Tuesday, 13 September 2011

(9.30 am)

DR ROBERT PERRY (continued)

Questions by MS DUNLOP (continued)

THE CHAIRMAN: Yes, Ms Dunlop.

MS DUNLOP: Thank you.

Hello, Dr Perry, returning to give further evidence.

A. Good morning.

Q. Good morning.

A. Good morning.

Q. Dr Perry, you have provided a statement for us on our topic B3 and that is [PEN0121759]. Perhaps we could have that in front of us.

You were sent the same schedule as all our other Scottish witnesses and like everyone else, you have answered those questions that you can.

A. Yes.

Q. You remind us on the first page that, of course, you didn't arrive in Edinburgh to work for SNBTS until 1981?

A. That's correct.

Q. So I don't propose really to ask you questions about the research in the 1970s because, as you point out yourself, the information you have about that is second-hand, or possibly even more distant than that?

A. Yes.

Q. Just looking at the first page, however, you make some introductory comments and you tell us that in January 1984 you were appointed acting director of PFC, following the departure of Mr Watt, that that appointment was made substantive in 1985 and that you reported formally to the committee of management of the Common Services Agency.

Dr Perry, I'm trying, if I can, to stay away from interpersonal questions, which relate to the individual holders of the particular posts.

A. Sure.

Q. I just wanted to ask you in more general terms to describe the relationship between the director of PFC and the national medical director of SNBTS.

A. Okay. Well, I'll do it as best I can. I think, as other witnesses have indicated and I certainly think it has been explored within the Inquiry, that the notion of an individual, a senior manager reporting to a committee of management -- that's what it said on my job description but in practice there was very little reporting went on.

I think my job description from memory actually said that I reported to the committee of management subject to the responsibilities and duties of the national medical director.

Now, in terms of my relationship with the national medical director, as far as I was concerned, he was -- I guess in a sense he was the closest I had to an operational manager. Or certainly I would have adopted that position because it was completely with the, you know, wide range of duties and responsibilities. It was important that you had somebody to defer to, to consult, to talk with and seek approval for various initiatives that you might want to take. So in terms of my relationship, that was very much, as far as I was concerned, a close colleague, but also, certainly in terms of medical issues and many scientific issues which Professor Cash was much more expert than I, there would have been a very frequent and fairly detailed relationship on those sort of issues.

I'm not sure whether that answers the question but he was de facto, I guess, my boss, as an operational manager in a unit of the SNBTS. You know, he was effectively the lead manager in the organisation and I was very happy to accept that as the case.

THE CHAIRMAN: Dr Perry, could I ask, in those days did you have annual assessments and so on?

A. Good gracious me, no.

THE CHAIRMAN: You didn't?

A. No.

THE CHAIRMAN: So there was no formal relationship of that kind that would identify him as your line manager?

A. No, there were no formal processes of appraisal or review or -- not on a personal level. Obviously, senior managers within the SNBTS would write papers on various topics, strategic issues and so on, but there would be no formal review process, either between myself and the committee of management or indeed Professor Cash.

MS DUNLOP: Thank you.

We did ask you, Dr Perry, in a follow-up letter, about the committee of management and you have provided a sheet showing the membership of the committee. It's useful for us to have a quick look at that. That is [PEN0121586]. We can see that this is a list of the members of the management committee over the period 1984 to 1985.

A. Yes.

Q. We have heard of Sir Simpson Stevenson before. We know that he had a background in Greater Glasgow Health Board?

A. Indeed, yes.

Q. In fact, doing some more digging, he is a former provost of Greenock, I understand. So background in local authority. I don't know that we would particularly recognise many of the other names. Professor Cash told

us that Mr Wallace was from the north from Inverness or Invernessshire. Obviously we recognise Dr Scott?

A. Yes.

Q. But the management committee looks to have been largely a lay body?

A. Yes, I think it was largely a lay body, although Dr Scott clearly was a senior civil servant, he was the deputy chief medical officer, and I think Mr Morison, as I recall, at that time was a senior civil servant within the Scottish Home and Health Department but don't take this as absolute fact. That's my recollection. Some of these individuals also appeared on the Blood Transfusion Service subcommittee, which was --

Q. Which appears -- and we will look at this in due course -- perhaps to have had a greater medical or scientific input, in fact, if you look at the expertise of the people on it?

A. Yes, I think that's absolutely right. I think, going back to my relationship with Professor Cash and the management committee, in terms of reporting to the management committee, I think it was primarily set up that way to establish and define the disciplinary procedures in the event that -- it was necessary for me to be called to account as an employee for a disciplinary process. It really prescribed who you

were responsible to, who you would appeal to in the event of a disciplinary process and so on, but really no more than that.

THE CHAIRMAN: I think I really must follow this because I have to understand why there appears to have been so little in the way of formal management structures. Can I start with asking: did you meet these people as a committee?

A. I met some of them but I can't remember ever having attended a management committee of the Common Services Agency. What I did attend as both acting director and as director of the Protein Fractionation Centre -- I was one of those that would have been described as "in attendance", that the Blood Transfusion Service senior managers, which were basically the regional directors, Professor Cash and the director of PFC would have attended the Blood Transfusion Service subcommittee.

So some of these individuals listed here would also have been members of the Blood Transfusion Service subcommittee, which was effectively the committee of -- you know, the subcommittee of the management committee, which dealt specifically with issues of blood transfusion and that was established, I think, because -- particularly colleagues in the blood

transfusion service -- this pre-dated me -- were very concerned that the management committee knew very little or had very little understanding about the complexities and the specific issues that faced an operational service like blood transfusion, and so there was an agreement that a blood transfusion service subcommittee would be established. So I met some of these individuals in their roles as members of the subcommittee periodically.

THE CHAIRMAN: Did this body ever transmit any instructions, any policy guidance or anything of that kind to your directly or through the subcommittee?

A. I'm hesitating so that I can give you an accurate answer but my best recollection is no, they did not. They would tend -- both the management -- and I'm not quite sure of how the management committee and the Blood Transfusion Service subcommittee related, but they would certainly have had a role in approving bids for funding for instance. They would have had a role in any disciplinary processes that did actually occur within the Blood Transfusion Service. But in terms of giving any direction to a strategy for producing products which were free from infection, for instance, they had no role in that at all and had very little knowledge -- I think they almost totally deferred to SNBTS managers and also

the Scottish Home and Health Department, where they did have medics and scientists that really understood to an extent what we were doing.

THE CHAIRMAN: Was there any other conduit by which the CSA could have passed down policy guidelines, instructions or any other form of information to you?

A. The area where we were most active -- but then this is my perspective and it's slightly biased perhaps, but it always used to feel like to me that the CSA always had an active role in, for instance, recruitment of staff. So they would have a very powerful interest in ensuring that the SNBTS and the units within the SNBTS were compliant with the terms of the Whitley Council, for instance, making sure that we employed people on the right basis, using the right criteria in the right grades.

So they had a direct role and they also had a role in terms of approving funding. But I think my experience and my recollection was that that was very indirect because the money really came from the Scottish Home and Health Department. So it always appeared to us, as managers within the SNBTS, that the CSA was just a post box.

So I think the simple answer to your question is that, as far as the CSA is concerned, I had no

experience of -- either personally or as group -- of the CSA being closely involved in any of the complex decision-making that accompanied the operational management of a blood transfusion service.

THE CHAIRMAN: What about the SHHD itself? Did it have direct or other contacts that in some way bypassed the CSA and the management committee to your knowledge?

A. I think there was quite a regular dialogue between particularly the national medical director but also to an extent regional directors as well if there was a specific topic. There would have been a direct discussion between managers in the SNBTS and officials from the Scottish Home and Health Department, particularly if there was a major area of funding that was required or a building development or a major new development, such as heat treatment of Factor VIII that required significant funding. Then the Scottish Home and Health Department will have discussed that directly with experts within the Scottish Blood Transfusion Service. And those discussions would not necessarily have included managers or officials from the Common Services Agency. My impression at the time was that the Common Services Agency, if there had been an agreement reached between the Scottish Home and Health Department and the SNBTS on a particular issue, then the

CSA would not have interfered or intervened in that because they did not have the expertise or knowledge.

THE CHAIRMAN: Yes.

Yes, Ms Dunlop?

MS DUNLOP: Thank you.

Dr Perry, can we turn back to the statement, please? As I said, I don't think we really want to detain you by asking you about the research in the 1970s and that is really what is dealt with on the second page. If we look at the third page, which is 1761, you are discussing here the information that Professor Cash brought from Bonn about the work of Behring.

A. Hm-mm.

Q. At this point you are a quality control inspector. Is that correct?

A. That's correct, yes.

Q. Yes. And I think you tell us in your CV and in previous evidence that yours was a new post and that you were mainly concerned with developing good manufacturing practice?

A. Yes, and implementing quality systems really following the first substantive medicines inspectors' visit to the PFC in 1979 and 1980.

Q. Right. Against that background, I did want to ask you how much awareness of the heat treatment research you

had around the time of your arrival, so 1981/1982. How much did you know about what was going on?

A. I think it's difficult to recall with any accuracy but I think it was a fairly small organisation, the PFC. I had a very good productive working relationship with people like Pete Foster and indeed my then boss, Mr Watt. And I certainly think, as part of the local management team, there would have been quite extensive discussion perhaps informally about significant international -- this was a learning process for me.

So Peter in a sense was my mentor in the early days of joining the PFC. So I think I became aware of the Behring process, this notion that you could heat delicate proteins in a manner which protected their activity, and I think I would have become aware of that primarily through Dr Foster at a fairly early stage, perhaps not as early as Dr Foster and Professor Cash but I would have been aware -- I certainly have a vivid recollection of this being discussed and talked about informally but almost being -- both with a sense of incredulity that it could actually take place, but also -- and I clearly remember that either Dr Foster or it's published data -- that the yield of the process was 8 per cent.

So almost a demonstration in principle that it could

be done but it had no practical applicability to the SNBTS because it simply wasn't the basis for creating a safe and sufficient and affordable supply of product for the population of Scotland. It just wouldn't have met the requirement.

So I think there was a recognition that it existed and that it could be done and I think, as others have said, Behring was a very respectable, competent organisation and I don't think we were necessarily challenging that. But it was the first point, as I think others have pointed out in this process, where there was a reasonable demonstration that, contrary to previous expectations it was possible to subject these delicate proteins to heat treatment and retain some of their biological activity.

Q. Yes. You go on to talk about the method not being routinely adopted at scale by Behring until 1985?

A. Hm-mm.

Q. I have drawn attention already to a statement in an article. We perhaps don't need to go to it, [LIT0010643]; which refers to a Behring pasteurised product having been available commercially since 1980, which is slightly surprising but possibly not widely available?

A. Well, I think what I'm pointing out there was that

I think it was available fairly soon after it had been developed by Behring but in very small quantities. And when I say "widely available", I'm not aware of the Behring product, for instance, being available on any significant scale from Behring for treatment of patients outside Germany for instance.

So I think there were early versions of the product that were used in Germany to do studies and so on but, as far as I'm aware, it wasn't routinely available -- the UK couldn't have gone to Behring and bought the product. It wasn't licensed in the UK for instance.

Q. In your answer on paragraph 5 you had the same impression, I think, as a number of witnesses that we were trying to suggest, as you put it, that there was widespread activity throughout Europe on this topic and I should clarify that that wasn't really the intention behind the question. It was just to try to find a form of words to replace the initial draft, which said "on the continent". So a suggestion of developments in the rest of Europe really did just mean Behring. So I think we are at one on that. I don't think anyone is suggesting that there were interesting developments at the time, other than those intimated by Behring.

Can we move to the next page, please? Paragraph 6 deals with research into viral inactivation from 1982

and the question of relative priorities. Can we have a look then, please, at the minutes of the meeting of the Factor VIII study group on 28 January 1982? That is [SNF0013813]. Perhaps the first thing to notice about this is to notice that you were there, fortunately.

A. Yes, indeed.

Q. But I also noticed that it wasn't a PFC group, it was a much more general Blood Transfusion Service group because we see representation from the Edinburgh centre, from the Glasgow centre, from the headquarters laboratory and from PFC.

It looks as though the main input from PFC was Dr Foster's talk. Would that be right?

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

Q. If we just scroll slowly through it, we can see that first of all Dr Prowse spoke about work at the Edinburgh centre. Interestingly, he is the only person who seems to have spoken at this meeting about pasteurisation.

A. Yes.

Q. Do you have any memory of that?

A. I don't actually. I know Dr Prowse very well and I think at the time -- and I think this is part of the reason for Professor Cash putting this group together -- was that there were a number of groups engaged in research into coagulation factors and other aspects of

transfusion medicine, and Professor Cash, or Dr Cash at the time, was of the view that all of these resources needed to be pulled together into a much more coherent group.

Now, Dr Prowse, who worked at the Southeast Scotland Blood Transfusion Service at the time, was quite a, even then, fairly recognised international expert on this subject. So I think what he was doing was basically giving an overview of international activity --

Q. Right.

A. -- in these various areas. To the best of my knowledge, there was no work going on in the Southeast Scotland Blood Transfusion Service on the pasteurisation or any other inactivation of coagulation factors.

Q. Quite. You see the point of asking about it?

A. Yes, indeed.

Q. What was Dr Prowse's particular background?

A. He was a biochemist, graduate of Oxford University, very, very competent biochemist, and I think for the large part of his working life he worked in the transfusion service. So he was a PhD graduate biochemist with a particular interest in plasma proteins.

