Wednesday, 7 December 2011

(11.30 am)

DR ROBERT PERRY (continued)

THE CHAIRMAN: Good morning, Dr Perry.

A. Good morning.

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir. In today's business we are hoping to conclude our topic C3A. We do have statements from Dr Perry and it had been my intention just to tender those as coming from a witness who had not appeared in person, but Mr Di Rollo and his team didn't feel that that was sufficient. They wished the opportunity to question Dr Perry in person.

I don't propose to ask questions of Dr Perry myself. I should simply draw attention to his two statements, which are [PEN0171244] and [PEN0171843].

I would now simply pass to Mr Di Rollo.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Dr Perry, thank you very much for coming back today to answer questions in relation to the topic C3A. There is a statement from you, [PEN0171244], which is the main statement given in relation to topic C3A. Just to introduce this, perhaps we could have that up on the screen. We see that topic C3A is concerned with the use

of blood product concentrates in Scotland in the period between the introduction of NHS heat-treated products in 1984 and the supply of NHS products sufficiently treated to inactivate Hepatitis C.

I think we are looking at this, obviously, as the topic says, in a Scottish context. The first topic that you were asked to consider in your statement is:

"Heat-treated NHS Factor VIII (8Y), treated at 80 degrees for 72 hours, was introduced in England in September/October 1985 but it was not until May 1987 that NHS heat-treated Factor VIII (Z8) treated with the same protocol became available for clinical use in Scotland."

You were asked what your recollection of events was at this time and in particular:

"What do you remember about the availability in Scotland prior to May 1987 of hepatitis-safe Factor VIII products supplied to England? From the copy correspondence attached, it looks as though you obtained BPL's 8Y product for previously untreated patients in Edinburgh in the summer of 1986. Was this product available only for patients in Edinburgh or for patients elsewhere in Scotland?"

You set out your response, which we see from your statement, and I don't want to have you read out your

statement or for me to read out your statement. But what I want to do is just go over certain matters concerning this, and the first thing really I would like to do is to remind ourselves of what the position was as far as PFC was concerned in January of 1986. So can we go to [SNB0015469]? I think this is a document that you have seen before and you were asked certain questions about it when you came to give evidence when we were looking at topic C3.

A. Yes.

Q. If we go to paragraph 3.1, under paragraph 3.1, the fourth paragraph down, it says:

"Directors will be aware that ..."

And this is reference to BPL:

"... are currently issuing a Factor VIII product which has been treated at 80 degrees/72 hours and preliminary clinical data indicates that this material is non-infective with respect to HTLV-III, NANB and Hepatitis B."

Then the next document I want to just remind you of is another document which is dated -- I think you accepted -- around January 1986, which is [SNB0015484]. This is an addendum to the development of new products, 1986/1987, and what's stated there is that:

"The heat treatment procedure now being applied to

FIX concentrates (PFC & BPL) and to Factor VIII (BPL) may well be effective in ensuring non-infectivity of products."

So that's information which I think again we have dated around -- it refers to "Smith, personal communication", and that's again around January 1986.

A. Yes.

Q. And then finally, the other document which I wanted to show you is a meeting at PFC between BPL and Scottish National Blood Transfusion, 17 March 1986. There is a note of a discussion. This is [SNB0075664]. 17 March 1986. The reference there is, if we could just go further down and find the relevant passage -- I think it may be over the page. Just go over the page again, please.

Yes, it's paragraph 5:

"Dr Smith outlined clinical trial results of the 8Y Factor VIII product so far. While results cannot be considered conclusive at this stage, he indicated that no cases of virus infection have occurred (attributable to 8Y material) after 12 months' experience of 8Y in virgin haemophiliacs."

That document is dated 24 March 1986.

Obviously it is important not to make claims for products which are not legitimate claims and one could

not say conclusively that the 8Y Factor VIII product -- there was conclusive proof or scientific proof that it would be non-infective for non-A non-B Hepatitis. The evidence as at March 1986 did tend to suggest that there was obviously hope in that direction. A significant development had occurred as a result of the evidence so far. Is that reasonable?

A. Yes, I think that's a reasonable summary of the situation. Certainly the evidence fell far short of anything that you would consider to be conclusive, as I think you have indicated, but I think by March 1986, as evidenced by these documents that were written around that time, I was certainly personally aware, and clearly the views of BPL colleagues was that the data that was emerging from the trials of 8Y looked very encouraging. And that was important because dry heat treatment, as it was known then, had during that period sort of gained a reputation of perhaps not being as reliable or hopeful as we hoped it might be in terms of non-infectivity. So any information that suggested that there was an absence of infectivity was important.

Q. I think, when you gave evidence on 28 October, which is Day 58, you may have referred to a six-month period after which one would then consider the 8Y as being safe. Do you recall that evidence that you gave on that

occasion?

A. Not specifically. I think a six-month period following the first infusions of a new product, I think that would be a highly optimistic view on the safety of a product but it would be indicative, I think, as has been mentioned. I have read minutes of the CBLA meeting, for instance, where the director, Dr Lane, reports that patients have now passed the point at which they might have been expected to develop symptoms or signs of non-A non-B Hepatitis.

Q. Well, that --

A. I think he describes it as having safely moved past that point but this was for a very small group of patients with a very limited batch exposure. So, as I say, I think six months --

Q. Just to remind ourselves, that document is [DHF0030476]. I think that's a letter from the BPL to all haemophilia directors in July 1985?

A. Yes. That's right.

Q. An information sheet there. We may have a look at this later today with Professor Colvin as well but if we just scan down there, the reference to "safely passing the point" is there somewhere.

A. That's right.

Q. Yes:

"Clinical trials at six haemophilia centres are in progress to gain evidence of reduction or elimination of viral transmission, and several patients have safely passed the point at which first evidence of NANBH virus transmission would normally occur with unheated Factor VIII."

Is that the passage you are referring to?

A. That's the passage I'm referring to, yes.

Q. That's dated July 1985, and so, when we get to March 1986, what Dr Smith relayed to you as well by communication, the signs are looking promising?

A. Oh, indeed, absolutely; I would agree with that.

Q. What I would like to do is to deal with the question of the possibility or otherwise of obtaining some of this material, 8Y, in Scotland, because we know that, in contrast to the Scottish product -- the Scottish product -- the protocol is different and, in contrast to the English product, where, as far as the 8Y is concerned, there are promising signs about infectivity -- or non-infectivity -- with non-A non-B Hepatitis -- in contrast, the Scottish product was known to infect at this time. That's fair, isn't it?

A. I think that's fair, yes.

Q. And what I would like to do is explore what possible procedures or steps might have been available to obtain

a supply of the English product for Scottish patients.
A. Sorry, are we talking around about March 1986 here?
Q. We are talking from March 1986 onwards, yes.
A. Okay. I think in March 1986 it wouldn't necessarily have been the case that we knew that the SNBTS product transmitted non-A non-B Hepatitis. I don't think we had any specific instances or data on that. We certainly didn't have information that it did not transmit non-A non-B Hepatitis.
Q. Was it thought that it would probably?
A. I think, as has been discussed before, our preoccupation during that period was HIV safety. So I can't say with any clarity whether or not we thought it was. I think there was a fairly low expectation that we would have delivered, through heating at 68 degrees for 24 hours, a non-A non-B Hepatitis-safe product.
Q. So if one --
A. From the experience of others and other organisations.
Q. Others in other organisations in other countries?
A. Yes.
Q. So similar protocols were known --
A. Yes, similar time/temperature profiles. I think we were fairly confident by that stage that it was HIV-safe, which was our priority, but we didn't have a high hope or expectation -- it may have reduced the infectivity

but we had no way of measuring that.

Q. It certainly wouldn't have come as any surprise if that was administered to a patient and they were infected; it wouldn't come as a shock?

A. No, the only evidence that you would have available for that, though, is if a previously untransfused patient emerged for treatment and that patient then subsequently moved on to develop clinical signs of non-A non-B Hepatitis.

So there were no simple laboratory methods for testing the vast majority of patients that were treated with the product to determine whether or not it was safe with respect to non-A non-B Hepatitis. The only way of determining that was to take clinical details and laboratory measurements of previously untransfused patients.

Q. So when was it in 1986 that it became apparent that the Scottish product would definitely infect, if you like?

A. I think -- and again this is partly from memory but also partly from reading back over the files. I think it's probably around the time that we became aware of a specific case of transmission of non-A non-B Hepatitis to a patient in Edinburgh treated with the NY 68-degree, 24-hour product.

Q. Right.

A. I'm not sure whether there are any other specific patients that we became aware of. I can't recall any but there may have been.
Q. In order to become aware, you would need a specific virgin patient in order to give you that information.
A. You would, yes.
Q. That would tell you for sure.
A. Yes, it would, I think, although I'm not a clinician. But my understanding is if a patient had been previously untransfused and had no other risk factors, then developed abnormal ALTs at the appropriate frequency of monitoring, then you could reasonably conclude that that patient had got the infection from the product.
Q. And that would be a significant development then?
A. I think so, yes. But I think, as you suggest, not wholly surprising.
Q. Yes. Well, I would like to take you through some correspondence then and see whether we can learn anything from that. Would you have a look, please, at a letter to you dated 27 June 1986. That's [SNB0075871]. Do you remember getting this letter?
A. No, I don't remember receiving it but clearly I received it and I am obviously familiar with it now.
Q. Right.
A. Yes.

Q. So a letter from your deputy, is that right?
A. No, it's from the deputy director of the Southeast of Scotland Blood Transfusion Service. That would be Dr McClelland's deputy director.
Q. And that's Dr Boulton?
A. Yes.
Q. He writes to you saying that:

"May I pass on to you a couple of verbal comments about blood products from Christopher Ludlam."

So Christopher Ludlam has passed some information to him and there is reference to:

"The 'virgin' patient with Christmas Disease who received heat-treated DEFIX towards the end of last year, and on whom Christopher reported at Scotblood, continues to show no elevation of ALT levels or other evidence of non-A non-B Hepatitis."

Then I think we can put that to one side for the purposes of the discussion.
A. Yes.
Q. Then:

"A young haemophiliac who previously had minimal therapy with Factor VIII received an infusion of the current heat-treated product a month ago. He now shows signs of liver enzyme rises indicating non-A non-B Hepatitis. Christopher is a bit ruthfull with his own

staff about this because he feels that this patient should have received 8Y or an equivalent product. However, the patient is apparently quite well clinically."

A. Yes.

Q. Can you explain then what the situation is in relation to the supply of 8Y and why perhaps Christopher would be "ruthful" with his own staff about the fact that that wasn't available?

A. I'm sure you have spoken -- I know you have spoken to Professor Ludlam about this. I think certainly by June 1986 Professor Ludlam would have been aware, as indeed anyone -- or people in the field in the UK were aware of BPL's very significant 8Y development, and he would have had access to the preliminary data that we had access to from BPL. He regularly attended the UK haemophilia centre directors' meetings, at which these sort of data would have been discussed.

So I think Professor Ludlam would have been aware that there was a product that was looking promising in terms of delivering the Holy Grail, which is a product which is non-infective, not just with respect to HIV but also non-A non-B Hepatitis. So I think, without putting words or thoughts into Professor Ludlam's mind, he would have -- I think the reason for him writing the letter is

that, following that particular incident, he would have been aware that there was a product available -- well, it was available in England and Wales.

It was a product made by BPL specifically for the English and Welsh population, and I think he is simply expressing the view that, had we access to that product, then that would have been a more appropriate choice of product for that particular patient, with hindsight.

Q. Were any steps taken up to this point to obtain access to this product?

A. No.

Q. So it was this event that seems to have triggered the steps that were taken to obtain access to this product?

A. That's my understanding, although the initial steps taken to access the product were taken by Professor Ludlam. So my assumption is and my understanding is that it was this specific incident that led to the subsequent correspondence which led PFC to engage in a process to get access to --

Q. What's the basis of your understanding?

A. I think this letter and the subsequent correspondence from Dr Boulton, where I think this is followed up by discussions between Professor Ludlam, Dr McClelland and Dr Boulton, where he specifically says, "Can we get access to 8Y? Do you think that's a possibility?"

Q. Right.
A. So my understanding is, although I have no evidence for this and, as I say, it was -- Dr Ludlam was, in a sense, at the epicentre of this particular issue, it certainly arose from his initiative, there was no specific action being taken by SNBTS to secure supplies from another manufacturer to treat patients in Scotland and that was for very good reason.
Q. Right. Perhaps we can come to that.
A. Sure.
Q. Can we just follow the correspondence through?
A. Yes.
Q. And I will come back to that. It will arise in the course of our discussion.

