Thursday, 8 September 2011

(9.30 am)

(Proceedings delayed)

(9.45 am)

THE CHAIRMAN: Good morning.

PROFESSOR JOHN CASH (continued)

Questions by MS DUNLOP (continued)

MS DUNLOP: Good morning, Professor Cash. Welcome back. We are going to be asking you some questions about our topic B3 today. On that topic you have provided a statement, which we will work through. That statement is [PEN0121912].

The first few questions referred to the period in the 1970s and research that was carried out in the 1970s, so we should remind ourselves that you became National Medical Director of SNBTS in 1979. That's correct, isn't it?

A. Correct.

Q. And prior to that you were in the Edinburgh and Southeast Scotland Blood Transfusion Service?

A. I was indeed.

Q. So when you became the National Medical Director in 1979, PFC will have been at Liberton; yes? And under the direction of Mr Watt, and they will already have been forging ahead with various research projects.

Can we turn to page 2, please?

Professor Cash you have helpfully reproduced the questions, so we don't need to revert to our separate questions document, but we can see that we did ask you a question about the MRC working party on post-transfusion hepatitis in February 1980, whether the representative from Edinburgh and Southeast Scotland who attended was Dr McClelland, and you have told us that Dr McClelland was a member of the working party and in fact Dr McClelland himself has unsurprisingly been able to go further and say, yes, it was he.

So question 4, we asked about the Behring work. You said in October 1980, you became aware of the development of an apparently hepatitis-safe Factor VIII by Behring, and we have discussed that in our preliminary report. As I understand it, that was the first international haemophilia conference. Is that correct?

A. I can't honestly remember. I have read Peter Foster's excellent documents and they have been a revelation to me. I can't honestly remember. Apparently I brought the news --

Q. You did. You brought the news from Bonn.

A. I have to say, it's nice to say that but I have no recollection of that at all, and I'm so grateful to

Peter.

Q. I don't think we need to go to it but you wrote a letter on 27 October 1980 to Mr Watt, basically communicating when you had learned about Behring's research, and we refer to it in paragraph 11.49 of our preliminary report. We also quote an extract from it. It says:

"Behringwerke are getting rather excited that their preparations of Factor VIII appear to be safe. The reason given is that they are heat treating the product for ten hours at 60 degrees in the presence of glycine and sucrose. Sounds unbelievable. Thought you might be interested."

A. I remember that well but I can't remember how I picked up that information.

Q. We now know that research on pasteurisation of coagulation products began in Scotland and it does seem, as we suspected, that that was in response to the news of what Behring had achieved.

Then in question 6 we asked you about the Factor VIII study group, which was established around about this time and had its first meeting on 28 January 1982, and we can see that you gave a more substantive answer to question 6, which focuses on that study group.

Can we look first then at your answer,

paragraph 6.1. You said that:

"This group was actually established in order to provide an opportunity for all SNBTS centres to feel they were involved in the task of providing safe and sufficient Factor VIII for haemophilia patients in Scotland, and to emphasise to all that this task was a top national priority."

Would you agree that to some extent safety and sufficiency were in tension with each other? We have heard that some of the processes to make the product safer had a cost in terms of yield.

A. Yes, I think at that stage, when we started out, I don't think you would have said there was much tension. As things developed, however, huge tensions developed and I think I referred to these in, I think, a later part of this witness statement. That's right. But the primary reason I have given for the group -- but there would be another reason -- would be that in 1979 -- or should I say, as a young lad watching PFC open in 1975, what was absolutely clear to me in 1975, was that we had a wizard fractionation centre but we had no plasma. I don't mean no, but if we were going to go for the WHO self-sufficiency, it was plasma. And bringing all these people together -- the fractionators, the plasma people, the scientists related to these -- into this group

actually proved to be magic, and indeed tensions developed, not least with John Watt.

Q. Well, we will probably come on to that but can we fast forward just for a moment, please, two pages in your statement to page 4 of [PEN0121912]? If we look at answer 9.3, you say:

"It cannot be over emphasised that for a small public service plasma fractionator such as the SNBTS, which exclusively relied on a fixed, indigenous, voluntary, unpaid donor base for its plasma source, and which in 1983 had achieved self-sufficiency but was expecting major new and escalating clinical demands, we were reluctant to encourage our PFC colleagues to pursue a heat treatment programme which led to high production losses."

So I'm not seeking to make any particular point. I think it's largely self evident, Professor Cash, but there is a difficulty of squaring the circle.

A. Absolutely.

Q. You want to introduce a new process to make the product more safe but that is going to result in there being less product, then that's going to be a different problem.

A. Yes, they would have to buy it, which was very unsafe.

Q. Yes. Can we return, please, to answer 6, which is on

page 1913? At the end of answer 6.2 you really, I think, refute any conclusion that concern about viral contamination of Factor VIII concentrate was in some way a low priority. I don't think we were trying to suggest that in the question at all; we were simply trying to find out what the factual position was and what it was people were mainly working on at that time.

Do you remember whether at that first meeting, on 28 January 1982, you knew that some initial work on pasteurisation had begun at PFC? Or is that just impossible?

A. I honestly can't remember, I would like to think so, I can't remember.

Q. On that topic, Dr Foster has explained that the very early work was being done by Dr MacLeod and that it was essentially exploratory, he was simply trying to see if they could reproduce the work of Behring. And indeed, his first report on what he had been doing post-dates that meeting in any case.

Can we have a look at the minutes of the meeting, please? It's [SNF0013813]. We see that that took place in the headquarters unit at Ellen's Glen Road. Was that where you were based?

A. That was my home.

Q. Right. If we look firstly at the report that was given

from the Edinburgh centre by Dr Prowse, this is the Edinburgh transfusion centre, I take it?

A. Yes.

Q. Yes. Actually, interestingly, and Dr Foster alluded to this yesterday, there is a mention of pasteurisation. Do you see that at the bottom of the page?

A. Yes.

Q. There is a heading, "Safer products, viral inactivation, pasteurisation, irradiation," and then "BPL", which is I guess probably beta propiolactone?

A. Yes.

Q. And UV radiation. Quite what Dr Prowse was meaning I'm not entirely sure but there is a reference. Can we then look at page 2, please? Go a little bit further down on the page. We see that there was a talk given by Dr Foster. He is really talking about research and development, I guess?

A. Yes.

Q. Yes. And he had some slides. Can we look on to the next page, please, and just scroll down page 3.

So Dr Foster is talking about yield and then he is talking about losses during processing, various quite technical details being imparted. If we just scroll slowly down we can get the general tenor, I think. A comment that we recognise from Dr Foster's evidence

I suspect, that more work is to be done on cryoprecipitate continuous thawing?

A. That was very successful.

Q. Yes. I had some explanation of that. Can we then move on to page 4, please?

Dr Foster ended his talk with a resume of PFC, R&D, current project priorities, which were... And we can see that he did give a list of five particular priorities, but just to demonstrate that he doesn't actually mention what Dr MacLeod was doing, but I think we have his explanation for that, which was that it was at such a preliminary stage.

Can we look at page 6, please? We can see your personal contribution and then the division of the personnel involved into small groups. Group A to be working on assays, standards. Group B to be working on the regional transfusion centre quality of plasma. Then group C, on the next page, product development, to be headed by Dr Foster. And then group D to be working on safety, coordinated by Dr Pepper. And actually the example which is given of a possible technique by which to improve safety, an example which is given is irradiation.

So that was the first meeting at the end of January 1982.

THE CHAIRMAN: Ms Dunlop, I don't know whether you might want to remind Professor Cash of the meeting on 9 and 10 February 1982, just before --

MS DUNLOP: I wasn't going to go there, sir, but I'm happy to if you would like to.

THE CHAIRMAN: The only reason for doing so is that there are references to pasteurisation.

MS DUNLOP: Right. I simply wanted to look at the minutes of the first meeting to show the set-up of the group and who was sitting in which subgroup and so on, but I'm happy to step into the meeting of 9 and 10 February.

THE CHAIRMAN: Possibly everything that needs to be looked at is in paragraph 1157 of the report and it's merely to provide that little bit of additional --

MS DUNLOP: Perhaps I can simply give the reference for it then and we won't specifically look at it.

A. I'm a bit deaf. I heard nothing of that.

THE CHAIRMAN: Nothing I say matters at all.

A. I'm sorry. I have a machine that I'll put on, sir.

THE CHAIRMAN: I only wanted you to have a reminder, as it were, that just a few days before, there had been a meeting of one of your action groups in the east here, at which explanations were given of the current work on viral inactivation --

A. That's right. I think I say in my statement that in

fact within days, that particular group was off with Duncan Pepper chairing it. Yes, that's right. The notion that it was -- if I may say so, the question was: was it not a high priority? I thought it was quite a high priority.

MS DUNLOP: I think the question was directed to the specific research, the pasteurisation project.

A. Oh, I see.

Q. And all that was suggested?

A. I thought it was about viral inactivation.

Q. No.

A. Okay.

Q. The question was: research on pasteurisation had begun in 1981; was it because this research was not a priority? That was all. It was simply an attempt to elucidate the prevailing circumstances --

A. I beg your pardon. I think I had misread that a little.

Q. But we do know that obviously the pasteurisation project became a major piece of work and plainly you will have learned about it in early course.

The chairman has drawn my attention to the fact that after that meeting, 28 January 1982, the subgroup, which was dealing with safety, did meet on 9 and 10 February of 1982 and that is set out in paragraph 1157 of the preliminary report. The minutes of that meeting are

[SNB0058387] but perhaps it's not necessary to look specifically at it.

There is also a second meeting. Again, I don't think we need to go specifically to the minutes of that but the safety action subgroup had a second meeting on 30 March 1982 and there is a long extract from the minutes of that in the preliminary report also at 1162.

We mention that in our question 7. Could we go back to Professor Cash's statement, please, which is document [PEN0121912] at page 1914.

We then asked you about the Budapest conference. That's the ISH and ISBT conference in Budapest in July 1982, and we know that Dr Foster prepared quite a long report -- I think it's about a 30-page report -- on that particular conference. At the conference Dr Foster procured a copy of a Behringwerke paper, published on 16 July 1982 and a copy of a typewritten paper on the Behring process, which he passed to you in or around April 1983. Perhaps we could have a look at your letter which you sent then. That's [SNB0073600].

Again, Professor Cash, I don't think we were suggesting anything at all in this question?

A. That's right.

Q. I mean, you said --

A. It's not for the first time I misread -- I apologise.

Q. Not at all. But you thought we were making some kind of point. I think we were just trying to tell the story. And the other interesting thing about the timing of this particular letter is the reference to Dr Ludlam's comments, and we saw yesterday with Dr Foster that around about that time Dr Ludlam was raising some concerns about -- I think we can just say neoantigens for shorthand?

A. Yes.

Q. And we looked at a trilogy of letters on that topic from around about that time. But what looks to have happened is that for some reason -- no doubt there was some conversation between you and Dr Foster or something -- Dr Foster was sending on to you a copy of the Behring papers that he had.

A. I think he must have assumed I had picked one up out of the meeting and I was very grateful.

Q. But in any event both you and Dr Foster knew about the Behring research anyway because the information had been communicated in 1980?

A. Indeed.

Q. Yes.

A. But this, as I think I said -- and I may be wrong. My interpretation of the Budapest episode was the fact that they were, I thought, giving freebies away signalled to

me -- this didn't go down too well with my old friend John Watt -- that the pasteurisation process might not be the right way to go simply because of the appalling losses, but that isn't, at this point in writing -- that's in my witness statement, where I talk about freebies. Behringwerke never give anything away -- well, none of them do -- for free, if it's going to be of any value to us. That's for sure.

Q. Perhaps we could go back to the statement, please, just to where we were, at 1914.

Actually, Professor Cash, you did start a train of thought in my mind with your comments about the value of the Behring work at that point and your hypothesis that if they were giving away free papers about it, it perhaps wasn't that successful. It's interesting to note that there was a subsequent approval of a licence for a Behring product by the Committee On the Safety of Medicines in 1984 and moreover, and we are going into the next question and answer now, Behring, I think, did certainly, in collaboration with another company, go on to market a product, although after a significant period of time.

A. Armour later came on to the market with a pasteurised product but they never lasted, and I'm sure it's because they -- it was a fundamental problem of yield and that

actually would make them hugely expensive to make, and the question of what they charged, I don't know. But yield is a huge -- was actually a bigger problem for the commercial people than I thought. But it was a huge problem for us and a very sensitive one.

Q. Just to look at what has become a frequently resorted to reference on my part, an article by Kasper and others on various different products. Could we have a look at [SGH0021947]. Can we scroll through this article, please to the tables?