Q. Thank you.

If we move on through this document, we have already

looked at Dr Foster's presentation, which we can see beginning at the bottom of the third page, PFC. We can see that Dr Foster gave a talk and had some slides?

A. Yes.

Q. Can we move on then, through the document, please, and obviously quite a lengthy or detailed presentation?

A. Hm-mm.

Q. If we move on to page 6, we can see the establishment of the four smaller groups and actually you weren't on any of the smaller groups?

A. No, I wasn't, no.

Q. Right.

A. No, although I would have been involved in some of them in a more informal sense. I think the purpose of -- it was my then boss Mr Watt who thought, quite correctly at the time, that the reason for having a quality manager in this group wasn't to contribute to the science and development but to make sure that there was a -- the cliche in the pharmaceutical industry is "building quality into the product". So even in the design of processes, the design and the strategic approach to producing a new pharmaceutical, you build quality into it by addressing issues of quality and good manufacturing practice right at the start of the process. So I was there to exercise that influence on

the activities.

Q. So your presence at the meetings and your involvement in the group was a kind of prompt to people to remember that aspect?

A. Yes, I think so but for instance, I did not have any expertise. I wasn't a biochemist, for instance. You know, these were relatively new fields of scientific endeavour as far as I was concerned and my role was -- my primary role was to develop quality systems and try and raise the standards, initially in the PFC but also fairly soon on, to actually start rolling out concepts of good manufacturing practice and quality systems and quality assurance to the regional centres as well.

Q. Right. Can we just look at the last page as well, please, to see the other two groups. We have assays, quantity of plasma, product development, coordinated by Dr Foster, and then safety, coordinated by Dr Pepper.

A. Yes.

Q. Right. Can we go back, please, to Dr Perry's statement? You do make a point in your answer, Dr Perry, with which we are now familiar, which is in relation to the difficulty of, if I can put it crudely, squaring the circle.

A. Yes.

Q. That there is a fixed supply from the indigenous

population, that demand from patients is increasing and that also these new techniques of viral inactivation, may have a cost in terms of yield, which is certainly something you do not want.

A. Yes.

Q. Where you are already facing the strain of trying to supply a need which you can barely meet.

A. Yes.

Q. You describe this in your answer and I think we understand that really, consistently with all of that, it was necessary to improve yield so that any yield loss as a result of introduction of viral inactivation procedures could be balanced out?

A. Yes, it was -- underpinning the activities of this group or the subgroups was almost an unwritten assumption that any proposition or strategy that led to a failure of our ability as an organisation to meet what was then recognised as an escalating need for product for all patients in Scotland wasn't really viable. So, yes, improving yield was really a prerequisite to everything that followed and that was an important group. And that's, you know, stating the obvious, why this group included people from regional transfusion centres who had an impact on yield, for instance, on how they processed the plasma, how they stored it and so on. So

it was fundamental to the endeavour of developing a better and safer product and more of them.

Q. Yes. Then you deal briefly with investigation of the Behring pasteurisation method, which I think we know enough about for the moment?

A. Yes.

Q. Paragraph 9 on the following page, please. You talk about the selection of heat treatment, which in practice at that time meant pasteurisation as a preferred option.

A. Yes.

Q. We understand that it's a gross oversimplification to assume that one could in some way just take the albumin process and apply it to Factor VIII. I think we do understand that. The only point that occurred to me in the preparation was that there must have been some experience that was available to be drawn on from the pasteurisation of albumin, not least the very protocol, the 60 degrees at ten hours?

A. Yes, it was a well established protocol for pasteurisation of albumin and indeed, pasteurisation was an established technology at that time in the food industry as well, for instance.

Q. Yes.

A. So pasteurisation wasn't a new idea; it was borrowed from other aspects of food technology and pharmaceutical

processing.

Q. You make a point, Dr Perry, which I think is important in understanding the two different processes, wet heat and dry heat. If we look at the final paragraph on this page, please, you say:

"Importantly, these stabilisers do not require to be removed following pasteurisation of the product in its final container."

This is a comment applicable to the pasteurisation of albumin?

A. Indeed.

Q. We learned a little bit about that a long time ago -- it feels like a long time ago -- in March. So with coagulation factor concentrates, the pasteurisation step, unlike albumin, was not the final step of the process. There was quite a bit to be done after that, is that right?

A. No. It was very much -- it was in the heart of the process, in the middle, and subsequent to pasteurisation of coagulation factors there was a very substantial process that would have to be developed, engineered and implemented, whereas for albumin, I think the observation that you could simply add something like caprylic acid to a formulated bottle of albumin and pasteurise it and then not have to remove that made it

a much more simple process.

Q. I wanted to ask you a question which I should really have put to Dr Foster but I forgot and I have checked with you and you told me you can deal with it.

A. We will see.

Q. Can we look at Dr Foster's manufacturing process statement, which is [PEN0121852]. And go particularly, please, to 1985 and these are three columns showing, as we see from the heading, "Outline processes for the preparation of Factor VIII concentrate of PFC between 1980 and 1991."

A. Yes.

Q. The references we see at the bottom reflect what actually happened, which is the use of dry heat treatment.

A. Yes.

Q. But I asked you to indicate where in the column we should understand pasteurisation as occurring, if, instead of dry heat treatment, this had been pasteurised product. So can you answer that for us, please?

A. The pasteurisation part of the process would have been a very substantial detour from any one of these flowcharts, as it were, and I think the closest we have to a process where the pasteurisation could have been included was in the third column. That's the Z8

process. And it would have been around about C11 or C12 there would have been a process of -- you have the supernatant, which is a Factor VIII-containing solution, following the original processing. It would have then been necessary to formulate that with fairly large quantities of sugar and perhaps amino acids. I'm not sure whether we used glycine at that stage but certainly very large quantities of sugar.

That material then, as I understand it, or recall, was dispensed into bottles or -- the fully engineered process would have been much more sophisticated than that but we never got to that stage. That would have then been pasteurised in a fairly simple, straightforward pasteurisation process at 60 degrees for ten hours but it would then be the subsequent reclamation of the Factor VIII from what is basically a very sugary solution, which is completely unacceptable for clinical use. You can't inject those sort of solutions. So the challenge after the pasteurisation, for any pasteurisation process, is how you remove the additives.

Q. Yes.

A. And you can either remove those additives by some form of ultra-filtration process or a precipitation process but again, with every process step that's included in

a Factor VIII purification protocol, you lose yield. Every time you process a solution of Factor VIII, whether it's by centrifugation, whether it's by ultra-filtration or by precipitation, you lose another 10 per cent, maybe 20 per cent of the overall yield. So the secret is to get a process which is as simple as possible.

Q. Yes, actually when we come to look at your costing, which we will look at later today, there is a useful diagram at the back of that.

Dr Perry, we probably think we know but it's good to ask: what does a chemist actually mean by the word "formulate"?

A. Formulation can either be how you prepare the active -- well, in the pharmaceutical industry, they would call it the "drug substance", the active drug substance, and how you mix it with other additives to make it both stable in a way that you present it, in a form that is suitable for patient administration, so in tablets, for instance. The active substance is obviously included with other -- they are called "excipients", to make it acceptable, to give to a particular volume so that it can be made into a tablet. So that could be formulation.

Formulation could also be the addition of various substances, chemicals, solutions, as part of an in

process. As part of the processing of the material. So formulation of Factor VIII to make it amenable to pasteurisation would have really meant adding sugars, adding stabilisers and additives and so on.

Q. Right, according, presumably, to a pretty closely defined recipe?

A. Yes, absolutely.

Q. And aiming to achieve a product that has a particular specification, if you like?

A. Absolutely, yes. So formulation could be a process that you go through to facilitate the processing or formulation could actually mean the formulation of the finished product.

Q. Yes, and here it's the former sense, is it?

A. Here it's the former sense. So you are formulating the in-process material to make it capable of being pasteurised at 60 degrees.

Q. Thank you. Can we go back then, please, to Dr Perry's statement to the point we were at, which is 1764?

Moving on to paragraph 10, we see that you tell us that you weren't directly involved in discussions between PFC and BPL at this time but you remember regular and frequent exchanges of information. Primarily between Drs Foster and Smith?

A. Yes.

Q. So I take it that it was well known in PFC. You have said it was a relatively small organisation. It was well known that there were these connections between Dr Smith and Dr Foster?

A. Absolutely. And Dr Foster would have regularly updated me as a colleague on any important news or information that he had gathered from those conversations.

So, yes, it was widely known, and as you know, Dr Smith actually was a previous employee of PFC. So there were a number of people that knew him and certainly when he was in town, for instance, there would be quite a friendly collaborative discussion on all sorts of topics.

Q. Yes, the timeline actually does include in it that Dr Smith visited PFC. So we can ask him about that. He was obviously popping in quite a lot?

A. "Popping in" is probably a little too frequent but he was certainly -- he certainly visited fairly frequently.

Q. So you will have met Dr Smith quite quickly after your arrival?

A. Yes, indeed.

Q. Then 11. I don't need to ask you about freeze-drying. 12 is the correspondence that we have looked at in relation to a meeting at BPL in December 1982. You have obviously read the letters, Dr Perry, and no doubt given

it a bit of thought. It does look as though there were two different conflicts, if you like. There was, on the one hand, the argument between having random named-patient usage of the new heat-treated products or properly formulated clinical trials?

A. Yes.

Q. Then the second argument, which is really not consistent with the first, is between clinical trials or no clinical trials because clinical trials might smooth the path of the commercial companies to obtaining a licence for their heat-treated product. Is that a reasonable summary of the dilemmas that were around?

A. Yes, I think it is. Yes. Also a prevailing view that there was, I think, a perception that some of the commercial organisations were claiming things about their products which perhaps weren't based too strongly on a body of evidence.

So I think the professional view was that we perhaps needed more data on this before one could start talking about a hepatitis-reduced product and so on; and that certainly didn't exist at that time, to the best of my knowledge.

Q. Can we look on to the next page then, please? We remind ourselves that the question relates to a particular letter from Dr Cash?

A. Yes.
Q. Perhaps we note without comment that you say Dr Cash typically expressed this view using arguably provocative language to emphasise his point. I did just want, however, to cover what you say at the bottom of this page about the point that's being made in a particular paragraph in the letter. Can we have a look at the letter, please? [SNB0043163]. We know that this is Dr Cash's letter back to Dr Lane after the meeting, 17 December 1982.
A. Yes.
Q. It's pretty obvious that when we first read the letter we didn't really understand the point because we thought maybe there was a "not" missing in the last paragraph that we can see. So it would have read:

"I would therefore conclude that at the present time it is not in our British transfusion service's best interests to permit the commercial people all the freedom they desire."

But you think that would be wrong?
A. Yes, I do.
Q. I think we now have Professor Cash very confused about what it was he thought.
A. I must apologise for getting involved in this because it wasn't my letter. My comment is really an

interpretation on the basis of my understanding of the point that Professor Cash is making here, both in this letter and in response to the previous discussions, and I thought it was fairly clear that he was making the point that, despite what had been said before, he now takes the view that we should give the commercial people lots of freedom because if we don't do that, they will consume all the patients that will be necessary for us to do our own clinical trials.

So my interpretation -- but this isn't a matter of fact, this is a matter of interpretation -- is that the letter is correct as written.

Q. Right. Of course, it's very characteristic of lawyers to pick over the wording of a document, no doubt excessively. So I think perhaps we can just let the matter rest with the kind of encapsulation of the different dilemmas.

A. Yes.

Q. And move away from it.

A. Yes.

Q. Understanding, I hope, what those dilemmas were.

Can we go back to the statement, please? 1767, please. You have a paragraph, paragraph 14, headed, "Dominant themes in early 1983". You say that:

"It is important to recognise that the pursuit and

maintenance of self-sufficiency and product yield was a high priority for SNBTS, particularly in light of the knowledge that the eventual introduction of NHS heat-treated products would, as a result of yield penalties, potentially reduce the overall amount of Factor VIII available to patients."

A. Yes.

Q. I just wanted to ask you whether there was a jealousy about releasing too much plasma for research. If there is always a pressure to meet Scotland's aim of being self-sufficient, then presumably any amount of plasma that was taken out of the system to be used purely for research must have been perhaps grudgingly given?

A. I don't think grudgingly given but certainly when I became director, it was an important issue for me that consumption of large quantities of freely-donated plasma from -- this was almost a sort of moral and ethical position that this plasma was given to treat patients. And although there was a wide recognition that you can't make advances without doing research and research requires raw material, we had to be as careful as we could and as economical as we could taking material out of the -- what I would describe as the regular supply chain to use for research purposes.

I think as a way of trying to manage this, I think

we tried to establish a level of something like 10 per cent of the plasma collected could be made available for research purposes. You simply can't develop a new or a modified pharmaceutical without doing laboratory studies, pilot studies, validation batches and so on. So it absolutely, inescapably requires you to consume certain amounts of material that you have for those purposes.

If the research goes well, that's absolutely fine. If the research stumbles or you come across problems, then if you are not too careful or even if you are careful, you can end up consuming quite large quantities of raw material which otherwise would be used for making products to meet patient needs.

Q. Right. But you don't remember it ever actually being an issue in the sense of people disagreeing about releasing an amount for research or anything like that?