The next letter is a letter dated 2 July 1986 from you to Boulton, which is [SNB0075909]. You replied on 2 July 1986 saying:

"Dear Frank, thanks for passing on Chris Ludlam's comments regarding Factor VIII.

"As you probably know, we are poised to introduce yet another Factor VIII product, which will be heat-treated to 80 degrees/72 hours and should therefore be comparable to 8Y and better than anything available commercially.

"I have no doubt that as soon as this becomes

available, virgin patients will be able to gain access to this product before stocks of the existing product are exhausted. However, this has not been formally agreed yet and we should not yet declare this as a policy."

That's obviously suggesting that Scottish product is going to be available relatively soon. You do not give a timescale.

A. That's right.

Q. And you are also dealing with the question of getting that product in preference to other existing products, so that an extra margin of safety is being given there --

A. That's right.

Q. -- to virgin or minimally treated patients?

A. That's right, that had been the expectation. Although, as I very cautiously put it at the end of the letter, I don't think deciding who the PFC product should be prescribed to and which particular patients is any business of the SNBTS or the PFC. So I'm simply saying --

Q. Whose job is that then?

A. That's the treating doctors.

Q. Right.

A. So I'm simply saying that, if that policy were to emerge

as a proposal, then, before we implemented it, we would not implement such a policy without consultation with the prescribing doctors.

Q. Very good. If we go then to a letter dated 4 July 1986 from Boulton to Perry. That's [SNB0075910]. This is from Boulton to you. This refers to a telephone conversation which you obviously had with Dr Boulton.

A. Yes.

Q. Do you remember that telephone conversation?

A. No, I don't.

Q. Does that mean nothing at all?

A. I don't remember the telephone -- I don't remember the detail. Clearly the telephone conversation took place and I have a very sort of generalised memory of this whole incident but I don't specifically remember what I was doing and what I was thinking whilst I was having this conversation with Dr Boulton.

Q. Perhaps the --

A. I think --

Q. There is an attachment to this letter.

A. Indeed.

Q. I think if we just have a look at that, [SNB0075911]. Could we just have a look at this? Is this what's referred to as being an accurate record of the telephone conversation?

A. Yes, it is.
Q. And whose writing is that?
A. I think that's Dr Boulton's writing.
Q. Right. And can you just tell us then what is going on in this document?
A. I think it's describing the transition from, I think, what Dr Boulton is describing as the "phase 2 product", which is the NY product treated at 68 degrees for 24 hours, and he is simply graphically describing his understanding of effectively how the batch dedication system would work.

So the phase 2 product being used up, the Z8 product, which is the phase 3 product, being produced. I don't think there is any timescale on this. I think he is just trying to illustrate the way in which the new product would emerge into use and then subsequently its introduction.

Q. Then we see --
A. But also importantly, and I think relevant to your interest today, is this notion that any previously un- -- or minimally treated patients could access this product prior to the point at which the NY 68-degree, 24-hour product was exhausted.
Q. So at the foot of the document it says:

"In the meantime, any Edinburgh 'virgin'

haemophiliacs who require therapy could be given ..."

Is that BPL 8Y?

A. Yes, it's 8Y. So I think he is suggesting that.

Q. Right. So whose suggestion is that then?

A. I think that arose out of our telephone conversation.

Q. Right. What was envisaged then?

A. I'm not sure what was envisaged but it was certainly a sketching out of an arrangement that could be explored to access 8Y for previously untreated and minimally treated patients in Scotland -- to a product which, there was some evidence to suggest, could be safer than the existing product.

Q. We now know, of course, that there is a "virgin", in inverted commas, haemophiliac in Edinburgh and we have a consultant who has indicated a "ruthfulness", if you like, that that has happened and there is not an availability of 8Y.

A. Yes.

Q. It has been pointed out to the manufacturer of Scottish product and the question has been asked of whether there is a possibility of English product being made available, and this seems to be a response in relation to that.

A. Yes.

THE CHAIRMAN: I'm not sure I know what that means. Whose

response and to what? I think you had better make it quite clear because this is a crucial bit, Mr Di Rollo, whether the product was available. And I did mention yesterday that there are contemporary documents reflecting the English position, to which we will no doubt come. But, you know, the question is not clear to me.

MR DI ROLLO: Well, perhaps the witness has an understanding of the position in terms of its availability to Scottish -- I mean, this all arises as a result of a request being made by a consultant in Edinburgh and you and Dr Boulton are discussing the matter in correspondence and on the telephone. So what do you anticipate is going to happen and how is it going to happen?

A. Well, picking up a point about availability of 8Y in Scotland, it was fairly clear to me at that point that both the supply of products in Scotland, and Northern Ireland at that time as well, and England and Wales, were administratively quite separate. They were quite distinct and there wasn't, as it were, a free flow of -- there wasn't a UK policy for the supply of plasma-derived products for UK patients.

So in terms of availability, it certainly wasn't a licensed product. It hadn't completed its clinical

trials. It hadn't completed its clinical evaluation. So availability in the sense that you could simply go out and either purchase or get supplies of this was certainly not an expectation.

We knew it was in very short supply. It was a relatively new product. It had only just gone into routine manufacture at BPL and I think it was widely understood and known that in England and Wales, in contrast to Scotland, they were very short of supply of coagulation factors from the NHS. And I think about 30 per cent of the supply was being met at that time from BPL.

So the general view at the time was that England was chronically short of products -- not just BPL's 8Y product but any products were in fairly scarce and short supply. So the idea that Scotland could simply dip in to the BPL supply of products to England and Wales and expect there to be a positive response, I don't think that was part of the expectation at the time.

Q. So why does it say:

"In the meantime, any Edinburgh virgin haemophiliac who requires therapy could be given BPL 8Y."

A. I think that's simply scoping out a possible line of investigation between Dr Boulton and myself. We discussed the issue and having discussed it, there was

a small but significant perhaps requirement for such a policy and we considered that that was at least a feasible proposition to explore.

Q. You see, it's quite a useful possibility from the English point of view because if they are doing clinical trials on their 8Y and they are looking for virgin haemophiliacs -- there might not be many in Scotland, there might be a very small number coming to light in the period in question.

A. Yes.

Q. But it would be useful for them to have clinical data as a result of that.

A. That's in the event what actually happened as a result of these discussions, which again were initiated by Professor Ludlam. But I don't think it was against any background that Scotland was simply ignoring a freely available supply of product.

Q. No, no, I appreciate you have to make a specific request under specific conditions. The question is whether it's practical and it can be achieved, whether or not there is a possibility of being able to obtain material that would provide some sort of protection.

A. Yes, well, indeed, as I think is evidenced by Dr Boulton's sort of sketching out of the arrangement. I think as a result of the telephone conversation, which

was triggered by Professor Ludlam's interest in accessing this material, we considered it was a feasible proposition and that it was very well worth exploring, which is exactly what we did.

Q. In relation to this timetable, it does look as though the Scottish product is going to become available, be produced -- am I right in thinking? -- from about September 1986?

A. No -- yes, I think that was the original expectation in June/July time.

Q. So when this correspondence is going on between you and Dr Boulton -- it's September it's anticipated -- we know that's not what happened?

A. Scottish product was going to be available for clinical evaluation with the half-life recovery studies and so on and the various evaluation exercises that it would have to go through.

Q. As he says in his document?

A. That's right. So we were looking at covering a fairly short period here by the time this proposition emerged.

Q. Right. Then the next document I want to put to you is [SNB0075913]. A letter from you to Dr Boulton:

"Thanks for your note of 4 July, which is about right in terms of the various phases of Factor VIII production and supply from PFC."

The first paragraph (a) you make a sort of indication that you rather think that your product is going to be even better than 8Y, and then you say that:

"While there will be no PFC product virucidally comparable to 8Y until September 1986, after that time it would be my intention to supply a phrase 3 product to virgins, since we hope to demonstrate by that time that it is virucidally equivalent, thus removing the need to go south. However, in the immediate future (July-September 86), we could probably get supplies for 8Y for special cases. It would of course be preferable if these could be obtained and supplied through PFC".

Could you just explain that statement then?

THE CHAIRMAN: And its basis. That's absolutely fundamental to understand.

A. Which one?

THE CHAIRMAN: :

"In the immediate future ... we could probability get ..."

I think it's that one.

MR DI ROLLO: Let's break it down. You are saying here that there is no PFC product which is virucidally comparable to 8Y until September. So there is a recognition there that the Scottish product is inferior to 8Y in this respect. Is that reasonable?

A. Yes, I think we would certainly agree, and we would have done at that stage, that 8Y was looking increasingly to be a product that was likely to be free from the transmission of non-A non-B Hepatitis, and we were also reasonably sure that our own product at that time did carry a risk of non-A non-B Hepatitis.

Q. Right. As a specific example of that, as we have discussed already, in May 1986. Just going on, you then say:

"After September 86, it would be our intention to supply the phase 3 product to virgins."

So therefore, the phase 3 product which I think becomes Z8?

A. That's correct.

Q. That product, it would be your intention to supply that to the virgins. That's the previously untreated or minimally treated, if we can broaden it slightly, to them.

A. Yes.

Q. And you then refer to removing the need to go south. And the need to go south is this obvious gap in the level of safety as between the two with regard to non-A non-B Hepatitis?

A. Yes -- well, I think the letter, which is, as you see, dated July 1986, is really just following up the

previous discussions, the telephone discussions that we had and beginning to scope out an outline plan for putting this particular system in place --

Q. Very well.

A. -- to cover this small period. Yes.

Q. And we then go on to the next page:

"However, in the immediate future, we could probably get ..."

That's July to September and as we have seen, that's when it's anticipated that Scottish product would come on stream, for virgins at least:

"... we could probably get supplies of 8Y for special cases."

And I take it that special cases are previously untreated --

A. Correct.

Q. Is that right?

A. Yes.

Q. I think we would like to find out what is the basis of you getting those supplies and why is it preferable to obtain these through PFC.

THE CHAIRMAN: Let's leave the procedural bit out until we have answered the first one.

MR DI ROLLO: Very well.

THE CHAIRMAN: So take them in stages.

A. The basis of the proposition that we could ...?
THE CHAIRMAN: Yes.
A. I think -- as I say, I'm not sure that I have got much to add but the basis of the proposition I think is as you have described it. There was at that stage evidence that 8Y was looking promising as a non-infective product, if I can call it that. And I'm suggesting there that perhaps with a degree of optimism and confidence -- although by this stage we hadn't actually made the approach, but we thought it was likely, given the small requirement, that if we had approached BPL, then it was possible or indeed -- and I'm saying there "probably" -- that they would respond positively to that particular request.
THE CHAIRMAN: This is very important to me, Dr Perry. I really do have to understand whether you had any information from England that suggested that you could get supplies or whether this is merely speculative.
A. This is speculative at this stage. We hadn't actually made the formal approach or indeed the informal approach.
THE CHAIRMAN: Why I am anxious about this is that you have already looked briefly -- and I think perhaps Mr Di Rollo will be bringing you back to it -- at the July 1985 document, [DHF0030476], and I'm

particularly concerned about the covering note that went with that, which is [DHF0030478], which I think it would be appropriate to see at the moment. Yes:

"The attached letter was sent out today to all haemophilia centre directors, as per the list you sent with your draft.

"Scotland was excluded but Northern Ireland was included in those notified, together with Wales."

A. Yes.

THE CHAIRMAN: If I understand correctly, that was the covering note with the circular, it makes sense of paragraphs in the circular that deal with the allocation of the product. Did you know about this at the time?

A. I don't think I saw this at the time, this particular circular, although I can't say -- I think these documents -- although it was excluded from Scotland, I'm sure haemophilia centre directors in Scotland would have had access to it through their network of contacts and so on. They would have been aware of this. But what the covering letter is signifying is that, as far as BPL was concerned, the constituency for who they were responsible to supply was primarily England and Wales.

MR DI ROLLO: That's obviously their constituency.

A. That's who the product -- and that reflected the administrative arrangements in the UK for the collection

of plasma, the collection of blood and the supply of products.

THE CHAIRMAN: Mr Di Rollo will explore it for you but this is the context in which I have to make findings on fact and I am concerned about this material.

MR DI ROLLO: If we go back to the previous letter, your letter to Boulton dated 7 July, it does rather look from that letter -- I mean, you have said to us "speculative" but you do use the word "probable", and it does sound as though you have a certain degree of confidence about getting hold of this material, if you ask for it.

