosis would have to be based on the available clinical information from the consultants involved in that patient's care, and their feeling, based on other, less specific tests, as to whether the individual did indeed have cirrhosis.

So it was not a clear-cut trigger point, particularly for haemophilia patients.

Q. I think we can see an example of the discussions that were held at SCGV0001034_014. There's certainly some earlier exchange with Dr Hayes in February 2003. This now is, I think, October 2003 and it's reference to a meeting on 10 October 2003.

If we go over the page, if we pick it up at the bottom of the page -- this is a general meeting about hepatitis C but then an issue is picked up at the bottom of the page where it says:

"Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of compensation, having contracted their infection through infection *[sic]* blood or blood products. Dr Keel explained that she and Bob Stock were to meet with colleagues in DH to work out a trigger for the 2nd level of payment which could include up to 580 patients with 30% of these being paid in the first year. She explained that it was not going to be easy to define the trigger and that whatever was agreed would need to be agreeable to the Haemophilia Society."

Then if we go to just, I think, one further document, SCGV0000265_004, we've got here a meeting which is then specifically focused on the ex gratia payment scheme. This is 14 October 2003. It refers to a number of people being present and the purpose of the meeting is to discuss the medical trigger point for the proposed higher payment.

Now, I'm not going to go through the detail of what was discussed, but do you recall whether there was, at this point in time, a series of meetings to discuss issues relating to the parameters and the working out of the ex gratia payment scheme or whether there were just one or two such encounters?

A. I honestly can't remember.

Q. One of the issues regarding the scope of the ex gratia payment scheme was the inclusion or otherwise of natural clearers. Do you recall any involvement with that decision-making process?

A. Well, I would have been involved because clearly it's a clinical matter but, I mean, a lot of my recollection in this area is -- has been jogged by reading the papers, rather than actual recollection of the events themselves.

Q. If we just look at one document, or possibly two, on natural clearers, DHSC0004510_080, "Meetings of Skipton Fund Teleconference -- 29 September 2004", and we can see there are a number of attendees from different departments, so you're there on behalf of the Scottish Executive, as is Mr Stock. There are representatives from the Welsh Assembly and from the Department of Health in England, with an apology from the Department of Health and Social Services in Northern Ireland.

If we go to the heading "2. 'Natural Clearers'", we can see reference to Professor Lee being invited to speak, and that's obviously Professor Christine Lee at the Royal Free Hospital, regarding her concerns about inconsistency in the reviewing of natural clearers by clinicians.

The issue I have been asked, in particular, to raise with you, Professor Keel, is why it was that Professor Lee, a haemophilia clinician, not a hepatologist or virologist, was being invited to address the meeting on this particular issue, and what weight was given to her views on the question of whether natural clearers should receive payments or not -- sorry, in deciding whether natural clearers should receive payments or not?

A. Well, again, I infer this from reading the document that Christine Lee was concerned about inconsistencies, I think, which related to the factthat, yes, further down at 2.4, very, very late clearance of hepatitis C. The 20 per cent who naturally clear the virus usually do so within the first six months. So this case that she was describing is very unusual and I imagine that she was concerned about that and wondered whether such an individual should be compensated or not, because the majority of natural clearers were not eligible for the

first payment of 20,000.

Q. If we just look at -- so that I can finish this topic before we break -- one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance.

If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim forms rather than reject them", and had asked for further clarification.

Then he says this:

"We have asked them to include the following explanatory paragraph in the letter:

"'patients would only be eligible for the first payment if (i) there was evidence they had developed chronic hepatitis C infection but this had resolved spontaneously (thought to be a reasonably rare situation) or (ii) had developed chronic hepatitis C infection but subsequently cleared the virus as a result of treatment. Patients who had, or were thought to

have, eliminated the virus in the acute stage, when they would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness."

The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice?

A. I'm not at all sure that that's the case, but I think this part about (ii) the Christine Lee issue, where clearly she wanted to know whether her patient, who had cleared the virus after 20 years, was eligible for treatment, and the -- for payment. The conclusion was yes, because obviously during that lengthy period, the patient was suffering from chronic hepatitis, even though eventually he or she -- well, he cleared it.

So I think that whoever crafted this, and I don't think it was me, would be drawing on that earlier

meeting with Christine Lee and ensuring that those unusual patients who experienced chronic infection but eventually cleared the virus, were given payment, first stage payment, because they'd been suffering from a chronic infection over a long period of time.

Q. If we just look at DHSC0004520_057 -- I'm sorry for trespassing into lunch but I probably should have taken you to this first, and that's my fault, Professor Keel.

This is a series of emails, and if we go to the third page there's an email from Bob, Bob Stock, to "Zubeda", and that's Zubeda Seedat in the Department of Health, London, and it says:

"I have discussed this with Aileen and offer the following amendments."

I don't think we can tell from this email exchange exactly what the amendments are, and then we see the passage set out and reference in that last sentence to "robust medical evidence".

So it would appear from this that you had had some discussion with Mr Stock --

A. Yes --

Q. -- and provided some advice on this issue?

A. It would definitely appear that I contributed to the paragraph that we looked at previously. I don't think I wrote the whole thing ab initio, and it was an attempt

to clarify what was a confused situation, certainly in the context of Christine Lee's experience.

MS RICHARDS: Thank you.

Sir, my apologies for running over beyond one o'clock. If we could take lunch now.

SIR BRIAN LANGSTAFF: Let's take lunch then and come back at 2.05. 2.05.

MS RICHARDS: Thank you.

(1.05 pm)

(The Luncheon Adjournment)

(2.05 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Professor Keel, I wanted to ask you now about a separate topic the issue of Better Blood Transfusion and clinical practice relating to the use of blood and blood components.

If we pick it up at DHNI0000013_052.

This is a document dated 2 July 2001 from Mike McGovern, who was in the Department of Health in London. We can see who it's addressed to on the left-hand side, so I think that's a range of CMOs or DCMOs and page 4, we don't need to go to it, but shows that you were copied in on this document.

It's headed "Better Blood Transfusion: Note of meeting with UK CMOs":

"We met with you last week to discuss and plan the arrangements for the second Better Blood Transfusion conference now set for 29 October 2001."