A. No, there were never any major stand-offs. No, absolutely not. Having said that, I personally experienced difficulties during my time as director, when one saw new developments moving along. And if the development stumbled or it required additional research work or additional batches to be made to validate a particular process, I was in a state of constant anxiety that these problems should be solved as quickly

as possible because it was impossible to go back to the regional transfusion centres and say, "Can we have another 20 per cent more plasma?" It just didn't work like that. So our plasma collection programmes were established prospectively and an unexpected increased consumption of raw material to meet a research programme would have caused problems. It was anxiety. I can't remember an occasion where we slowed down or abandoned a line of research because we thought we were consuming too much material for research. I can't think of that happening.

Q. Thank you.

THE CHAIRMAN: Dr Perry, you clearly lived at this stage with a well established policy that favoured the pursuit and maintenance of self-sufficiency.

A. Absolutely, yes.

THE CHAIRMAN: What did you understand the origin of that policy to have been?

A. The policy of self-sufficiency? For me, when I joined the SNBTS in 1981, it was one of the first things that I picked up from --

THE CHAIRMAN: Almost a mantra?

A. Almost a mantra. It was a given that the Scottish service had agreed and there were discussions with the Scottish Home and Health Department, and

self-sufficiency was our target. I think I have mentioned before -- and this is very much summarising it, but as far as I was concerned from 1981 onwards, it was absolutely clear that self-sufficiency was the only game in town, as far as we were concerned. And that culture and that ethos really pervaded everything we did. And for very good reason. It was clearly understood why we had that particular position.

And I think I have said this before, that every bottle of product or every vial of product, every dose of product that we could make from Scottish donors avoided the need to import material from what we perceived and believed were less safe parts of the world, and particularly the American commercial material. So it wasn't just a sort of random process of pride or national pride that we would be self-sufficient, there was a very good reason underlying it. And certainly I internalised that at a very early stage. Every morning I woke up, basically the reason for going to work was to make sure that we could avoid having to import product from areas that were believed to be less safe than Scottish donors.

So where it actually came from, I think certainly pre-dated me. I think certainly Professor Cash -- and this is from me reading the sort of historical archives.

There were discussions when he took over as national medical director that, I think, one of the clear discussions he had before taking up the post was, you know: is part of the job here to establish self-sufficiency? And I think the answer to that was yes. I know there is a discussion about what we mean by "self-sufficiency" but perhaps we don't want to go into that now.

But leading from that process were discussions between Professor Cash and George MacDonald in the West of Scotland and various other haematologists and haemophilia directors, where they sought to establish what that meant, and the figure that I always had in mind was 2.75. That was the magic figure.

THE CHAIRMAN: It's repeated frequently. It's fascinating to try to work out how a senior employee coming into an organisation picks up the ethos of the organisation. In some cases it would be, no doubt, by being handed a bit of paper that set out the policies, policy statements, policy documents and whatever, but that didn't exist here?

A. No.

THE CHAIRMAN: It must have been personal communication from a very early stage.

A. It was certainly communication and -- but also, in

a sense, leadership. It was in the fabric of the building, it was in the fabric of everything that was discussed, that, you know, the PFC was established at great expense to the taxpayer and its job was to meet the needs for Scottish patients.

So, you know, I guess I'm just a single point in this process, but for me it became very clear very early on what we were there for and that included -- and in a sense, failing to supply was -- it sounds a bit romantic but failure to supply was not an option.

THE CHAIRMAN: Almost a cardinal sin.

A. Not quite a sin but I think it would have been seen as an admission of failure of delivery against our mission and purpose. Certainly that's how I perceived it anyway.

THE CHAIRMAN: Professor James has suggested a question. Do you think the management committee knew this?

A. I don't think they lived and breathed self-sufficiency to the extent that SNBTS did. I think they were aware of self-sufficiency and they knew it was an important topic, and I think in a sense they wouldn't have got in the way of certain initiatives to establish that. But then, it wasn't necessary for the management committee to make difficult financial judgments. I think the funding of self-sufficiency was primarily a process

between the SNBTS and the Scottish Home and Health Department. So again, I think they were largely a well informed post box in this process.

MS DUNLOP: In paragraph 15 we asked about reciprocal reporting between England and Scotland and your sense of this issue was that there was established cooperation, particularly between senior operational managers at PFC and the counterparts at BPL.

A. Yes.

Q. And I think we suggested to you, just to be strictly accurate, you would reverse the orders of Smith and Snape, if you wanted to keep the counterparts the same. So your counterpart will have been Dr Snape and Dr Foster's counterpart Dr Smith?

A. Yes.

Q. Can you just tell us a little bit about Dr Snape?

A. Dr Snape at that time -- I believe it's correct. I think he was the quality assurance manager at BPL. So I think he was my counterpart. Also at some stage he was technical director but that encompassed quality assurance, but in terms of my relationship with him, I think it was primarily on matters of quality assurance, standard operating procedures and so.

Q. Was he a chemist too?

A. I think he was, yes.

Q. Then we moved on to ask you about a meeting in March 1983. I don't particularly want to ask about that. You weren't there.

Can we move on to the next page, please? Dr Foster's memorandum to Mr Watt of 3 May 1983 is a document at which we have looked on a number of occasions already. I wonder if you remember from the time any of the discussion around this memorandum?

A. I have no vivid recollection of this, although I do have a memory of the context in which this discussion was taking place.

Q. Let's put it in front of you. It's [SNB0073635]. Will you have been one of those who received it?

A. Yes, I would have been a head of department at that stage, yes.

Q. Yes.

A. I suspect -- well, it's possible, although I have no evidence for this -- that Dr Foster would have discussed it with me before writing the document.

Q. Right.

A. But I have no recollection of that. But it's quite possible.

Q. Yes.

A. Because it does actually -- you know, there are quality elements in here about, you know, a strategic approach

to a safe supply and I think, as others have said, it's quite an important document in a sense because Dr Foster is saying -- which I think we probably all understand already but just to clarify in my own mind, Dr Foster is actually saying that until this point in time, our strategy was directed towards hepatitis, which provided an opportunity for a phased introduction of product because unfortunately there were already many patients that were infected with non-A non-B hepatitis and indeed Hepatitis B, and therefore that provided an option of introducing a safer product, or a safe product, for a smaller group of patients who perhaps hadn't been exposed to infection.

And Dr Foster is simply saying, "But we now have this thing called 'HIV', and it turns out that HIV is caused by a virus in the blood supply, then all patients are susceptible to HIV". And what he is suggesting is we have to move from a strategy of a phased introduction to almost a total introduction for all patients.

Q. Yes. He is actually making a particular point of distinction from the current strategy, isn't he?

A. Yes.

Q. If we look at (i), he is saying that at that particular point in time, the haemophiliacs most at risk were the severes. So you had a new infection?

A. It was the opposite.
Q. Yes.
A. It was the opposite for HIV to that which had been established for the hepatitis risk.
Q. Yes. And that's because you are starting at some point in the early 1980s, you assume, with a population which is not affected at all; therefore the people who are using the most of the possibly infectious product, are most at risk?
A. Absolutely.
Q. Not a difficult point?
A. That's absolutely the case, yes.
Q. We have looked in some detail at this memorandum. I don't think I need to take up a lot of your time with it, Dr Perry, but Dr Foster goes on to argue a bit about a policy case. This is at the bottom of the page. There may be a long incubation period and people may also start wanting to go back to cryoprecipitate?
A. Yes.
Q. In which case your raw material at PFC would disappear very quickly.
A. Yes.
Q. He has actually already commented higher up that there is already evidence of a panic recourse to cryo. So he then, if we turn on to the next page, please, sets out

a worked example of what might be possible?

A. Yes.

Q. We understand that this would be, I gather, a process that you could start twice each week. So you could start with your 1,000 kilogramme pool, which we understand to be equivalent to the 4,000 donations with which PFC were making a batch at that point?

A. Yes.

Q. And that that could have been done twice a week. He says at the bottom that what would be required would be the purchase of ultra-filtration equipment, some other minor items, for example a stirrer, and perhaps some extra staffing. And obviously in vivo recovery in Factor VIII yield would have to be adequate. So some further work is going to be required?

A. Yes.

Q. We have tried to work out what happened after this memo and I think we are clear that this wasn't put into effect, the process wasn't all implemented?

A. That's correct.

Q. If we look at Dr Cash's letter, of 1 June 1983, [SNB0073708], we can get some information. I apologise in advance for going back to the question of funding around about this time. It's quite challenging to work out exactly what was going on on the financial front.

A. Hm-mm.
Q. The easy part really is to note that Dr Cash has already made contacts with a view to clinical trials, but the harder part is working out exactly what was intended by way of funding and what was then current, and one of the things to note here is the summary of the figures at the bottom.
A. Yes.
Q. So Dr Cash is saying there are two inextricably linked items. The first is that there are going to be optimal additive blood bags, which are going to cost £75,000 as recurring expenditure. So every year there is going to be a need to spend £75,000 on optimal additive blood bags.
A. The reason there is a linkage there I think is because that was a development which increased our ability to collect more plasma. So that's a plasma supply cost.
Q. Right. Then something described as "the pilot stage of heat treatment of Factor VIII", which is to cost 74,000 non-recurring and 13,000 recurring. So can we look on to the next page, please?
A. Yes.
Q. Dr Cash is suggesting perhaps a slight redraft -- sorry, can we just go back to the page before?
In the third paragraph he says he is particularly

pleased that you and your colleagues are currently engaged in a costing exercise designed to expedite the heat treatment programme. The figures that are going forward to the Blood Transfusion Service subcommittee of the Common Services Agency are figures that have been prepared earlier, as it were?

A. Yes.

Q. It is not any figures that someone has worked up in response to Dr Foster's memo?

A. No, I think -- it is not a recollection, it's an interpretation. I think these are figures because they are really quite modest, the £74,000 non-recurring, for instance, is from various pieces of equipment that were necessary, perhaps ultra-filtration equipment. The £13,000 would have been the cost of the pharmaceutical grade sugar that was necessary for the process that would have been formulated. So this was very much the cost of a pilot scale approach.

Q. Yes. One of the things that threw me initially, Dr Perry, was it did look like quite significant expenditure for a pilot stage but you think this genuinely could have been expenditure related purely to a pilot stage?

A. Yes, I think so. I can't give you a breakdown of what the £74,000 would have included but --

Q. I have looked for that. Believe me, I have looked for that.
A. Perhaps Dr Foster can provide more information and I can't quite remember what the processing option was that was preferred at that time. But if, for instance, it was an ultra-filtration process, which was basically passing the liquid, that is full of sugar at this stage, to remove the sugar so that the product is formulated in the right excipients, then that's very expensive equipment. All pharmaceutical equipment is expensive.
Q. Right.
A. So that doesn't seem to me to be an unreasonable figure.
Q. Sorry, Dr Perry, I'm just going to ask you to repeat that last word. You said the product is formulated in the right excipients?
A. Yes.
Q. Is that just the right specification?
A. That's right. It's to turn the in-process material -- this is the material that is full of sugar and other additives -- and remove that to the extent that the final Factor VIII product is basically formulated with the right concentration of sugar, salts and other additives.
Q. Right?
A. Which we call "excipients".

THE CHAIRMAN: Could we get a spelling.
A. It's E-X-C-I-P-I-E-N-T-S.
MS DUNLOP: "Excipient", not "excipience"?
PROFESSOR JAMES: An "s", a plural, so not a "ce".
MS DUNLOP: I'm not going to suggest to you that we start rummaging around even more and find out if it's the funding for a pilot stage because it says it's the funding for a pilot stage. So I think we can be reasonably sure that these figures are already in the pipeline for the meeting on 25 May.
A. Yes.
Q. And a parallel exercise seems to be going on as a consequence of Dr Foster's memorandum, where someone is working out the cost of what he is suggesting.
A. Yes. I think what Dr Foster is doing, which he always did extremely well, was to look forward, beyond the simple process design stage of the development, and say, "What will this look like in production?" It was his nature as a chemical engineer, or a biochemical engineer, to look at the implications of scale-up and how a laboratory activity will be translated. So he is simply flagging. He is looking forward and saying, if the process development is successful, this is his basic outline structure of what it would look like in routine manufacture, and this is what it might cost. But

I would be fairly confident, although I can never be 100 per cent after 30 years, that these figures would have referred to the pilot scale, the ultra-filtration equipment and so on.

Q. Right. Perhaps I can reassure you that I'm going to look at funding today as a three-part exercise. This is only part 1. But it's not very long.

We know that there was a pot -- we have been calling it -- a pot of up to £650,000 which had been designated by SHHD as available to meet works necessary in consequence of the report of the medicines inspectors. So we have seen that already. If I can find all my finance papers, we will see it again in a minute.

Can we look at [SGH0019769], please? We can see this is the Blood Transfusion Service subcommittee meeting on 25 May.

A. Yes.

Q. Before we move any further through it, let's look at the membership. Both Dr Bell and Dr Scott there.

A. Yes.

Q. We know that Vaughan Ruckley was a vascular surgeon. Sir Simpson Stevenson we have covered already. Mr Duncan, Professor Cash has told us, was a trade union official?