A. Yes, I was casting my mind forward and rehearsing, when I was writing the letter -- and I don't think -- these sort of letters between myself and Dr Boulton weren't carefully crafted. They were between --

Q. But I mean, we know from events that you did make a request?

A. Well, absolutely.

Q. And it was complied with?

A. I would certainly agree that at that time, and as evidenced by the letter, I was, I wouldn't say confident, but I thought it was well worth a try. If I had thought it was a complete non-starter, then I think the correspondence would have looked different.

Q. Right. Very well.

A. So I certainly don't want to give the impression that I was denying that this was a feasible proposition; otherwise, we wouldn't have embarked upon it in the first place.

Q. Thank you. Before leaving this letter, I did want to just confirm the point about supplying through the PFC. What's the situation in relation to that? Why does it have to go through PFC?

A. Well, it didn't have to. I think I'm expressing it as being preferable because we were the central locus for supply just in terms of practical issues, and through our regional transfusion centres that would have been a system that would have created at least some sort of central control over the availability of what would have been -- and at the time we were speculating that it would be successful. But if it was successful, I think we were just speculating that it would be important that we could demonstrate some sort of a central management of a very, very scarce material.

Q. Right. There is a letter dated 7 July 1986, [SNB0075914]. I think if we look at the bottom of the letter, we will see that it's from Dr Boulton again.

A. Yes, it's 7 July.

Q. "Last week, Dr Ludlam wrote to Brian asking if it would be possible to obtain some of the BPL products for use

if a previously untreated haemophilic presented for replacement therapy.

"He said it would be difficult to estimate his potential use accurately, but I understand that he has no haemophilics on his books at the moment who have not been treated. He has actually asked for 100,000 units, which I make 500 vials of 200 units in each. He says that this should be sufficient to cover surgery in such patients. But it strikes me that this is a considerable quantity, representing about half of a batch which would be produced from PFC.

"Before I write back to Christopher, would it be possible for you to obtain perhaps 10,000 -- ie 50 vials, which would at least enable us to cover the initial injection for such a case and if the need were to arise to call up more from Oxford over the course of 24 hours or so. I think that whereas a request for 100,000 units on site is unreasonable, a request for 10,000 units could be justified. However, even if this is difficult to get, how about 4,000 -- ie 2 boxes with 10 vials in each?"

A. Yes.

Q. Is this a follow-on from what you have already been discussing?

A. I think we are following the chronology of this

generally. I think this is a proposition now turning into a plan.

Q. Right. And you have not yet at this date actually made a request, I think. Is that right?

A. No, but interestingly -- and Dr Boulton, who was the SNBTS consultant clinician with a specific interest and responsibility for coagulation factors, was basically reflecting his knowledge and understanding of the dire supply situation in England and Wales, which is why he is suggesting that -- I think what he is basically saying, between the lines, is 100,000 units would be met with a sharp intake of breath and possibly a "no", so I think he is trying to titrate the plan down to something which had a reasonable chance of succeeding.

Q. Right. And then you write to England on 15 July 1985, if we could have that up, [SNB00075202]:

"We are now involved in the clinical evaluation of our respective heat-treated Factor VIII products. For our present product (68 degrees/24 hours), we are primarily concerned with half-life and recovery, since it is unlikely we will achieve freedom from NANB. However, since we anticipate future trials of a product subjected to some more substantial conditions of viral inactivation, I believe it would be helpful if we exchanged our respective trial protocols with a view to

achieving commonality wherever possible."

Does this have anything to do with what's going on, what we have already been discussing?

A. No, I don't think it does. I think this is a separate, offline, discussion about basically clinical trial protocols for our respective products.

Q. Right. If we move on then to a letter dated 24 July 1986, [SNB0075980]. This is to you:

"Factor 8Y to PFC":

"Following your letter on your requirements for virgin haemophiliacs in Scotland and Northern Ireland, I tried to contact you by telephone last Thursday in order to begin supply as soon as possible. As you were down in London, it was obviously difficult.

"However, with Dr Lane's agreement I had spoken to Jim Smith and he hoped to see you last Friday with a novel proposal: perhaps Scotland would like to participate in our trial of Factor 8Y.

"Provided that you were agreeable and that the patients met the criteria and given agreement by the haemophilia directors involved, Jim can provide 8Y from batches set side for trial purples. I assume that everything went well, as I have not had any adverse comment from Jim.

"In case there are some patients who do not strictly

meet the criteria for trial now or in the future, I have put aside some 8Y for immediate dispatch to PFC (or any other destination), if you require it. I can arrange same day delivery if necessary. Would you like this additional product to be [sent] to PFC now, or have you made adequate arrangements for cover with Jim?

"Please do not hesitate to phone me in order to save time, and we can take it from there."

Can we just go over the page:

"There is one point, however, that you need to consider. Current batches of 8Y on issue are not made from certified anti-HIV screened donations. The first individually screened product will not be released for issue until August. Subsequent batches will all be made from screened plasma. In the light of press statements from Armour Pharmaceutical and rumours from the Haemophilia Service, this may have implications for both laboratories. In addition, two Parliamentary questions have been submitted on this problem relating to both Elstree and PFC."

If we go back to the first page of that letter, it does look as though the request that has been made is going to be granted and the response from England -- this is obviously a letter from you?

A. Yes.

Q. I don't know if we have the letter from you. I don't think that we do. But in any event, it does appear that you have made a request, a specific request, for 8Y and that request has been granted and there has been suggestion that Scottish patients participate in trials but, of course, that doesn't appear to be an essential aspect of the supply of the product.

A. No, I don't think Mr Pettet is making that a mandatory condition. Basically, there is a letter from myself which sets out our proposition that we would like to access small supplies of 8Y for these particular circumstances.

Q. We will just see if we can find that.

A. I'm sorry, I don't have it with me but I have certainly seen it.

Q. We will come back to that in due course.

A. And I recall that I had a telephone conversation with Mr Pettet and perhaps Dr Smith, Jim Smith as well.

THE CHAIRMAN: Can you just excuse me a minute? We will have a search made here, Mr Di Rollo, and see if we can pick it up.

MR DI ROLLO: I think it's a letter obviously around the time of the letter of 1985.

THE CHAIRMAN: It must be between those two dates in July, yes.

MR DI ROLLO: I have made some mistake in relation to that. I think if we go to [SNB0060336].

A. Yes, this is -- what is the date of this letter? That's 10 July. That's correct. So this really -- this letter closely followed the telephone conversation and the other correspondence that we have looked at with Dr Boulton, which I think there is also annotated a note from myself that I have written to BPL requesting supplies of 50 vials.

Q. I think it's quite important actually to be clear about this because the letter does refer to providing this product in Scotland and just looking at the letter, you say:

"Very occasionally a haemophiliac without previous exposure to Factor VIII concentrate presents in Scotland for treatment. One such virgin patient presented very recently and was treated with our current product and subsequently developed markers for non-A non-B Hepatitis, although he remains clinically well. It is our intention, as you probably know, to introduce a product heated at 80°/72hr within the next two months and which will be comparable in terms of non-infectivity with your 8Y product. Pending the introduction of this product in Scotland and Northern Ireland, I write to ask if it would be possible for you to supply PFC with

a very modest quantity of 8Y (50 vials) to cover the treatment of similar virgin patients, who may appear between now and September. This request originated from our own haemophilia directors and in the light of our imminent introduction of a product comparable to 8Y, does not seem unreasonable and should not place an overwhelming burden on your supply."

You are obviously conscious of asking for a bit of a favour but you are minimising the request as much as possible, I suppose, and you don't want to place an overwhelming burden on their supply?

A. I'm trying to scope it in a way which gives it the maximum chance of success, I think.

Q. It does refer to haemophilia directors, plural.

A. Yes, I think although the original request was specifically and directly from Professor Ludlam, I was just trying to give it a Scotland-wide context.

Q. Right.

A. I didn't see there being any advantage in really focusing in on one particular geographical area.

Q. So I mean, in terms of this aspect of matters, I mean, the reference to Edinburgh haemophiliacs in the note of the telephone conversation that we saw, we now see that in your request you are anticipating that it doesn't just apply to patients in Edinburgh but it applies

throughout the country, in other words that you were dealing with the potential at least for a haemophiliac without previous experience presenting for treatment throughout the country.

A. Yes.

Q. And the point here is it's until an equivalent Scottish product is available?

A. Yes.

Q. This is to cover this situation?

A. Yes, it's an interim arrangement which was envisaged at that time to be of two or three months' duration.

Q. Right. There doesn't seem to be any indication in this letter of you having in mind the idea that it should be restricted to clinical trials or anything of that kind?

A. Certainly not in this letter, no. I'm just trying to take the first step, which is demonstrating in principle whether this was a feasible proposition.

But I should perhaps add a little context to this, and you may come on to it later but I'll raise it now just in case it's relevant: the responsibility for providing products to the NHS in Scotland was certainly one that was borne by the SNBTS and indeed the PFC. But there was a very clearly established arrangement and understanding between SNBTS as the manufacturer and supplier and the prescribing doctors, that for those

products that were not available from the SNBTS, the SNBTS had no role or remit to go out and source and supply products which it was, for whatever reason, unable to supply.

These were specialist products for inhibitor patients and so on and that was very carefully established. If there was a product that a haemophilia director needed or required for whatever reason for his or her patient, that would be a prescribing decision taken by the haemophilia doctor.

So it wasn't part of our role -- and I apologise if this sounds defensive, it's not intended to be. It was not part of our role to cover every eventuality for patient treatment in Scotland and then put in a plan to cover that. If there was a perceived requirement to, if you like, cherry-pick another product from another source, it was not the responsibility or the role of the SNBTS to do that. That was very much a responsibility of haemophilia directors and that was a very clear understanding.

Q. If a haemophilia director has pointed out that there is a gap or there is a need and he points that out to SNBTS --

A. Yes.

Q. -- SNBTS apparently here have taken on board --

A. We have received a very specific request to assist, on this particular occasion, and that's what this correspondence refers to, a very specific request for a very particular circumstance. And on this particular occasion, this haemophilia director had asked for the SNBTS to use its good offices to maximise the opportunity, the possibility, of success. But there were very many other circumstances where haemophilia doctors would have wanted a product to treat inhibitor patients which wasn't available from the SNBTS, a product called FEIBA, Factor VIII inhibitor bypassing activity. And that would not have been sourced through SNBTS and we would have not been involved in that.

There were other patients that periodically reacted adversely to our product, and in that circumstance haemophilia doctors would have explored other products from other manufacturers, including commercial manufacturers, and chosen the product of their choice.

Q. Right. The situation is that a request was made and SNBTS became involved and the request was able to be met?

A. Yes, we became involved enthusiastically and positively but it was not something that I would have expected to be part of our scope of activity to identify this particular issue and for the initial request to come

from SNBTS.

Q. Let's follow through and see how matters develop. This is your request, and I have already been to the letter dated 24 July which was, I think, the response to this letter. If we then go to a letter dated 24 July 1986 from you to Dr Boulton, which is [SNB0075982]:

"Dear Frank,

"Supplies of 8Y:

"I have now confirmed that BPL are happy to supply 50 vials of 8Y to PFC, on the understanding that in the event that the material is used in suitable virgin patients, appropriate serial samples would be taken to contribute to their overall infectivity study.

"I think this is reasonable since the product is still in clinical trial. I will pass on the product to you as soon as possible and I would be grateful if you could inform Dr Ludlam of this arrangement."

So that's your response. Obviously you haven't sent him a copy of the actual letter that you received from Pettet?

A. I might have done but I haven't actually indicated that that's the case here.

Q. I appreciate that this is a very brief note, the first paragraph, but it's not quite so restrictive as -- Pettet's complying with your request is not ...?

A. It's a very high level executive summary of what I understood to be the basis on which the arrangement was to take place.
Q. All right.
A. But we knew -- I knew Mr Pettet very well and we had a good understanding, and I think interestingly and very positively, he wasn't trying to place excessively burdensome conditions on the supply of this particular product.
Q. In terms of Dr Ludlam's use of the product thereafter, if he had a virgin haemophiliac, he couldn't in any sense be described as misusing the product at this point. If he had got the 8Y from you and used it on a patient, he has got permission, it has all been done through the proper channels, in order to use this product.
A. To use the product in a previously untreated patient?
Q. Yes.
A. Yes. Absolutely. That would be perfectly appropriate and it would be done under the umbrella of the clinical trial and there would be an expectation if possible -- and often I think it's not possible. I think the clinical follow-up for these particular studies is intrusive, it's invasive, it places a great burden on the patient. So it could be the case that a doctor

enters a patient into a clinical trial for very good reason but then for various reasons, the patient cannot comply or does not wish to comply with the really quite extensive frequent follow-up samples that need to be taken.

Q. Also he might have a situation where he can't comply with the requirements to fulfil a clinical trial because it's an emergency and he can't go through the procedure.