If we just go to paragraph 2, under the heading "Discussion", the first sentence refers to what that day is going to focus on. Then picking it up in the third line of paragraph 2:

"Despite work over the last three years, local audits still suggest that the use of blood components remains highly variable between clinicians and hospitals, and needed to be explored as a marker of surgical/clinical practice. Most importantly, and in the aftermath of the recent HCV ruling [obviously a reference to Mr Justice Burton's judgment], the risk of blood transfusion would need to be recognised up front and put in clear perspective for the public, patients and clinicians."

Then paragraph 3:

"The main issue therefore was about risk -- scoping the risk of receiving blood components risk against effectiveness, communicating this to patients and the service in the context of the benefits, and reducing the risk through best clinical practice. This approach would require a full and honest partnership between the blood services and the public. It would

need to be based on an agreed recognition of the risks, a policy that did not promote blood transfusion as safe, and fully governed by informed consent."

Then paragraph 4, just the first sentence:

"The overall purpose of the day would be to publicise a new open up-front partnership between the UK NHS blood services and the public."

Now, before we look at what happened following on from this discussion, and in particular the second Better Blood Transfusion conference, what can you tell us about any steps taken by SHHD in the 1990s to promote the better or safer use of blood and blood components?

A. Well, I recall that Brian McClelland and I -- he was a consultant with SNBTS based in Edinburgh -- we co-edited a report which came from CRAG, the Clinical Resource and Audit Group, which was a predecessor of the Clinical Standards Board for Scotland, on optimal use of blood. Now, unfortunately, I haven't revisited that report for years. I think it came out in the mid-'90s, and it was very much focused on reducing inappropriate use of blood and blood components.

So that is one piece of work that was Government-sponsored, and would have been publicised through the Boards.

Q. In paragraph 2 of this minute which I referred to,

Dr McGovern says that local audits still suggest highly variable use of blood components as between clinicians and hospitals. Was that the case in Scotland as well as the rest of the United Kingdom, that there was still a problem here about the way in which blood and blood components were being used?

A. Indeed. Yes.

Q. Then the other matter which this touches on in the passages which I read out is the importance of ensuring a clear and common understanding about the risks of blood transfusion, and that might suggest that there had not been such an understanding, a public understanding at least previously. Again, would it be fair to say that that was as applicable to Scotland as it was to the rest of the United Kingdom?

A. Yes, it would be.

Q. Can I then ask you to look at a couple of documents, then, which post-date the Better Blood Transfusion conference referred to here.

SCGV0000096_014.

This is a minute from you to Mr Stock dated 28 June 2002, and it's obviously in anticipation of a meeting of the MSBT. We don't need to look at most of the material. If we just go to the third page, we can see the last paragraph is headed "Better Blood

Transfusion", and it says:

"Apparently the HSC on this is to issue during the first week in July."

That's Health Service circular, I assume.

"Clearly we will have to think about producing a Scottish equivalent, which hopefully will be able to point to proper funding for the effective use of blood project!"

Now, I'll show you in a minute the circular that was produced in Scotland, but can you assist us in understanding the reference to "the effective use of blood project" and "proper funding" for that project? What was that?

A. What ultimately transpired was a Better Blood Transfusion Programme, which needed a programme manager and people to implement its recommendations in the Service. So clearly funding would be needed, because this was additional work for the Service. So I can't remember whether that funding was ultimately found from within the SNBTS allocation or whether additional funding was provided from the centre for the project, but I suspect it was the former. But whatever the funding mechanism was, it was clearly identified as a need and found.

Q. Then just to complete the picture in relation to the

Health Service circular, SCGV0000098_179.

This is towards the middle of the following year, we can see the date, 19 May 2003, and it's issued by the Scottish Executive.

If we look down the right-hand side, bottom half of the page, it says:

"General enquiries to:

"Dr Aileen Keel.

"Deputy Chief Medical Officer ..."

Then we can see the text of it:

"Dear Colleague

"1. Better Blood Transfusion Programme;

"2. Availability of imported fresh frozen plasma from [SNBTS]; and

"3. SNBTS information leaflets on blood products."

And the second of those obviously is in relation to vCJD risks.

But the first paragraph refers to an annex providing details of the Better Blood Transfusion Programme now being progressed across NHS Scotland.

I'm not proposing to go to any further documentation but can you tell us in very general terms, the kind of steps that were taken in Scotland in relation to the Better Blood Transfusion Programme at

this time?

A. Yes. Well, as I say, a proper program was set out, programme manager appointed, and I say in my written submission I recall him as a very energetic and effective programme manager. And reporting to him, there were 18 nurses appointed throughout the country to lead small teams within hospitals to spread the word about the need for more appropriate use of blood and blood products.

We also established our steering group, which was chaired by a cardiac surgeon actually from Aberdeen, which oversaw the programme over a period of years.

Q. For the benefit of others, I won't take time going to it but there's a newsletter from the Better Blood Transfusion Programme towards the end of 2003 which gives some details of the programme, and it's at SCGV000098_124.

Professor Keel, you'd been obviously working in the field of haematology clinically throughout the 1980s. Do you have any recollection on clinical practice -- or, sorry, reflection on clinical practice in relation to the use of blood and blood products during that time, in the context of the kind of issues then later explored through the effective use of blood project in the Better Blood Transfusion Programme?

A. Yes, I think broadly, the perception of blood amongst non-specialists was that it was a very safe product and, of course, it was and is, but not 100 per cent safe, as this Inquiry knows very, very well. But amongst clinicians, I think the perception in general was that it was an entirely safe thing to do to transfuse a patient. So for example, in contrast to today's practice, patients would often be "chalked up" following surgery in a way that wouldn't be done now unless the haemoglobin level had really fallen much lower than the trigger points used in those days.

So perceptions amongst the general clinical professionals have changed radically over the last 20 or 30 years. When I was training and practising as a junior doctor, blood was used much -- well, much more widely, particularly in the area of surgery, or even, for example, patients coming into the general medical wards with anaemia. I mean, nowadays we would withhold blood. We'd identify the cause of the anaemia, treat it, and only if the haemoglobin was very low would blood transfusion be used as a means of getting it up.