I am afraid I haven't brought my hard copy of it today for some unaccountable reason but it's Armour. We can see that interesting footnote there, that Humate P, which received its FDA licence in May 1986, was manufactured by Behringwerke and that it is a pasteurised product.

A. That's correct.

Q. So there is that. Then we can also, if we go on to the Cutter table, please, see Cutter with their product, Koate HS, presumably meaning heated in solution, receiving its FDA licence in April 1986, it also being a product heated in solution. 60 degrees for ten hours.

Another reference just on this point about the fate of Behring's research in this area. Can we look at [LIT0010643], please? This is just one of these

articles that I noticed in my preparations as we do. It's an article on the use of pasteurised Factor VIII concentrate and if we look at page 2, there is a very interesting, perhaps, comment under the heading "Methods", where the authors say that:

"The pasteurised Factor VIII concentrate, Hemate P Behringwerke, has been commercially available since 1980."

That's actually a slightly puzzling comment, given what we have heard so far about the research but perhaps that refers to Germany, I don't know?

A. Yes, I know some of the authors very well, particularly Piero Mannucci, and I would defer to Peter Mannucci in terms of what was available commercially because that's just about all we could get hold of in Italy, Milan. So if he says it was available at that time, I would tend to accept it. We really didn't know much about this. In fact a lot of this we now know about as a result of this Inquiry.

Q. Yes.

A. Peter has done all the research.

Q. Yes, I can imagine.

Can we go back to Professor Cash's statement now, please? That is [PEN0121912] at page 1915. We are still talking about the early days of the pasteurisation

project. That is 1982. We have already looked at what you tell us in paragraph 9.3 about the dangers inherent in launching a project which might consume large quantities of plasma but result in a lower yield. So that must have been very much in your mind at the time?

A. In my position, in which I was responsible for getting the raw material and (inaudible), if we didn't get that right, it would have resulted in patients having to be exposed to purchased commercial stuff. And so yield became a hugely important issue and a very, very lively and emotional one in the group, yes, between John Watt and I.

Q. Yes. In question --

A. I should just say, when Peter Foster and his guys said, "Can we have another 100 litres to run a batch for research?" for us that was -- you know, "We need it for the patients, please, and so long as you are successful, that's fine". But if they hit the rocks, which you do if you are researching, that was a complete write-off and loss. So there was great tension and a lot of patience on all our sides. It was fun.

Q. I didn't catch that?

A. It was fun.

Q. It was fun?

A. Yes.

Q. Right. In question 10 we tried to take a bit of a snapshot of the position in England at this time and you gave some information in your response about liaison between Scotland and England. You talk a bit in 10.2 about relationships and you say that you had previously attempted to organise a joint meeting, and I want to come back and look at your efforts to do that in 1980 in a moment. Then you say in 10.3 that:

"Dr Smith acquired much of his early training and experience in plasma fractionation at PFC."

But of course he will have left and gone to England before you arrived in headquarters in 1979?

A. Absolutely.

Q. Then 10.4, we had asked about a particular letter from Dr Smith in which he said that, as of October 1982, BPL was doing only a little on heating Factor VIII. It would have been, I think, better if I had included the whole of his sentence in the letter because Dr Smith has explained the context of that comment, and perhaps we can just briefly look at the letter. That's [SNB0073267]. The comment concerned is in the fourth paragraph. He says:

"We are doing a little on heating Factor VIII but only for the moment on the gentle conditions for fibrinogen removal."

Dr Smith is going to testify before the Inquiry --

A. I have read his --

Q. Yes. So I think you will be aware then, if you have read his material, that it wasn't that he was understating the work that was going on at BPL, it was that they were genuinely not working on viral inactivation; they were working on the precipitation of fibrinogen.

A. So that they then could heat it.

Q. Well, indeed. Can we go back to the statement, please? This is [PEN0121912] at 1916. We are at question 11. We asked about freeze-drying, I think, under a slight misconception because of a reference to freeze-drying in some of the correspondence at the time.

Then question 12, we asked about the meeting at BPL on 15 December 1982, and you said:

"There is no doubt that the meeting on 15 December 1982 at BPL was a very difficult one."

If we look on to the next page, we can see that you have given us a very full narrative of events around about this time and the context in which the meeting was taking place. The first thing you tell us is that in December 1980 you had attempted to seek BPL's management support for a meeting, which would explore the issue of a joint BPL/PFC approach to the manufacture

and associated research of Factor VIII concentrates.

I wanted to have a look at your letter from that time, which is [SNB0043282]. So you wrote to Dr Lane, who was really Mr Watt's counterpart. Is that right?

A. Indeed, that's Richard, yes.

Q. And he was a medical doctor?

A. He was, that's correct, and that's -- yes. That's an interesting point.

Q. It's interesting. Is it significant for our purposes?

A. I don't think so.

Mr Watt was a vet and he sometimes felt he was a little overwhelmed by medics -- I'm thinking of him in the Scottish context -- and was a little sensitive about that. But, yes, Richard was a medic.

Q. And we see your suggestion in paragraph 2:

"He wanted to arrange a workshop on fractionation aspects of Factor VIII concentrates."

Indeed, you were inviting everyone to come to Edinburgh. But it didn't happen. It seems from your answer, Professor Cash, that you later received some information on the topic from Dr Gunson. I just wondered if you want to explain a little bit what Dr Gunson told you.

A. Well, I was very distressed. I perhaps should very briefly say I was appalled when I was appointed to

discover this whole saga, that I knew very little about, of PFC fractionating for England plasma. I'm sure you are well aware of all of this.

Q. Yes.

A. And I was very distressed to hear this because I was absolutely certain in my mind that if in fact ministers had approved that and pushed that on, it would have brought a lot of relief for our colleagues south of the border and it would be the beginning of a UK fractionation, getting together and cracking some of the problems that we were already cracking.

So against that background, that -- and John Watt felt this -- which we will come to, I suspect later -- very, very keenly indeed. Against that background I tried again, when I was now national medical director, and this was specifically about Factor VIII and I was -- I mean, that's a fairly bland letter -- I was very angry that we couldn't get something going together. And if you look in your -- I think you call it "Court Book", I call it the "Inquiry archives" -- you will find a lot of correspondence of me pushing, of different people pushing, to get the BPL management to get us all together and so on. In the context of this -- this is Factor VIII -- I was extremely distressed because I felt that if we got together, at the time I felt we could

crack the problems quicker.

It didn't happen and you asked about -- Harold Gunson was a dear friend and he was the DHSS adviser in blood transfusion and I was the Scottish Home and Health Department adviser, and we had one fundamental difference in philosophy. We were very close friends. One is he believed he should serve his master, and that was the Department of Health. I didn't actually ever accept that. I was there to advise and give the best advice I could and that did raise problems, and occasionally, Harold -- but only occasionally -- would reveal to me certain truths as he saw them. And as a consequence of that I took the view, because Harold had said this, that in fact one of the reasons -- and in fact it occurred time and time again -- why we couldn't get together with BPL -- that it did not enjoy the support of DHSS.

Now, there are other issues which I hope will be raised in the Inquiry in relation to things like NIBSC, the National Institute of Biologics and Control. We eventually won against the opposition, the very formal opposition of the DHSS. The first alert I got that I had a problem with one was Harold Gunson, and I went down to London to see the civil servants involved and so on. You asked how did I know it was DHSS; it was

Harold.

Q. You are right, we do have a lot of documents but we haven't found the actual reply to this letter. Did you get a knock back?

A. I have to say, I regret I don't recall. I have certainly not found a copy in my files either.

Q. Anyway, we know now that part of the background perhaps to the meeting in 1982 was that you had made this unsuccessful attempt to forge a kind of joint approach with BPL. Then --

A. I could just emphasise that Richard Lane and John Watt, I discovered, had fallen out in a huge way and it had become very personal. And I think I say in my statement that when I was appointed, I discovered that there were real problems there at the very personal level, many of which I didn't understand, and against that background, again, there is a background there, we tried to get going and started things again.

Q. Right. Can we go back to the statement, please, at 1917.

So you say that as at December 1982 your view was that the efforts at bridge building had, before and after 1979, all come from the SNBTS and had been comprehensively rejected by BPL and DHSS. Then you tell us that you had, in the period 1980 to 1982, sought the

support of SHHD officials to use their influence to ensure the Committee on Safety of Medicines explored what could be done to enhance the safety of commercial coagulation factor concentrates imported into the UK. I just wanted to ask you what influence you thought they had on the committee?

A. Well, I have no idea and -- I have no idea because I never got any response, and I should add that John Watt was on that committee and I pursued poor old John, you know, to get in there and John made it very clear to me that it was quite inappropriate for him to do this, to take the message from Scotland, because he said that it's not for us, a public sector fractionator, to start pointing the finger at the commercial people about their safety and so on. And John made it very clear he couldn't tell me what would happen because it was all very confidential and they had to sign state secrets and goodness knows what. So I have no idea, whether my civil servant colleagues in the department actually pursued this or whether John did. I have assumed, to be honest, the answer is no.

Q. So --

A. But I don't -- the chairman of that committee would be the person, and I think at that time it was Joe Smith.

Q. Yes. Well, you mention Joe Smith, Joseph Smith, who was

from NIBS & C, I understand it was colloquially called, National Institute of Biological Standards and Controls, to give it its full title, I think. And of course, he was the chair of the biological subcommittee of the Committee On the Safety of Medicines.

A. He was.

Q. Yes, and then you mention also John Holgate of the Medicines Control Agency.

A. He was a doctor.

Q. Right. You think or you discovered that those two individuals seemed to be party to the proposition that UK clinical trials of commercial plasma products should be encouraged and that was a position with which you fundamentally disagreed?

A. Yes, as I recall -- and I am recalling -- I would need (inaudible) -- I think John and Joe were at the meeting at BPL.

Q. Well, can we have a look at the minutes, please? That's [DHF0030059].

A. Redacted.

Q. Yes. I think actually we do have an unredacted version somewhere but this is the version with which we have to work at the moment. So we will confirm your recollection after this. But just to look at the minutes, not perhaps terribly easy to follow for lay

people, or at least not terribly easy to get oneself into the mindset of the meeting, but interesting to note the recital on the first page that there seems to have been a suspicion of, I suppose, almost manipulation by the commercial companies in response to a drop in prices. Do you want to just have a look at that? It's suggested in these minutes that:

"Intense competition and unacceptably low prices is alleged to have resulted in the withdrawal of Hyland Hemofil II from the UK market and the threatened possibility of a second major company withdrawal in 1983."

The minute then actually goes on to suggest that certain things may, therefore, happen in consequence. I'm not sure if the minute is suggesting that this is a deliberate strategy but in any event point 2 is interesting, that:

"Because of the withdrawal of certain products, there will be a clear field of entry for commercial hepatitis-safe Factor VIII which, by nature of its special product status (unproven), can command a price structure more in keeping with market expectations."

Do you remember any of this discussion at the meeting? It does look as though everybody at the meeting had quite a suspicious attitude to what was

going on on the part of the commercial fractionators.

A. I don't remember the detail. What I can tell you is the whole pricing structure and the market place in terms of cost of Factor VIII -- the whole of that decade is a major issue.

I don't know whether you have picked up, sir, but there was a point -- and you have got the documents in your archives -- in which in England the DHSS price set -- because they had moved into a market position -- they called it "cross-charging". And the DHSS set the price for BPL Factor VIII and the commercial boys had no difficulty in coming in below it and they sold -- and as a consequence of which the haemophilia centres opted away from BPL to prefer the higher risk stuff on the basis that it was cheaper.

So the whole area of pricing, when you are in a marketplace, is very tricky and there was a lot of things going on between the companies.

Q. Right.

A. My concern about this meeting in that context was -- and I think I have said it in my statement -- I felt -- I still recall the feeling that that meeting had been in a sense called by the commercial people and were using surrogate BPL and the Department of Health, John Holgate and so on, and Joe Smith to give it a stamp. And

particularly I was very upset to find it was chaired by my old friend Arthur Bloom, I really was.

Subsequently the whole notion of using British patients to clinically trial the commercial stuff fell flat on its face. I think I was reading a letter from Chris Ludlam the other day as part of the -- in which he would have nothing to do with this.

Yes, it was a bad meeting and I clearly behaved not very well.

Q. Well, perhaps we should just stick to looking at the minutes for the moment.

We need to look at page 2 because we notice that there is a loss of yield referred to which we should note in passing. Then in paragraph 3 the minute goes on to say:

"The above statement defines the need for centralised, fully controlled prospective trials of HS, hepatitis-safe materials, best operated through a properly executed national clinical trial lodged with the regulatory authority."