A. Absolutely.

Q. You give the person the product and he wouldn't be doing anything inappropriate in that situation because it has all been cleared with --

A. Nor was there any suggestion in the follow-up to the enactment of this particular arrangement that if Professor Ludlam or anybody else had used the product for another reason, that the whole arrangement would collapse.

As I say, I don't think BPL or Mr Pettet or indeed Jim Smith or anybody else was trying to place really excessive control on the use of the product. So once the product is in the hands of the doctor, the doctor is basically free, I think, to use the product wherever he or she thinks it's appropriate to use, and I would have thought that was quite reasonable.

THE CHAIRMAN: Mr Di Rollo, Professor James would like to

ask a question.

PROFESSOR JAMES: Do you mind if I ask one question? You have referred to a Scotland-wide context in respect of this.

A. Yes.

PROFESSOR JAMES: You alluded then to "Professor Ludlam or anybody else". I just wonder whether to what extent the four other haemophilia centres in Scotland were informed about this, what initiatives they took. So far we have very much concentrated on Edinburgh but I'm just interested in whether there was any more sort of systemic involvement in this in any way.

A. To the best of my knowledge, I didn't specifically inform other haemophilia directors that we had access to supply of 8Y. As I say, I think the -- my understanding of the arrangement at the time was if asked to provide assistance in accessing an alternative product for a haemophilia director, then we would have made our best efforts and our good offices to secure that. But I don't think I would have considered it my responsibility at that point in time to say the SNBTS has now formally accessed product for the whole of Scotland and I don't think we received any other specific requests from other haemophilia directors.

PROFESSOR JAMES: You refer to a Scotland-wide context.

I just wondered if, you know, you had let the other haemophilia centres know that it was conceivable that you would be able to access this for virgin patients or anything like this.

A. No, but I think in terms of laying out the ground and the arrangement with our colleagues in BPL, who we were basically asking to do us a favour, if one uses a colloquial expression, then I wanted to prepare for a situation in which another haemophilia director in Scotland could have made a similar request to Professor Ludlam.

I guess -- and this is with hindsight and I haven't got any evidence to support this but I think my thought process at the time would have been that Professor Ludlam is working closely with other haemophilia directors in Scotland, would have informed them either formally or informally through the communication channels that they had, that this arrangement had been put in place in Edinburgh.

PROFESSOR JAMES: Thank you very much.

Thank you very much, sir.

MR DI ROLLO: Thank you.

So I think there is another letter we should put up. I refer you to it because it is dated 28 July 1986 and it's [SNB0075986]. This is again you to Mr Pettet at

BPL and you refer to the letter of 24 July:

"I have indeed spoken to Jim and have confirmed locally that the supply of 8Y should be conditional on users participating in the clinical trial of your product, at least until a PFC lookalike product is available (two months time approximately). I have now written to Jim confirming these points and I have asked if he can now send (immediately) 50 vials to PFC as a contingency stock of non-infective material in the unlikely event that a virgin haemophiliac presents for treatment in the near future."

Can you just explain what the clinical trial aspect of that is?

A. I think this was a suggestion of both Jim Smith and Norman Pettet, and probably also contributing to that was Dr Lane -- that if the product were to be used in a previously or minimally treated patient in Scotland, then we would do our utmost best to collect follow-up samples or the haemophilia doctor would take the sample, have the test done and report those results according to the protocol which we had provided with the product.

Q. So the purpose --

A. So the clinical trial is the long-term follow-up of patients as part of the BPL study to demonstrate whether or not the product was indeed safe with regard to non-A

non-B.

Q. Obviously the English are doing you a favour by providing this material but there is benefit to them by having this data in relation to virgin haemophiliacs, and they want to just ensure that that's information they are going to get?

A. I think that's absolutely right. So there was a quid pro quo here. Where the balance of advantage rests, I'm not quite sure but I think the whole arrangement did sort of illustrate the difficulty of the supply situation in England and Wales, and again at this time I think the emphasis was still on HIV safety of plasma products and all product that was produced by BPL and supplied outside of England and Wales would have required England and Wales to compensate that by purchase of commercial product.

So even though we are talking about small numbers here, there was a very important principle that was being established, and at that time I think Scotland was perceived as being in a very strong position with regard to HIV safety. So there was always an argument in the background which is, why would we want to export (sic) NHS product from England, which was perceived and believed to be much safer than commercial product, at a time when they had a shortage? So I think there had

to be some sort of -- reward is the wrong term but --

Q. Something in it for them?

A. There has to be something in it for them otherwise they would be seen to be acting not in the interests of their particular constituency, and that goes back to the issue of availability.

Q. If we move on to the next letter, which is [SNB0075990], this is from Jim Smith, I think:

"Dear Bob, as requested in your letter of 24 July and agreed verbally by Dr Lane, I'm sending you attached 50 vials of 8Y 3312 in case you wish to protect category 1 patients before your Z8 is ready."

What did you understand by category 1 patients?

A. Previously untreated and minimally treated -- patients that were eligible for clinical trial basically.

Q. "Please issue one of the attached copies of the trial protocol to the responsible physician in each event and let me know whom I should nag for data."

That refers back to what we have just been discussing.

A. Sure.

Q. And it does seem to be anticipated that there is a short period of time obviously during which this requirement is going to arise because the Scottish product will be ready quite soon and the other thing is that he refers

to a responsible physician, which presumably means that it's not just necessarily Dr Ludlam who is potentially at least going to be involved in this. Is that right?

A. I think it's just reflecting the Scotland-wide context that I established when I initially approached BPL. So yes. Well, it's reflecting also that there is more than one doctor, even in a particular centre, that might be responsible for patient treatment.

THE CHAIRMAN: Of course, one possible view of the correspondence to date is that Mr Pettet may have been relatively generous but when the issue passed over to Jim Smith, it tightened up to be one related to the conduct of clinical trial.

A. Yes, I think Jim Smith typically, and having a particularly close interest in this but also as a genuinely close friend and collaborator with PFC, was taking the opportunity to just put some -- not constraints but to put some boundaries around this arrangement and to maximise the possibility and the probability of him getting the data that he wanted.

THE CHAIRMAN: But also, of course --

A. I think from the point of view of his relationship with Dr Lane, the director, he would have to be seen to be doing that.

THE CHAIRMAN: Of course.

A. But it was a perfectly reasonable request to make.
THE CHAIRMAN: Are you aware of the terms of the circular of 5 July that indicated that the product was for distribution essentially to England and Wales with an exception related to clinical trial?
A. I don't think I was, no, no. I don't think I was.
THE CHAIRMAN: You see, it may be necessary to take all these documents together. If indeed your discussions with Jim Smith made it clear that this was for clinical trial, I ought to know that. If it didn't, I ought to know that. So I really have to press you a little to tell me, if you can, how matters developed behind the scenes, as it were, as a background to this correspondence.
A. My understanding is that in terms of the clinical trial in England and Wales -- although by this time the product was also in routine use; it wasn't just in clinical trial. But as far as the clinical trial was concerned, I don't think there were any efforts, direct efforts, made by BPL to recruit patients in Scotland.
I think that would have been seen as an inappropriate cross-border operation which wasn't part of the understanding between the two organisations.
THE CHAIRMAN: I think I can understand that. But it's not quite the question. The question is whether the supply

of the 50 vials, by the time it came to be made, was on condition that it was applied for clinical trial purposes.

A. Yes, I think that was the arrangement. It was very clearly established that this was Jim Smith's proposition, which was that the product -- BPL's response to our request was that, we can supply the product but we would like to do it, for obvious reasons, under the auspices of the clinical trial, and that was to maximise their opportunity to get data. But I think it fell short of a requirement that was going to be rigorously policed by Jim Smith, Norman Pettet or anybody else.

THE CHAIRMAN: It always becomes very woolly and I think my interest -- I suspect this is also Mr Di Rollo's -- is whether there was, as from this time, an arrangement that made 8Y available to Scotland on request, for specified purposes perhaps, but for purposes that would be persuasive of the need to supply the product in Scotland. If so, a follow-on question would be why it wasn't used. Why advantage wasn't taken of it, as it doesn't seem to have been. So I want to press you on what you remember the arrangement was, if I can.

A. The arrangement is really, as I have described it, that we demonstrated in principle that our colleagues in BPL

were prepared and able to supply small quantities of product for specific clinical situations, and the specific clinical situation was a previously untreated patient, and their positive response to our request demonstrated the principle that that was viable.

I think if that had been then extended to an arrangement where BPL were being asked to supply product for all sorts of other reasons, an 8Y product, then I think they would have resisted that, for the reasons that I have described.

So my clear understanding at the time was that this small supply of product was for very specific requirements. Having said that, it was no part of SNBTS's or PFC's responsibility to monitor the prescribing activities of doctors, who ultimately were going to use this product.

MR DI ROLLO: The point, I think --

A. I'm not sure whether that answers the question. Probably not.

Q. One of the things that Professor James asked you about and, obviously, the chairman has also raised is that clearly nothing was done by you to make it known beyond Dr Boulton, I think, and the southeast that this product was available for virgin haemophiliacs in Scotland. It is a fact that you didn't do anything further?

A. It is a fact that there is no evidence that I did anything further, that's absolutely right.
Q. I think you are telling me in evidence that it's not your responsibility to do that because that's not what SNBTS's responsibility is. Is that what you were saying?
A. I'm certainly not trying to say we had no involvement in this; clearly we had an involvement in this in response to a specific request. I'm trying to describe the arrangement which existed between ourselves and our prescribing doctors in Scotland that, in circumstances where prescribing doctors required product that wasn't available from SNBTS, ie it wasn't part of the portfolio of products that we manufactured, it was not the responsibility of SNBTS to go and source those products. Indeed, I think the haemophilia directors took the view that that would be wholly inappropriate for a manufacturer. It's a bit like asking Armour Pharmaceuticals to source a product from Baxter that they don't themselves prepare.
Q. There is an obvious problem here, Dr Perry -- and it does matter very much -- the question as to what could have been done in order to alert physicians throughout the country that there was this potential of a safer option. We have seen in the correspondence that

plainly, in ordering the material from England and getting a supply from England, it was anticipated that there was a Scottish-wide problem.

Scottish hospitals would be supplied with Scottish Factor VIII and if, into a Scottish hospital, whether it be in Edinburgh or Lerwick or Stornoway or anywhere else, a virgin haemophiliac presents, if they had a supply of this material or access to a supply of this material, then that would have provided, as we know, an added measure of safety for that patient.

A. Indeed.

Q. Now, the question is whose responsibility is it to take it to the next stage.

A. There were basically two options, and, of course, with hindsight, the best outcome would have been that either myself or Dr Ludlam, as chairman of the Scottish haemophilia centres directors study group -- either of us could have more widely notified the other four haemophilia centre directors that this product was available and, to the best of my knowledge, that didn't occur.

Q. Can you give us any explanation or indication as to why that may not have occurred?

A. I have attempted to give you the explanation why I didn't take that particular position, because I didn't

think it was a responsibility. Again, against this backdrop of being quite clear to make sure that, as a manufacturer, we were not exceeding our brief, I thought it was not the responsibility of SNBTS or indeed the PFC director, the manufacturer, to make wider notification of this. This was a specific facilitating arrangement that we carried out on behalf of Professor Ludlam.

Q. Would that be a conscious decision, "It is not my responsibility," or would it just be something that just didn't occur to you?

A. No, I think it was part of the background context in which I operated and it was just reflecting that general principle of operation, that --

Q. So --

A. There were previous discussions, certainly in the very early 1980s, about the idea of SNBTS becoming the supplier of all products, even those commercial products that we didn't make, and, to the best of my knowledge and recollection, that was quite roundly rejected. Whilst treating doctors in Scotland were very happy to receive products from SNBTS directly and through our supply chain and so on, they certainly were very resistant to the idea that we, the SNBTS, should also be responsible for procuring other products which we were

not manufacturing or supplying.

Q. The problem is that you have, in your role, detailed information about the relative merits of certain products, which certain physicians at least, perhaps not Professor Ludlam but other less well informed people, wouldn't have.

A. Yes.

Q. We have seen the correspondence, we have seen the minutes of the meeting and the data from England and all the rest of it.

A. As indeed the haemophilia directors would have as well. I think, arguably, I would have regarded at that time the haemophilia centre directors were at least as well informed, if not more so, of the various different products that were available and the various views that were being held on their relative safety.

Q. All that needed to be done, I think, is a circular to haemophilia directors to say, "We have got this stuff from England, it's available in certain very limited circumstances to deal with a specific problem while our product is being developed," and that might have at least have then provided that cover beyond Edinburgh.