Q. I'm going to turn now to the issue of vCJD. Now, you were provided with a lot of documents in relation to vCJD and you referred to a significant number of them in your statement, and I'm not going to take time going

through those, not least because in terms of the national UK-wide picture in relation to vCJD, the Inquiry has already received quite a lot of evidence. I just want to ask you about, really, a couple of issues.

The first arises from your statement, WITN5736003, page 27. It's the bottom half of the page. You were asked a question at question 50 about an MSBT meeting, in fact a meeting that you were not at, and advice from Professor Kennedy that recipients of blood from a CJD patient should not be informed. You were asked your view and you say this -- you weren't at that meeting you, as far as you can remember, you were unaware of Professor Kennedy's advice until reading the minutes -- but then you say this:

"I agreed with his view. It seemed to me that telling individuals that they **might** be at risk of an infection which had a universally fatal outcome, but no diagnostic test and certainly no treatment, would not be the right thing to do."

Now, set against that might be the idea that that's -- and I don't mean this pejoratively -- but a paternalistic approach: there's the patient's right to know, issues of autonomy. To what extent was that weighed as part of your thinking or the thinking of your

colleagues at this time in the late 1990s; do you have any recollection of that?

A. Well, I think the way that I thought about it, and I think I was not alone by any means in this view, is that the patient's right to know, which is extremely important, nonetheless needs to be set in context. But what we're talking about here was an absolutely devastating diagnosis for anybody to be given: universally fatal, no diagnostic test apart from [audio disruption] treatment. And what we were dealing with in the context of blood transfusion was a highly theoretical risk.

The evidence here was -- well, there was no evidence, it was a theory that blood transfusion might be a means of transmitting the variant CJD organism.

So, against that background, I agreed with Ian Kennedy's advice that we shouldn't be burdening individuals with the worry or concern -- those aren't adequate words. I mean, I can imagine myself being given that news that I'd received an implicated blood donation, it would have been one of great distress. So that was the thinking behind my views and, obviously, Ian Kennedy's views.

Q. Now, we know that as matters proceeded, there were certain notification exercises, as I think they've been

termed elsewhere. Again, I'm not proposing to go through the detail of them. Some of the documentation is referred to in your statement and the Inquiry has a wealth of information on that issue.

But do you again recall your own views as time went on, about some categories of patients, at least in due course, being notified of the possibility of having received implicated products? In other words, did your views change?

A. Well, I think you may be referring to a question that I was asked further on in this statement around the names of individuals being on a central registry without their consent.

It seems to me, as in so many other areas relating to blood transfusion, the thinking involved over a period of time between 1996, when variant CJD was first identified, through the following decade or so, and part of that thinking evolution was thinking around the ethics of retaining data centrally on individuals who had received implicated products and whether that was the right thing to do or not.

And I think my -- I think my thinking was along the lines of: they should at least be given the opportunity to know more about the situation.

Q. Can we turn to the next page, and this is a slightly

different topic in relation to vCJD. We can pick it up in the bottom half of the page. So we can see in that first paragraph on screen reference to plans in relation to the introduction of leukodepletion of blood donations and then, in 1999, the use of UK plasma in the manufacture of blood products being abandoned. Then you say this:

"In December 1997 a policy of withdrawal/recall of blood components and tissues from patients who had gone on to develop vCJD was instituted. Over subsequent years, additional precautionary measures were introduced, including deferral of previously transfused donors in 2004."

Now, you've referred there to precautionary measures and certainly that's the concept that appears throughout a lot of the documentation relating to the decision making regarding vCJD in the material that you've been supplied with. Did you, at the time, as far as you can recall, have any particular views about whether the precautionary approach, in introducing the kind of measures that you've referred to here, whether that was the right approach or whether too precautionary an approach was being adopted?

A. I certainly had supported a precautionary approach. But I do think that the risks, such as they were, were

perceived as greater, for example, in relation to whole blood and blood components than to fractionated blood products. And albumin comes to mind. I think as part of the raft of measures to abandon use of UK plasma, of which albumin is a product, a very frequently used product in the NHS, in that -- the suggestion was that we should stop using UK-sourced albumin.

Now, albumin has, because of the way it's manufactured, an incredibly safe track record, had never been known to transmit anything in the way of viruses or other infections. So I felt that the precautionary principle was entirely appropriate in relation to whole blood and blood components but perhaps could be more nuanced in relation to fractionated products.

Q. Is it right to understand from the documentation that there was a particular concern in Scotland about the implications of this raft of precautionary measures for the future of the PFC, and from time to time it appears those concerns were voiced with you and you were asked to raise them, albeit, as I understand it, decision making effectively was on a UK-wide basis, so Scotland didn't take, in practice, a different course. Was that an issue that you recall coming to the fore at all?

A. I don't recall ever being concerned about the future of the PFC. Certainly in the light of the ban on UK

plasma, its operations had changed radically, but it was still fractionating plasma, albeit from abroad. So I don't think, in my memory, there was ever any ruled out as to the future of the PFC and, you know, that would not anyway, or should not anyway have stood in any way in the path of precautionary measures.

Q. The last issue in relation to vCJD I wanted to ask you about is this: the Inquiry has heard evidence from individuals who had been informed that they may be at risk, having received an implicated product experiencing difficulties in accessing medical and surgical treatment, being put to the bottom of lists, issues relating to the sourcing of surgical equipment for the purposes of medical procedures and the like, and I should say that's not specific to Scotland. That, again, appears to have been a concern UK-wide.

Were you aware of that difficulty, and do you know whether any particular steps were taken by the Scottish Executive to try to address that problem?

A. Well, I was very aware of the issues arising from the need to manage patients who were considered at risk of variant CJD because they'd had human growth hormone treatment or dura mater patch or whatever. I mean, there was really a dual system set up to deal with them in terms of surgery, in that special surgical sets were

used for those patients clearly identified and sent for sterilisation separately.

There was a greatly increased emphasis on use of single-use instruments, disposable instruments, rather than resterilisation, because even the sterilisation processes were certainly not, from the beginning, adequate to get rid of the prime protein that was associated with vCJD transmission. So, in parallel with all that was happening in hospitals, there was loads and loads of research going on in terms of decontamination of surgical instruments.