So the meeting then goes on to make certain proposals. We have looked at this before but the proposals are that:

"(a) Random exploitation of the haemophilia service by commercial organisations for the study of

"hepatitis-safe" products should be discouraged.

"(b) that the haemophilia services should create a formal basis for controlled clinical trial of alleged "hepatitis-safe" products in line with the requirements of Medicines Act.

"(c) that the haemophilia services, PHLS and NBTS, should combine resources in a manner likely to advance economic treatment of NHS haemophiliacs with safe products."

Was it not simply the case, Professor Cash, that the reality was that these products were around and some kind of strategy had to be formulated to deal with them?

A. Yes, that I don't doubt. The question is: why are we going to do the clinical trials in the UK? Why couldn't they be done -- Piero Mannucci would have leapt -- in Italy. Big centre in Milan. Louis Aledort in New York, a huge haemophilia centre. Why couldn't some reciprocity -- I'm repeating some of the discussions I had at the time. Was there not a reciprocity between FDA and the Medicines Control Agency, the subcommittee, that they could agree on these things?

My problem was, as I have said in my statement, that the number of patients in the UK that were either PUPS, previously ... or (inaudible) was in Edinburgh, had been on Factor VIII. They were not PUPS, they were older

haemophiliacs but they had never had anything but NHS stuff. The number of these that you could study was very small indeed, and my concern was that at a stroke they would be taken over by these people now contaminated with commercial stuff and when we came, which we anticipated at that time, within months, to say, "Hey, we have got some British stuff that needs clinically trialing," there would be no patients left. And I was simply batting along saying, "Go off to Italy. Go off to the USA," where these companies had huge markets. And there were a lot of patients, and ethically -- there wasn't an ethical/moral problem because these were patients in the States and in Italy that were getting these products in bulk anyway.

Q. Right. Can we go back to the statement then, please, still on 1917 and looking at 12.13.

You said that you had the feeling throughout the meeting that a decision in favour of this development -- that is the introduction of clinical trials on UK haemophilia patients -- would somehow be an advantage to BPL and DHSS. Would it not be fair, however, to recognise, Professor Cash, that the situation on the ground in England was very different, that they were falling much shorter of self-sufficiency than you were in Scotland? So they were dependent on the commercial

fractionators to a greater extent and had to have strategies for dealing with them.

A. Yes, but I still feel that -- you know, I mean, as I think you know and I think I have said, we reacted after this meeting very positively and it was very interesting that the Oxford -- that's a big centre with Charlie Rizza as the director -- agreed they would come in and contribute to the Scottish study. They no doubt would have said the same when BPL came along.

So, yes, I completely agree. There was an issue for the licensing authority to get appropriate confirmation that what they had done in terms of viral safety in fact worked. I was simply saying that if you looked at these companies in a world market situation, they could have gone elsewhere, in which in no way were either the patients or the local fractionators threatened. And I have to say I was quite paranoid about that.

Q. I follow what you say, Professor Cash. I suppose that initially one might wonder, well, would it not have been all right just to think that these trials might take place in England, where the situation on the ground was different and that that wouldn't affect you, but I think you go on to deal with that.

Can we go on to the next page, please, of the statement, where you talk about previously untreated

patients or previously untransfused patients. You say that you were hoping, SNBTS was hoping, to seek access to some of the patients in England and Wales for trials as well.

A. Yes.

Q. And you have just --

A. Arthur Bloom promised us, you know, I can give you -- yes.

Q. You have just told us that in fact that was possible, ultimately, with Oxford?

A. Yes. There is a record in the archives somewhere of Charlie Rizza saying, "Yes, you are on, we will come in on this". There is also a record, as I have said, of Chris Ludlam in Scotland saying, "We do not want to have anything to do with this".

Q. Yes. We have certainly looked at that letter and I guess we will look at it again, but you obviously travelled back from the meeting and felt that you wanted to send a letter.

A. As usual I was pretty upset with my performance in having lost the plot a little and it got heated and I thought I had better -- having tried to get on good terms with BPL, we had this meeting and Cash doesn't do too well and, yes, the letter was...

Q. The letter, whether it was an attempt to build bridges,

I don't know, but it does also seek to take forward your arguments.

A. Oh, yes, I wasn't backing off.

Q. [SNB0043163]. At a very prosaic level we can see that Dr Lane had at least provided you with transport to and from the airport and you were grateful for that.

A. No, Richard, he was a gentleman.

Q. Yes, right. But you have been doing some further thinking and you need to help us with this, Professor Cash. You are now of the opinion that Arthur and Charles should not write a leader for the Lancet or even a letter.

A. Yes.

Q. So it had obviously been suggested that something should be penned for the Lancet on the topic. Was that supposed to be guidance about these --

A. I can't honestly remember, I regret because it is an issue but I can't remember.

Q. Right:

"Nor do I believe you and Arthur should pursue John Holgate and Joe Smith."

Which might suggest they weren't at the meeting but, as I say, we will need to check that.

A. Yes.

Q. "I don't believe it's in the best interests of the NHS

fractionation centres at this time to encourage the commercial manufacturers to undertake clinical trials with a view to obtaining product licences."

So whatever, even modest encouragement for the commercial fractionators might have been in the pipeline, you thought should be taken away?

A. Hm-mm.

Q. Yes.

A. May I -- I mean, I'm surmising but I could well imagine in the DHSS, particularly in the medicines commission -- this is John Holgate, for instance -- they could genuinely, for the very reasons you have given, in England say, "Look, we would really like to get on and get some trials done so we can give these people their product licences and let's get on". I can understand that. My argument, I'm not going to repeat it, but I was unhappy with that.

Q. Yes. You were perhaps trying to think a little bit more long-term. Is that a fair comment?

A. Yes, more long-term and -- I'm very biased. More on behalf of the patients.

Q. You explain your reasoning in the fourth paragraph, the large paragraph there. I'm going to the end of your answer here. We actually wondered if there was a "not" missing in this --

A. I think that's right. I think I said, "Thank you very much --"

Q. And you thought there was and actually Dr Perry says --

A. I think re-reading it -- it's not for the first time that you read something I have written and you say, "What does that mean?"

Q. Well, Dr Perry, whose suggestion seems very logical, he says there isn't a "not" missing. So he is telling you what you were thinking.

A. Yes, I think he is right.

Q. Can we look at his suggestion at [PEN0121759], please? So the letter that was sent having said that it was in the British fractionator's interest to permit the commercial fractionators all the freedom they desire, can we go to page 1766 in Dr Perry's statement, please? He says:

"The letter is correct as written."

He thinks. He says:

"My interpretation is that Dr Cash felt that our longer term NHS interests would be best served by not placing pressure on commercial organisations to conduct formal clinical trials of their so-called hepatitis-reduced products, using scarcely available UK patients so that NHS manufacturers would be able to access these patients for clinical trials of NHS

products when available."

So I think the logic that he is suggesting is that if you leave the commercial organisations free to do what they want to do, rather than subject them to some kind of list of requirements, that will probably be better for the UK fractionators than actually setting out a defined pathway for them through clinical trials by which they might eventually secure a United Kingdom licence.

So having looked at his suggestion, you think the letter is correct as written, do you?

A. I would need to just check that. Just read it again. I think the notion that we should leave the commercial chaps to do what they feel is necessary -- I don't have a problem. I don't think we have any locus at telling them what to do. The notion that BPL, the other NHS fractionators, should be seen to be encouraging such a development, I was opposed to that.

Q. Yes, this looks to have been what was being discussed at the meeting, and you will have to correct me if this is wrong because you were there, but the personnel at the meeting are concerned that rather than some kind of haphazard use of these new products, perhaps on named-patient bases or something like that, that there should be properly controlled clinical trials. So they

are, as it were, countering one imagined problem by saying that things should be regulated, but the other point of view is that once you start regulating and insisting on formal clinical trials, you are making it easier for those companies to obtain a licence to market these products within the UK. Is that a reasonable summary?

A. It is, but I would like to emphasise that I didn't wish to stop them getting product licences. I wished to stop them using these valuable, valuable patients such that -- I'm repeating myself -- certainly it would prevent us from -- but I would be strongly supportive, and was, that everything should be done to ensure the data was generated on these products, to prove they were safe for the licensing purposes, so that you weren't on a named-patient basis. Yes, I was simply saying, "Would you go away and do that work, excellent stuff, elsewhere?"

Q. Can we go back to the statement, please, at 1919? We see that consistent with what you are saying today, the statement outlines that thinking in 12.142 and then 12.143. You say you thought that the development in the UK was a sophisticated marketing exercise by US commercial fractionators rather than one directed to product safety. You say:

"I believed it was primarily designed to once and for all take out those irritating Scots with their pious public sermons proclaiming the sanctity of national self-sufficiency."

A. Yes, it has gone again. Sorry, what can I do now?

Q. I was just wondering if you could help us with the logic of that. What did you think was really going on?

A. I thought, if we woke up one day and were told by Charlie Rizza and Arthur Bloom, Chris Ludlam, "Sorry, we have no patients for your trials, John Watt, Richard Lane, because we are using them all for these commercial guys" -- I was fairly close to some of the commercial guys. I won't mention which. And I saw this as a possible way of -- and again this may be paranoia -- of grievous damage to the position of Peter Foster and his crew and Richard Lane and Jim Smith.

Q. When you say you thought it was "designed to take out those irritating Scots".

A. Yes.

Q. What you were thinking was that the commercial companies would gain such a head start that when you came to launch your product, there wouldn't be any previously untreated patients left and your product really would be doomed, which would result in --

A. I wouldn't use the word "doomed". We would still have Christopher Ludlam as our friend.

Q. I really mean the success of your product would be adversely affected?

A. Yes, we are not going to get on to this today, I hope, but the whole question of Crown immunity, licensing and so on and so forth, the departments of health could well say, "You don't need licensing. Your stuff is fine." But we couldn't validate it soon enough in any reasonable time and that's bad for the patients.

I can't emphasise that this was about patient -- quality of patient care, and as for irritating Scots, they were exceedingly irritating to my mates, that I knew very well, in the commercial industry. I think I have already told you about Dr Eibl.

Q. We already remember that, Professor Cash. Six foot something in his socks?

A. There were others, but we were also irritating, I can assure you, as Scots, to the DHSS and that was really quite difficult.

Q. You go on in that paragraph 12.143 to say that you thought that this position would have found support in all the Scandinavian countries, France and the Netherlands. It would be of interest to obtain a non-redacted copy of [SNB0049164]. Can we look at that

now please? I didn't want to leave a loose end, Professor Cash, because you are here referring to the European trial of Hemofil T?

A. Yes.

Q. By which we actually --

A. That's Mannucci's --

Q. About which we ourselves have been learning a bit in the past couple of days. But this document is a set of notes on a talk given by Dr Mannucci at a seminar in Cardiff which we know was towards the end of October 1984 or thereabouts.

So we are going a bit forward in time but at that seminar, Dr Mannucci was giving a report of the story so far and certainly I can see the gap to which you are alluding.

I thought that the document had been redacted in the second line. I'm not at all sure that it has. We don't have any copy of this which has the words complete or any mark that shows there has been redaction. I think it has possibly been left blank and the writer has meant to complete the text and never has, whatever. If we want to find out what countries were involved in the Mannucci trial, however, we can look at the final article on that, which is [LIT0010369]. I think there is a big clue just in the list of authors. We can see

that Dr Savidge, Geoffrey Savidge.

A. Knew him well.

Q. Is one of the contributors. And if we look at the second page of the article, we can see under the heading "Patients" that the haemophilia centres concerned were those in Milan, Heidelberg, London and Paris. I think in fact it's clear from the article that the centre we are talking about in London is St Thomas', which was Geoffrey Savidge's.

A. Yes.

Q. So in fact, as it turned out, not an extensive United Kingdom participation in this study but certainly one centre taking part.

A. I mean, if you want to explore that, you really need to get Geoff up because he is an amazing guy.

Q. Unfortunately Professor Savidge has recently died, so we can't get any further information about that participation. But I did just want to answer the question that you had posed in the statement about what countries took part in the trial of Hemofil T and now that you know that, that there was participation from Milan, Heidelberg, London and Paris, how does that fit with your thinking?

A. Only that -- I mean, I know the London, which is what we talked about, and that comes as absolutely no surprise.

Indeed, in your archives, you discover a letter from me to the general manager of SNBTS, that is much later, talking about Geoff and his attitude and so on and so forth, and he was an old friend but a very -- they used to describe him as a very robust character. So that comes as no surprise.

I'm quite surprised with Paris to be honest. But there will be all sorts of interesting things there that -- I mean, I would have said, for instance, under no circumstances would Netherlands, anything in the Netherlands, and Pim Van Aken was reminding me the other day that there was a centre in the Netherlands that was heavily committed to commercial use of products, which was very atypical.