A. I would agree with you, yes.

THE CHAIRMAN: The SNBTS and haemophilia directors met on 5 March 1986, when perhaps not too much of this would be

known, but they weren't due to meet again for some very considerable time.

A. Yes.

THE CHAIRMAN: So Mr Di Rollo's suggestion of a circular telling people about developments is quite important.

A. I would agree with you, and I did spend a little time establishing whether or not such a message did go out from either PFC, myself or the wider SNBTS, and I can find no evidence of that taking place. I think, with hindsight, I would certainly agree that that would have been an appropriate thing to do but I would still suggest that a more appropriate thing to do would have been for the haemophilia centre directors themselves to have -- in the knowledge that this was available -- we had established the principle with Professor Ludlam -- then there was a possibility that they too could have communicated amongst themselves.

THE CHAIRMAN: Mr Di Rollo, I don't have a note of all the meetings that may have taken place over the period from March. I know that that was the date of the joint meeting. But it might be relevant if you do have information as to when the haemophilia centre directors were meeting. I have got better notes of when the SNBTS directors met but that's not enough, I think, for this purpose. So if you have dates of the meetings --

MR DI ROLLO: We will certainly have a look for those, sir.

I think I didn't just -- in your last answer you said:

"I would certainly agree the more appropriate thing to do would have been for haemophilia centre directors themselves to have ... "

And then I missed the next part. What did you say?

A. Communicated amongst themselves of the availability of this. But I think I'm trying not to suggest that we could not have had a role to play here, and I think with hindsight I would agree: if I had my time again, I think I could have quite simply a written to other haemophilia centre directors -- actually, it would have been to regional transfusion directors as well, who were responsible for supply of the product -- and made them available.

It's quite possible -- I have absolutely no evidence that this took place, but through various informal channels and communications I would have mentioned that this actually happened but I have no evidence for that.

Q. Thank you. I'm conscious of the time. I'm very nearly finished but I probably have five or ten minutes left.

THE CHAIRMAN: We will rise at that point.

(1.07 pm)

(The short adjournment)

(2.00 pm)

MR DI ROLLO: Dr Perry, just to complete the correspondence, the letter [SNB00076022]. This is a letter that you sent to Dr Boulton, dated 4 August 1986:

"Just a note to conclude these discussions."

I assume that is the ordering of the 8Y but I think in fact discussions may be broader than that because it's dealing with discussions regarding the infection of Dr Ludlam's virgin patient. Is that right?

A. Yes.

Q. "Could you let me know the batch of Factor VIII involved in this transmission of non-A non-B Hepatitis to Dr Ludlam's virgin patient. While this outcome of treatment is not surprising, we need to know the batch number and dose to keep our surveillance cross-referencing records complete."

Could you just explain what's going on in this letter for us then?

A. I think it's simply a reminder to Dr Boulton that we did, as part of our quality system, capture any specific instances of generally called "adverse reactions", of which transmission of a virus is obviously an adverse reaction. And we hadn't received notification of this particular incident and we were just seeking the details of the batch numbers, so that we could put it into our

files --

Q. What would the procedure be for obtaining notification of an incident of this kind?

A. I'm not absolutely sure. I think -- there is certainly a yellow card system in place in the UK for all medicines, in which it is the responsibility of the prescribing doctor to record any adverse events. That said, I think the transmission of non-A non-B Hepatitis, although it's an adverse event, it's not one which is outside of the range of risks that are associated with the particular treatment. But in any event, I think SNBTS and certainly PFC, kept files on any instances of untoward reactions that occurred with any of its products.

Q. I don't quite understand what a doctor should do then in terms of notifying you. What's the protocol?

A. My understanding -- and I'm not absolutely sure that it applied to SNBTS.

Q. This is in 1986?

A. This is in 1986, but even in 1986 I think there was a yellow -- it was called "the yellow card system", and that was a process for reporting adverse events to the Committee on Safety of Medicines. For that to have any validity, the product would need to have had a current product licence and then the

Committee on Safety of Medicines would then keep a register and a record of any adverse events associated with any particular product or type of product.

So that system would have operated, and I'm not sure whether the transmission of non-A non-B Hepatitis to a recipient of these products would have been seen as sufficiently outside the normal expectation as to have warranted a report. But as far as the internal SNBTS system, it was simply a record of any particular adverse events so that if, for instance, a particular batch of any product caused an adverse event in a patient, and it happened twice, then we might think there is something systematically wrong with the product. So it gave us the ability to carry --

Q. "We need to know the batch number and dose to keep our surveillance cross-referencing records complete."

What are surveillance cross-referencing records?

A. I think that's just a simple description of the record-keeping system that we had for adverse events.

Q. The reason I ask you this question is I'm really interested to know whether this was the infection which told you and others that the Scottish product was liable definitely --

A. I think so. I think this probably does refer to the index case, as I might describe it, for this particular

transaction, which was getting the dose of 8Y. I think the timescale is exactly that.

Q. This letter tells you that the infection of Dr Ludlam's virgin patient is the case which informed SNBTS that the Scottish product was infectious for non-A non-B Hepatitis?

A. That's correct, yes.

Q. And --

A. But prior to that, we didn't routinely receive -- well not to the best of my knowledge -- routine reports of patients who had seroconverted, who had signs of non-A non-B Hepatitis or indeed Hepatitis B, simply because I think it was generally considered that most patients, if not all patients, that received concentrate, coagulation factor concentrate, did in fact inevitably go on to develop that particular disease, certainly prior to 1987.

Q. If we go back to the [SNB0075202] letter, which I showed you in error this morning, there is something of interest in it on this topic. Just the phrase that you use in that letter -- this is in July 1985, so this is the year before:

"It is unlikely we will achieve freedom from NANB".

Is the predicted situation with the Scottish product at that time. That's the state of mind at that time?

A. That's correct, yes.
Q. Right. I think there is one more letter that I would like to draw to your attention, I think, just to complete this. This is [SNB0076024]. This is a letter just confirming the receipt of the material. 20 vials has gone to his centre and you enclose the BPL trial protocol. As I understood it, I think 50 vials was what was sent. Is that right?
A. That's correct.
Q. So what happened to the other 30 vials?
A. I think the other 30 vials would have been entered into the PFC stock system and held in PFC.
Q. Do you know what happened to them after that?
A. I don't, no. I think they eventually all found their way to Dr Ludlam but I'm not sure for what particular purpose. So we have no follow-up on the specific use of the products.
Q. They certainly didn't go anywhere else other than Dr Ludlam; in other words, there is no --
A. Not to the best of my knowledge or recollection, no.
Q. So there is no record of anybody asking for this material from anywhere else, other than Edinburgh?
A. No, there is not.
Q. All right.
THE CHAIRMAN: Would there be a stock card for this material

similar to what we have seen for product being entered?
A. I think there would have been. I think it would have been entered into the standard PFC stock control system, which would have included the batch history sheet and so on. So it certainly would be possible, I think, to see what the stock record actually said and I'm quite happy to go away and explore that.
THE CHAIRMAN: It must be quite unique, from what you have told us, among the stock records.
A. Not completely unique. There were other very rare occasions when we would access a non-SNBTS-produced product for distribution. A useful example is C1 esterase inhibitor. So that would have been entered into stock in a similar sort of way.
THE CHAIRMAN: One might expect a subset of records dealing with these since they wouldn't be linking through to production --
A. That's right. I think the trace-back would have been very limited. But we would certainly have used that conventional stock keeping product distribution system which was in place for PFC products, if only to ensure that we had effective means of recalling the product if there was a defect or an adverse event reported with it.
MR DI ROLLO: [DHF0030478] was drawn to your attention this morning. I wonder if we could just have a look at that.

There is a question I want to ask you.

The letter was sent to all haemophilia directors in England and Wales dated July 1985. Scotland was excluded but Northern Ireland was included and the chairman drew this to your attention this morning. What I wanted to ask you was whether you knew or could give us an indication as to why Scotland would have been excluded?

A. I think Scotland was excluded because it wasn't seen by BPL to be a constituency for which it was responsible for supply of product.

Q. What about Northern Ireland?

A. I think Northern Ireland -- we were certainly supplying Northern Ireland but Northern Ireland did not supply enough plasma to meet all their needs for Factor VIII, so the supply of Factor VIII from SNBTS was in proportion to the amount of plasma that they sent, and they supplemented that by purchasing or obtaining supplies of product from elsewhere.

Q. If Scotland had wanted to get involved at this stage, would there have been anything to stop it? If it had said, "We were quite interested in this," would that have been possible?

A. In the clinical trial?

Q. Yes.

A. I think yes, that could have been done because the clinical trial and the arrangements for the clinical trial were discussed primarily with the UK haemophilia centre directors and Scottish haemophilia centre directors -- it was a UK committee. So there was certainly opportunity for those sort of discussions to take place.

Q. Right.

THE CHAIRMAN: We will leave aside clinical trial and think of issue for routine clinical use. What would the position have been?

A. Oh, I think that would have been for routine use. I think the arrangements were reasonably well segregated in terms of administrative arrangements. The position, I think, at that time in England and Wales was that product was supplied back to the regions, the regional health authorities, in proportion to the amount of plasma that they sent.

So there were very good, if you like, financial and self-sufficiency reasons why it would have been not considered appropriate for England simply to respond positively to a request from Scotland, for the reasons that I have described. Scotland was perceived and believed to be in a much better state of affairs in terms of HIV safety and access to NHS products from

voluntary donors and so on, and for every vial of product which came from England to Scotland, that deprived a patient in England of an NHS product. So I think that would have been seen as --

MR DI ROLLO: Were there ever any discussions of exchanging products? You know, "We will give you some of ours, if you give some of yours". Was that ever discussed?

A. I don't want to create the impression that there was a complete, impermeable barrier to mutual assistance between the two services, and there were red cells and platelets and so on that were supplied across the border but it was by exception, certainly not by routine.

Q. If a particular need or requirement was identified, as it was ultimately in May/June/July of 1986, then it does look as though arrangements could be made. There was a good relationship between the two bodies?

A. Absolutely. There was no statute or directive that would have prevented that. I agree with you, yes.

Q. You mentioned in your evidence the position about dissemination of information, that it might be possible to use the 8Y and you have given evidence about your own position. I think you also mentioned the position as far as haemophilia directors in Scotland were concerned. Who would be the best person to ask as to why that information wasn't further disseminated, if it wasn't,

down the chain?

A. Well, I think, the best person to ask from -- I have suggested that there are two routes by which it could have been disseminated, either via the haemophilia directors communication system or via the SNBTS communication system, and you have already asked the person from the SNBTS who was in the best position to communicate that, and that's myself. From the haemophilia centre directors, I think that would be Professor Ludlam.

Q. Right. I said I would come back to this so I really just want to give you the opportunity to say something about it if you want to. You said there may be good reason why manufacturers would not get hold of products from others, I think you said at the beginning of your evidence today. Do you remember that passage? Maybe you have forgotten it by now. It's just if you want to add something, or do you feel we have discussed it sufficiently?

A. I think this is the position and understanding that was established between ourselves as the manufacturers, that's SNBTS, and the users, the prescribing doctors. And as I say, I think there was a fairly well understood arrangement in place whereby, if the SNBTS wasn't able to supply a product from its own portfolio, then the

responsibility for seeking an alternative to the product that wasn't available from SNBTS should be the responsibility of the haemophilia directors. I don't think that's a particularly surprising position. If you regard the SNBTS as a manufacturer and supplier, as I say, the analogy is you wouldn't expect another commercial company who weren't making a particular product to go out and source on your behalf -- that is a haemophilia director's behalf -- a product from another commercial supplier.

Q. Right.

A. And it's simply preserving a distinction between the manufacturer and his or her responsibility and the prescribing doctor, and I think those boundaries are very well established and certainly increasingly reinforced by the regulators. But even at that stage it would have been -- I think without very substantial discussion and agreement and boundaries established -- for the SNBTS to act as the supplier of all products for Scotland, and that was debate and that was discussed and it was agreed that SNBTS was responsible for its own products but not other people's products.

Q. Right.

A. So the notion, for instance, of a haemophilia director or any other doctor wanting a product that we didn't

have, that would have been the responsibility of the haemophilia centre director to source that product, and there is an argument, I'm suggesting, that that is the case with the supply of 8Y from England.

Q. Would you just give me a moment?

THE CHAIRMAN: I can see that in a situation in which SNBTS is in competition supplying two products of the same class, but something like FEIBA may raise a different issue, since SNBTS were never in a position to produce that class of product.