So it certainly added to the operational burden on the NHS having to manage these patients in very specific and -- in a way that enhanced the safety of the whole system.

Q. I'm going to move now to a separate topic, which is the question of public inquiries. It's right, I think, to understand that throughout the 1990s and into the 2000s the policy of the Scottish Home and Health Department, continued by the Scottish Executive, was that there should not be a public inquiry into the circumstances by which people had come to be infected through blood and blood products; that's right, isn't it?

A. Yes.

Q. What was your understanding, in broad terms, of the

reasoning for the maintenance of that line?
A. I think, in the main, that there had been examination in various fora, including the internal departmental report that we talked about earlier, there'd been examination of the issues in some depth, and no new evidence had emerged which ministers felt merited a public inquiry.
Q. It could be said that there's a degree of circularity to that position, because it may only be through the holding of a public inquiry, with its powers to call for evidence from a wide range of sources and scrutinise it, that such evidence might come to light. Do you have any observation on that?
A. Of course you're right, it could be that additional information would have emerged in the course of a public inquiry. But the view held at that point was that it wouldn't be appropriate, because the evidence as available at the time that the calls for public inquiries were being generated had been examined, and that it would only be if additional evidence emerged that a public inquiry might augment, improve or enhance that evidence gathering?
Q. Leaving aside the internal investigation that we looked at before lunch, in what other ways had these issues been examined in Scotland?
A. I'm not sure I quite understand the question.

Q. You referred to there having been examination in various fora, including the internal departmental report, and you said there'd been an examination of the issues in some depth.
If we leave aside the internal investigation report, because of course that had a very specific scope, what other fora do you have in mind in giving that evidence?
A. Well, I suppose there's reference in an earlier document, which I think you called up, to DH having looked at such issues over the years. You know, the Advisory Committee structure, ACVSB, latterly MSBT, had also examined -- well, had looked at all of the issues over the years. I think that's what I had in mind. But obviously the internal inquiry on the specific issues of Factor VIII safety had gone into that in some detail.
Q. Then if we look at DHSC0041159_205.
This is an internal Department of Health minute, not copied to you, dated 20 May 2006, and it's from Gerard Hetherington. I just want to ask you about something on the second page which refers to you. So if we look at the bottom of the second page, we have the heading "Demand for a Public Inquiry":
"6. Ministers pointed out that demands for a public inquiry were intensifying. MS(PH) [the

Minister of State for Public Health in England] was particularly concerned that this issue should not be forced in England because of decisions in Scotland.
"7. We have consulted Dr Aileen Keel DCMO in Scotland. Advice from SE officials to Scottish Ministers continues to be very strongly against holding a public inquiry. The Executive is examining the validity of a vote in the Scottish Parliament Health Committee in support of a public inquiry. It is understood that the casting vote of the Chairman may be disallowed."
First of all, do you know anything about that latter issue there, about the voting issue?
A. No, I don't.
Q. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair?
A. Yes.
Q. Was the question of holding a public inquiry at this time or any earlier time ever looked at from the perspective of wanting to understand how it could be that so many people were infected and dying, or had died? In other words, did the sheer scale of what had happened not give rise to sufficient public concern to

justify the establishment of an inquiry?
A. I don't know what the criteria are for setting up public inquiries but I guess maybe scale of problem might be one of them but, again, I'm not sure that the scale of the issue here, while of course absolutely horrendous for those who contracted viruses through blood and blood products, I'm not sure that I agree that it was on a massive scale.
Q. We know, of course, that in due course in Scotland the Penrose Inquiry was instituted and we saw yesterday that you'd given evidence to the Penrose Inquiry. Did you have any role in giving advice in the decision-making process that led up to the decision to establish that Inquiry?
A. Well ...
Q. As far as you can recall?
A. I can't recall clearly, but I'm sure my advice would have been sought.
Q. I don't think we've got any particular documentation that answers that or provides any further information in regard to that.
Once the Penrose Inquiry was established and up and running, obviously you gave evidence, as we saw, on the issue of look-back. Did you have any other role in relation to the Inquiry in the course of it, in terms of

giving advice on matters related to the Inquiry?
A. Not that I recollect.
Q. One of the issues that's been explored with other witnesses is the difficulties that might arise if a body that might itself be criticised if there were to be a public inquiry is the body charged with deciding if there should be a public inquiry, and an issue that's been explored with other witnesses is whether there should be an independent body or independent position that might be able to either take the decision as to whether there should be a public inquiry or provide advice, at least, in that regard. Do you have any views on that suggestion?
A. Well, I haven't thought about it before now but I guess that such a body would have to draw up the criteria that I mentioned earlier around what would trigger a public inquiry. So I suppose there might be some benefit in that.
Q. Just a couple of then miscellaneous issues -- I don't mean to undermine their importance by describing them in those terms -- that I wanted to ask you about now.

If we go, please, to SCGV0000246_051. This is a minute from you, 18 June 2001, to the Chief Medical Officer. It's triggered by, again, I think, the Burton judgment but I'm not going to ask you about that case

itself. But paragraph 1 says:

"As you can see from the attached, I raise the issue of the possible need for a public education campaign arising from this judgment ..."

Then if we go to paragraph 3:

"I think I am fairly clear in my own mind that while public education campaigns will not remove liability in such cases, they may well reduce it. In any case, such a policy is consistent with the trend towards greater openness in general in the NHS."

I wanted to ask you about that general issue that you referred to there: the trend towards greater openness in the NHS. Now, that might suggest that there had not previously been as much openness in the NHS as perhaps there could or should be, would that be a fair inference to draw?
A. Yes, I think the NHS in, let's say, the first 50 years of its existence, was a thing of its time. Society was much less open in those days than it is nowadays. So the NHS was simply a reflection of society. Our thinking, as I said a while ago, of course, has evolved immensely over the decades. You use the word "paternalistic" in reference to a comment that had been made earlier by somebody, I think a non-medic but the medical profession is often accused of paternalism, and

I think that probably -- not probably, definitely -- in years gone by, led to a lack of openness with the patient about what exactly, you know, was happening.

And certainly it's only in, I would say, the last 20 years or so that we've begun to talk about coming to joint decisions with the patient, rather than the doctor handing down on high to the patient what is going to be done.