A. He was indeed, yes.

Q. Professor Cash couldn't remember who Dr Kirk was?
A. I can remember his face but not what his day job was.
Q. Was he a medic?
A. I don't think he was but I can't be sure.
Q. We have Mr Wallace --
A. He may have been a haematologist but I can't be sure.
Q. Right. I'm not sure that we know who Dr Horn was?
A. No.
Q. And Mr Walker. Anyway --
A. I think Mr Walker was from the Scottish Home and Health Department.
Q. All right. So a number of those with relevant qualifications, certainly, a number of members with relevant qualifications to sit on the Blood Transfusion Service subcommittee. Is that fair?
A. There was certainly a number of members -- those from the Scottish Home and Health Department would certainly have an interest in the activities of the Blood Transfusion Service. I wouldn't wish to judge whether they were qualified to discuss detailed matters of blood transfusion but let's assume for the moment that they were, yes.
Q. Right. Well, some comments to different effect, which I can hear on my right.
If we look at the page 2 of this document, please,

I think we will see the reference to the pot. It's about the middle of the page.

A. Yes.

Q. This is for the financial year 1983 to 1984?

A. Yes.

Q. That there is additional provision of up to £650,000 in relation to the Medicines Inspectorate recommendations. Do you see that?

A. Yes.

Q. Right. We can see if we go to the bottom of that the subcommittee is deciding that those items marked with an asterisk in appendix 1 should be submitted to SHHD as a bid against that pot. We need to look then at page 7 and we can see that marked with asterisk is pilot stage of heat treatment of Factor VIII.

A. Yes.

Q. So at least after that meeting on 25 May there seems to have been an acceptance that this could go forward as a bid against the £650,000 and that there was enough of a connection with the Medicines Inspectorate. But this wasn't the body that had to be persuaded ultimately. You referred to them earlier, this committee as a bit of a "post box"?

A. Yes, I think they would have -- so long as they had knowledge that their colleagues in Scottish Home and

Health Department were reasonably comfortable with what was being proposed here and why it was being proposed, then they would have accepted that as a justification. After all, the money came from the Scottish Home and Health Department fairly directly.

Going back to your earlier point as to whether these individuals were qualified to make the judgment, I think the lay people wouldn't have understood many of these issues. Processing of SPPS would have been Greek to them frankly, and they wouldn't have understood the heat treatment of Factor VIII and what the implications were. So I don't think there was a detailed analysis of these. I think they were basically looking at -- it was a formal process of looking at the bottom line and saying, "Is that within the allocation?"

Q. Right. There is further correspondence over the summer and we are not going to look at all of it but can we just look at one letter we have looked at before, which is [SNB0037641]? This is the letter from Clive Wooller, general administrator of the CSA, to Mr Murray at SHHD.

A. Yes.

Q. He is attaching an annex with some specific costed proposals. He says:

"The specific costed proposals are set out in the annex to this letter."

He says:

"The proposals have been approved in principle by the management committee."

He is wanting them put forward. But recognising that the department will wish to give further consideration to certain of the proposals including their eligibility for funding from the source requested. I don't think we actually looked at the annex last week. So let's look at it now. It's [SNB0037643]. I think it may be on the last page actually. Can we look at page 3?

A. Okay, yes.

Q. "PFC ..."

Then third last item:

"Heat treatment of Factor VIII. Equipment, 74,000 and revenue implications, 13,400."

A. That's correct.

Q. So we are following the same figures, although the reference to its being the pilot stage seems to have been dropped but that may be something to do with Mr Wooller's shorthand.

THE CHAIRMAN: Ms Dunlop, can you remind me who the general administrator was. What was his position?

MS DUNLOP: He is from the Common Services Agency, Clive Wooller. The process seems to be that the

management committee looks at the proposal and says, "It looks all right to us but --"

THE CHAIRMAN: Through a glass darkly.

MS DUNLOP: Yes. They are not the ones with the purse strings. So what they are doing is authorising its transmission to SHHD, as I understand it. Is that correct?

A. I think so. I think -- that was my -- although I perhaps have to say that at this point in time I wasn't the acting director of PFC but I was aware of these processes that went on. But I think that's right. I don't think, as I have said, the management committee or the subcommittee would have looked in detail at the pilot scale process and what the strategy was and so on. It would have been very much looking at the numbers.

Q. Then we have the reply to Mr Wooller, which is [SNB0111251]. This is actually 20 September 1983. We can see that people are still talking about the financial year, 1983 to 1984. We can see that from the heading. And then in the third paragraph, the same figures. It's the £74,000 for equipment and the £13,400 for recurring revenue implications. But -- and it is a "but" -- the department is not accepting that this expenditure does arise from the recommendations of the Medicines Inspectorate.

So the response from SHHD is no, it is not going to go against the pot of £650,000 but the department is prepared to consider the matter further.

A. Yes.

Q. So there is to be a resubmission:

"You may wish to reconsider the position and resubmit details of estimated expenditure requirements in 1983 to 1984 and subsequent years."

A. Yes.

Q. Right. We have seen these before, Dr Perry, but I don't think you have seen them recently.

A. No, I haven't. I may not have seen them at all but --

Q. Possibly no, although you come into the story after the turn of the year because it's obviously you taking up responsibility for advancing the next costing?

A. Absolutely.

Q. Just to set it in context, we are going to look at [SGH0019496]. This is back to the Blood Transfusion Service subcommittee but in November, 23 November 1983, and it's the same point, there is a kind of statement of position about what SHHD are willing to do, that there is money expressly for the purposes of meeting the cost of developments arising from the recommendations of the Medicines Inspectorate. That's in paragraph 1.

A. Yes.

Q. Then there is reference to money being made available if specific and costed proposals are received. Then if we look at the next page, 9497, we can see that note at the bottom about heat treatment of Factor VIII?

A. Yes.

Q. So really the same point being made, that there is to be a new proposal and details of estimated expenditure requirements.

A. Yes.

THE CHAIRMAN: That's quite favourable at that stage. The 650,000 is not to be used for heat treatment, but they can be the subject of a second application and grant.

A. That's my reading of these documents, yes, absolutely. And as you can see, the subcommittee really seeking advice from the Scottish Home and Health Department to provide, you know, basically the informed basis as to whether the SNBTS proposals are reasonable because they didn't have the basis to make that evaluative judgment themselves.

MS DUNLOP: Yes. Can we go back to your statement then, please, Dr Perry. Your statement is [PEN0121759] and we are now at page 1769.

We had asked you, Dr Perry, about the slightly delphic passage in Dr Cash's letter about what was actually going on from the point of view of

presentation, and I think, with respect, your answer, having looked at that chain of letters and memoranda, is slightly off the point.

We asked you for your best guess as to what you thought Dr Cash was saying and I think you are suggesting that Dr Scott had taken the view that the development of the heat treatment programme was a response to views expressed by the medicines inspectors but in fact, in the light of the correspondence, it looks as though it was the other way around. Dr Scott was saying, "No, this is not a Medicines Inspectorate related piece of funding but try again, present it in its own right".

A. I think perhaps my speculation is wrong on this occasion.

Q. Please, Dr Perry, don't think we are at all critical of that because we all find it a difficult letter to understand.

A. I think my reason for making this supposition is that I was aware, although I couldn't place it in time, that there was a concern, I think, within the Scottish Home and Health Department, and indeed perhaps in the wider -- in the CSA as well, that simply because a medicines inspector visits part of the Scottish Health Service, as it was then, and makes some

recommendations, that is not necessarily the basis for providing funding. There is a due process to go through. But I think I may have conflated two positions and come up with the wrong interpretation of those letters.

Q. In sense I suppose it's a little bit like the BPL meeting in 1982, that there are possible different conflicts that, on the one hand you are making the point that just because it seems to be connected to a Medicines Inspectorate recommendation doesn't mean it will be funded.

A. That's correct, yes.

Q. Another point can be made, though, which is: even if it's clearly not connected to the Medicines Inspectorate, that doesn't mean it won't be funded?

A. Absolutely.

Q. It's a little bit complicated. You go on to say that you think Dr Cash was signalling the need for an alternative strategy, including a presentation or restructuring, in order to circumvent any CSA/SHHD constraints and secure the necessary funding.

A. Yes.

Q. You go on to say:

"Such an approach would not have been

unprecedented."

And I think we understand from this that, as in most parts of human experience, it can depend on the way you present something whether it's going to succeed or not. Is that really what you are saying?

A. I think that's exactly what I'm saying, yes. If you can tell the story in a different way, it might stand a better chance of meeting the -- or being approved by the pay master, as it were.

Q. Yes. You say that:

"Notwithstanding the above funding issues, the development programme continued to progress at pilot scale within existing resources."

A. Yes, that's my recollection, absolutely.

Q. Because actually we have left a bit of a loose end. If there was the requirement for the 74,000 for equipment and the 13,400, the snapshot we are taking is of a point where that has not been authorised?

A. Yes, that's right.

Q. But you say you think that that didn't hinder research. That people carried on with the research within existing resources.

A. I think the research was still going on. The process was still being developed, it was still in the process of scale-up. So my recollection is that the

availability of specific sums of money actually wasn't on the critical path at that point in time and Dr Foster and his colleagues continued with the development programme.

Q. Right.

THE CHAIRMAN: Dr Perry, it's easy to speculate but all sorts of different people at different levels of the organisational structure, if I can misuse that expression for the moment, would have different motives at this time. I suppose the Medicines Inspectorate's report indicated a failure prior to that date to keep up with necessary developments in various facets.

A. Yes.

THE CHAIRMAN: There are those who would see that as a criticism.

A. Yes.

THE CHAIRMAN: Dr Cash may have seen the allocation of money as an opportunity to capture some of it for a favourite project that even he might have recognised wasn't necessarily within the scope, but it was available funds so he might have wanted it. Perhaps we just can't ever extricate the various --

A. You are absolutely right. It is the nature of human endeavour that if you passionately believe in a particular requirement or a development in the

service, then you can present this in different ways to secure funding. I don't take that as a criticism of myself or anybody else; it's the nature of business and management, I think.

MS DUNLOP: Indeed.

THE CHAIRMAN: It just makes it difficult for us in retrospect to try to work out exactly what was going on.

A. I think what Professor Cash's view, and certainly mine and certainly Mr Watt's, was that we had two major themes that we were developing, which was the heat treatment programme, which was very much top of the agenda but also the response to the medicines inspectors' criticisms of 1979 and 1980.

MS DUNLOP: Sir, that's the end of part 1 of the renewed examination of the question of funding. So it might be a good point to break.

THE CHAIRMAN: It's perfect.

MS DUNLOP: Yes.

(11.04 am)

(Short break)

(11.25 am)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir.

Dr Perry, can we go back to your statement, please? That's [PEN0121759] at page 1769. Just looking at that

paragraph beginning "In any event", you are talking about the rate determining factor in moving the programme forward being the organisation and conduct of suitable initial clinical trials.

Dr Foster has explained to us -- and this is moving into the next question as well -- that he met Professor Johnson in Stockholm in June 1983 and there was the enticing prospect of a much better process step, which Professor Johnson had discovered and was going to share with PFC.

A. That's correct, yes.

Q. And if it had worked, it would have reduced greatly the volume of material to be pasteurised, which would be a very efficient innovation?

A. Yes.

Q. You are talking about the rate determining factor being clinical trials but it seems from Dr Foster's evidence at least as though something that was also slowing the project at that point was waiting for information from Professor Johnson?

A. I'm not sure that Professor Johnson's involvement actually slowed it down. I think by the second half of -- we already had a process, a draft outline process which had been established. I think the Johnson variation on this, if you want to put it that way, held

the prospect of further improving the process but I think already the process had been established to a certain extent, to the point at which we needed, before we moved on any further, to do clinical evaluations in patients. That's why I place clinical trials as being on the rate-determining step. Not that we were at the end of the process but we needed to establish -- this is my best recollections -- the proof of principle that subjecting the Factor VIII product to pasteurisation in our stabilisation system didn't lead to any unforeseen adverse events in patients, and that experiment needed to be done.

Q. Right. Can we look on to the next page, please? We asked you, both in this question and the following question, about Mr Watt's resignation.

A. Yes.

Q. You say:

"It is not possible to meaningfully judge the general impact of his departure."

We can't quarrel with that, Dr Perry. I suppose, though, it must have taken up quite a bit of management time, certainly Professor Cash's time?

A. What, following Mr Watt's resignation in July, I think it was?

Q. Yes.

A. I wouldn't be convinced of that, actually. I think there was a -- I think Mr Watt had perhaps signalled before that he at some stage was going to move on. He had other interests outside PFC. He had his own consultancy and he used to do -- although his main job was PFC director and that was certainly full-time. He worked tirelessly. He worked through the night most nights. Extraordinary man in that respect. But he also had other interests as well, personal consultancy projects in different parts of the world. So when he announced his retirement in July, I wouldn't actually necessarily as far as -- from my perspective, I didn't see vast amounts of management time or energy being consumed on the consequences of Mr Watt's departure.

I think he was surrounded by a reasonably competent team, including Dr Foster, dare I say myself, and others and I think, you know, business as usual was the way forward. A process was put in place by the CSA to actually find a replacement for Mr Watt and life went on pretty much as usual, I think. That's from my personal perspective. Others may see it differently.

Q. Well, indeed. And Professor Cash certainly described being extremely surprised but you personally weren't as surprised, perhaps?

A. I was surprised. I had worked with Mr Watt for about

two and a half years by that stage and I enjoyed the relationship with him. He was extremely helpful in terms of explaining the issues. He was fairly idiosyncratic. He had a good sense of humour. He was very inclusive in his approach, certainly with PFC staff. So I'm not sure I was surprised more than slightly disappointed actually that early on in my career in the SNBTS the man that was my boss and whom I had grown fairly fond of and respectful of was actually going to leave.