So, you know, there may be somebody in Paris that was in some way, as Geoff was -- Geoff couldn't be doing with public sector, socialist manufacturers. There may be somebody in Paris with similar views, I just don't know, but I would have been, as I said, very surprised if in Finland, if in Sweden and Denmark, that they would be included. And I have some relief that they are not.

Q. Right. Can we just, before we leave this article, look and see the results, headed fortunately "Results":

"21 patients were included in this study. 13 were followed up regularly as planned. Seven missed some

visits critical in the evaluation of post-transfusion hepatitis, and one that was followed up regularly for 37 weeks then defaulted."

So in fact they only ended up with results on 13. You say in your statement that 70 per cent of the patients developed non-A non-B hepatitis. I think in fact it works out as 84 per cent. So it was even higher than you thought. Can we look at the next page, please? Yes, there we see the 84 per cent non-A non-B hepatitis developed in 11 of the 13 patients.

Right, can we go back to the statement then, please? Move to the next page.

Staying with the theme that there would be need for previously untreated patients in the United Kingdom on whom you could test your new product in due course, staying with that, you say that in 1982 you were uncertain that you had the support of DHSS, Medicines Control Agency, for this latter proposition:

"Nor, I regret to say, the SHHD."

I just wondered what support you might have sought, particularly from SHHD.

A. I think what I'm alluding to there is, I'm reasonably certain that if you take that date, on no occasion -- and Peter Foster will shoot me down -- on no occasion historically has the SNBTS, PFC, got into the concept of

clinical trials. And I'm pretty sure about that but Peter usually keeps me right. And we were moving inexorably to a situation whereby first we were going to look for product licences -- and I don't want to get into the Crown immunity debate.

And that, the whole question of obtaining product licences, there was a period of time in that period when the Scottish Home and Health Department were very hostile, and notably the chief pharmacist -- doing their job. But they were very hostile. And if we were going to conduct clinical trials, and we did in 1988 and 1989 and the 1990s, then a whole set of circumstances arise where you would need extra funding. So the notion of SHHD being involved and working with us was very important indeed and at that point I would have assumed that I would have thought it was quite difficult.

Q. When you say "SHHD were very hostile," you mean they were hostile to the notion of your moving towards product licences?

A. Oh, yes. You have got lots of paper that will tell you that. It became a very big issue in which CLO were involved, the CLO lawyers were involved and so on and so forth. Yes. And another issue that was, in a certain sense, not well resolved, but, yes, was a big issue.

Q. Sticking with the statement, you go on to say in

paragraph 12.2 that you feel an apology is due for the use of the word "furtive", and no doubt you understand that your apology has been communicated to the two individuals concerned. I certainly don't want to take up time talking about the use of this particular word. We should take it, should we, that it was on reflection perhaps just the wrong word?

A. Yes, I have no hesitation. I think the fundamental problem I had -- and it wasn't about Peter and Jim Smith -- it was about: how did the SNBTS as a whole -- this working group that we talked about -- get engaged in the area of fractionation? And that was difficult because it was heavily controlled by John Watt and so on, and I felt that Peter and Jim were often in bed. So I didn't regard them as being furtive but -- I don't want to pursue it. I'm delighted they know that and I have spoken to Peter...

Q. I just wondered what point you were seeking to make when you were instancing the collaboration between Dr Foster and Dr Smith and speaking of it in negative terms. What point were you making?

A. I was -- I think there is another statement in which, if that's all we have got, I was absolutely delighted that it was going on and there is no doubt in my mind, if it hadn't been for the fact that Jim Smith was a product of

PFC, had developed a lot of personal, excellent relationships, it wouldn't have taken place.

What is absolutely sure: it did not enjoy the formal support of the top managers of the institutions concerned. Not that they were necessarily opposed to it but it was something that -- it was furtive, it was out of sight of top senior managers. And I was, in principle, unhappy with that but I wasn't unhappy with Peter or Jim; I was absolutely delighted they were getting on with it.

Q. So we should take it, should we, that you thought that that collaborative relationship was a good thing?

A. Oh, yes. I have said in another statement something is better than nothing, and when you look at the something, as Peter -- that they delivered, these two, it was fantastic.

Q. Can we go then on to question 13? We did look at --

THE CHAIRMAN: Do you want to do that yet?

MS DUNLOP: I was thinking perhaps we could just get to the end of the meeting and its aftermath but I'm happy to stop if --

THE CHAIRMAN: No, no, not at all.

On one view of what you have been telling us so far, the only practical way of getting real cooperation would be to have furtive meetings since disclosure would have

brought down the wrath of the gods.

A. Well, I'm not -- you see, I'm not actually sure about the wrath of the gods, sir. We just couldn't do it. And the thing that terrified me was -- it did terrify me -- the good luck that Jim Smith and Peter Foster were close personal and professional friends. I'm very -- I was very disturbed at running an outfit, which was about patient care, on good luck.

What we know is that the people handling IVIGG development in England and Wales didn't have this close association with PFC. As a consequence of which, IVIGG availability in England was three, four, maybe five years behind PFC. And I personally took a view that was a serious indictment of what we had failed to do at the top level, but as far as Factor VIII and IX were concerned, lucky us. That's not a good way to run a business.

Q. I think nowadays it would be referred to under the guise of succession planning. So you have to have a system which will survive the departure of the individuals involved, as I understand it, and I think the point you are making is that this maybe wouldn't?

A. No. If dear old Jim or Peter had fallen under a bus, we'd have been pretty good because we had Ron the Mackintosh. But without Jim, I think we would have been

in some difficulty. I really mean that. And it was very personal. Jim is still at heart a Scot, although he lives down south. As you will discover.

Q. I'm trying not to ask any questions about who is a Scot and who is not, because it all seems to me to be a bit jumbled up. I think we will stay away from that issue. But there was a response. Dr Lane wrote back to you. That's [SNB00043160]. You say yourself in your statement:

"It was a pretty formal response."

You take issue with any implication that you changed your position because you say you made your position very clear at the meeting.

A. Yes.

Q. Yes. So Dr Lane is saying that he thought there was an agreement that Professor Bloom and Dr Rizza would inform the haemophilia directors about their right to know the proper basis supporting manufacturers' claims of safety for products in connection with hepatitis-reduced Factor VIII. In other words, because it's a little bit delphic that, but in other words, moving in the direction of clinical trials, but there was also to be advice taken from medicines division. So I suppose he is saying, "We did decide to do something" and you are saying, "Really, we shouldn't be doing anything"?

A. With the commercial.
Q. With the commercial companies, yes. Yes, you wrote back, [SNB0043159].

I think 3159 is in transit. So that, sir, is definitely a good place to stop. It's not quite in Court Book yet. So we will look at that, I hope, after the break.

THE CHAIRMAN: I can't quite envisage the transit process.

MS DUNLOP: I can't either but I certainly believe it when I'm told.

(11.07 am)

(Short break)

(11.30 am)

THE CHAIRMAN: Yes?

MS DUNLOP: Thank you, sir.

Professor Cash, just before the break we were going to look at the letter which you sent back to Dr Lane, which is [SNB0043159].

So it does look from your letter back to Dr Lane that you were very receptive to any suggestions about the form in which communications should take place but you were adhering to the substance of what you were trying to say.

A. Indeed.
Q. Is that a reasonable way of putting it?

A. Yes, I think that's fair.
Q. Yes. I think, to conclude this little chapter, we should also look at [DHF0030892]. That seems to have been connected to the meeting. Confusingly it's dated 11 January 1982 but we have already been through quite a tortuous process of looking at surrounding documents and we think it was probably 11 January 1983. So it's one of those letters that people write in January and forget that there has been a New Year because this looks to have been a circular letter sent out really dealing with the same subject matter.

Have you seen this recently, Professor Cash?

A. I don't recall, no. I'm sorry.
Q. I'll just give you a moment to look at it.
A. Please. (Pause)

Could you remind me who wrote this. This is Charles, is it? Charlie?

Q. Yes, Messrs Bloom and Rizza are the signatories of the letter.
A. Okay.
Q. I'm not sure if this particular letter bears their signatures but we do have somewhere a copy that has their names on it. Can we just check the second page, I'm not sure but I think this may be a redacted copy because it is a "DHF" reference. It has gone from the

Oxford Haemophilia Centre, which is a bit of a clue.

A. That's what made me think it would be Charles.

Q. Yes. (Pause)

So if this is the outcome of these discussions that we know were going on in December 1982, it does look as though what happened was rather more along the lines of what the other people at the meeting wanted, which is formal clinical trials. But if we go back to your statement, please, [PEN0121912] at 1920, it does actually look as though the UK participation, as judged from the final article on the Hemofil trial at least, was limited.

A. Yes, my memory is that the majority of people didn't react terribly well to Charles and Arthur's letter.

Q. Right.

A. I had no ...

Q. You tell us in 13.3 that in February 1983 you did actually make contact with the directors of the haemophilia centres in Oxford, Edinburgh and Glasgow in order to stake an SNBTS claim on access to their patients. Who made that contact?

A. Me.

Q. You?

A. Yes. I think I wrote to them all.

Q. Certainly such information as we have about the trials

of commercial products doesn't seem to reveal the participation of any Scottish patients or Scottish haemophilia centres. Does that accord with your understanding?

A. Yes, but I really don't think we would have been informed.

Q. Yes?

A. Yes.

Q. Yes. Moving on and looking at question 14, we are talking about the first half of 1983. You said in your answer that:

"The development of tests to eliminate potentially fatal thrombogenic episodes in patients receiving certain batches of Factor IX concentrates were first conceived and developed by an SNBTS team."

Connected to that, I think, is your 1975 publication. I thought we should look at that. That's [LIT0010959]. This is work that you did when you were at the Southeast Scotland blood transfusion centre?

A. Yes, indeed.

Q. Could you just tell us in a very lay-friendly way what it is that makes Factor IX dangerous from the point of view of thrombosis?

A. I think in 2011 I would have to say I really can't remember and don't know. This is purely science but

I think in general terms to the layman, it became evident -- and to the best of my knowledge it was Piero Mannucci that first alerted the world -- that there were patients receiving Factor IX concentrates that were going on to have massive strokes, myocardial infarction. In other words they were thrombosing up in their arteries. And the question arose, could we develop -- and if asked why, it could be that the Factor IX was activated in some way. It wasn't in its benign, non-activated state. Or it could be that there were actually thrombogenic materials contaminating the Factor IX concentrates.

I suspect in 2011 they have the answer, ie they produce high pure IXs and there is no problem. So it was contaminated. I don't know. However, it was a major, serious problem that -- and it was significant in the sense that after we had developed this -- and we started this work -- batches of material were demonstrated beyond peradventure to be potentially highly dangerous.

Q. Yes. The context of this article is that the team was really examining some new-ish products that would be prepared, some new Factor IX products. Is that right?

A. I honestly can't remember. I'm pretty sure we used old ones as well. We got stuff from Peter Foster. But as

I recall, at some point -- and I'm not sure -- I think I should emphasise that the paper headed by Cash, the key guy was actually Roger Dalton, the vet, my good friend Roger, and I'm not sure whether the work using this basic technology -- I mean, I made the observation with this team here and then handed it over to the likes of Jim Smith or the PFC and so on, and I'm not entirely sure whether the newly developed products of IX were done by Roger Dalton and I.

Q. You certainly seem --

A. The high purity ones.

Q. I'm sorry?

A. Sorry.

Q. I was just going to say it certainly seems from the material that we have looked at from time to time about Factor IX, that there wasn't any great difficulty in getting dog studies carried out. You seem to have enjoyed the cooperation of various different vet schools. This one, it was the Glasgow vet school?

A. This one was Edinburgh.

Q. There is another one where it's the Glasgow vet school. Another one at the time of the heat treatment of concentrates, some studies were done in Cambridge and so on?

A. Right. Because the Glasgow lassie moved to Cambridge.

She became a senior lecturer.

Q. I see. Could we go back to the statement now, please, at 1920? We are going on to talk about events in March 1983 and thereafter.

Question 16, you referred to the working group meeting on 22 March 1983 and your answer, about whether there was even then some sort of read-across from discussions about heat treatment to this new problem of AIDS, your answer is that in March 1983, a specific link between the two -- that is between heat treatment research and the newly arrived threat of AIDS -- would have been taken for granted. But you say:

"The assumption was later shown to be simplistic."

In what sense was the assumption simplistic?

A. Oh, I think -- I think I'm referring to the notion that different heat treatments -- and Peter Foster has gone into this at great length. Different heat treatments will do different things because different viruses are -- that's really all.