Now, I think that is exactly the way things should be but, nonetheless, it is still not an infrequent occurrence that a doctor will have a conversation with a patient and say, "Well, we could do course A or course B, what do you think?" and for the patient to turn round and say, "Doctor, you know best, so you decide".

However, that doesn't take away from the fact that having the conversation, giving the patient the option to share more fully in the implications of their diagnosis and what treatment or treatments are on offer is absolutely the right thing to do.

So I think that this comment here about more openness in general in the NHS, and that trend, is just consistent with the trend in general society.
Q. The next topic I want to ask you about relates to documentation and issues about what files were retained

and by whom. I don't know whether you're going to able to cast much light on the issue in light of the limited material available but I just want to ask you about it. If we go, first of all, to SCGV0000170_150, please.

So this is from you to Mrs Towers, 24 September 1999. And so, in terms of timing, it's whilst the internal investigation is ongoing and you say this:

"In the course of our investigations in this area it has emerged that Professor John Cash ... took him on his retiral some files which may be relevant, which he has 'gifted' to the Royal College of Physicians in Edinburgh. Both Angus Macmillan Douglas and I have tried without success to persuade him that it would be much more convenient to allow SNBTS and Departmental staff access to the files in another location, eg St Andrew's House. Professor Cash is extremely resistant to this idea, for reasons best known to himself. In the course of our conversation he actually said to me that the files now belong to the College! I said that I did not see how that could be, but that I could seek your advice on the question of ownership."

We saw from a document that we looked at earlier that obviously some files from Professor Cash did become available because we saw Christine Dora's comments on them, but what, if anything, do you recall about the

issue thrown up by this minute, the documentation that had been retained by Professor Cash and your ability to access that?

A. At the risk of sounding flippant, what it really reminds me of is John Cash's desire always to be mysterious and to hold in his ownership something that others don't know about and I think the files are an example of that.

Again, my recollection, although it's hazy, is that the files, actually, when we finally got our hands on them, added nothing to the sum total of knowledge here. But of course we had to try to get hold of them and actually it should have been much more straightforward than it was because the files did not belong to Professor Cash, they were not in his gift to give to the College of Physicians, and he should just have handed them over to us.

Q. And as I say, I think it's right to understand from later documents -- I don't think we need to put them on screen but I'll just read an example into the transcript, SCGV0000173_044 -- that there were then files handed over by Professor Cash which were looked at in the course of the investigation.

Then I'd asked you earlier about your involvement in the Penrose Inquiry. When the Penrose final report was produced, I think you were still, just, the Acting

Chief Medical Officer. April 2015 was when you ended that role. Were you involved in advising the Scottish Government about the Inquiry report and its one recommendation and how that should be implemented, as far as you can recall?

A. Yes, I think I was, before I moved out of Government.

Q. And in broad terms, do you recall the nature of the advice that you provided in relation to the Penrose Inquiry report?

A. Well, the only thing that sticks in my mind is the one recommendation, and the advice would have been that that was already or had already been implemented, ie the offering of an HCV test to anyone who was concerned that they may have contracted the virus through blood transfusion.

Q. Two final questions, Professor Keel, from me. The first is this: during the time you worked in your governmental position, so from 1992 through to 2015, was any assessment ever undertaken by Scottish Home and Health Department, Scottish Executive, Scottish Government, into the needs of the infected and affected communities in Scotland?

A. I'm not absolutely sure. However, needs assessments were conducted by various other agencies, if you like. For example, Health Protection Scotland and other bits

of CSA did conduct needs assessment. However, I can't be confident that the needs of those affected by this virus were part of that collective endeavour. However, I do recall that in terms of practical support short of providing financial support, that we did engage with the ABPI over the difficulty that some individuals with hepatitis C were encountering in relation to life insurance and mortgages, and I know that we also explored with the NHS their access to whatever treatments -- it would have been interferon at the beginning -- were available to treat the condition.

Q. Then, Professor Keel, looking back now, is there any aspect of the Scottish Government's response to those infected and affected that you consider was misjudged or wrong?

A. While notwithstanding the existence of this Inquiry and certainly notwithstanding the compen -- or the financial support that has been provided for these patients, and fully recognising the fact that they have been through significant physical and mental problems arising from their infection, I still believe that the logic here would have been not to set up a financial assistance scheme specifically with this group of patients, because it elevated their problems to a higher level than many other groups, who were pursuing -- equally justifiably,

seeking compensation for other ills that the NHS allegedly had inflicted on them. I didn't see the logic in that.

And in terms of public inquiries, well, I mean, I hope this one will indeed shed further light on the issues but, at the time that the public inquiry was being resisted in Scotland, I believed and I still believe that, at that stage, no additional evidence had emerged that would have merited a public inquiry and, therefore, I think that, at that stage anyway, it would not have been appropriate for Scotland.

MS RICHARDS: Those are the questions I am proposing to ask Professor Keel, sir. We obviously need to give an opportunity to Core Participants through their legal representatives to suggest any further lines of questioning.

Could I ask that we take a slightly longer break, having finished earlier than our normal break time. Could we take 45 minutes?

SIR BRIAN LANGSTAFF: Yes, certainly.

Let me explain. Those who are participating in the Inquiry have a right, through their Recognised Legal Representatives, to put questions through counsel to you. Plainly, they have to be given an opportunity to formulate those questions in the light of everything

that you have said and, since you have only just finished, they have to be given time to do that. I don't know how long that will be, I don't know how many questions there will be, but your evidence has been of such interest I wouldn't be surprised if there are quite a lot. We'll find out.

But we won't sit again until 3.40. We may not sit then if there are questions coming in still or questions coming in late, so we won't sit before 3.40, in other words you're free completely until then, and then I can't tell you how long you'll be detained after that. It depends how long it takes for the various issues raised by the questions to be properly ventilated. But that's what we'll do.

3.40, not before 3.40. You'll be told, of course, if it's going to be any later.

MS RICHARDS: Thank you, sir.

A. Thank you.

(2.56 pm)

(A short break)

(3.44 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Professor Keel, the questions I'm going to ask now, because they've been suggested on behalf of Core Participants, may dot around from topic to topic

rather than following a single thread at any one time.