Q. You describe him working through the night?

A. Yes, yes, yes. I don't want to sort of turn him into some sort of cult figure but he certainly did. He used to go home in the evening and he would sit and draft vast quantities of letters to all sorts of people and then he would arrive back in the morning with a big sheaf of letters that were to be typed up and so on. I think, like us all, he might have exaggerated his nocturnal activities to an extent but he was certainly very energetic.

Q. In terms of the impact his departure had on PFC, do you remember that eventually there were a couple of staff who left and went to work with Mr Watt?

A. Yes, there were. I can remember two, yes.

Q. How would you describe the impact of those individuals

leaving?

A. One of then was quite an important individual, a middle manager who had extensive experience, and we were quite disappointed and we had to work round that, which was my task to do this because this individual left subsequent to Mr Watt's departure. So this is when I was in charge but I don't think there were any, what you might describe as absolutely key individuals, that left taking with them intellectual capability or intellectual property. I think the programme that had been established prior to Mr Watt's departure carried on, ably led by Dr Foster.

Q. Then you give us a little more detail under that heading. Paragraph 22. I don't want to ask you questions about the interpersonal relationship but Professor Cash did mention to us some information about the process of recruiting a successor to Mr Watt?

A. Yes.

Q. To some extent you have dealt with this already, Dr Perry, but we know from contemporaneous correspondence that Professor Cash was trying to establish a formal reporting relationship between whoever succeeded Mr Watt and himself. So he would clearly be, I suppose, the line manager from Mr Watt's successor. That didn't happen because formally the

reporting structure continued to be that you reported to the committee of management of the CSA.

A. That's correct.

Q. But you have explained to us that de facto, perhaps the relationship between yourself and Dr Cash was slightly different and I think earlier you used the word "defer", so there were issues on which you would defer to him?

A. Absolutely, yes.

Q. Yes. One point that Professor Cash made was that, I think it was SHHD had taken the view that if a formal reporting structure had been introduced so that the successor reported to Dr Cash, that would have, in essence, downgraded the position of director of PFC. Do you see that line of thought?

A. Yes, I read that and I was quite -- I have to say it was -- I think it's the first I have heard of that. Not that that's particularly materially relevant, but I certainly was aware, after my appointment, that Professor Cash had expressed the view to either the CSA and/or Scottish Home and Health Department that he would have liked the PFC director to report directly to him, but I wasn't aware of that at the time, during the recruitment process.

Q. Right. You took a bit of persuasion to apply for the job, did you?

A. That's not my recollection.
Q. Oh, right.
A. I think I was aware like everybody else, that Mr Watt had resigned in July. I had been in post for about two and a half years, thoroughly enjoyed it. Found it an extraordinarily exciting, varied, intellectually stimulating environment, but I was by no standards an expert in fractionation. So I expressed some reservations about applying for the job but a number of people kindly suggested that I might have some of the qualities necessary for being the PFC director and they encouraged me to apply, which I then did.

I remember having one conversation with Professor Cash saying, "I have no formal qualifications or knowledge of complex biochemistry and that might be a disadvantage for somebody that's basically running a biochemistry-based pharmaceutical plant", but he was quite clear that that was not an essential requirement and I moved forward my application.

Q. Were the two of you having lunch at the time?
A. Probably, not in Corstorphine.
Q. No. I was going to ask that.
A. I subsequently, and the record shows, applied for the job. Mr Watt retired. His resignation was brought forward or he left fairly precipitously at the end

of December. The plan was -- I think it was March or April. And they were left with a hole and they asked me to act up as director, and having already applied for the job, it would have been a little illogical or inconsistent to say, "No, I will not act up". So that's how I came to be the acting director.

Q. I see, so you had applied --

A. I had applied for the job, absolutely.

Q. I think we know, Dr Perry, that Mr Watt was asked to go at the end of 1983. That's our understanding.

A. Yes.

Q. So you are not in a position to contradict that. Is that right?

A. Absolutely not, no.

Q. Right.

THE CHAIRMAN: Dr Perry, who asked you to become acting director?

A. I think my recollection is that John Cash asked me informally, and then I was subsequently written to by Mr Mutch, the secretary of the Agency, to act up and I gladly accepted the opportunity, I think. There was certainly no equivocation. As I say, I had already applied for the job. I was interested. By that stage I had become quite passionate about getting the job. It wasn't a trivial application, it was a real --

THE CHAIRMAN: So that was consistent with what you told us earlier, that the CSA took an active interest in appointment and promotion --

A. That was a pure piece of administration and there was a due process that they went through and they would do that stuff --

THE CHAIRMAN: You see, as a lawyer, I would rather have thought that the ability to appoint carried certain implications as to authority more widely, but you think it's just a little bit of administration?

A. Yes, I had no relationship with Mr Mutch. I knew him, he was a perfectly pleasant man but in terms of him being the head of the CSA and actually on the committee of management, he certainly wasn't somebody that you would go to for advice or guidance on any issue, frankly.

THE CHAIRMAN: Just as Simpson Stevenson, you wouldn't expect to get much from him?

A. No, one always got the impression that the occasions on which you would interface with the Common Services Agency would be on areas of staff recruitment because we were constrained in our ability to -- this was a major issue for me at the PFC in terms of the relationship with the CSA, that they often appeared as a slightly interventionist bureaucracy when you least needed them to be but when you really needed

some support and guidance, they had neither the competence nor the experience to provide that.

So if, for instance, we were looking to recruit a member of staff with a particular set of skills, if those skills didn't match the job specification for a particular grade in the health service, then we were unable to appoint them. Because they didn't meet the entry qualifications. So there was a great deal of time and conflict with the CSA in resolving these recruitment issues. But I digress. I apologise.

MS DUNLOP: That's quite all right.

But the CSA, as one might deduce from its name, was responsible for the provision of a number of different services to the NHS.

A. Absolutely.

Q. For example, the Central Legal Office?

A. Yes.

Q. So it had quite a big basket of different responsibilities?

A. Very divergent responsibilities, yes.

Q. Yes, and no doubt those who sat on the management committee wouldn't have claimed to be knowledgeable about the particular subject matter of some of those services?

A. Absolutely not.

Q. Yes. It took until 1985 before your appointment was confirmed. Did it feel like a long time?
A. Yes, it did actually. It was about a year, I think, after I acted up. I think there was one interview -- and I can't remember the exact time line for this -- where they deferred a decision and I continued to act up and then there was a subsequent interview where I was the successful candidate. So it was about a year. I think it was in April -- at the beginning of 1986 that my appointment was confirmed.
PROFESSOR JAMES: 1985.
A. No, 1985 -- I acted up from January 1985 for a year and I think it was around about the turn of the year or early in 1986, or maybe late 1985, that I was substantively appointed.
MS DUNLOP: January 1984 you began to act up.
A. Yes.
Q. And you acted up for about a year, I think?
PROFESSOR JAMES: So it would be 1985.
MS DUNLOP: It would be 1985.
A. Yes, I'm sorry. Yes, you are absolutely right, sorry.
Q. Right. Let's move on.
We asked you about events at the end of 1983 and the beginning of 1984, particularly disclosure of information from Dr Smith about dry heat experiments,

and we have learned also that at the end of 1983, PFC did some dry heat experiments?

A. Yes.

Q. But I'm planning to ask Dr Cuthbertson about those and I take it that's appropriate, is it, rather than you?

A. Oh, yes. And he is looking forward to it.

Q. Well, that's good.

You did suggest something at the end of your answer on paragraph 25, which is interesting, Dr Perry. Can we look at page 1771, please? Maybe I have inferred from this more than you intended, Dr Perry, but that sentence at the end, where you say:

"In the event that the PFC process was unsuccessful, it could revert to the BPL dry heat method and vice versa."

A. Yes.

Q. We understood from Dr Foster that there was a kind of informal cooperation about conferences?

A. Yes.

Q. One of them was at a conference and the other one couldn't be there, there was reporting.

A. That's correct.

Q. And that, no doubt, was a very efficient use of time and expense.

A. Yes.

Q. What seemed to me to be hinted at here was almost the same sort of thing but with the science: that it was no bad thing that BPL were working on dry heat treatment and PFC were working on pasteurisation, because there would be a sharing of knowledge?

A. Yes.

Q. Is that what you were meaning?

A. I think that is what I was meaning. I don't want to overemphasise the point and I don't think it was designed to be like that. So it might be a little bit of a post hoc rationale in a sense but it did provide, I think -- genuinely at the time we felt there was some merit in pursuing basically the two options that existed, either pasteurisation or dry heat, and we would have the benefit of being able to back the one that seemed most promising.

But, as I say, that wasn't specifically and proactively designed into the collaboration. I think it just emerged like that. But having established it, I think -- I certainly genuinely felt it was quite useful and important because we were dealing with quite complex issues associated with the pasteurisation process; it wasn't straightforward. There was never a guaranteed outcome from that, particularly after clinical studies.

So the idea that there was somebody else independently pursuing an alternative option just seemed to me to be a good idea. This was after I had taken over as director.

Q. Yes. Of course. It would work best if each side told the other what it was doing and what its results had been.

A. Yes, which is pretty much what happened, I think. That was certainly my recollection, although, as has been amply established, there was no formal process for doing this but the Foster/Smith collaboration was highly productive. There were, you know, absolutely no personality issues. They were both dedicated, very able expert scientists in the field and I guess we were blessed in the fact that they actually also functioned very efficiently and effectively as a pair of scientists, albeit with different masters.

THE CHAIRMAN: Dr Perry, I would like to follow it just a little.

I think I can understand that, at a practical level, as among scientists, particularly scientists who were getting on fairly well in exchanging information informally, it would be recognised that there was the prospect of an advantageous outcome if you have two contemporaneous but different lines of research going

on. However, the ability of one to exploit the results of the other might be a different matter. And, for example, if one were to assert intellectual property rights against the other, that could frustrate the whole arrangement.

A. Absolutely.

THE CHAIRMAN: In the first place was there any arrangement that you knew of as between the English and the Scottish scientist that would have given either of them a right of access to the results of the other's research?

A. I'm certainly aware that, certainly from the perspective of the PFC -- and this was the policy of my predecessor as well -- any development, any invention, any patent or any intellectual property that we established would be made freely available to the rest of the service.

I think to an extent, although I can't judge to what extent that took place at BPL, my understanding was that was a fairly reciprocal arrangement. I think that was also underpinned -- and I remember discussions, although I can't place this in time -- that legally the whole position of one part of the Crown preventing access by another part of the Crown to intellectual property through patent was just simply a non-starter. So one part of the health service could not -- this is my understanding. I'm not actually suggesting this is an

absolute fact. Therefore, I guess to an extent we assumed that any intellectual property development that one part of the National Health Service in the UK developed would be freely available to the other.

That was certainly our intention, and from a PFC perspective that's how we did it. On the other hand if one part of the Health Service, ie BPL, licensed in a process from a commercial organisation, which BPL certainly did, that was clearly not available to us.

THE CHAIRMAN: Yes. Perhaps some time we will extricate the various legal complexities around this, perhaps not.

MS DUNLOP: We have seen, Dr Perry, as an example of a situation in which there couldn't be full and free disclosure, collaboration with Professor Johnson --

A. Yes.

Q. -- over the period summer 1983 to summer 1984?

A. Yes.

Q. When Professor Johnson was working on a process which he was hoping to patent, and obviously there had to be a degree of confidentiality about that?

A. That's absolutely right, yes.

Q. That's, I think, consistent with the explanation you have just given?

A. I think so, yes, although, I would just add a footnote to that, that we would have done everything we could to

have made sure that BPL was included in -- was able to access any technology that came out of it. That may or may not have been successful but it would have certainly been part of our starting point, to try and negotiate, in any formal contract that we had with New York University and Professor Johnson, to make sure that other parts of the NHS were able to benefit from any outcomes and that, I think, to an extent, probably caused a problem for NYU to some extent because making something freely available for a small country like Scotland is one thing but making it available freely to a much bigger population of the UK was a significantly greater commercial issue for them.

Q. Right. We are at paragraph 26 and I don't think I need to ask you anything specific about this. You made the point and I think we have covered this already with other witnesses, but after the meeting, the November meeting, at which Dr Ludlam gave a verbal description of the reactions his patients had experienced, he did administer unheated material, as you say, as a placebo control to confirm that the adverse reaction that the patient had had was, I suppose, a physiological reaction, rather than being in some sense psychological or explained in another way?

A. Yes, that's what he was trying to demonstrate, yes.

Q. Yes. Then you go on to point out -- and others have made this point too -- that just because something can be described as a "minor reaction" doesn't make it acceptable?

A. Yes, I had at that time, and certainly today, absolutely no problem with the notion of a reaction being described as "minor" at one stage in its evaluation and then becoming more significant. I think there was a -- I think frankly Dr Ludlam's report on our pilot batch of product, that had been infused in this patient, he was simply signalling that there is something unusual happening in response to this particular product, and as a manufacturer that was very, very important information. So even a minor reaction, if it was reproducible, once you have got to the process of introducing the product into routine use, that would have been unacceptable.

Q. Yes. Paragraph 27, we had asked about whether there was any possibility of changing tack. That is moving from pasteurisation to dry heat treatment around the start of 1984, and you answered that and I think in your letter we also confirmed with you that that reference to 1986 should be 1984?