Q. It's not that there is going to be some magic bullet that will deal with the whole problem of viral contamination?

A. That's right.

Q. Then question 17 focuses on a memorandum written by Dr Foster in May 1983. We have looked at this

memorandum and Mr Watt's letter to you and your letter back. I don't think we need to look at the memorandum because we are pretty familiar with it, but I would like to look at the letter that Mr Watt sent to you, which is [SNB0073638]. Have you seen this letter again recently?

A. Yes, I have, thank you. Yes.

Q. So it looks that Mr Watt is telling you that, as a result of the pilot scale work that has been going on, there are some batches ready for trial. We can see that if we look on to the second page. He says:

"The non-heated material, 760, had failed its laboratory release criteria. There was an associated lot of heated product."

So I think we can understand that it would be most logical to take one lot, as homogeneous as possible, and then to split it and to heat-treat one part of it and not heat-treat the other?

A. Yes.

Q. We learned from Dr Foster that this would be standard, that if clinical trials were to be carried out, you would become involved because you would be asked to arrange it. Is that right?

A. That's right.

Q. That's what Mr Watt seems to be asking of you. He says:

"I believe it is sensible to get some clinical

experience of lot number NY761 as part of the overall process introduction."

Then on to the last page of the letter in the last paragraph. He slightly changes tack because he goes on to talk about the possibility of accelerating the heat treatment programme and he says that colleagues, presumably within PFC, are costing expedited heat treatment. Then he goes on to say:

"In case public opinion rather than science may dictate the best course of action."

Dr Foster's interpretation of that was that Mr Watt was not so much meaning that the Blood Transfusion Service would simply bow to public opinion, more that the science might be missing or might not yet be complete?

A. Yes, I think I share Peter's view.

Q. Have you read the transcript of Dr Foster's evidence?

A. No.

Q. No, right. But you would agree that that's a reasonable interpretation of what Mr Watt is saying?

A. Yes.

Q. Right. Then your letter, which is [SNB0073708]. So you replied to Mr Watt on 1 June and he had already made some contacts with a view to getting NY761 put into patients. I think we know that in fact it went to

Dr Forbes and Dr Ludlam for clinical trials. Is that right?

A. I think that's right, yes.

Q. You go on to say that you would regard the last paragraph of the letter to be the most important and you are particularly pleased that Dr Foster and his colleagues are currently engaged in a costing exercise. So you were very much behind any idea of moving quickly on the heat treatment programme, were you?

A. Yes, absolutely.

Q. Professor Cash, we found the next paragraph slightly delphic. You say:

"We must conclude that with the existing set of instructions the agency has received from SHHD with regard to the way it is to spend its development monies, and noting the reaction of the deputy chief medical officer to the concept that heat-treated Factor VIII is related to the interests of the Medicines Inspectorate, then there are no funds available in 1983 to 1984 for your proposals. However, in the light of the current pressures, (AIDS, et cetera), the department may wish to reconsider its instructions to the CSA and/or find additional monies (less likely)!"

The deputy chief medical officer we are to think of here is Dr Scott. Is that right?

A. Graham, yes.

Q. Professor Cash, we have done a bit of digging around this period to try and find out what the position was about funding. So I would like just to put some documents to you, so that, I hope, we can enlighten ourselves as to what the situation actually was.

Can we look firstly, please, at [SGH0019251]?

This is a Common Services Agency document. I think from its tone it looks to be a paper for a meeting of the Blood Transfusion Service subcommittee on 25 May 1983. Can we remind ourselves of structures here. We know that, by statute, a statutory provision, it's the Common Services Agency which was responsible for having a blood transfusion service?

A. Yes.

Q. Is that right?

A. Yes, indeed.

Q. And that the Common Services Agency had a subcommittee, the Blood Transfusion Service subcommittee?

A. That's correct.

Q. Whose job was, as you would see it?

A. Dear me. That's a very big question. Whose job was to supervise --

Q. Oversee?

A. That's a good word.

Q. Is that a better suggestion?
A. Coordinate, you name it. Yes, I would be content with that.
Q. And if there was a need for money for some new proposal, was it the case that you would put your proposal firstly to this subcommittee? Is that how it worked?
A. Yes, yes. Often in -- often, having briefed the Department of Health -- the SHHD, that we were going to do this -- to give them as much -- because ultimately it would land on their desks. But, yes, the proper procedure was it would be the CSA, on our behalf, who would make bids for money.
Q. I see. And they would make their bid to SHHD?
A. They would indeed. And SHHD would assume that the CSA had carefully vetted these bids and that they had the agency's support.
Q. Right. Can we look at -- I think it's the last page of this document. Number 7, I think, is the paragraph of interest.

You see that there was a pot, as it were, possibly going up to £650,000, expressly for the purpose of meeting the cost of developments arising from the recommendations of the Medicines Inspectorate. And the intention was that that would be made available in the course of the year:

"... on the department being advised that specific and costed proposals have been set in hand."

So that's the background position, if you like, as at May 1983.

A. Yes.

Q. Then can we go, please, to [SGH0019769]? Here we have the Blood Transfusion Service subcommittee. They are meeting on 25 May 1983 and perhaps one of the interesting things to note is that Dr Scott is present. So was he actually a member?

A. You bet. In his first witness statement Graham declares that he served on the subcommittee and had some significant influence. Absolutely right, he did.

Q. Right. And --

A. And John Walker, I should say, J Walker is the undersecretary.

Q. Okay. I recognise Mr Ruckley, that's Vaughan Ruckley. He is a vascular surgeon?

A. Yes.

Q. Perhaps you had better tell us who the others were.

A. Bob Wallace was a lay member from Inverness-shire. Nice man. A Bell you know. He was the SHHD medic. Mr Duncan was a very interesting man. He was a professional trade unionist, a layperson. David Horn was a chest physician. J F Kirk. I don't know who --

it escapes my memory. Vaughan Ruckley of course you know. Graham Scott, deputy chief medical officer. Sir Simpson Stevenson. Almost certainly I think, Sir Simpson at that time was chairman of the CSA itself.

Q. He had a background with Greater Glasgow Health Board?

A. Yes, indeed.

Q. Yes?

A. And John Walker was the undersecretary in the Scottish Office, with responsibility for transfusion.

Q. Right. So as well as the members, we can see that there is quite a batch of people in attendance. We recognise a lot of the names. At the stage we are at, we probably recognise just about all of them but anyway.

A. Yes.

Q. Can we look at page 2, please, of these minutes? At the bottom. We note firstly the mention of the £650,000 pot or kitty and looking at the bottom:

"The subcommittee decided that those items in appendix 1 marked with an asterisk should be submitted to SHHD as an bid against the provision of up to £650,000 which was available to meet the cost of developments arising from the recommendations of the Medicines Inspectorate."

So those items marked with an asterisk are to be put forward as items which should be funded in order to

comply with the recommendations of the Medicines Inspectorate?

A. Correct, against the pot that we had been given.

Q. Yes. Can we now look at page 7, please?

There we see with an asterisk "pilot stage of heat treatment of Factor VIII".

A. Yes.

Q. So it looks from the minutes as though funding for the pilot stage of heat treatment of Factor VIII was to be requested as a step which was necessary to comply with the recommendations of the inspectorate. We can see that the committee has approved this in principle. That's that column on the right-hand side. And there is the asterisk showing what the nature of this expenditure is seen to be.

This is a sequence of meetings and correspondence and the next document is [SNB0037641]. Actually, in our database it says this document is unreadable. I'm not sure it's quite that bad. But it's a letter from Mr Wooller. This is Clive Wooller, is it?

A. Yes, Clive. A great chap.

Q. He was the general administrator?

A. Yes, a great man.

Q. General administrator of the Common Services Agency?

A. Yes.

Q. Right. He is writing to Mr Murray at the SHHD:

"Dear Murray ..."

We can see from the heading this is to do with revenue allocations and the recommendations of the Medicines Inspectorate. And he is referring to a letter of 14 March 1983 from Robertson, the Scottish Office finance division, which intimated the revenue allocations for 1983 to 1984 for the Common Services Agency:

"I'm writing to request that additional provision is made to the agency for the purpose of ..."

I'm not sure if it is "meeting the cost". I think it might be "meeting the cost":

"... of developments in the Blood Transfusion Service arising from the recommendations of the Medicines Inspectorate. The specific costed proposals are set out in the annex to this letter from which you will note the total additional provision being requested is ..."

And I can't actually make out the figures. It looks like it might be 400,000-odd?

THE CHAIRMAN: 447,000.

MS DUNLOP: All right, well ...

A. Recurring.

THE CHAIRMAN: And 165,000 non-recurring.

MS DUNLOP: Certainly from the hard copy. Anyway, we have the order of the figures:

"Proposals have been approved in principle by the management committee. I should be grateful if early confirmation of the level of approved funding could be given to enable the developments to be set in hand, although it's appreciated that the department will wish to give further consideration to certain of the proposals, including their eligibility for funding from the source requested. I'm copying this letter to Robertson."

So that's the chap in the finance division. That's 6 June.

Professor Cash, I couldn't possibly describe this as a question because it's a long narrative but there will be a question at the end.

The next letter is from you, [SNB0111207].

Actually, I'm sorry to jump about but before we look at 1207, I wanted to look back at Professor Cash's letter again, [SNB0073708]. It looks, really, from that letter as though what you were saying was that it had been suggested that the funding of heat treatment of Factor VIII was related to the recommendations of the Medicines Inspectorate and that the deputy chief medical officer had not liked that suggestion?

A. That is correct.
Q. That does look to be what you are saying in your letter?
A. Yes.
Q. But what's slightly surprising about that then is the fact that the expenditure related to heat treatment features in the minutes of the meeting of 25 May with an asterisk; in other words, it was to be --
A. I completely agree and Graham was there.
Q. Yes.
A. I am afraid I can't give you much information but I'll do my best to answer the last question.
Q. Yes, I know. I think when you see the next letter it might help a bit. It's [SNB0111207]. You are writing to Mr Wastle?
A. John, yes.
Q. Is that the correct pronunciation?
A. Yes.
Q. Yes. So he was within the SHHD and he would have, what, some responsibility for passing on the funding bid?
A. Yes, yes. He was part of what I used to call the "serious civil servants", the non-medical chaps, and he would liaise with the treasury and other senior civil servants, yes.
Q. You called them the "serious civil servants"?
A. Yes, I don't wish to say -- but medics, scientists in

general in government are really rather -- you must know this -- second-class citizens within the Civil Service.

Q. Right.

A. And you will find that Graham Scott and the chief medical officer defer to the secretary.

Q. I see.

A. And there were a number of occasions we had in our work in which the medics had to defer to the administrative folk and that's the way it has always been, I think.

Q. Presumably, though, Professor Cash, it would have been a question of the nature of the topic. If the topic related purely to a medical matter?

A. But even there on occasions a non-medical civil servant may go elsewhere to get a medical opinion. I mean, I don't understand it. I think it's all about who is really responsible closely to ministers.

Q. Well, be that as it may, when we look at your letter, you do record -- and this is against number 1 -- considerable concern, which seems to have been expressed at that meeting of 25 May, as to whether all the items listed as related to the Medicines Inspectorate were a legitimate interpretation of the inspectorate's concern for good manufacturing practice. That is abbreviated as "GMP" within the transfusion service.

You are writing this letter, you say, to brief

Mr Wastle and then you say that the subcommittee had also approved, in principle, certain proposals which were not Medicines Inspectorate-related. And the third paragraph, you say that there were several items of non-Medicines Inspectorate expenditure which were concerning you and one of those was the pilot stage of the heat treatment of Factor VIII. You say that:

"The relevance of this to the Medicines Inspectorate was hotly debated by the subcommittee."

Importantly, for our purposes, you say:

"Perhaps I should simply say that these collective proposals are designed to produce a Factor VIII product which is safer -- with respect to hepatitis and possibly AIDS."

So I don't know if this is jogging your memory, Professor Cash, but around this time were you trying to secure funding for particular projects by linking them to this pot of money that you had been told was available?

A. Yes, I can't honestly remember that. What is absolutely certain, I do recall that my good friend, Dr Graham Scott, took a view at the meeting that some of these things on the list were not related to Medicines Inspectorate and should be excluded. And I'm not aware of consciously fiddling and so on and so

forth. I was simply aware that the heat treatment programme was critically important.

The other one, which was the optimal additive solution, that provided us, with the OAS solutions, with the extra plasma we needed to allow Peter and his colleagues to do their tricks. But I'm not aware -- but I'm not aware of deliberately -- but -- and I actually haven't seen my submission -- I mean, it has appeared in the asterisk. That's the treasurer of the CSA with the asterisk. And I can't be sure that I put that in that list, I regret to say.