A. Yes, yes, I agree that distinction but there is also another argument, which makes this distinction slightly more blurred, that both BPL and SNBTS were part of the UK National Health Service. So we were naturally collaborating organisations that weren't acting in competition. So I agree that distinction.

MR DI ROLLO: You were collaborating and cooperating and you yourself had a very good relationship, you had connections there.

A. Yes.

Q. And you got on well with the people there and if you spoke to them on the phone or corresponded with them, you would get a good hearing, obviously, from any requests that were made; and as we saw in relation to this, when a request was made, it was complied with?

A. Yes, we certainly had a good relationship and I think the evidence here is that we responded very quickly to the request from Professor Ludlam and we had a very successful outcome, so that would not have been untypical.

Q. It was obviously somebody must have thought that a good way of getting this material was to go through you because you would have your connections and knowledge and --

A. Yes, I think -- I'm not sure how valid that is and I did read those kind words by Professor Ludlam and I'm not sure whether it's completely true. I think in some situations, a senior and well respected haemophilia director would in some situations have much more clout and much more influence than a manufacturer of the product.

Q. Thank you, Dr Perry.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: I'm obliged. Dr Perry, could we look together, please, at the letter of 10 July 1986. That's [SNB0060336]. This was your letter that you wrote to Mr Pettet --

A. That's right.

Q. -- following upon your telephone conversation with

Dr Boulton. Is that correct?
A. Yes.
Q. And that arose as a result of then Dr Ludlam's request for, I think, 100,000 units. Is that correct?
A. Yes.
Q. But we see that what is asked for there is 50 vials, which represents 10,000 unit?
A. That's correct.
Q. In other words, one tenth of Dr Ludlam's original request?
A. Yes.
Q. Am I right in thinking that -- how can I put this? -- this letter is a carefully worded one?
A. I think it was carefully worded and probably following a discussion with Mr Pettet as well.
Q. Did you discuss with Dr Boulton how likely it was that if a request for 100,000 units had been made, it would be likely to be accepted?
A. The honest answer is I can't remember, but I think it almost certainly would have been part of the conversation given the size of a request for 500 vials, half a batch and so on. I think also Dr Boulton -- and I think in his letter -- suggested that that would be almost the maximum amount that you might need for a piece of surgery in one such patient, and he thought

that was excessive because you could start with the smaller quantity of product and if there was a requirement to follow that up, we could go back to BPL and seek additional supplies.

Q. Would I be right in thinking that this letter was pitched at a level that you thought was likely to succeed?

A. Yes.

Q. You talk there, I think in the letter, of a very modest quantity. Do we see that?

A. Yes.

Q. And also I think it starts off by saying:

"Very occasionally, a haemophiliac without previous exposure presents in Scotland for treatment."

A. Yes.

Q. With that in mind, can we turn to this question of the possible dissemination of information that a supply of 8Y had arrived in Scotland, and you remember that that was discussed with you in some detail just before lunch?

A. Yes.

Q. I think you accepted that with the benefit of hindsight, you could perhaps have disseminated that information to the various haemophilia directors. Is that right?

A. Yes, I think so, yes, I think that's correct.

Q. I just wonder about that. Given the very modest

quantity that had been received, what do you think the benefit would be in telling all the haemophilia directors that such a very modest quantity had arrived?

A. I think the benefit would have been that we could have demonstrated to all haemophilia treaters in Scotland that for the particular scenario described by Dr Ludlam, we had responded by obtaining a small stock of product and this could be made available to any treating doctor in Scotland. So I think it just simply broadens the constituency that could have benefited.

I don't think we would ever have been inundated but had we come back with very substantial requests from individual directors, particularly in Glasgow and so on, whether BPL would have been able to increase the supply significantly beyond the 50 vials or 100 vials and so on, I really don't know.

Q. I mean, clearly, from what you have said previously, it wouldn't be normal practice of SNBTS to advertise the fact that they had a product that was not an SNBTS product?

A. No, it wouldn't have been, no.

Q. But again, I think this whole process was something of a one-off, was it not?

A. It was a one-off in response to a specific request from

a colleague.

Q. I just wonder -- again, you accept this is with the benefit of hindsight -- that if such information had been disseminated, that it might not have perhaps have created an expectation that might not have been capable of being achieved or met?

A. It depends on the size of the demand against it but I think, again with hindsight, I think we found that the product that was supplied for this particular use was never actually used in Edinburgh. A very significant proportion of patients, haemophilia patients in Scotland, were in Edinburgh.

So I think it's possible. But had this been for a Scotland-wide use, then I think we would have had to have been alerted to the possibility that we would have had to have increased that particular demand, but again I think in all honesty, what was in my mind was that we were responding to a specific request from a specific doctor and if other doctors in Scotland wished to access these products, then they were certainly free to do so, either between ourselves, via Dr Ludlam or directly with BPL.

Q. I was coming to that. You said, I think, previously, that the haemophilia directors were at least as well informed as you were in relation to developments and so

on. Is that not correct?
A. I think it's certainly fair to say that haemophilia directors were fully aware of the existence of 8Y. They were fully aware of its emerging track record in terms of safety and indeed, they would have participated in the discussions of haemophilia centre directors, where the BPL developments would have been shared with the whole of the UK haemophilia centre directors at their regular meetings. So, yes, they were at least as well informed as us.
Q. In relation to the question of dissemination of information, presumably, would I be right in thinking that if Dr Ludlam knew about the arrival of this stock then it would be likely that other haemophilia directors would be aware of it as well?
A. I can only speculate and I can conjecture but I would have thought that if Dr Ludlam had gained access to a supply of 8Y, then one way or another other haemophilia doctors in Scotland would have had that knowledge, but I have no evidence to back that up.
Q. All right.
THE CHAIRMAN: It's not the sort of information that transmits by osmosis or some other way.
A. No, indeed.
THE CHAIRMAN: It has to be communicated.

A. It has to be communicated.
THE CHAIRMAN: Do you really have any knowledge of that?
A. I don't have any knowledge that that took place. I know that the haemophilia directors of Scotland met fairly regularly. We were a very -- I was going to say close knit but that's wrong. But they were a very close organisation, a small group of doctors, and maybe I misinterpreted the extent to which they did work closely together on these types of issues. I think where they did collaborate closely was on policy and so on, but it could well be that their particular practices in different parts of Scotland were quite different and their supply arrangements were quite different.
THE CHAIRMAN: This was the reason why I referred to the meetings of the haemophilia directors and it might be worth our while just having a look at such minutes as might exist around the time to see what happened in fact, Dr Perry.
A. Yes.
MR ANDERSON: Just to put this in context, you say in your main statement, [PEN0171244]:

"Although we now know that 8Y was a hepatitis-safe product, its initial introduction in England and Wales was not accompanied by an expectation that the product would necessarily be hepatitis-safe."

Would I be right in thinking that in the period we are talking about, July 1986, that was still the perceived wisdom, as it were? There was a hope that it may provide a non-infective product but no evidence that that was necessarily the case?

A. Well, there was some evidence. I don't think it's true to say that there was no evidence that 8Y was safer than previous generations of the product. I think as evidenced by various comments that I made in the March meeting and so on, I think there was a belief that it had an enhanced, an increased margin of safety over -- but it was certainly not at the stage where you could necessarily assume that this was a hepatitis-safe product.

I think, had one put forward that proposition in any formal public way, then you would have been very severely criticised for this. It didn't meet any of the prevailing standards for demonstrating product safety at that point in time.

I think that position moved on quite quickly from there, once you had more time points and more patients and more batch exposures and so on, but I think at this time there was not a general acceptance that 8Y was a hepatitis-safe product. Intuitively it was reasonable to assume that 80 degrees for three days was likely to

give you a higher level of virus kill than 68 degrees for 24 hours, but intuition has often got us into trouble in the past.

Q. All right. Finally on the question of the possible dissemination of this information, I think we heard earlier that in July it was thought that the Scottish product, 8Y, might be available in September. Do you remember that?

A. That's right.

Q. I think we have seen that the 50 vials of 8Y arrived in Scotland on about 5 August. Do you remember that?

A. Yes.

Q. Can you remember -- I appreciate this may be difficult -- as at about 5 August, when was it thought that the Scottish product might be introduced?

A. I think we were still expecting it to be available for clinical evaluation in September/October time. I don't think at that stage we had reached the point where we had discovered what I think have been described as 11th hour problems with freeze-drying and so on. So I think this slightly pre-dated it.

I think at that point we were attempting to cover a very small window before Z8 came on stream and would be able to support the same group of patients.

Q. So if after 5 August you had written to the

haemophilia directors advising them of the arrival of the English 8Y, you would be looking at a period of, what, something like a month or something? Is that right?

A. A month or two, yes.

Q. Finally, Dr Perry, can we turn to another matter? You may recall that my learned friend Mr Di Rollo put to you that if Dr Ludlam had used the 8Y that had been received from England on a previously untreated patient, it couldn't be said to be misusing it, and you agreed with that proposition. Do you remember that?

A. That I would agree that it wouldn't be misuse?

Q. Yes.

A. Yes, I agree, I don't think it would be misuse.

Q. I think there may be some misunderstanding perhaps on my learned friend's part, because we know that in fact it was not used on a previously untreated patient?

A. That's my understanding, yes.

Q. And this is Day 54, page 127. Professor Ludlam gave evidence that in fact the 8Y was not used on a previously untreated patient but rather on a patient who had an allergic reaction to a Scottish product.

A. Yes.

Q. Is that your understanding?

A. That's my understanding, yes.

Q. Can I just ask you two things in relation to that? If the 8Y had been used on such a patient, presumably there would be no benefit in carrying out samples and carrying out the clinical trials. Is that right?
A. Correct. Yes, if it was a patient that had substantial previous treatment with coagulation factors, which by definition this patient had, then there would have been no attempt to enter that patient -- that patient simply wouldn't have met the criteria for the trial so wouldn't have been entered.
Q. I appreciate, Dr Perry, this is really a clinical matter but if a decision had been taken, as it was, to use this on a patient who had allergic reactions to the Scottish product, I take it that could hardly be described as a misuse of the product?
A. Absolutely not. I don't think it was a misuse. I think in the day-to-day business of seeing patients, which I have never done in my life, being a supplier of products, I think if a patient presents with a particular set of conditions or a particular profile, then you have the ability to treat that patient effectively, then I think that's quite appropriate.
It was certainly not part of the understanding that we had with our colleagues in England and Wales, that we would vigorously audit the use of the product once

supplied. And I think to be fair, if BPL had discovered that this product had not been used to treat a -- I don't think they would have reacted particularly badly either. I think it would have led them to have some concern about future issue of product, if it was simply going to be used for other indications, but in this particular circumstance, I wouldn't regard it as a misuse. But if one was seeking to get wider and further supplies for a bigger community of previously untreated patients, it might have created difficulties, but that circumstance never arose.

Q. Thank you very much, Dr Perry.

THE CHAIRMAN: Do you know that Professor Ludlam scrounged some from Newcastle?

A. I don't think I knew at the time and I guess that illustrates one of the --

THE CHAIRMAN: It might do.

Mr Johnston?

MR JOHNSTON: I have no questions, thank you.

THE CHAIRMAN: Ms Dunlop?

Questions by MS DUNLOP

MS DUNLOP: There are a couple of points, sir, which I think I might be able to contribute. The first is just that reference Mr Anderson made. I think it was to Day 54 That is 13 October.

Maybe we will get the transcript up. I'm actually currently looking at page 142. I don't know if we could get that on the screen? This is simply to clarify what happened to the 50 vials.

THE CHAIRMAN: If you can.

MS DUNLOP: Not completely.

THE CHAIRMAN: Not completely, yes.

MS DUNLOP: I think we are looking at 142. Well, Mr Anderson referred to 127. I think maybe if we look at 127 first, just to see that.

I'm not sure if it's 127. If we go to 142, please. I think that may be the reference.

THE CHAIRMAN: I think the story must begin a little bit earlier than that.

MS DUNLOP: Yes, I think just at the bottom of the previous page. I think this is the reference. Then if we go on to 142:

"When the initial stock was used up, a further supply was obtained from Newcastle. So obviously you did use those 20 vials?

"Answer: We used them, not in a previously untransfused patient but I think in another patient who had allergic reactions to the Scottish product.

"Question: Right. What happened to the other 30, do you know? Did you get them in due course?

"Answer: I suspect we used those and when those were used up -- I'm sorry, I don't know, you would need to ask blood transfusion issue departments."

THE CHAIRMAN: That's the high point.