A. Yes.

Q. So if we can just note that in passing.

A. Yes.
Q. It's time to go back to finance. Paragraph 28 on the next page. You are dealing with costings and timescales for SNBTS introduction of heat-treated Factor VIII. You say that when you became acting director in January 1984, you were responsible for taking the matter forward?
A. Yes.
Q. That is obtaining funding for the heat treatment programme.
A. Yes.
Q. And we know that you prepared proposals and cost estimates. Can we look first, please at [SNB0074276]?
So we can see that by 9 February you have prepared a paper giving costings for the heat treatment programme. Is that right?
A. Yes.
Q. Yes. And you are saying that the estimated capital cost is slightly higher than that originally proposed, £75,000. Do you think your reference to "slightly higher" is a reference back to the £74,000 for the pilot stage?
A. Yes, it is.
Q. Right.
A. Yes.

Q. Then you say:

"The revenue costs are associated mainly with substantial quantities of pharmaceutical grade sorbitol."

A. Yes.

Q. The costing that goes with this is [SGH0020068]. That's the front sheet. If we look at page 2, we can see you have given a bit of explanation.

A. Yes.

Q. The state of play is that two small lots of heat-treated Factor VIII were issued for clinical evaluation during 1983, and there is going to be more material available for clinical trials. You then set out a timetable.

A. Yes.

Q. According to this timetable, by April 1985 or in April 1985 all Factor VIII produced by the new method will be available for clinical use.

A. Hm-mm.

Q. But you have built in, as you say, an assumption that the clinical evaluation is satisfactory.

A. Yes, yes.

Q. And also that certain building modifications can take place.

A. Yes.

Q. Then there is a description for the readers of process

methods. Did you write this or did Dr Foster write bits of it?

A. No, I think I wrote it.

Q. Right. Who are you writing it for? Are you writing it for lay people or are you writing it for medics or chemists or ...?

A. I'm writing it as a substantive proposal to the CSA for funding, in the knowledge that it will be passed from the CSA to people that would probably understand its content in Scottish Home and Health Department.

Q. And --

A. But also perhaps for colleagues within the SNBTS as well, because there was an SNBTS process for looking at bids for funding and so on. So there would be a peer review-type process within SNBTS. So it would have been written for a fairly broad audience.

Q. Right. Can we look at the next page, please? "Prevention of recontamination". I think that links back to the point you made earlier about pasteurisation being more implicated because unlike albumin, you can't pasteurise in the final container?

A. That's correct, absolutely.

Q. Yes. Then you say:

"A particularly difficult feature is the need to recover Factor VIII which has been diluted in large

volumes of concentrated sugar."

A. Yes.

Q. So you have this very sugary solution and the sugar serves its purpose but then it has to come back out again.

A. Then you have to get it out and you have to remove it in such a way that doesn't damage the Factor VIII molecule.

Q. Yes. Can we just scroll down through that then, please? Then we come to the figures. Can we go on to the, following page, please? This is not, as I understand it, the pilot stage. This is the full thing?

A. Yes, that's my understanding, yes, absolutely.

Q. Yes.

A. Yes, certainly. If we are describing building modifications and air handling systems and so on, that would certainly be -- one wouldn't introduce those before you had a definitive, finalised process.

Q. Yes. Certainly we can see that the annual cost, the revenue costs, at 27,000, are significantly more than the 13,400 that we saw earlier, in the reference to the pilot --

A. Yes, but this would have been at full-scale, this would have been for all plasma, whereas the pilot scale, only a proportion of the Factor VIII would have gone through this process.

Q. After this there is a bit of correspondence in which that figure is itself tweaked a bit because there is an additional amount coming in.

A. I was just going to make the point that in terms of pharmaceutical development, the timescales for these things were very, very short. And getting accurate estimates for a process which hadn't been worked up, it was necessary to make often estimates of what the costs would be, knowing that the process for obtaining funding through the NHS processes and procedures was always about 18 months ahead. So it was necessary, often, to make judgments and estimates and sometimes guesstimates of some of these costs, so that when you were ready, in a fast moving environment, which it was in the mid-1980s in terms of these types of processes, one had to be slightly ahead of the game in terms of bidding for money. And often that meant making bids for finance which hadn't properly been worked up and evaluated because you simply didn't know what the final process looked like.

Q. Yes. I think we don't find it difficult to imagine, Dr Perry, that it was certainly not a case of saying, "Good, we have fine-tuned our process, now, let's apply for some money". It couldn't have been like that?

A. No, it couldn't have been.

Q. No?
A. No.
Q. Can we look on to the next page, please? That's the diagram I mentioned earlier.
A. Yes.
Q. Would that have been prepared by Dr Foster?
A. It certainly wouldn't have been prepared by me. So I think it would have been -- either Dr Foster or there were other people in PFC that might have -- one person who sadly died, a guy called Sam Keddie may have done that but it would have been done in close consultation with Dr Foster.
Q. Yes. When we looked at the columns earlier, from the flowchart, and we spoke about the deviation or the digression from the vertical flow, this is what it would have consisted of?
A. Absolutely, yes, this is the excursion that the product goes on for the pasteurisation process. So you start with the Factor VIII solution and then you have to go through a pasteurisation system. It has to be diluted and so on. You can see all the various steps where it is capable of losing Factor VIII yield. So yes, I'm stating the obvious, but pasteurisation actually is a summary of a fairly complex process.
Q. Yes. In fact, Dr Foster told us that the key feature of

any pasteurisation process is heating in solution?
A. Yes.
Q. Yes. So in fact you can call this the "pasteurisation process" but it looks as though the heating part is on the top left and much of the rest is concerned with --
A. Recovering the product after the process, yes.
Q. Yes.
A. I think the reason both Dr Foster and myself would want to emphasise this point is just to give those that aren't familiar with working in these environments that -- to an uninformed audience, you know, you can ask the question: why didn't we pasteurise sooner? It was a simple enough process and I guess the act of pasteurisation, ie heating a solution at 60 degrees for ten hours, isn't that technically demanding. But the chemistry involved in preparing the material so that it's stable under those conditions and removing these additives afterwards is where the complexity exists.
Q. Yes. Right.
Can we go back then, please, to Dr Perry's statement, [PEN0121759] and we are now on 1773.
So we know that you have prepared this cost estimate, complete with diagram, and you submitted it to the CSA and we can just look briefly at the minutes of the meeting on 22 February 1984. That's [SGH0019972].

We recognise these names now, Dr Perry?

A. Yes.

Q. So if we just move to page 3, and again we have seen this before but what seems to be numbered paragraph 2001, we see the approval of your cost estimates?

A. Yes, that's correct.

Q. Although by this point it's going forward in Professor Cash's name?

A. Yes.

Q. Yes. Right. Can we go back to the statement, please, and on to 1774? I think you have made this point already, Dr Perry, that the timescale was actually quite ambitious?

A. Yes, I think it was.

Q. There wasn't much slack in it. There wasn't any slack in it perhaps?

A. No. Some of my colleagues would probably nowadays describe it as "ridiculously ambitious" but we lived in a world where we were fairly confident, we had an optimism that these problems could be solved. But I think it was clearly overly ambitious, although possible.

Q. Yes. With a following wind?

A. With a following wind.

Q. And you say by today's standards it's difficult to envisage how the proposed timescale could have been shortened. Do you think that a project like this today would take a lot longer?

A. Yes, it would take significantly longer. The requirements for validating the process, for doing proof of principle experiments, for clinical studies, for instance, would have been vastly longer than we would have had today. And also it would have been done within the context of a very rigid and very sophisticated regulatory process.

So the development from scratch, basically, of a new complex Factor VIII product, which involved heat treatment, which itself was recognised as being a very high risk type of process because of neoantigen formation, certainly to do that sort of process today would be four or five years.

Q. Right. I don't think we should really ask you to give your views about the extent to which all of these additional processes add value but we can certainly see that they add complexity and time.

A. They certainly add complexity and time and I think -- I'm a great advocate of the regulatory process, although sometimes the value for money that you get out of new regulatory processes and procedures can be debated, but

inevitably and inexorably it extends the time period, and certainly it was a feature throughout this period for us. I guess in some sense it was one of the upsides of operating under Crown immunity, that we had much more freedom to act and we didn't have to go through any formal regulatory processes to get our new methods approved by the licensing authority and so on. I'm not advocating that but at the time it did mean that we could shorten timescales for certain aspects.

Q. Yes. No doubt it's impossible to generalise anyway about whether the developments are helpful or unhelpful?

A. Yes.

Q. I suppose it all depends --

A. Yes, absolutely.

Q. And I don't need to ask you anything further about paragraph 29. You have given us your answer about how Dr Craske obtained his information. Issues of funding. This is just to look very quickly at funding for the last time, since it's part 3 of a three-part examination. We know that there is an exchange of letters in the summer of 1984 and because you feature in them we will just look at them briefly. [SNB0074523]. It's a gentle reminder letter, I think, perhaps.

A. That's exactly what it is, yes.

Q. A gentle but persistent reminder letter to Mr Wooller

because you need to know about the money?

A. We needed some of the money but we were also signalling we weren't going to be spending it during that financial year. So we were requesting carryover into future years. That's my reading of it.

Q. And that's 13 August 1984. If we look at the response, which is [SNB0074527], that's 17 August 1984. So a very prompt response.

A. Yes, absolutely.

Q. From Clive Wooller?

A. Yes.

Q. No problem with carrying over the expenditure and he is confirming that there will be formal authorisation --

A. Yes, that's correct.

Q. -- of the £90,000?

A. Yes.

Q. Yes. Right. Can we go back to the statement then, please? Dr Perry, just to ask you some questions about the end of 1984, which you describe as "a critical period in our understanding of AIDS".

A. Yes.

Q. You give a little summary of the main developments at that time?

A. Yes.

Q. Information from Dr Ludlam, information from Groningen

and then information from Cardiff --

A. Yes.

Q. -- as well. Can we turn over, please? Dr Perry, I don't want to go over this period in great detail again, not least because that was done when you were here in June, but there is a particular aspect of the information transfer during that period that I do need to ask you about.

A. Okay.

Q. The first question is in relation to the question of infection of patients at Edinburgh Royal Infirmary with PFC product. I'm actually not very clear about when and how you personally first learned the information. Do you have any recollection of that?

A. Erm --

Q. Before you answer, Dr Perry -- I'm sorry, I'm interrupting you. We are trying, if we can, to tell this story accurately, plainly?

A. Yes.

Q. So it's useful to look at the contemporaneous documentation, certainly, because that has a reliability that people's recollections in 2011 probably don't have.

A. Yes.

Q. But I am interested in getting your answer, in you giving us your recollection as best you can, rather than

trying to fit your recollection to what you know other people have said.

A. Yes.

Q. So can I ask you perhaps to banish that for the time being?

A. Yes, okay.

Q. I know that's difficult but going back then to the question: do you have an image of yourself standing or sitting somewhere and hearing the news for the first time?

A. The first -- taking your specification on board.

Q. My instructions.

A. My instructions on how I should place myself for this question, the first unprovoked memory I have of this is when I returned from Groningen and I had a conversation with Dr Cuthbertson, because he appeared at my office first thing in the morning to inform me that recall had actually taken place of the implicated batch because subsequent information from Dr Ludlam and so on had confirmed his understanding and concern that the product had transmitted HTLV-III. That's my first actual memory. Having said that, I remember hearing that in the context of having previously known that there was an issue associated with this batch before I went to Groningen.

Q. Right.
A. I don't know whether that answers your question. I can't remember where I was, what I was doing or what my reaction was when I heard for the first time that a batch of product -- now, that might be just the way my -- you would think I would remember the actual event where I was told that there was a batch of product -- but that's not -- within your instructions, my first actual memory is on return from Groningen, hearing that the recall, which we thought was a possibility before I went to Groningen, had actually taken place as a result of discussion between Dr Cuthbertson and, I think, Dr Boulton and Dr McClelland in my absence.
Q. Right. I think we have actually got there quite quickly, thank you, Dr Perry, because what I was trying to establish, so that we can prepare as clear a narrative as we can of that little period, is whether you went to Groningen knowing that there was a problem.
A. Yes. I went to Groningen knowing that there was a potential problem. I went to Groningen knowing that there was a potential problem, that it was very preliminary data, it was fairly confidential because clearly we didn't want to set a hare running on the basis of evidence which turned out to be false. So, yes, I was certainly aware of the potential problem when

I went to Groningen.

Q. Yes. I expect you have looked at the transcript of Dr Foster's evidence, have you?

A. Yes, I have.

Q. So you know that he has given evidence about initiating experiments on the Friday?

A. Yes.

Q. That's 26 October.

A. Yes.

Q. And in fact, as I understand it, there are two different sets of experiments. There are experiments which he asks Dr MacLeod to carry out, which are heat-treating samples to which various additives have been added?

A. Yes.

Q. That's the MacLeod experiments, if you like.

A. That's right.

Q. And then there are the McQuillan experiments and Mr McQuillan is working with the simple, unadulterated product and heating it. Is that right?

A. Yes, that's absolutely right.

Q. And of course, a difficulty at this point is that PFC is not manufacturing product at the end of October 1984 because there is a plant shutdown?

A. Yes, that's correct.

Q. So these experiments are dependent on being able to find

material with which to work from somewhere?