Q. Well, Professor Cash, "fiddling" is your word, not mine.

A. Yes.

Q. All I'm suggesting --

A. That's what Graham Scott --

Q. Well, all I'm suggesting is that for somebody in charge of a public body, who is trying to secure funding for a project they consider to be extremely important, it seems logical to try and access money which has been earmarked for that public body in some connection or another. So not necessarily fiddling, Professor Cash.

A. No, but I just make the point -- and we may get to this at another stage of the Inquiry. This was the period of time when the Scottish Home and Health Department officials -- and they were, in terms of writing,

medically qualified people -- reacted very strongly against the Medicines Inspectorate, what they were doing, what authority they had, what control and so on and so forth. And it was a very difficult period for everybody and I'm not -- I can't be sure, unless I see what I actually submitted, the document I submitted to the treasurer, whether I included it in this pot.

I take your point that, "There is some money, go and get it". I take your point and maybe I did, when we look at it. On the other hand, it may well be that people genuinely took the view -- and I would be with them -- that this was about safety of product and the medicines inspectors are about safety. It's operating within the Medicines Act and so on.

What I do recall vividly is Graham Scott implying -- whatever word we use -- that I was trying to extract money under false pretences, you know, putting things in, you know -- into lists that aren't appropriate, and I honestly, without seeing what I actually did, wouldn't be able to comment on that. I take your point.

Q. I think we should just try and perhaps look at events over the ensuing months because it's perhaps important to separate out two points: one, is a proposal connected to the recommendations of the Medicines Inspectorate? And, two, even if it's not, should it be funded? These

are not necessarily connected.

A. Yes, indeed.

Q. So can we look at the end of this letter? You are actually asking for some flexibility. So you really wanted an instruction which advised the CSA to regard the Medicines Inspectorate items as a high priority but not an exclusive priority?

A. Yes, indeed.

Q. Right.

A. Indeed.

Q. Then a bit of a gap but if we look at the next letter in this chronology, [SNB0111251]. This is the reply to the supposedly illegible letter. That is the one which Clive Wooller sent to Mr Murray on 6 June. This is Mr Wastle replying on 20 September 1983. He is apologising for not replying earlier. And recording that the department has had to consider whether there is a connection between some of the development proposals and the recommendations of the medicines inspector. They are willing to make available for the year 1983 to 1984, £71,285 recurring expenditure and £30,000 non-recurring. Then he goes on to deal with heat treatment. He says:

"The department does not accept that the heat treatment of Factor VIII arises from the recommendations

of the medicines inspector but it is prepared to consider this matter further."

The entry on page 3 of the annex to your letter seeks:

"£74,000 non-recurring for equipment and £13,400 for recurring revenue implications."

Then there is perhaps a bit of an accountancy point about -- the chairman will guide us on this -- whether the equipment costs should be a charge on capital. They possibly should.

THE CHAIRMAN: Yes. I'm just wondering whether you and the department are wholly out of tune with each other because they are applying the strict government accounting rules that only the purposes for which money is voted can receive the benefit of that money. And no doubt there would be a supplementary vote at the end of year to cover the Medicines Inspectorate. And the auditor general wouldn't be pleased, Dr Cash, if things weren't (a), allocated to the right head and (b), distinguished as to capital and revenue.

A. I have no problem with that, sir, they had a tough job.

MS DUNLOP: I think one of the things which is slightly surprising is the reference to this being pilot scale funding, because actually it's very close to the same level that is subsequently sought for the full-scale

project. But I think that may be just a terminological difference rather than anything different.

It does look as if what is being sought is funding for the heat treatment programme.

Then if we look at you again, writing back to Mr Wooller on this topic on 4 October, [SNB0037646]. We are obviously missing a memo of 27 September but you write back and -- have you seen this letter recently?

A. No.

Q. No, right. I'll give you a minute --

A. Oh, maybe, yes.

Q. I thought it was perhaps one of the ones --

A. Yes.

Q. -- passed to you --

A. Rather late at night, I am afraid. They came through very, very recently. Yes.

Q. Yes. So there was a bit of detail about different items of expenditure?

A. I had been long out of the job.

Q. If we look at the second page, looking at the allocations made against a known £550,000 available but, I mean, I'm not sure about the reason for the discrepancy. We know that the pot was originally 650. It seems to have been. But you say you have:

"... reached a point where there is a major

difference of opinion between professional colleagues in SHHD and those at operational management level in the SNBTS with regard to their respective views on good manufacturing practice."

So there is obviously some debate going on?

A. At the very least.

Q. Yes. Perhaps rather understating it. But you certainly didn't want to hold up the implementation of the approved expenditure. You conclude by saying that:

"You may wish to draw the intention ..."

This is Mr Wooller:

"... may wish to draw the attention of SHHD colleagues to the fact there are several other items of importance to the operational management of SNBTS which have not been forwarded to SHHD because they were not considered to be related to the Medicines Inspectorate reports. These matters, I would submit, are now of relevance in view of the nature of the department's reaction to heat-treated Factor VIII."

I think what we should take from that paragraph is that you understood that it wasn't essential that suggested expenses be linked to the Medicines Inspectorate, that there was another avenue through which you could pass your bids?

A. Yes.

Q. Or along which you could pass your bids?
A. Yes. And I think this was the beginning of the problem I had in which I discovered that having spent a long time with the directors arguing the toss about the bids and so on, they didn't go on to the department, and I got very concerned that they stuck at the CSA -- just a matter of principle -- and that our departmental colleagues didn't have sight of some of the sort of things that were developing. I think that is the reference there.
Q. Right.
A. They were not forwarded to SHHD by the treasurer and ...
Q. Just to conclude this section of narrative, can we go to [SGH0019496], please?

This is the Blood Transfusion Service subcommittee meeting again, on 23 November 1983. I think in fact there was a meeting in between in August. Did it meet quarterly? Is that about right?

A. It did indeed.
Q. This seems to be another of these background papers, I think, if you look at it.
A. Yes.
Q. It specifically relates to the Medicines Inspectorate in the context of funding. I think it's paragraph 1 that's more important. It's reminding the subcommittee that

there is money available to meet the costs of development arising from the recommendations of the inspectorate and that that money would be made available when the department, SHHD, was advised that specific and costed proposals had been set in hand. Annex A gives details of the developments for which the department has agreed to made additional provision.

If we turn over the page, there is annex A. We can just see that at the top right-hand corner. But it's really the note at the bottom that I think is most interesting:

"Heat treatment of Factor VIII. While the department does not accept that this item arises from the recommendations of the Medicines inspectorate, it is prepared to consider this matter further on receipt of a new proposal and details of estimated expenditure requirements in 1983 to 1984 and subsequent years."

So it looks, Professor Cash, as though the position towards the end of 1983 was that, whatever suggestion had been made, this money should be made available for heat treatment because of the Medicines Inspectorate, that might not have worked but that you were being invited to put forward --

A. Yes, I think that was in John Wastle's letter actually. There had obviously been a mess-up and they finally came

back and said, "Look, for goodness sake, in terms of heat treatment, let's have a separate submission outside the Medicines Inspectorate and see where we go from there". That's my understanding, yes.

Q. Right. We do know that Dr Perry coordinated the preparation of a costing for the heat treatment programme and I don't think we need to look at it. In round terms it's about £90,000 and he sent it with a covering letter. If we look on to see what happened to that bid, firstly [SGF0011986].

This is a memo from Dr Bell, which we gather is all that survives of a particular finance file from SHHD. But it's advice from Dr Bell to Mr Murray and it concerns heat treatment, obviously, heat-treated Factor VIII. The CSA case for funding the production of heat-treated Factor VIII seems to have been based on a paper that they had put to the BTS subcommittee in February 1984. And the BTS subcommittee had approved it on 22 February. Have you seen this memo again recently?

A. Yes, I think it was probably one of those -- I'm just looking at it again. (Pause)

Q. Perhaps, Professor Cash, this memo does illustrate the respective territories of the medically qualified civil servants and the non-medically qualified civil servants,

because Dr Bell says at the end:

"It is not for me to say how this development should be financed but I can say that it is a genuine technological advance and a failure to bring it about would be very difficult to defend publicly."

Actually we can see some of the reasoning. What Dr Bell describes as the "policy case". He gives a little bit of factual information about the situation concerning non-A non-B hepatitis. He goes on to highlight the fact that the commercial manufacturers are beginning to produce heat-treated products.

A. That's right.

Q. The potential threat to self-sufficiency really. So not that different from the view you yourself had been taking.

A. No, in the whole of this area, at this time, Bert Bell was one of the -- not strong supporters, he was a Department of Health man and he was immensely supportive, and you see, he attended every directors' meeting --

Q. Yes.

A. -- religiously, absolutely religiously, with his friend Bob.

Q. I'm sorry, I didn't hear that?

A. With his friend Bob Roberts, Mr Roberts. And he wasn't

necessarily involved in the discussion but was listening to them and after the meetings would often phone me for clarification and so on and so forth. Yes, it doesn't come as a surprise, this letter, at all to me.

THE CHAIRMAN: Bob Robertson was the serious civil servant, was he?

A. He was indeed, sir. He was the minder for Dr Bell.

MS DUNLOP: Right.

A. A very nice gentleman too.

Q. So Dr Bell very much in support, May 1984. Can we then look at [SGH0019972], please? Sorry, it is going back to time.

This is just so that we know that the proposal was approved at the Blood Transfusion Service subcommittee in February 1984. We have the minutes of that as well.

Can we just scroll through that, please? We can see the Medicines Inspectorate is still on the agenda but if we keep going, we will find the heat treatment reference:

"Heat-treated Factor VIII concentrate, item 2001."

If that's right. So that's the approval in February and we have an exchange of letters in the summer, showing the formal authorisation of the £90,000 required. I don't think it's really necessary to go to them but just to give the references, to show that that

did happen in the summer, [SNB0074523] and [SNB0074527], please? So formal authorisation to the expenditure of a total of £90,000 on equipment will be issued to Dr Cash in the next few days. So August 1984, Clive Wooller is telling Dr Perry that the money is coming through.

THE CHAIRMAN: Can you give me the date of 4523?

MS DUNLOP: We can look at that too. I thought there was a problem with court book but there wasn't, it was my mistake. So [SNB0074523]. Dr Perry has actually sent what I think is a reminder letter really. Dr Perry has sent to Mr Wooller a kind of reminder letter.

A. Then I think Clive Wooller's response is --

Q. Pretty swift. So that was a bit of a lengthy excursus but just to try to follow through, what happened about funding for the heat treatment programme, Dr Foster gave a one-line answer, which was that issues of funding didn't delay the heat treatment programme. But just so that we could check that out, we have now looked at the correspondence and the authorisation of the money. Would you then share that view?

A. I would share it on no recollection or memory but my view is that Peter was so close to the -- if he is saying that, yes, I would instinctively share it and respect his view.

Q. Can we go back, please, to your statement. That's [PEN0121912] at 1922?

We come now to the departure of Mr Watt. I should say, I'm skipping over these questions where you say we should be asking Dr Foster. We have and we know about the contact with Professor Johnson over the 1983/1984 period.

But coming to Mr Watt's departure, I think it might be useful for us to look at a letter written by him, [SNB0111214]. You have plainly seen this letter before, Dr Cash. Have you seen it recently?

A. No.

Q. I think perhaps we should just take a moment so that we can read it. I am afraid we hadn't found it until quite recently. (Pause)

A. Is there a date on this?

Q. Yes, I'm sorry, I think it's 4 July 1983.

A. Okay, thank you.

Q. Look at page 2. Thank you.

When you first heard of his resignation, Professor Cash, was it a surprise?

A. A colossal surprise, yes. He walked into my room and said, "I'm leaving," and I laughed. I was surprised and very dismayed, yes.

Q. Right. You prepared some notes, I think. Can we look

at [SNB0111217]?

We can see that this document dates from August 1983 and it's a "strictly confidential" document. But it does just seem to be your thoughts on the situation that now presented itself, with Mr Watt leaving.

A. I haven't read this for a very long time, I am afraid.

Q. Right. (Pause)

I don't think we want to go through all 11-pages of this, Professor Cash.

A. Excellent.

Q. But the document is there as a record of what looks to have been a profound effect that the news had had on you?

A. Absolutely.

Q. Yes, and a sense on your part of a lot of analysis and planning which needed to be done before a successor could be recruited. Really, in a nutshell, about the way forward from here.

A. Yes, if you had asked any people in this business, finding top directors of fractionation centres in the world is exceedingly difficult, and indeed, dear old Bob Perry, I had to twist his arm and do all sorts of things to get him to act up initially. Very reluctant.