The first question arises out of the issues of Better Blood Transfusion and educating clinicians on the better use of blood. Was there resistance from clinicians to the Scottish initiative to ensure the better use of blood?

A. Not that I recollect.

Q. And then turning next to the internal investigation report, we explored the question of whether, for example, patient records could have been looked at. Would it be your expectation that it would be recorded in patient records that a patient had been informed of a positive test result?

A. Certainly in the case of HIV I would expect that to be recorded in the notes, because explicit consent was needed for taking blood for HIV. As far as HCV is concerned, I can't be confident that it would uniformly be recorded that the patient knew the result.

Q. And then I explored with you when we were considering the internal investigation the Scottish Executive's acceptance of the evidence provided by consultants, in terms of the information that was provided to patients. Does it follow from that acceptance that the Scottish Executive disbelieved the patients who said that they had not been provided with information, or that the

Scottish Executive's position was that those patients were misremembering or providing the investigation with unreliable information?

A. We certainly didn't disbelieve them, but there seemed no easy way of proving that they hadn't been told -- double negative there, sorry -- but I can see where you're heading. You're suggesting that we were inconsistent in our approach to the evidence or the allegation that the -- the evidence that the consultants presented, which I have already acknowledged was patchy because of the lapse of time between the mid-'80s and 2000 when the Inquiry was taking place.

They said, and we believed them, that there was patient literature available in the mid-'80s which patients had access to, but we weren't able really to lay our hands on that.

So there was a lack of confirmatory evidence, really, on both sides, I suppose. But we certainly didn't disbelieve the patients.

Q. The next question requires you to cast your mind back to the time you were working in Glasgow with Professors Forbes and Lowe. Were you involved in the testing of immune function deficiencies in bleeding disorder patients in Glasgow in 1983 or 1984?

A. No.

Q. And did you have any awareness at that time of the thinking that immune deficiencies might be indicative of HTLV-III positivity due to exposure to factor concentrates?

A. No, that was not something that crossed my mind.

Q. I asked you, when we were looking at the look-back, about the request that had been made by Dr Ludlam regarding DEFIX. Over what time period, roughly, as far as you know, was DEFIX used for reversing the effects of warfarin?

A. Gosh, um, I can't even remember when DEFIX was first produced. In the '80s, I guess. Over a period of many, many years. I mean, it was -- my recollection was it was still being used in -- certainly in the '90s I don't know about current practices because I'm not up to date on that.

Q. Would SNBTS not have records of the hospitals to which DEFIX had been supplied for this purpose?

A. Yes, they would. However, that doesn't mean that there was a record of which patients received the DEFIX because I think I mentioned yesterday there was no prescribing database which was set up for DEFIX prescriptions to ascertain whether the DEFIX that had come from SNBTS to a particular hospital had gone into a particular patient. It would have meant trawling

through patient records, probably many thousands, tens of thousands of them.

Q. In relation to I think your earlier evidence that there might be tens of thousands of patients treated in that way, as DEFIX was a pooled product and not heat treated until October 1985, does this mean that there are potentially thousands of patients who were HCV-infected as a result of this treatment, and some who may have been infected with HIV as a result of that treatment?

A. I guess those possibilities can't be excluded.

Q. And was that issue ever investigated by the Scottish Health Service or the Scottish Health Department, to your knowledge?

A. Not on a population basis, but I suspect that if a patient treated with non-heat treated DEFIX appeared to be suffering from hepatitis, then the clinician looking after them would have been monitoring them, and then, maybe when the test appeared, testing them for HCV.

Q. Can I ask you next about the line to take, or the policy position that we see articulated in the various briefings about the best available treatment in the light of medical knowledge at the time.

Now as I think I may have mentioned, Professor Keel, when I asked you about that first of

all, that is a line that we've seen in Department of Health material as well, as in the Department of Health in London. Do you know what the origin, from the Scottish perspective, was of that particular line to take?

A. No, I don't know what the origin was.

Q. Were the commercial factor concentrates given to the children at Yorkhill the best available treatment in light of medical knowledge at the time?

A. I suppose with hindsight the answer is no. That was Dr Willoughby's preferred clinical practice, and he would definitely have had views on the relative safety of those products compared with the SNBTS products. But he also had views, I think I mentioned this yesterday, on the ease of administration to paediatric patients of the PFC product, and my recollection is he felt that the commercial products were easier to make up in volumes appropriate for children.

Q. Was the PFC product NY the best available treatment in light of medical knowledge at the time for a previously untreated or minimally treated patient in 1986?

A. Well, again with hindsight, clearly not. But in that chronology, the only safer product would have been 8Y, which, as we discussed this morning, was not available in sufficient quantities. Even if we had known for sure

that it didn't transmit non-A, non-B, it wouldn't have been available in sufficient quantities to supply Scotland. So clearly NY transmitted HCV. There's no doubt about that. Anybody who got it, got hepatitis C. But the risks of transmission of that virus, which hadn't even been identified at the time, were, in the views of clinicians, outweighed by the benefits from using that product, which, as I've already said on more than one occasion, were potentially life saving.

Q. You told us your understanding that the mean age of haemophiliacs in the '60s was 37. To what severity of haemophilia patients --

A. Of death.

Q. I'm sorry?

A. Mean age of death.

Q. Yes, I'm sorry, you're absolutely right. To what severity of haemophilia patients did that statistic apply in your understanding?

A. It would have been severe haemophiliacs, maybe some moderate were in that. I don't know how the number was calculated.

Q. And can you recall what the source of your knowledge was in relation to that issue?

A. No, I can't, sorry.

Q. And is there any evidence that you can point to

demonstrate that haemophiliacs would have died if they did not receive Factor VIII concentrates as opposed to treatment with cryoprecipitate?

A. Again, I think we partially covered this this morning. In the event of a potentially life-threatening bleed, such as intracranial bleeding, then cryoprecipitate would definitely not have been the best treatment for these patients to receive. You would have to give enormous volumes of cryo to try to stop the bleeding. So absolutely clear in my own mind that giving coagulation factor concentrates in the event of a life-saving bleed was potentially life saving.