MS DUNLOP: That's the reference but the other reference I want to make, because I think it contributes to what Mr Di Rollo was trying to elucidate, is to Day 55. That's 14 October. So the following day. Page 63 of that, if we could, please. Slightly further down:

"Just one last matter, professor. When this supply of 8Y was obtained in the summer of 1986, was it for Edinburgh patients or was it for everybody in Scotland?

"Answer: Well, as I think is clear, I requested it and it was held primarily at the protein fractionation centre and therefore it was available for anyone who wished to apply to use it.

"Question: Yes. And Dr Perry didn't sent you all 50 vials?

"Answer: He sent me 20, I think.

"Question: But as matters turned out, I think you used the whole 50 vials. Did you ever mention to any of your colleagues in Scotland that that stock existed?

"Answer: I assume that would be a responsibility for Dr Perry. He had a new product available for patients.

"Question: Right. Is that a "no". Do you have any memory of ever saying in a conversation, "Oh, there is a stock of 8Y at PFC?"

"Answer: I'm sorry, I can't remember.

So that was canvassed with Dr Ludlam. I just wanted to draw that to your attention, sir.

THE CHAIRMAN: Thank you.

Dr Perry, thank you very much.

A. Thank you.

PROFESSOR BRIAN COLVIN (continued)

THE CHAIRMAN: Professor, welcome back.

Ms Dunlop?

MS DUNLOP: Yes, sir, I would really propose the same arrangement. Albeit at rather a lick, I did proceed through Professor Colvin's evidence the last time he was here and it's really the turn of my colleagues to pose questions to him.

Questions by MR DI ROLLO

MR DI ROLLO: Professor Colvin, I would like to thank you for coming back. You seem to get the Friday night at the Glasgow Empire slot in this Inquiry, I am afraid.

I think the last time you were asked questions by my learned friend, as she indicated, she went through some material with you and perhaps I should recap where we are with you.

You provided a report, which is [PEN0171674], which is your report, and she took you through that report in a bit of detail. I'll just remind everyone what matters were canvassed with you.

I think she put to you the UKHCDO haemophilia working party report for 1986 to 1987, providing a snapshot of the position in September 1987. She went to the preliminary study, which was published in 1986, which was heat-treated Factor VIII concentrate in the United Kingdom. She mentioned the cryoprecipitate study and there was then a discussion about infectivity in the donor pool.

And then reference was made to your work, the effect of dry heating of coagulation factor concentrates at 80 degrees centigrade for 72 hours on transmission of non-A non-B Hepatitis, and reference was made to your report and your assertion that it would have been unwise to have made claims for a product where there was still a level of uncertainty, and clearly it might be even more than unwise, it would be not the right thing to do at all.

There was then reference to Professor Mannucci's paper, which is a document at [LIT0010456]. Then there was detailed reference to the questions in your report, and you were basically asked two questions by the

Inquiry and you have answered those to some extent in your report, and you have given other evidence about it.

So it's really to that that I want to turn. What you said in your report at page 5 of [PEN0171674]. The first question:

"Had you been treating patients in Scotland in this period, what would you have done?"

And the period that we are interested in is the period of the C3A topic, which is essentially the period during which in Scotland there was a heat-treated product but which was not thought to provide safety from non-A non-B Hepatitis, whereas in England from July 1985, there was available to haemophilia directors a product which the signs increasingly became clear that there was at least hope and a good feeling that the product may well provide a margin of safety. So it's in that context that these questions are being asked.

What you say there is you would have used DDAVP where this was appropriate for mild Haemophilia A and von Willebrand disease patients. You then go on to say:

"Where necessary, I would have used the concentrate that I believed on the evidence available to me was least likely to transmit non-A non-B Hepatitis (or HIV)."

The position, I think, in England -- I don't think my learned friend actually put this document to you but it's [DHF0030476]. I think reference was made to it or has been made to it and obviously you are familiar with it. This is a letter which was sent to haemophilia directors in England and Wales. I imagine that would include yourself at that time. Is that right?

A. Yes.

Q. And it is referring to a new Factor VIII concentrate, type 8Y, and going down the letter, it says in the fifth paragraph:

"Clinical trials at six haemophilia centres are in progress to gain evidence of reduction or elimination of viral transmission and several patients have safely passed the point at which first evidence of NANB virus transmission would normally occur with unheated Factor VIII.

"In accordance with regulatory requirements, the product should be issued by clinicians on a named-patient basis until a product licence has been granted. A product licence application will be lodged with the medicines division in the autumn.

"Factor 8Y will be issued through regional blood transfusion centres unless special provisions exist by

agreement for product to be sent direct to the haemophilia centre. Allocations to the BTS will provide the pro rata requirements for distribution agreed between BPL and BTS, except for 8Y required to fulfil the special needs of clinical trials to provide information for product licence application.

"It is recognised that, until the new production unit at Elstree is completed, output of 8Y will meet about one third of current demand for concentrate and for this reason attempts have been made to define those patients most likely to benefit from the security inherent in 8Y. Therefore, haemophilia centre directors are being asked to compile lists of their patients considered at risk and most centres have complied. It is the considered view at BPL that where possible liaison between the haemophilia services and the BTS should aim at directing Factor 8Y to these patients using the existing framework of distribution and supply."

First of all, you did receive this letter? I think you have told me that.

A. I would imagine so. I don't recall specifically having received it but I don't doubt that I received it.

Q. Do you remember compiling lists of patients most at risk?

A. No, I don't.
Q. Are you able to help us with who they would be?
A. Yes, I think if you look at my report, you can see that I have suggested that I would have used heat-treated commercial Factor VIII concentrate where essential, especially for more significant bleeding episodes or major surgery, where the use of substantial quantities of concentrate was anticipated.

So what we had really was a policy of trying to look after those who had been least treated and trying to look after, really, children. So until the spring/summer of 1985, I was still trying to use cryoprecipitate for the children but I then changed over to 8Y really as soon as it became available, and I think probably around the time of this letter.

As far as adults were concerned, particularly, I am afraid, people who had been given a lot of treatment in the past, or who were due to have major surgery which would require a lot of concentrate to be given, then it was very often the case that we had to consider using commercial heat-treated concentrate because, as I think was made clear around that time, the provision of 8Y was only sufficient for a proportion of the patients under our care.
Q. Would that proportion of patients then include the adult

patient who had never previously received Factor VIII in the past?

A. Yes, I would certainly try to do that, assuming that the patient wasn't suitable for DDAVP, and it would also depend a little bit about what was going to happen to that patient. So if you were going to take a tooth out, then you might be confident that there would be enough 8Y available to allocate what you had for that patient. If on the other hand, maybe there was going to be major abdominal surgery or neurosurgery, then you might take the view that there was a danger of using up more than was appropriate of the supply available to you of 8Y because it would take 8Y away from other patients.

Q. Right. So if you knew that you were only going to have to use a small amount, then it would be essentially a no-brainer. You would use the 8Y rather than other types of Factor VIII concentrates?

A. Yes, indeed, that was what was available to us and we thought that was the best concentrate to use at the time.

Q. Yes. Can I ask you this: when would it be suitable or appropriate to use fresh-frozen plasma? Would you ever use that?

A. I think never.

Q. Right. Never ever?

A. If you had a patient who had an inhibitor to Factor VIII and you were performing plasma exchange, which is a very rare procedure and in very unusual circumstances, you might include fresh-frozen plasma in that equation. Maybe if you were dealing with a patient who was requiring a very large volume of blood transfusion after perhaps major heart surgery, then it's possible that fresh-frozen plasma would be part of the group of blood products that you would use whether the patient had haemophilia or not. But I don't think that by the time that cryoprecipitate was described in 1965, you would ever, after 1965, have used fresh-frozen plasma alone to treat Haemophilia A.

Q. I'm not asking about treating necessarily Haemophilia A. Supposing you had somebody who was mild or not even mild --

A. If you were dealing with mildness in Haemophilia A, you would use DDAVP, if you could. If you were treating patients with Haemophilia A who weren't suitable for DDAVP, then you would probably use cryoprecipitate. What we were, of course, doing was -- in the early days of my career, we were using fresh-frozen plasma to treat Haemophilia B, but shortly after I qualified, Factor IX concentrates became available and in those circumstances really fresh-frozen plasma also became redundant for the

management of Haemophilia B. So that I can't immediately think of any circumstances in which I would use fresh-frozen plasma to treat haemophilia in 1986/1987.

Q. All right. We have seen a phrase "category 1 patients". Is that familiar to you?

A. Not at all, no.

Q. Right. It has been used by, I think, Jim Smith at one stage.

A. Okay.

Q. But that doesn't ring any bells --

A. The concept of a category 1 patient rings no bells with me.

Q. Right. But you would, for the reasons I think you have explained, put a previously untreated patient, whether an adult or a child, in a particular category with a view to --

A. At that time I would have tried to put them into a clinical trial because such patients were, and indeed are -- I don't mean to be unsympathetic at a personal level but they are a valuable resource. Where you have a patient who is untreated, then if you want to try to find out more about how best to manage haemophilia, then with appropriate patient or parental consent, a previously untreated patient is of clinical and

scientific research value. So one would be reluctant to miss the opportunity to obtain valid consent to take part in a clinical trial.

Q. I can understand that but of course, looking at it from the patient's point of view and the protection of that individual patient as opposed to patients generally --

A. I think one would be looking at that. I think the point of clinical trials is that you know that there is no best treatment for a patient. If you know what the best treatment for a patient is, then they don't go into a clinical trial. You can't justify entering a patient into a clinical trial if you know what the right treatment is.

Q. What I'm trying to get at then is you think that the best course of action for that patient, from the practicality of it, is to receive the 8Y at this time if --

A. I can only go back to what I said before: there was an air of uncertainty, that the 8Y study that we actually were undertaking, which was published in 1988, didn't fulfil the criteria of ISTH, the International Society on Thrombosis and Haemostasis. The numbers involved were not sufficient and a better study, I think, eventually reported in 1993. So I think one has to say -- and I repeat it -- that if you know what the

right treatment is, then you cannot justify a clinical trial.

Q. Sometimes you do not know necessarily what the right treatment is but you have an option to take and it's a question of what the safer option is, is what I'm asking about?

A. It's the perceived safer option. So I think there was a growing perception that 8Y was a reliable product. That's a fair statement. But had we known that 8Y was completely safe, then we would, I think, have been unable to enter patients so easily into a clinical trial. Although, of course, even these days, we couldn't compare one product with another because we knew that wasn't an ethically acceptable thing to do. And we have to accept that we didn't have enough product to treat all the patients either in England or in the United Kingdom as a whole with a particular product.

Q. But what we see here is that haemophilia directors being asked to compile lists of their patients considered at risk and that would include, as I understand it, the previously untreated patients?

A. Yes, it certainly would.

Q. All right. Did you ever in your experience hear of a situation in England where a previously untreated patient was given Factor VIII product inappropriately?

Did that ever happen?

A. That's a very big question because it would mean that I would have to know what "inappropriate" meant in the circumstances. I think that it would have been inappropriate to treat a patient in 1986/1987 with an unheated Factor VIII concentrate, for instance. But I know of no such instance. I don't think that it would have been inappropriate to treat a previously untreated patient with a licensed product that had been properly prepared, and so I know of no personal incident where a previously untreated patient was treated in a way that I would have regarded as being inappropriate. But, of course, I wouldn't actually know what my colleagues elsewhere were doing in individual cases.

Q. No.

A. I hope I knew what I was doing but I don't think that an inappropriate action would have come to my attention.

Q. All right.

If in the spring or summer of 1986 you had a choice of the 8Y on the one hand and the then available Scottish product -- which was the protocol was not the same and was known or at least suspected as not being protective in relation to non-A non-B Hepatitis, which product would you have used, given that stark choice?

A. Well, I think it is a somewhat artificial choice, as you

will appreciate.

Q. I do. It is hypothetical.

A. I think that by the time we had got to that position, there was a hope that the 80°C/72-hour product was going to have a good record. So if you had given me a bottle of each concentrate and said, "Which one are you going to give this particular patient?" I would probably have used the 8Y.

Q. Right.

Thank you, I have no further questions.

THE CHAIRMAN: I would just like to be clear that you are being treated quite fairly there. If both products were freely available and sufficient, one can see one situation, but would that necessarily be the case?

A. Perhaps you could repeat that question, Lord Penrose.

THE CHAIRMAN: Yes. I think you have made the point earlier that if one had to confront the situation of a patient needing major surgery, the volume of the material required and the volume of material available would come into it.

A. Yes.

THE CHAIRMAN: I just don't want you to be put in a position of answering an apparently simple question without having the opportunity to qualify it, if you think qualification is appropriate.