So the loss of John Watt in terms of the total organisation was a very severe blow because we were at

a time in particular of great change, great strides forward, and the market didn't deliver lots of people that had the experience and they were able to have confidence, the people that were working under them.

So, yes, it was a very severe blow and I have to confess I did my very best to get him to change his mind.

Q. Right. I did actually notice, in preparing for today, Professor Cash, a document from around the time -- I think it may even be early 1984 -- which records that Dr Perry will not be applying for the job. So it's something of a surprise to discover that it was Dr Perry who succeeded Mr Watt.

A. Yes.

Q. There must have been a bit of arm twisting, as you say.

A. I could bore everybody by giving you the details, but yes. A lot of lunches.

Q. There isn't anywhere specially close to Ellen's Glen Road for lunch, is there?

A. No, it was Costorphine.

Q. We do also have a letter -- I'm not going to go to it, but we have the letter that Mr Watt sent to Professor Johnson telling him of the decision and describing it is "multifactorial" -- that's [SNB0073794] -- that spawned the question that we put to

you.

So can we go back to the statement, please, [PEN0121912], that Mr Watt had said in his letter to Professor Johnson that his decision was multifactorial. There are plainly a lot of interpersonal issues involved here, Professor Cash, and our only purpose in looking at the issue is to try to analyse, if we can, whether it had any effect on the heat treatment programme. You gave the answer that you think it had a profound effect, Mr Watt's departure had a profound impact on the morale of PFC staff, but you have some doubt that it impacted adversely on the continued development of PFC's heat treatment programme.

Dr Foster doesn't really think it affected the heat treatment programme and I think, as you have said before, he should know. Is that right?

A. Yes, I have said the same thing, and the prime reason there was that Peter Foster, the solid rock, was still there, as far as that programme was concerned.

Q. You do say in the last sentence on that page that you have always believed that the departure of key PFC engineering staff to Mr Watt's consulting company proved in due course to be detrimental to PFC. Dr Foster told us that only two people left and that they were at senior technical level; they were section managers.

A. But one of them was a wizard in the engineering area and there is no doubt that that became a problem later on.
Q. Can we just go over the page, please? One of the issues which cropped up or became focused in the ensuing months seems to have been the question of line management for the director of PFC.
A. Yes.
Q. Right. In this connection can we have a look at a letter that you wrote on 5 January 1984. This is [SNB0111346]. You mention this letter yourself.
A. Yes.
Q. This is you writing to Mr Mutch, the secretary of the Common Services Agency, and you are itemising various decisions which may be required. We certainly note there that there are some references to heat treatment.
Can we go over the page, please? I think by this point you had reached the view that the replacement for Mr Watt had to be directly responsible to you. That is what you wanted to happen, isn't it?
A. Yes, I did, I did, I did. I wasn't terribly worried about myself, I was more worried that one of John Watt's problems was his immediate superior was a charming chap called John Mutch, who was the secretary, and he was responsible to Mr Mutch. Mr Mutch, I don't think had an O level in biological science, so he was not

a scientist. He was a very charming man. And it became very evident to me, after John Watt left, that Mr Mutch was very unfamiliar with what was going on, and I could well understand that and appreciate it, and I became frankly alarmed that we were going to reappoint somebody who would hang there, not clearly responsible to somebody that could have an empathy, and so on and so forth.

So, yes, I reckoned that there needed to be a better management structure, to ensure the PFC director had the support he really needed.

Q. We did investigate this circumstance further, Professor Cash --

A. Yes.

Q. -- the proposition that there was a flaw in the line management arrangements for Mr Watt. Can we look, please, at [PEN0121742]? You can see the enquiry that was made in May of this year. We did ask in the first instance the Scottish Government for information on this but they suggested that we should go to the Central Legal Office in view of their connection to the Common Services Agency. And that's what this is, it's the response from the Common Services Agency, or on behalf of the Common Services Agency, as was.

We can see the two bullets. We asked:

"The underlying reasons as to why Mr Mutch was Mr Watt's line manager and whether Mr Mutch was an appropriate person to supervise Mr Watt. We understand in this respect that Mr Mutch may not have had a scientific background and would not necessarily have had an understanding of certain of the operational aspects of the PFC."

Then, if we look at the response, the response details the establishment of the CSA management committee and recommendations which were accepted by the CSA management committee, 1978, those being recommendations from an ad hoc committee on the management of the blood service.

I think the important one is, if we look at the passage over the page:

"There shall stand referred to the Blood Transfusion Service subcommittee the control of the establishment of staff within the Blood Transfusion Service and the appointment and dismissal of staff, with the exception of the National Medical Director ..."

That's you:

"... regional directors, other consultant medical staff and the scientific director of the Protein Fractionation Centre."

So it does look, Professor Cash, as though the line

of the responsibility went, not to Mr Mutch, but to the committee, doesn't it?

A. Well, it does there, yes, but -- I mean, that document clearly indicates this and you then have to say how are you responsible, in terms of line management, to a committee.

Q. So the committee is to be line managing you, the regional directors and Mr Watt, essentially?

A. I presume so, yes.

Q. Yes.

A. Even then I felt my position was anomalous in terms of people who I could report to that had an understanding and knowledge of what we were on about and that's where the medics in the Scottish Office, in my view, played, or certainly could have played, a very important role indeed.

But it's difficult and if you take -- I mean, a good example of the area in this morning is, for whatever reason -- and I can't remember what -- I got the wobbles about pasteurisation, as to whether it was going to be a runner, and the real question is John was heavily supportive (inaudible), so was Peter, and, as an organisation, we didn't have the management structure to seriously consider changing, you know, tack or considering that. It was seen, as far as John was

concerned -- and I respected him -- as a threat to his responsibility, and so his position, and that raised its own problems.

I mean, the management issue -- and I don't know whether you have got the documents that exist, in which I get a letter back, eventually, from Mr Mutch telling me that really -- because we are now in the position of appointing Bob Perry, or moving towards that -- if, I was told, Bob was to report to me, the salary that could be paid -- and if we read the document, the salary that could be paid would be lower than it had been hitherto, and (a) I felt that's dreadful, that's unacceptable -- but it really is managerially unacceptable. You should pay a guy what he is worth. However, I apologise.

THE CHAIRMAN: Not at all. I wonder if we could look at this in perhaps a technical way, as a management structure, Dr Cash. As you know, I have been concerned from time to time about the implications of autonomy as among the several directors of various branches of the service. If we look at paragraph 5 on page 2 of this document, can you help me to understand it? The control or establishment ... is to lie with one structure and then excepted are national medical director, each of the regional directors, other consultant medical staff and

the scientific director of PFC, all of whom appear to be answerable directly to a committee.

A. That's right.

THE CHAIRMAN: Is that the way it was intended to work?

A. I have no idea, sir.

THE CHAIRMAN: Is that the way it worked?

A. In 1974 a letter was written by the Scottish directors to say that the bringing in of the CSA and what we see will be very bad news indeed. So they foresaw this, and it was in 1974 this was created.

THE CHAIRMAN: I think you know that I have seen that letter but in terms of strict managerial structures, this appears, on one view perhaps, almost to be the antithesis of a management structure.

A. Indeed.

THE CHAIRMAN: In respect that it's a series of individual cords with no interconnection at all.

A. Yes. I should add, Professor James, in 1974 also came out the edict that all consultants in the NHS are equal and the notion of having a chief in a ward is to be abandoned, and there is no doubt whatsoever that created prob -- that all the consultants in the SNBTS, including the directors, were on an equal footing managerially, and from a management point of view it didn't make any sense at all. I tried.

MS DUNLOP: Can we go back and perhaps turn to a different topic? Go back to your statement, [PEN0121912] at page 1923. We went on to ask you about what was happening in England. There was more attention, apparently, being paid to dry heat treatment.

A. Sorry, where are we?

Q. We are just at the very bottom of the page.

A. Good. Thank you very much.

Q. Yes. So we recorded a finding on our part of a paper from the Central Blood Laboratories Authority on heat treatment, that they thought pasteurisation was more homogeneous and efficient and, to satisfy reliability in manufacture, was to be preferred. So it looked to us as though there was a sense in England of dry heat treatment being the second choice technically but, because of the pressure in haemophilia care, it was the one that had to be pursued.

Just again to tie off another loose end, you found it difficult, you said, to answer the question because you didn't have Dr Gunson's letter of 26 June -- it's actually 29 June -- to which Dr Walford's letter is a reply. Well, here it is, [DHF0014561].

If nothing else, this letter, which is from Dr Gunson to Dr Walford -- we know that. But, if nothing else, this letter shows us how much uncertainty

there was about heat treatment, and AIDS in particular, in the summer of 1983. The part of relevance is in the second paragraph. He says:

"I was told last week, (I think by [redacted] ... "

I don't know but somebody:

"... but so many people have spoken to me about AIDS recently, I can't be sure!) ... "

So, obviously, there were a lot of things going on in the summer of 1983:

"... that some of the chimpanzees had developed hepatitis ... "

So this was back to Travenol and their trial of Hemofil. Also concerns about cost, and then a reference to the meeting of the Committee on the Safety of Medicines on 13 July. It's actually the biological subcommittee. Anyway.

So I think it was our suggestion that the reference to dry heat treatment not being encouraging was based on news about the chimpanzees developing hepatitis. That's simply speculation, Professor Cash, but certainly it seems that that news was around at the time, and you went on to talk slightly more generally about attitudes to plasma products in the summer of 1983.

Can we go back to the statement, please, at 1924? You thought it was interesting that Dr Walford was

suggesting that the introduction of clinical trials may need to be considered to prevent what she describes as unjustifiable demands by clinicians.

I suppose we should really look at Dr Walford's letter. We looked at it several times before but let's just look at it again. I'm sorry, it's not on my list. [DHF0025668]. She knows about the chimpanzees as well.

A. Yes. It's the last sentence in paragraph 2, I think.

Q. Yes. The sentence immediately before it is interesting too, though:

"The possible cost implications of the introduction of heat-treated Factor VIII into this country will not be material to the committee's deliberations, which one would expect to be confined to the matters relating to the quality, safety and efficacy of heat-treated Factor VIII and other coagulation concentrates."

She is not expecting to be at the meeting on 13 July.

Just one other factual matter, Professor Cash. You said in your statement that we should note that Dr Walford was a member of the Committee on the Safety of Medicines. With respect, I don't think that's quite right. Can we have a look, please, at [MIS0010291]? This is a partially de-redacted set of minutes of the meeting held on 13 July 1983 and I think that the

members are the people listed on the left. This is in fact the subcommittee on biological products, but it was the subcommittee on biological products which dealt with coagulation factor concentrate.

So we can see the members there, including Dr Lane and Mr Watt, certainly outnumbered by the column on the right, who were also present, and then there are the attendees, I think, under Mr Watt's name. I think that probably tells us that these people were in attendance, and then on the right there are the people who were also present.

So would it not have been the format for something like this that there would be civil servants in attendance, not least to provide secretarial services and clerking services, and then there would also be invited guests, perhaps to speak on a particular topic that was on the agenda? That would be the sort of structure of a body like this, would it not?

A. I don't know this body. I know the Expert Advisory Group on AIDS and I don't think you could necessarily conclude in that way. First of all a column of this size you wouldn't need taking notes, I think, of the meeting. So the real question is: who were they and what were they doing? The notion that somebody, a senior civil servant, who is not technically a member

of a committee, in my experience didn't really necessarily mean that he or she could (sic) have a major influence on the agenda and the conduct of business and so on and so forth.

So I apologise if I have implied that Dr Walford was a member, but I was aware that she was in attendance, and if you look again at Harold Gunson's letter -- he is saying, "Are you going to be there?" -- there is a lot of cross fertilisation going on.

Q. Just to be completely clear about your position, Professor Cash, the thrust of what you were saying was that, just because a senior civil servant is not technically a member, it does not necessarily mean that he or she could not have a major influence on the agenda. There is a lot of "nots" in that but I think one of them might have been missed out in the transcript.

Your point is that, without even being a member, a senior civil servant could still influence the deliberations and the discussions?

A. Yes, sure, and I'm not uncomfortable with that, I think it just needs to be recognised. They are reporting to ministers after all.

THE CHAIRMAN: Ms Dunlop, do we have an equivalent list for the CSM itself, as distinct from the subcommittee?

MS DUNLOP: No, I don't think so, sir. This being the only meeting that we have really examined, the decisions about the factor concentrates appear to have been taken by the Subcommittee on Biological Products, which then provided its formal recommendations to the CSM.

THE CHAIRMAN: Yes, I think I understand that but, of course, Professor Cash's comment relates to the CSM.