Q. If the severity of non-A, non-B hepatitis testing was not appreciated in the first half of the 1980s or the mid-1980s, why was so much time, effort and money put into research at BPL and PFC to produce a product that did not transmit non-A, non-B hepatitis?

SIR BRIAN LANGSTAFF: I'm not sure that's really a question which she can answer. That really is a comment.

MS RICHARDS: It's a -- (overspeaking) --

SIR BRIAN LANGSTAFF: A question dressed up as a comment, which I think is ultimately for me to evaluate.

MS RICHARDS: I absolutely take that point, sir.

Surrogate testing, Professor Keel, and we touched on this earlier. We saw from the documentation

references to ALT testing and not anti-HBc testing. When you were providing advice on these issues in the various respects in which we looked at in the course of your evidence, was it your understanding that only ALT testing was a possibility?

A. I think at that time that ALT was the main factor under consideration. Now, I -- my recollection, again, is very unclear in this. But I think probably that the anti-HB core testing issue had been put to bed before I came into post. So the ALT issue was still current in a way, and it was the one that cropped up rather than HBc testing.

Q. Does it follow then that it was your understanding that in the 1980s, the question of using anti-HBc testing as a form of surrogate testing was not a live issue in the 1980s?

A. I'm not -- I didn't say it was not a live issue. It wasn't the forefront of the issues raised with me when I came into post.

Q. Then, in your evidence earlier about what might be done if donors had elevated ALTs, your evidence was to the effect that what would you tell them about the reason for the elevated ALTs, as it might be drinking or being overweight or other matters.

The question arising from that is this,

Professor Keel: why would that be a bad thing or a reason not to do the testing and telling a donor that they have a deranged liver function which might be due to non-A, non-B hepatitis infection or might be due to one of those other factors would then enable a donor to make good choices for their health as a consequence?

A. Well, certainly telling them that they had deranged liver function which might be the result of a virus as yet unidentified, I think, would have been pretty unsatisfactory from that individual's point of view.

Yes, of course you could say you could screen for elevated ALT and tell people to lose weight, stop drinking, but that really is not the function of our blood screening test. The blood screening test is to protect the population from donors who might be carrying viruses.

So allied to the issue of how you deal with donors with elevated ALT levels, theoretically speaking, is the issue of what that would mean for the Blood Service. What proportion of the population might fall into that category could be very significant and, therefore, erode the blood supply available to the population.

Q. You said in your evidence earlier that we know with hindsight that, prior to the introduction of successful viral inactivation, et cetera, 100 per cent of

haemophilia patients would have contracted non-A, non-B hepatitis. Was that advice that you provided to ministers, as far as you can recall?

A. I think it does appear in some of the briefings, maybe earlier on. And the reason for saying that is -- well, it's a fact, because of the large donor pools that were -- from which the factor concentrates were made. It only took one positive donation amidst the 3,000 -- I think was what SNBTS were dealing with -- commercial producers were dealing with [live stream froze] of 30,000. So you therefore "contaminate", I use that word in inverted commas, an enormous plasma pool that is then being made into various products, all of which carry the virus.

Q. The Inquiry has heard evidence about a paper from 1983 by Fletcher and others, which suggested that -- the fact that you've just referred to -- 100 per cent of haemophilia patients contracting non-A, non-B hepatitis. I'm hesitant to ask you about a paper that you haven't been provided with in advance of your evidence but, in any event, do you know whether that was a paper that you were aware of? Does it ring any bells at this stage?

A. No, I'm afraid not.

Q. The next question moves to 2003. The announcement in January 2003 of the potential figures of 20,000 and

25,000 for stage 1 and stage 2. Now, you've told us about the extent of your involvement with that earlier. We touched in your earlier evidence on interactions you had with Peter Hayes about the stage 2 issues, and the documentation referred to in your statement suggested that you made contact with Peter Hayes in February 2003. At that stage, was it your understanding that there would be a Scotland-specific scheme or did you anticipate that there would be a UK-wide scheme?

A. I can't recall. I'm not really sure of the relevance to the issue of deciding on a trigger point or not. I did further, of course, discuss that matter with colleagues in the Department of Health. So it wasn't -- it wasn't confined to Peter Hayes. So I suppose that fully reflects the desire, at that stage, to see the scheme implemented on a UK-wide basis.

Q. The next question relates to natural clearers. Do you know when and by whom it was decided that acute natural clearers would be excluded from the scheme?

A. I think we decided that fairly early on, on the grounds that those who cleared the virus within six months of acquiring certainly had not suffered any long-term harm, and most of them would have been asymptomatic anyway, even during the first six months.

Q. So is it your understanding that that had already been

effectively decided by the time of the January 2003 announcement?
A. I can't recollect the timing of it.
Q. And did you provide, as far as you can recall, any medical advice about the possible impact, in particular psychological impacts, of hepatitis C infection on such patients?
A. I can't specifically recall but I'm sure the psychological -- potential psychological distress would have been discussed. But if you're talking about natural clearers, as I've already said, most of them wouldn't have known that they had a virus during that period before they cleared it. Many were totally asymptomatic. I think most were asymptomatic.
Q. And then still on the topic of natural clearers, given that chronic clearance of hepatitis C was unusual, how would the typical transfusion patient who did not, unlike bleeding disorder patients, potentially, have the benefit of previous regular results of blood testing, prove that they had cleared at the chronic and not the acute stage?
A. I think that would have been very difficult unless they were being monitored by some other clinician, and their LFTs tested on a regular basis.
Q. Moving to a different issue entirely. You referred to

engagement by the Scottish Government with the ABPI on life insurance and mortgages. Was any assistance ultimately offered to the infected as a result of that engagement, and if so, what?
A. I can only remember one meeting, and I can picture the room that we were in, in the new Parliament, with the insurance industry, at which these concerns were voiced. But I really have no recollection of further follow-up or what the outcomes of those discussions were.
Q. Next question is about look-back again. Was part of the rationale for requiring a UK-wide introduction of HCV look-back influenced by who might be expected to pay for it? In other words, would it assist in looking to Westminster to fund the look-back if it was UK-wide?
A. I don't remember that being a factor. I think the main issues driving a UK approach were to avoid confusion of patients who were potentially identified through the exercise, and also to avoid confusion of clinicians who'd be involved. So doing it across the UK was seen as the best way forward.
Q. The infection of thousands with hepatitis and HIV from blood and blood products has been described, I think first by Lord Winston, as the worst treatment disaster in NHS history. Is that a characterisation that you disagree with?