A. I think the point that I was making, and I think the question that I understood was that here we have a previously untreated patient, who is having a single experience of Factor VIII, and I'm bringing in one bottle of 8Y and one bottle of something else to be given on one occasion or not more than two occasions, what would I choose, there I think that I would have chosen the 8Y for that particular occasion had there been an unlimited supply and I was actually going to be only doing a very small procedure. I'm very conscious of the fact that in the UK at the time there was not enough 8Y to go round, and that that was particularly the case in England.

THE CHAIRMAN: Mr Di Rollo, I think that I was trying to avoid what you had earlier, I think, described as a "no-brainer", which on the one for one I would certainly think it is. I think you might want to perhaps explore it a little more fully.

MR DI ROLLO: There is obviously an artificiality about this because Professor Colvin never had this situation and was never likely to have this situation in front of him.

What I'm simply suggesting, in the assessment of the relative merits of the product -- and obviously there are qualifications because the hypothesis that I'm putting to you assumes you have got one bottle of each

and I'm asking to you choose which one you would use, and it is very simple from that point of view. I'm not asking to you consider the potential qualifications that might arise or difficulties that might arise in relation to supply --

A. I think that --

Q. -- but a straight choice between the two. I think you have made it clear what your answer would be.

A. As Lord Penrose implies, simplicity is sometimes a facade but let me put you to you another position which is slightly different but not very different.

A year or two earlier I had had a young woman who was pregnant, who, during her pregnancy, had a cerebral haemorrhage and it was found that she had a very large arterio-venous malformation within her brain, and it was quite clear that we needed to give her immediate or fairly immediate factor concentrate, and what I instructed my registrar to do, and indeed was part of myself, was to contact Oxford to find out whether they had any material which they thought, at any level, was less likely to cause hepatitis. And they provided a very small amount of material for me, which I think effectively -- because it was quite early on; it was probably 84, I think -- may have saved this patient's life. So it is true that when one was in this very

difficult position, dealing with individual patients, then you had to think very carefully and very quickly about what was the best concentrate for this patient.

Equally, I'm sorry to say, we had patients about the same time who had been treated a lot in the past and needed an operation, perhaps an elbow replacement, and I had to say to them, "Look, you need an elbow replacement. We have previously only given you NHS material. There is this thing called AIDS around, which is worrying us very much. We don't know what it is due to -- this is 83/84 -- and either we don't do this operation or we use commercial concentrate which conceivably could cause a problem." And after discussion with the patient -- I can remember very clearly sitting with the patient, and I know the exact date on which this particular patient received a bottle of commercial concentrate -- this was before heat treatment -- which resulted in HIV infection.

So every day almost in this period, individual physicians had to make individual choices about what they perceived to be the best treatment for a particular patient.

So in a way, your question is not inappropriate, if I may say so, because I understand exactly what we had to do but the choices that we made were not made with

full information. So we had to make our best judgment. I am afraid it was a little bit like -- not that I go to the horse races, you understand -- but it was a little bit like going to the horse races and looking at the field and saying, "Which of these horses am I going to back?"

Sometimes you will see, looking at previous form, that a particular horse is worth backing, and maybe it will romp home but there is a real risk that it won't. If of course you know which horse is going to win, then it's pretty easy to decide what to put your money on. And I think what you are asking me to do in a way is to go to the haemophilia races -- I don't mean to be trivial about this, this is quite a serious point -- and decide which horse we are going to back, and we don't know which one is going to come home first.

MR DI ROLLO: I appreciate you are making a serious point and I think I have your answer in terms of the question that I did ask. I think you are telling us -- and have told us -- that you would probably go with the 8Y in that situation.

I appreciate that obviously your answer is qualified by a number of factors but it really boils down to this, Professor Colvin, doesn't it, that if there is one product which has a known risk of transmitting non-A

non-B Hepatitis and another product which has a hope that it won't do that, although one cannot be sure about it, one would tend, one would have thought, to go with the latter rather than the former?

A. Assuming that you feel confident. That is the correct answer, and I think that throughout this discussion -- and indeed when the question was first put to me for my written opinion, there is in my mind an assumption of retrospectoscopic knowledge.

Q. Again, that's what the state of knowledge is in terms of what information was available, as I appreciate is important to bear that in mind. And what you have told us, I think, is that there were occasions where stark choices of that kind in fact did have to be made?

A. Absolutely.

Q. I'm not actually suggesting to you that there was such a stark choice here in Scotland at that particular time. But I wanted really to ask your view as a haemophilia doctor as to giving us some kind of insight into the relative merits clinically of the two products at the time.

A. I think the other thing to say is that we did have opinions which of course weren't always based on science. So when I started to work in haemophilia care in 1970, I, like many of my colleagues, was very

strongly attached to the concept of the National Health Service, and the concept that we could deliver healthcare for people with haemophilia within the National Health Service, and the advent of commercial concentrates, I think, was both a surprise and a challenge to us, and some of my colleagues took the view that the commercial concentrates were much better prepared than the National Health Service concentrates, and I think, because of my enthusiasm for the National Health Service, I probably went on using National Health Service products in a way which differed sometimes from the way my colleagues saw the value of the commercial products.

I'm not saying which of those was the correct answer but I think what I am saying is that it is perfectly appropriate and understandable for physicians to use what you might call their common sense or their opinion or even their intuition to deliver the service in a way which is both acceptable and different from somebody else's way. Certainly it was my experience through the whole of this period that whilst UKHCDO gave valuable guidance and I'm grateful to my colleagues like Professor Arthur Bloom and Dr Rizza for the leadership that they showed, there is no doubt that individual physicians thought very deeply about what they should do

and didn't always come to the same conclusion.

So I would repeat that it wasn't easy to know what the right answer was, and the responsible physicians acting within the spectrum of appropriateness sometimes came to different conclusions.

Q. I think we understand that, Professor Colvin. Thank you.

I have no further questions.

THE CHAIRMAN: It's ten past three. I think that the stenographer must have a break, if the questioning is going to go on. I think probably you want to have a break anyway. Is that possible or does it cause you significant inconvenience?

A. Me, Lord Penrose?

THE CHAIRMAN: Yes.

A. I'm free until the flight leaves at 6 o'clock this evening.

THE CHAIRMAN: I doubt if we can entertain you quite that long.

(3.15 pm)

(Short break)

(3.34 pm)

THE CHAIRMAN: Have you completed --

MR DI ROLLO: Yes, thank you, sir I have.

THE CHAIRMAN: Dr Colvin, Professor James asked me to ask

you a question. The context is an answer you gave on page 92, where you said that in the period that we are dealing with, in the early part of 1986, you said that if you were dealing with mild Haemophilia A, and you would consider DDAVP if it was suitable and if that weren't suitable, then you would probably use cryoprecipitate. It's in relation to the wider use of cryoprecipitate that he wants me to ask a question. And it's this: if you were in the hypothetical situation, let's say in the early summer of 1986, of anticipating, as was the case in Scotland, that by the late summer/early autumn there would be a Factor VIII product that had effectively been inactivated, but a case arose for treatment, would you have considered using cryoprecipitate as a stop gap treatment rather than using Factor VIII that had come to be suspicious?

I hope I have made it sufficiently specific.

A. Yes, I think one of the great difficulties in answering such a question is trying to put oneself exactly into 1986. If we are in 1984, then I think it's a little bit easier to say yes, but if we are in 1986, we are almost at the point where we have stopped using cryoprecipitate.

Of course, the trouble is that, of course, my study of cryoprecipitate was published in 1987. If one looks

at the letter from the haemophilia centre directors' organisation, which was published in the British Medical Journal in June 1985, which I think is in the papers, [LIT0010333], this is a letter called "HTLV-III, haemophilia and blood transfusion", sent by Arthur Bloom, Charles Forbes and Charles Rizza, they point out the dangers of using cryoprecipitate, and the last sentence of their statement -- this is the middle of 1985 -- says:

"When testing ..."

That's testing for anti-HIV or, as it was then, HTLV-III:

"When testing is fully implemented, the role of single donor cryoprecipitate in the management of haemophilia can then be reassessed."

I guess by sort of 1985/86, we would really reach the point where perhaps that was the case, that the donations by 86 would have been tested. The donations would have been tested for anti-HIV and therefore if it really wasn't possible to use DDAVP and if you really thought that you were very worried about an existing heat-treated concentrate, then I think by that period of 1986, maybe there was a brief window when cryoprecipitate was a possible treatment.

What would I have done? I think it's really rather

difficult to answer that question from the distance of 25 years. What I can say is that I was fairly keen on cryoprecipitate until sort of 1984/85, when HTLV-III became a reality and when heat treatment also became a reality.

I suspect that by 1986, despite my publication in 1987, I would have thought twice about using cryoprecipitate. But I think it would not have been an unreasonable point to have made, and the fact that I allowed my paper to be published in 1987 implies that I thought even at that time it was a reasonable approach to the problem. But you would have to take every case on its merits. As I implied in my previous answer, one had to factor such a lot of different issues into the equation before you made a decision, and the decision you made wasn't necessarily the right decision and it was perfectly possible for another physician to make a reasonable different decision.

THE CHAIRMAN: I think that in the preliminary report at paragraph 8.156, the letter that you refer to and a reply by Dr Mitchell and others making the point that perhaps one has to be a bit more discriminating, that point has already been made, but thank you for developing the point.

Mr Di Rollo, do you see any need to follow up on

that?

MR DI ROLLO: No, thank you, sir.

THE CHAIRMAN: Is that a sufficient answer?

MR DI ROLLO: Yes.

THE CHAIRMAN: Mr Anderson?

Questions by MR ANDERSON

MR ANDERSON: I am obliged, sir.

Professor Colvin, good afternoon.

A. Good afternoon.

Q. Just one or two brief questions if I may. You recall that when you were last here on your fleeting visit on 14 October, counsel to the Inquiry, Ms Dunlop, put your report to you and the two questions that contained. I wonder if, just for convenience, we can have that put up in front of us. It's page 5 of [PEN0171674]. We can remind ourselves that the second question there was:

"Would you have been concerned that there appeared to be a hepatitis-safe product available in another part of the UK that was not available for your patients?"

You say in your report:

"In my view, there was no evidence in the period 1984-1987 that any Factor VIII concentrate was hepatitis-safe."

If we then go to what you said in evidence; you may recall that you said:

"As you know, question 2 I found rather reminiscent of the question of: when did you stop beating your wife? It kind of assumes an answer."

And I'm reading here from the transcript on page 156 of Day 55. You said:

"So the answer to your question is that we were in the position where we could only do what seemed a good idea at the time. This sort of decision-making was based partly on science and partly on intuition and I think the answer is that at an objective level you couldn't say that one product was better than another, despite this encouraging information. Then I think you really are down to making your own judgment about what is most likely to be true."

Firstly I take it that that remains your position?

A. Yes.

Q. Again, this may be obvious but is this simply another way of saying that in relation to choice of treatment, it becomes a decision for the treating clinician in each individual case?

A. I'm sure that is the case.

Q. There has been evidence taken from various directors of haemophilia centres in Scotland that in relation to this period, 1984 to 1987, that we are discussing today, their choice of blood products, their protocol, was

consistent with the general guidance from the UKHCDO. Are you in a position to say whether you understand that to be so or not?

A. No, I don't think I am.

Q. Simply because of an unfamiliarity with the position and so on?

A. Yes.

Q. Right. All right. Thank you very much, Dr Colvin.

THE CHAIRMAN: Mr Johnston?

MR JOHNSTON: I have no questions, thank you.

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: I have no questions for Professor Colvin, thank you.

THE CHAIRMAN: Professor Colvin, thank you very much indeed.

A. Thank you, sir.

THE CHAIRMAN: Ms Dunlop?

MS DUNLOP: Sir, I don't have any further witnesses to give evidence on topic C3A. There are no statements from witnesses who have not attended, so I have no statements to which I need to draw your attention. There is, however, one document which is a comment by Dr Iain Macdonald, former chief medical officer, on some evidence given by Professor Ludlam, about the possible scope for a CMO letter, and that is a matter which was addressed by a special application lodged by the

Scottish Government and which you, sir, have allowed to be received.

I think it's appropriate to mention it at this juncture because this is the topic to which it relates. I just need to check with Mr MacFarlane whether it's best to say that we will insert a court book reference into the transcript so that people can look at it once it has been processed and been given a court book number. I'm being assured that we can do that. So once we have a court book reference for this document, we will be able to insert this into the transcript. Subject to that, I have no further remarks to make in relation to that topic.

THE CHAIRMAN: Right. So is that the end of today's business?

MS DUNLOP: Yes, it is.

THE CHAIRMAN: Thank you all very much.

(3.44 pm)

(The Inquiry adjourned until 9.30 am the following day)