A. It wasn't too difficult to find. Well, I think to do small-scale laboratory experiments, which were the MacLeod experiments, then there would have been raw material to do that. But I think that getting material that was directly obtained from process would have been difficult. So it would have been restricted. But there may have been ways round that. The McQuillan experiments, which was simply taking bottles of product that already existed and subjecting them to different time and temperature profiles, was very straightforward.

Q. Yes. Can we look, please, at a document, [PEN0121376]. This is the letter that you wrote to Dr McClelland on 26 November 1984?

A. Yes, that's right.

Q. And I think what had been confusing me was it looks as though what is being said here is that the first communication of the news to PFC was on 1 November and, given Dr Foster's description of Dr Cuthbertson receiving a phone call and Dr Foster being there, that's very difficult to synchronise, if you bear in mind that Dr Foster and you are in Groningen. So this is a long way round but I hope that it appears clearer at the end, but we now understand that that contact, which you have numbered 1 in your letter.

A. Yes.
Q. That's the McClelland/Cuthbertson contact, is not the first intimation of a potential problem?
A. No, I think it's quite likely -- I would find it difficult to believe myself that I hadn't been forewarned by either Dr Boulton, Dr McClelland, that they had had contact with Dr Ludlam concerning a infective batch of product. So I think I would have been forewarned but it would have been suggested to me that this was provisional. Dr Ludlam was quite careful that he wanted it to be kept confidential at this stage until he had obtained confirmation that these results were real. So I think, although I cannot remember the point at which I got this information, I would have been forewarned prior to that time. Certainly not on the 26th. But I would have thought on the Monday or Tuesday of the following week.
Q. Yes. You see, it's very difficult --
A. I would have had a heads-up from somebody that there was a potential problem.
Q. Yes. It's very difficult, Dr Perry, isn't it, not to slip back into what you think would have been the position but we do have your evidence that the contact in connection with the recall, you thought, was taking place against a backdrop that this was not the first

news you had had?

A. That's right.

Q. And that is an actual memory, is it?

A. Well, to be very rigid with your instruction, my clear memory is returning from Groningen and having Dr Cuthbertson inform me that our suspicions -- or the provisional information that we had received the previous week had now been confirmed and as a consequence we had to do a recall.

Q. Yes.

A. I was -- so it wasn't -- my feeling wasn't one of great surprise but it was of great concern and disappointment, that what we had hoped was not a real effect had actually taken place and there was evidence of HTLV-III in a number of haemophilia patients in Edinburgh.

Q. Yes.

A. So I am extrapolating but extrapolating backwards from my own memory when I returned to work on the Monday, if you see what I mean.

Q. And that's Monday, 5 November?

A. That's right, yes.

Q. Right. Thank you. Because you were away up to and including the Friday, the 2nd?

A. Yes, that's right.

Q. Can we go back to the statement, please, [PEN0121759] at

1776? This is not then news to us, Dr Perry, that paragraph, about the evaluation of heat treatment at 68 degrees?

A. Yes.

Q. Then you say:

"SNBTS is aware of no reports of HTLV-III or HIV transmission by its Factor VIII products following this course of action."

A. Yes.

Q. I just wanted to digress slightly to look at a time when it was thought that that might not have been so. Can we look firstly at [DHF0018523]? Can we see the date? It's 28 November 1985. This is somebody in the Department of Health in London contacting the chief medical officer. That would be the chief medical officer for England and Wales, I take it?

A. Yes, I think so, yes.

Q. Yes. And referring to:

"Some hearsay evidence that haemophiliac patients are seroconverting to become anti-HTLV III positive despite being given heat-treated Factor VIII."

Then you are mentioned -- by "you", I mean PFC --

A. Yes.

Q. -- in paragraph 2.

A. Yes.

Q. "In particular the protein fractionation laboratory in Liberton in Scotland, introduced on a short-term basis, a very quick method which they thought might inactivate the virus at the beginning of this year. I believe that it is this latter which may be implicated in the information I have received."

Then we now have:

"The BPL laboratory at Elstree were rather late starters but are probably now producing the safest product in the world."

Can we then look at a publication, [LIT0010664]? We can see this is from a magazine, "Vox Sanguinis" is that the voice of blood?

A. Literally, yes.

Q. From 1988. The authors are from Edinburgh, not Dr Brookes, she is from Dundee.

A. Yes.

Q. But we recognise the names, I think?

A. Yes.

Q. It's quite a short paper. It refers to batches of heat-treated Factor VIII concentrate being found to contain anti-HIV positive plasma donations and these being batches that:

"... have been dry heat-treated at 68 degrees for two and 24 hours respectively. No HIV seroconversions

occurred in 13 susceptible haemophiliacs receiving a total of 540 bottles of these Factor VIII preparations."

A. That's correct.

Q. So this is the result of a bit of detective work that was done in connection with donations that were later found to have been positive. Is that right?

A. Yes, it's a study that was possible because of a look-back following the introduction of HIV testing.

Q. Yes.

A. In October 1985 HIV testing was introduced and it was possible to -- those donors that presented as positive, we could look at previous donations and through that process we identified two or three batches of Factor VIII that would have had infected -- definitely would have had infected donations with respect to HIV included in them, and by following up the patients we were able to demonstrate that there was no transmission.

Q. Yes. I think Dr Foster has actually given us a table in relation to --

A. That's right, indeed, yes.

Q. Yes. So we have that information about that piece of research that was done.

Just to give everyone a chance to have a look at it, can we scroll a little bit down, please? We can see

that in relation to the Edinburgh centre it says:

"No new seroconversions have occurred amongst haemophiliacs treated at this centre since heat treatment of Factor VIII concentrate was initiated by SNBTS in December 1984."

A. That's correct.

Q. And then it goes on to narrate exactly the circumstances you have described about the tracing of positive donations and looking specifically to see if those had had any effect.

A. Yes --

Q. And there was no doubt that both batches were contaminated before treatment.

A. I think one of the early indications that we had, which demonstrated that our actions, taken in December 1984, were effective.

Q. Yes.

A. Ie we knew retrospectively that these batches were infective, potentially infective, but that the heat treatment clearly eliminated that infection because none of the patients seroconverted that received those batches.

Q. Can we just look over the page, please? Of course, there is another piece of documentation about possible infections and I think we should just look at that too,

if we could, please. It's a letter from Dr Forbes, which I'm sure you have seen before as well.

A. Yes.

Q. Can we look at [SNB0047776], please? We can see that this is you writing to Dr Rotblat. Is that right?

A. Yes.

Q. At DHSS in March 1986?

A. Yes.

Q. And you are enclosing a copy of a letter from Dr Forbes detailing seroconversions in Scotland following the use of heat-treated Factor VIII, but you go on to say:

"You will, of course, appreciate that these cases are equivocal and there is a general consensus that the seroconversions are related to previous treatment with untreated material of either commercial or NHS origin."

The letter we have looked at before, [SNB0047732].

A. Yes.

Q. Just looking at the three patients, patient number 1, a large number of batches, particularly in 1984, we can see, 1983 and 1984, factor consumption, quite a bit higher certainly than the previous years, and then a list of batches used in 1984 to 1985.

A. Yes.

Q. Although there isn't actually a factor consumption figure for 1985, but we can see that the test results

are given higher up and there is a negative test in October 1984 and then a positive test in October 1985?

A. Hm-mm.

Q. But it would be possible for that negative test in October 1984 to have been in a window period or at a time when the patient was in the process of seroconverting, I suppose?

A. Or the infection occurred between -- sadly and tragically in this case -- October 1984 and December 1984, when we introduced heat treatment.

Q. Yes.

A. The patient was clearly being quite intensively treated throughout 1984, so he would have received fairly significant quantities in that two-month period of Factor VIII, on either a prophylactic or an on-demand basis.

Q. Then if we look at the second patient. Can we go over the page, please? The second patient is actually a Haemophilia B patient.

A. Yes.

Q. We looked at this letter last week and I think it actually is not difficult for the Inquiry to work out the likely identity of this individual. That statement that there had been no treatment in 1985 doesn't appear

to be completely accurate?

A. Okay.

Q. But in any event, if this is Factor IX, then we know that there wasn't heat-treated Factor IX issued by the NHS until the autumn of 1985?

A. That's right. That's correct.

Q. Although I think there is evidence that there was some purchasing of commercial heat-treated Factor IX at the Royal Infirmary in Glasgow in the summer of 1985.

A. Oh, there would have had to have been because there was no supply from the -- the SNBTS withdrew completely its supply of all Factor IX product, pending its safety studies in dogs to demonstrate -- so it was absolutely the case that unfortunately haemophilia centres in Scotland had to make commercial purchases of Factor IX during that period to cover the needs of their patients.

Q. When did you withdraw your Factor IX?

A. I think we withdrew -- we quarantined, because I have been asked a specific question on this. We ceased to supply unheated Factor IX, I think it was May 1985 but we didn't formally recall it, we quarantined it because we weren't confident that commercial supplies were necessarily reliable or that they may result in unpredictable clinical reactions.

So we maintained stocks of unheated material around

Scotland to meet an emergency requirement for a patient treatment but to the best of my knowledge it wasn't used. Between May and October 1985, my understanding is that all patients in Scotland would have been treated with commercial product. Or certainly that's the system that we set up.

Q. Yes. Can I just ask you, Dr Perry, you have mentioned quarantining of product. Can we go back to Factor VIII and December 1984? I think we understand that the first step that was taken in relation to heat treatment was to heat-treat a three-month supply?

A. Or a one-month supply, yes.

Q. I think Professor Ludlam said it was a one-month supply but there are references to its being a three-month supply.

A. Okay.

Q. Anyway. We will no doubt be able to firm that up but a shorter stock perhaps, or a stock that would last a limited period of time was initially heat-treated --

A. Yes.

Q. -- at the end of 1984. And we know that in order to do that -- or we think that in order to do that, some product was brought back to PFC from further down the supply chain. Is that right?

A. It could have been brought back from Glasgow, where we

knew there were very substantial stocks. I can't, without going back to the records, really establish where that material came from but -- I would have thought -- again, without being prompted by evidence, my expectations was we would have had enough material in the PFC to subject it -- although it is equally possible that I may have taken a view that what we wanted to do was get, you know -- on the basis of a first in, first out stock control system, we didn't want to introduce the newer material into supply in advance of the older material. So we might have brought material back that had already been issued to subject it to heat treatment, but I can't be sure without checking the record.

Q. I think, though, we should just clarify something which has been suggested earlier, that some of what was heat-treated might have been brought back from patients?

A. It was --

Q. Did you ask patients, "Bring back your stocks" and then heat-treat it and reissue it?

A. We never did and I don't think ever still do, directly communicate with patients but once we had established in principle and in practice that we wanted to introduce heat-treated Factor VIII for the entire Scottish population, it was certainly my expectation, and I think the correspondence certainly backs this up, that it was

the intention that all product, right down to the patient's domestic refrigerator at home, would be recalled and replaced with heat-treated material.

Q. Yes. You see, there are two different points, Dr Perry, there is the question of recalling unheated product so that patients wouldn't use it, when they could be using something safer.

A. Yes.

Q. And there is a question of recalling product for the purpose of heat-treating it and reissuing it.

A. Yes. We certainly wouldn't have recalled from the patients to do the initial heat treatment.

Q. Right, thank you.

A. We certainly wouldn't have done that.

Q. Right. Because?

A. Well, the patient's stocks would have been necessary to treat a bleed in the middle of the night or unexpectedly. The reason we wouldn't have done that was because there was plenty of material within our own control or within the SNBTS to enable us to heat-treat stocks. I think the recall from the patients would have been right at the end of the process, as we did, what I described to myself as the exchange transfusion throughout Scotland of heated material for unheated material.

Q. Yes, I follow. I should have asked Professor Ludlam about this and I forgot. So we will ask him when he comes back next month but you are telling us it certainly wasn't your job to be in direct contact with patients?
A. No, absolutely not, no.
Q. So you are passing a message, as it were, down the line?
A. Yes.
Q. It's up to the haemophilia centres to make the practical arrangements necessary with their patients to do that exchange. Is that right?
A. That's exactly how it was intended to work. In fact, I know it sounds cumbersome now but that's how the communication system operated. We would have certainly rehearsed it with the haemophilia directors beforehand but the instruction would have gone from myself to the regional transfusion centres, who were our regional representatives, and they would have liaised with the haemophilia centres and the various other holding points because they were the distribution points. Every product that we made was distributed via a regional transfusion centre. It therefore followed that recalling them -- and they held the records of where these products were issued to. Therefore, in order to effect an effective recall, you had to recall

it via the regional transfusion centre. So they would have issued the instruction to the haemophilia centres or the haemophilia treatment hospitals, to recall the product from the haemophilia centres and they in turn would have recalled it from patients.

Q. But in relation to Factor IX, you didn't then issue an instruction down the line to recall unheated Factor IX?

A. Not at that point.

Q. No.

A. Because we weren't confident that supplies of the commercial material (a), were secure and (b), this was very early on in the introduction of heat treatment of Factor IX. We couldn't be absolutely sure that the treatment of patients with a heat treated Factor IX product commercially may not have led to -- it could possibly have led to patient reaction, in which case there would have been a need to revert to the unheat-treated material, which we knew was at least efficacious.

So it was just a precaution against the heat-treated material not being either suitable or available.

Q. Right, but once you had your own heat-treated Factor IX in the autumn of 1985 ...?

A. Then we recalled the unheated material very formally.

Q. And you do exactly the same exchange process as you had

done with the Factor VIII?