A. Well, there have been many other treatment disasters. Thalidomide comes to mind. I think it's very difficult to categorise such events by degree of severity and I don't think I'm in a position so to do.
Q. In terms of the issue of precedent setting, and financial assistance, are you aware of any group other than those infected through blood and blood products, relying on the financial assistance given to recipients of infected blood or blood products as a precedent for wider no-fault compensation?
A. Am I now relying on -- is that your question?
Q. Yes. Were you at any time aware or are you now aware of any groups pointing to the provision of financial support to the cohorts of individuals with whom this Inquiry is concerned in saying: well, they've had financial support, so too should we?
A. Well, I've been seconded out of Government for 7 years, so I certainly can't comment on current thinking in that area. But as I said, I've said many times, the concern around introducing the HCV assistance scheme was that it would activate other groups that we knew were already out there, others unknown to us, to make claims.

I mean, I'm not in principle against a no-fault compensation scheme. Many countries have them. But most of the payments arising from some such schemes are

relatively modest, and they take a great deal of designing. So I mean, my mind was open as to whether we explored that possibility. During my time in Government, I think it was always in the 'too difficult' box to really pursue and come out the other end with a scheme that would fit with the NHS.
Q. You were in Government for approximately 12 years following the announcement in 2003 that there would be an ex gratia payment scheme for those infected with hepatitis C.

In those 12 years, did the establishment of the Skipton Fund create the dangerous precedent that you'd feared?
A. No, it didn't, but that doesn't mean that there aren't disgruntled groups of people out there who have not been able to bring the lobbying power that, for example, The Haemophilia Society got to this area. So I think the concern was valid. The fact that it hasn't actually come to pass doesn't mean it wasn't a valid concern.
MS RICHARDS: Sir, those are the questions I'm proposing to ask from those put forward on behalf of Core Participants. I'm just going to turn and see whether there's anything -- no, there's nothing from Dr Keel's legal representatives.

Do you have any questions for Professor Keel?

SIR BRIAN LANGSTAFF: Only one question, which arises out of the questions you've just been asked on behalf of Core Participants. You were asked why the look-back exercise needed to be conducted on a UK basis, and you said that otherwise the patients might become confused and clinicians might be confused. Can you help me, starting with clinicians, why would clinicians practising in Scotland be confused that the Scottish Government, Scottish Health Service, the NHS in Scotland, was saying, "We want you to have a look-back for those involved in Scotland"? What would be the source of their confusion?

A. Well, it would have been perfectly feasible to proceed on the basis of Scotland going it alone, if you like. But you have to remember that patients cross the border between Scotland and England, and vice versa, so that there was that. It was just seen as desirable that in such an important area, that the whole of the UK did it roughly at the same time.

Now, the starting gun was fired but by no means everybody was at the same place in terms of preparation. So the time courses that were run across the UK, between the different transfusion services, varied a bit, but they all started roughly at the same time -- well, at the same time, some had done more preparation before

that starting date than others. But given that, you know, public awareness was going to be raised around the exercise, that was another reason for wanting to do it, as far as possible, starting at the same time.

SIR BRIAN LANGSTAFF: So are you really describing confusion or an element of "Why are they doing it there and not here?"

A. I'm sure that question would have been raised, yes.

SIR BRIAN LANGSTAFF: Do you still want to maintain the word "confusion"? It's your word. I'm just asking about what gave rise to it and I'm not sure you've really explained it to me so far.

A. Well, I think clinicians would have said -- well, if we'd gone ahead in Scotland with our own exercise, I think clinicians south of the border would have said, "Why are we not doing it here?" Indeed, some small areas in England had already, as Jack Gillon had done, begun their own little exercises in various places.

So it didn't come as a bombshell to England that this was going to happen, but I definitely think if we'd gone it alone, so to speak, English clinicians would have been a bit bemused as to why they weren't being asked to do it at the same time.

SIR BRIAN LANGSTAFF: Now this leads on to the question, really, about testing for HCV, hepatitis C, when it was

introduced. Before it was introduced my understanding is, at least the understanding of the Inquiry is, that there were a number of pilot schemes operated, certainly in England, which -- in which areas everyone was being screened, whereas in other areas they weren't.

Do you recollect there being any particular concern or confusion amongst patients and clinicians as to why that was happening "there" when it wasn't happening "here"?

A. No, I don't recollect. I suspect that that kind of local testing was not visible to the wider patient community.

SIR BRIAN LANGSTAFF: So the difference is the degree of publicity, is it?

A. In part, yes. Those centres that were ahead of the rest of the country in introducing testing, were of course using the first generation HCV test, which, for reasons that I'm sure have been explained already, and I think I mentioned yesterday, were not considered satisfactory enough for screening the whole donor population, and being able to absolutely depend on the results that were emerging, and there were no confirmatory tests at the beginning.

So I imagine that those places that were using, in the early days, HCV tests were using the first

generation tests.

SIR BRIAN LANGSTAFF: Yes, well, that's all that I'm going to ask. Thank you very much.

MS RICHARDS: Professor Keel, was there anything further that you wanted to add?

A. No, I don't think so. Thanks, Ms Richards.

SIR BRIAN LANGSTAFF: Well, can I thank you. You'll have understood from the number of questions and the length of time that it took to assimilate them the considerable degree of interest which your evidence has given us. I know it's taken two days, which is a long-ish time compared to some of the evidence which we've heard, but I'm sure that anyone listening will have thought the two days entirely justified by the questions and answers that have been asked and given. So thank you very much.

A. Thank you.

SIR BRIAN LANGSTAFF: Tomorrow?

MS RICHARDS: Tomorrow, sir, we have the evidence of Jeremy Hunt, Secretary of State for Health in the UK Government, 2012 to 2018.

SIR BRIAN LANGSTAFF: So Jeremy Hunt MP tomorrow.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: 10.00.

(4.21 pm)

(The hearing adjourned until 10.00 am the following day)

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