A. Precisely.

Q. Good. Just to complete that letter -- we were sidetracked because we were talking about Factor IX?

A. Sorry.

Q. No, it's my fault. The third patient, we see, during 1984 and 1985 he has had FEIBA only. So we may well be talking in relation to patient number 3 about somebody who was infected by commercial product.

A. I think that's the most likely explanation, yes.

Q. Yes.

A. Certainly FEIBA is a commercial pooled product from the US.

Q. Just to look over to the conclusion of the letter, please, if we could look at the final page, Dr Forbes has been looking at seroconversion intervals?

A. Yes.

Q. And doing a bit of detective work also. Right. Can we go back to the statement, please? Can we go to 1777? We did ask you, Dr Perry, about the minutes of the heads of department meeting on 26 October.

A. Yes, indeed.

Q. And I think this just fits with the discussion we had earlier about there having been some earlier intimation to you of a problem and you are, I think, in the end not

very clear what your state of knowledge was on the morning of 26 October. Is that right?

A. Well, I think I am quite clear --

Q. Right.

A. -- that I had no knowledge whatsoever but that is from just looking at the -- that is not -- that's not from a memory. That's from the evidence that I have seen, I think, unless --

Q. That's from Dr McClelland's contemporaneous memo, saying that he received a phone call from Dr Ludlam on the evening of 26 October, is it?

A. Correct, but also Dr Ludlam's evidence that it was on 26 October that he was telephoned by Dr Tedder.

Now, I cannot conceive of an alternative source of information that would have given me knowledge that these patients had seroconverted, or potentially seroconverted, before 26 October. I think it's perhaps just a coincidence. I think HTLV-III, the development of heat-treated products was so high on the agenda, it wouldn't have been unusual for me to have concluded at that particular point in time that it was useful and indeed important to record the actions that we were taking in response to this emerging story of HTLV-III, and indeed what we were doing to actually respond to that. So I think -- I agree, it looks as though I knew

something because the minute is quite difficult to understand but I really don't think that's the case.

Q. Yes. Actually can we just look quickly at that minute, so that everyone is aware of the entry that we are talking about? It's [SNB0103479]. It's just the passage at the very end of the minutes, please, so on the second last page. It's under "AOB" and it's that reference there, headed "AIDS".

You have used the word "coincidence", Dr Perry. You think it's a coincidence that on the Friday morning you are taking this initiative at the meeting?

A. Absolutely. I cannot conceive of where or how I could have obtained information before it was passed from Dr Tedder to Dr Ludlam. Dr Tedder phoned Dr Ludlam, as I understand it, immediately the results were available from the laboratory. Either I'm a clairvoyant or it is a coincidence. I think with hindsight it would have been not an untypical thing for me to have done, to have decided on that particular morning that, just as a process of good management, we should set about making sure that we carefully record the actions that we are taking in response to this unfolding problem of HTLV-III.

For me that is the explanation.

Q. Thank you. Bear with me a moment, Dr Perry, sorry.

A. Hm-mm. (Pause)
Q. Of course, when you write this or when you take this step at the meeting on the Friday morning, you know that you are about to go to Groningen?
A. Yes, indeed.
Q. Yes.
A. Yes.
Q. So, doing the best you can, what would your state of mind have been on that Friday morning, knowing that you are going to Groningen? Are you thinking that you might learn more interesting information there or something of the sort?
A. The meeting was specifically on fractionation, it was a fractionation meeting that was established, and at that time -- well actually, many of the meetings concerning blood transfusion were about coagulation factors, HTLV-III. It was what was being widely discussed, for obvious reasons.

So, yes, it's quite likely my expectation was that there would be some useful information that we could bring back. Indeed that was part of the reason for me going, not to specifically to look at or listen to all the individual presentations, but I knew the meeting would have several experts, international experts -- it was a well attended meeting -- that we would have the

opportunity to talk with.

I'm not sure that that would have influenced my particular comment then, as I say.

Q. It's really impossible to reconstruct, isn't it?

A. It's impossible to reconstruct. What I think is most likely is that I did hear about this early on the following week. I was probably briefed confidentially by either Dr McClelland or Dr Boulton, probably Dr Boulton; I think Dr McClelland says he was sick. But this is a reconstruction from the evidence of others that I have read and I, sadly, don't have any vivid memory of these various transactions, although as an event covering a period of ten days, I remember the -- I remember it quite clearly as a key event in my lifetime, as it were.

Q. Do you remember the mood?

A. Absolutely. But drilling down into the detail of exactly what happened and what conversation took place when, I haven't retained that, I am afraid, other than through the documents that we have seen.

Q. How would you describe the mood at PFC?

A. I guess, because Dr Ludlam was quite clear that he wanted this information to be kept confidential -- and we would have respected that for obvious reasons -- my personal response to it was one of, I think, grave

disappointment. As I say, the PFC existed basically to protect patients from the risks of infectious disease by -- and I think also the general view, although there was no evidence for this, that HIV -- I think there was a belief that HIV had not entered the UK blood supply.

I think the general view was that we had more time. This was clearly an issue that was developing in the US but there was no evidence to suggest that there had been a major transfer of HIV across the Atlantic, as it were.

So it was surprise, disappointment and real concern and I think it's difficult to underestimate [sic - overestimate] the impact of this, plus the Groningen meeting, in terms of framing the action that we then took. This was a strategy-changing moment. For the first time we had evidence from the Groningen meeting that the product that we were making could be inactivated fairly simply but also, and importantly, there was HIV in the UK, and certainly the Scottish, blood supply.

Q. So one shouldn't underestimate the importance of all of these developments?

A. Absolutely not. This ten-day period brought together, almost coincidentally, the report to Dr Ludlam and the information that we got for the first time from the Groningen meeting, from the CDC and the Cutter people,

who demonstrated for the first time that HIV is fairly heat-sensitive and, as I think as I have said in another statement somewhere, the risk/benefit balance changed overnight. It was dramatic and it was quite clear, moving from a position where everyone was very nervous about introducing heat treatment to a position where the advantages clearly outweighed any of the risks.

Q. Yes. Excuse me a moment. (Pause).

THE CHAIRMAN: Dr Perry, I think that I understand the change in the risk/benefit analysis. One thing that has caused me concern from time to time is the basis of what appears to be the confidence that HIV had not arrived in Scotland.

A. Yes.

THE CHAIRMAN: The literature suggests three major sources of infection: intravenous drug abuse, which we know happened in Edinburgh, the transfusion itself, and male homosexual practices.

A. That's right.

THE CHAIRMAN: It may well be that there was confidence that the most dangerous, if I can put it that way, of the male homosexual practices had their origin in the west coast of America and New York and some other places. What was the basis for confidence that that had not led to infected persons in Scotland?

A. I wouldn't actually describe it as there was a confidence that it hadn't transmitted but there was perhaps closer to a hope or a belief that it hadn't yet travelled across, and we must remember that although HIV is a well-known entity for everybody in this room now, at that time it was a new disease, it wasn't understood, there were still alternative ways to describe the AIDS condition and its causation and so on, and little, if anything, was known about the epidemiology and the extent to which it was travelling around the world and whether there were any regional differences and so on.

But I take your point. With hindsight, it could have been clearly proposed or suggested that HIV could indeed be in the UK population. We just hadn't seen any evidence of it.

THE CHAIRMAN: My problem is the basic logical one that there was no basis on which you could exclude the possibility.

A. That's right.

THE CHAIRMAN: And yet practically some people at least who might have been in a position to understand the problem did seem to proceed on the basis that it was excluded on a practical level.

A. I don't think it was the sole determining factor; it was one of a number of factors that led to a situation in

which it was concluded or it was decided that -- I think we are talking about heat treatment of coagulation factors. It was but one factor in determining the action or the lack of action that should be taken in respect of heating products.

I'm aware that, I think, other witnesses have been asked that if you went back to the beginning of 1984 and if the transmission had taken place then, would that have changed one's position in terms of introducing heat treatment and I suspected that that might come up today and I have thought about it a great deal and frankly I can't sensibly answer the question. My best guess is that at the beginning of 1984 there would have still been serious concern over whether heating products, using processes that we had no experience of, might have caused a bigger problem.

I think at the beginning of 1984, although HIV was seen as a significant issue, I don't remember the precise epidemiology but there was also a view that if you became infected with HTLV-III, it didn't necessarily mean that you got AIDS and I think some of the statistics that were around -- and I can't place these in time. I think it was suggested that at that point in time, the beginning of 1984, only 1 per cent of people that got HTLV-III, as it was then, would get AIDS. The

epidemiology was brand new. Nobody knew what the epidemiology would look like as the years rolled by.

So my best guess is that even if we had had evidence of HIV in the donor population, at that point in time that in itself wouldn't have been sufficient to take what would have been seen at that time as a very dramatic step in terms of potential damage to a Factor VIII product. We might have known that HIV was in the donor population but we would have had no knowledge whatsoever of our ability to inactivate it using heat treatment. But that's a personal view.

THE CHAIRMAN: Well, you are the person who was there at the time, Dr Perry, and I think that it is extremely difficult to get over to us -- and we can't really ignore everything we have heard from all sorts of other sources -- just exactly what the atmosphere was.

A. Sure.

THE CHAIRMAN: But thank you anyway.

MS DUNLOP: Yes. You are right, Dr Perry, that it is something I was going to come to. What you have just said is really your question 36 answer. Can we look back at the statement, [PEN0121759]? We are now at 1788.

I'm not going to ask you to supplement any further. You have given us a fairly full written answer and you

have already added some extra comments today. I think the only thing I should do is that in paragraph 3 you make a reference to the studies in late 1983. Not least because Dr Cuthbertson is coming tomorrow, I think there is a slight error in the protocol that's described there, that it actually was 70 degrees for 72 hours.

A. Sorry, yes.

Q. But we have got that in a further statement from you anyway.

A. I apologise for that.

Q. It doesn't matter. Just before we leave your statement, I also wanted to ask you a little bit about the licensing of your heat-treated product. Professor Cash told us that you -- I think it was you personally -- made contact with Dr Duncan Thomas of NIBS and C?

A. Yes, that's right.

Q. Could you just tell us a little bit about that?

A. I think, as Professor Cash has explained, it wasn't clear, you know, where one could obtain authority for taking what was a very profound step in terms of the action that we were proposing, to heat-treat the entire supply of Factor VIII for patients in Scotland. I think John Cash, understandably, was looking, as indeed I was, for some sort of framework in which that decision could be placed and referenced.

We had a good relationship with colleagues in NIBSC. Dr Duncan Thomas was the head of the haematology area there and very experienced in coagulation, and I think it was probably no more than taking Duncan Thomas through our strategy and our rationale and just establishing the extent to which he thought that was a sensible and appropriate thing to do, and the answer was he did.

But it was no more than that. It wasn't any formal process. He wasn't the licensing authority, he was a colleague who was part of a national control laboratory and we valued his opinion and experience. So it was really just a process of sharing our decision with other colleagues that we could find and seek their support.

I can't place it in time but I think we did something similarly with the Medicines Control Agency, as it was then, to let them know of our actions and so on, and I think equally this was the point at which the UK licensing authority -- basically on the basis of Groningen data and on the basis of the observation that HIV had entered the donor population, this risk/benefit balance had dramatically changed. So the view was that this was a risk worth taking.

Q. Yes. And actually no one said to you that there was

some sort of regulatory process that you must go through before you did your exchange or anything like that, and if you had, you wouldn't have been able to do the swap as quickly as you were?

A. No. I think there has been a great deal spoken about Crown immunity and what that meant. I have to say, as an operational manager in a period of enormous concern but also a belief that we could do something very quickly and very effectively, I think, even with hindsight, the concerns over the regulatory process weren't at the front of my mind.

I know we operated outside of the formal licensing system and my personal energies at that point in time were towards making sure that all the patients in Scotland got the heat-treated product as quickly as possible and as cleanly as possible. Ie, built into this was this very important component of recalling deep down into the supply chain the stocks of the unheated material.

Q. Yes. In conclusion, Dr Perry, we should note your supplementary responses, which are [PEN0121582], just to confirm that we haven't missed anything.

It was in response to our letter that you provided the list of members of the management committee. That's question 1. Question 2 is that small point about

reversing Drs Smith and Snape.

Then question 3. I think we have really moved on from the need to probe the questions of funding that were puzzling us at that point. I'm hoping that we have more or less got to the bottom of what was in Dr Cash's letter.

4. You have corrected that reference to January 1986 and it should be January 1984?

A. Hm-mm.

Q. We have asked about the initial notification, paragraph 5.

Paragraph 6. We clarified the exact protocol that Dr Cuthbertson used.

A. Yes.

Q. And in a trailer for tomorrow, as you have said, Dr Cuthbertson is going to be able to answer some questions on it.

A. Yes.

Q. So that concludes your supplementary responses as well, Dr Perry. Thank you very much.

A. Thank you.

THE CHAIRMAN: Do you have --

MR DI ROLLO: I don't wish to ask any questions, thank you.

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

MR JOHNSTON: I have none either, thank you, sir.

THE CHAIRMAN: Thank you very much, Dr Perry.

A. Thank you.

MS DUNLOP: Well, I'm sorry, sir, it's going to have to be a half day.

THE CHAIRMAN: I could repeat my French phrase from last week.

(1.00 pm)

(The Inquiry adjourned until 9.30 am the following day)

I N D E X