The other thing I would like to ask Professor Cash is this: might it be that membership of the committee was rather more inhibiting in the exercise of power than merely attendance with a supervisory function outside of it?

A. It might.

THE CHAIRMAN: So perhaps not being a member makes the person even more powerful?

A. Indeed.

THE CHAIRMAN: Yes.

MS DUNLOP: We can certainly look into the membership of the CSM.

THE CHAIRMAN: Actually, does it matter terribly?

MS DUNLOP: Right.

THE CHAIRMAN: I think on any view we would be treating Diana Walford as a very important person, with a considerable amount of influence, and perhaps membership of the committee is not of primary

importance. I don't want to take up time doing things that aren't going to count, as it were.

MS DUNLOP: I think there can be -- and I'm as guilty of it as anyone else -- a bit of inexactitude in speaking about the CSM, and for our purposes I think what we really need to look at is the Subcommittee on Biological Products because that seems to be the decision-making body of relevance. I had thought that Professor Cash was suggesting that Dr Walford was a member of that. So that's really why we are looking --

A. No, I take the point. These committees were supposed to be totally independent of government -- they were supposed to be -- and therefore the notion that you would find a distinguished civil servant actually a member, in my experience, of any of the committees I served on wouldn't apply. They would be there, however, and, as I know, they would influence, particularly the chairman.

Q. Certainly, Professor Cash, we have, in block 2 actually, looked at a lot of paperwork to do with this particular meeting, and there is a sort of background paper, quite a lengthy background paper, which does seem to deal in advance with the issues which are going to be discussed at the meeting and even perhaps to head in the direction of suggesting some conclusions. So perhaps that chimes

with the wider point you are making?

A. Yes. When you come to look at HCV donation testing kit evaluation, you will see a repeat of that phenomenon: decisions being made within the Department of Health, and when it comes to the committee that's supposed to be responsible, we know from the documents the cat is out of the bag, it's all over.

So these members, as the chairman is actually implying, that you think have the authority, they don't.

THE CHAIRMAN: Well, perhaps those of us who have some experience of being provided, not just with an agenda, but with draft minutes for such a meeting might sympathise --

A. In advance.

THE CHAIRMAN: -- with that, with your point of view.

MS DUNLOP: I think, sir, that's an appropriate point at which to break.

(12.57 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you. Professor Cash, we are going to go back to your statement and just finish the last few pages of it. Could we then return to [PEN0121912] at page 1924.

In question 26 we asked about the trial -- I think it's actually the trial of batch 761 -- and we saw that batch mentioned in the correspondence as a batch that was ready for trial. The next part of the story on that, I think, is that it went out to Dr Forbes and Dr Ludlam.

Could we look first, please, at [SNB0015188]? This is the haemophilia and blood transfusion working group, which met on 14 November 1983. You were there and Dr Forbes, Dr Foster, Dr Ludlam, and we can see a heading there "Heat-treated Factor VIII concentrate". Both Dr Ludlam and Dr Forbes were asked to report on their clinical evaluation of the trial batch.

Dr Ludlam is reporting that he had used his supply to treat one patient on three occasions over a period of one to three weeks. The product seems to have given good results, but the patient experienced minor adverse reactions on each occasion and had become anxious:

"It was not clear whether or not the product was the only cause of his upset."

Dr Forbes had just received a supply of material actually. It's from a different batch. I'm wrong about saying it was the same batch. From a different batch and was about to put it to trial.

So we have that experience that Dr Ludlam is

reporting and that's November 1983. Can we look next, please, at [SNB0015311].

On the same topic, Dr Ludlam wrote to you on 11 January 1984 and this is his letter. He says he is writing to let you know the outcome of infusing the heat-treated Factor VIII and this is batch 761. He describes the patient's response, the reaction that the patient experienced, that those reactions were significant and unacceptably adverse reactions, and you have marked that and written -- I think it says "Agreed, JDC," does it?

A. Yes, correct.

Q. In your question 26 we just asked about those two documents, firstly the minutes of the meeting in November and secondly the letter. Can we go back then to the statement, please? It was simply that we saw a bit of a discrepancy, and I see we have Dr Ludlam here and we will be able to ask him about it tomorrow. But it seemed to us that there was a little bit of a difference between the description at the meeting and the letter. The letter seems to describe a more serious problem than the report at the meeting. We really asked two things: whether there was an explanation for the apparent difference and whether the letter was written at your request?

You say in your answer that you do not think you asked Dr Ludlam to change his mind. I suppose implicit in that answer is that you see a bit of a discrepancy as well?

A. Oh, yes.

Q. Yes?

A. But I can't imagine how you thought I had written to Dr Ludlam saying, "Hey, could you just send another letter that kills the product". I couldn't see that.

Q. I suppose it might have been the case, Dr Cash, that you would just want Dr Ludlam to put the report in writing so that you could perhaps show a letter to somebody else.

A. No, but I didn't -- okay, I didn't in fact communicate in any way, and I interpreted the question you were asking as though somehow I was encouraging Chris to give a much worse picture and I do apologise. I wasn't and I don't recall asking him. I'm not sure, if I asked, Chris would respond. He is a man in his own right. He is the director of the haemophilia centre. He would do what he thought was right.

Q. So it wasn't, for example, part of putting together a case for funding or something like that?

A. No, I could have used the minute of the meeting, you know, in terms of a reaction.

Q. Let's move on.

Can we go to the next page, please? You refer to dry heat experiments, which took place at PFC at the end of 1983 and we have been told that actually Dr Cuthbertson was responsible for these or certainly involved in them, so we are proposing to ask Dr Cuthbertson about that.

A. Yes.

Q. Then there is a series of questions which you think should be directed to others or you don't recall.

29, we asked about the advent of hepatitis-reduced products in general, and then 30 is connected to funding and we have already looked at Dr Bell's minute.

Then 31, we mention the meeting in Cardiff in October 1984 and we have already referred to that as well and referred to one document which summarises what Dr Mannucci had said.

Then we make a reference to the plasma fractionation conference in Groningen attended by Dr Foster.

Just so that we are accurate about this, I think the question is probably not very well worded, but can we have a look at Dr Foster's report from Groningen, please? [SNB0086528]. I don't think we are at odds, Professor Cash. Can we just go to the next page, please? Thank you.

We see that at the bottom of that page there is a report of a report on heat inactivation studies and Dr Foster has written "probably by Cutter". Over on to the next page and Dr Foster has told us that there is a mistake in the first temperature shown there. It should be "60 degrees wet heating (German method)" and then "68 degrees dry heating".

So it seems that the information imparted at that conference was in relation to dry heating at 68 degrees for one hour, which is shown as having a considerable effect. So that's the information with which Dr Foster returns from Groningen.

Then the other information is from the Mannucci paper, or the notes of the Mannucci talk, which perhaps we should just look at again actually. That's [SNB0049164]. If we could look at that, please.

This is the Mannucci Hemofil trial. Can we just scroll through it, please and on to the next page:

"He [that's Mannucci] also commented that as far as the AIDS antibody is concerned, using LAV antibody tests, there is apparently no seroconversion of any patient after one year."

So I think all that we were trying to focus on in the question is that these strands of information were emerging towards the end of 1984. You thought that we

were reading the documents differently. Can we go back to the statement, please. I don't think we were.

You explain that:

"The importance to SNBTS of the Groningen information was that the sensitivity of HIV to heat was confirmed and the type of product and heat treatment given by Cutter was very similar to ours and there did not appear to be any immediate adverse clinical reactions.

A. I think there are two hugely important things and one I'm sure you will be looking at later is the data on HIV in terms of the kill, in terms of heat treatment, was in vitro after spiking. In other words, they weren't heat-treating it and banging it into patients and saying it was all right.

It's in vitro technology, and as you will see to come, there was a major problem we had in introducing that fundamental technical knowledge here in Scotland. The second thing that's missing is closest to my heart. I was very impressed, like Peter and Bruce Cuthbertson, with the spiking in vitro. What really impressed me, because I knew when it happened I would have to face -- what really impressed me was that the patients who reported didn't drop off the needle. In other words, there was a product -- as I recall it was Cutter -- that

was very similar to ours, dry-heated, that actually patients had no reactions and there was -- and that for me -- and it will emerge later -- was the most important thing of all.

We came to a conclusion: therefore, our product is safe.

Q. Right. I can understand the second point you make, Professor Cash, that that would be very reassuring but I think we might need a bit of help with the first point, that there was a major problem, you say, in introducing that fundamental technical knowledge here in Scotland. Can you elaborate on that a little bit, please?

A. If I may, but I will be guided by you, this emerges in another witness statement with the full list of references. It was a problem with the Scottish Home and Health Department and not simply of funding. They were -- we were doing spiking studies. I think Bruce Cuthbertson, who ran the show from about late 82/83 -- but we were using what we called "duff viruses", you know?

Q. Yes, Mumps being one of them, I remember that.

A. It doesn't matter --

Q. Yes.

A. Then we came -- as we approached in 84/85, we wanted to

put actually HIV, which is what these people did and we ran into serious problems and --

Q. Right.

A. In brief the Scottish Office chaps said it is not safe to introduce HIV into PFC and do these spiking experiments. We took the view, it's coming in the back door in terms of plasma every day. There was a major -- another major problem and you will not miss it. It appears in another witness statement with lots of references.

Q. Right. Is this into 1985?

A. Yes.

Q. That episode, right.

A. We didn't resolve that, I think, until late 86/87.

Q. I see. Then we went on to refer, in paragraph 32 and thereafter, to the infections in Edinburgh and you make some brief responses there --

A. Yes, I can't remember.

Q. -- but I think don't have anything particular to contribute. Thank you.

Then can we look at question 36, please? This was our final question.

We asked about the possibility of moving to dry heat-treated product at the beginning of 1984 instead of at the end and you have suggested that it would be more

productive to invite Drs Perry and Foster to respond to this question. We have, but you have given some thoughts. You point out that the 12-month period between dry heating experiments in 1983 and the introduction of dry heat-treated product in 1984 is quite short, and indeed we have looked at a table in Dr Foster's paper showing how swiftly Scotland was able to move to wholesale production of heat-treated product.

Then you say, in your second paragraph, that the batch was processed in the first week of November 1983, almost certainly before the first experimental dry-heated batch:

"It follows that if my recollection is correct, your proposition is a non-starter."

I think what we were really not spelling out -- perhaps we should -- but we were imagining that all the same events as happened in December 1984 had just happened earlier and that would have had to have included recall of product as well.

A. Can I say -- and it is -- if we hadn't gone to Groningen and listened with our own ears, we might not have been issuing our heat-treated stuff for many months after. It was that crucial meeting and talking -- for Peter and the guys to be talking with the scientists involved. We reached a point, I think, in September 1983, before

that, between November -- I beg your pardon, September 1984. Before that period we were into all sorts of hassles with Dr Joan Dawes saying, "I think I can see damaged neoantigens", and there was a real problem of the technology here and I was chairing all these meetings and we were just terrified that we might do something damaging.

So the one year was remarkably short. It would have been actually in my view -- I don't know what Peter Foster said -- it would have been much longer if we hadn't gone to the Netherlands.

Q. Right. Then in 36.13 you record some more recollections, I think, from that period. The same point really, that there was great concern among the clinicians that any form of heating might be associated with protein denaturation.

A. I don't know whether Peter -- there were people writing in the Lancet and BMJ:

"Under no circumstances give this stuff to these patients."

Q. And we know that --

A. As the poor old national medical director of the Scottish service this was -- and one of the authors, as I recall, was an ex- Edinburgh immunologist, a great chap.

Q. This is the letter by Bird and others that was in the Lancet in January?
A. Yes.
Q. Yes. Before that even, we have a handwritten letter from Dr Hann at Yorkhill, protesting --
A. The UK haemophilia directors, there are guys getting up there, saying, "This stuff is dangerous, do not use it". I mean, it was a pretty heated and, I think, we owe a lot not only to Groningen but to Professor Ludlam, and some of these guys who were prepared to do it.
Q. Do you remember that time, November/December 1984, quite clearly?
A. Yes, I do actually.
Q. Yes.
A. At least the panic and alarm and the sweat and the terror and the loneliness of it, when the boys came in and said, "John, we think we should do this and this and this", and they are all looking at me. It is up to you, you are the medical director, to press the button. And there were two problems: were we going to accept the Groningen view that it was okay, our product was going to be okay? Point 1. The second was, which I think would be refused now: what's the legal position of pulling that product that has already been issued and heating it? And I can tell you, some weeks ago I took

back some excess heparin to the pharmacy, my local pharmacy, and they said, "Bin it. We are not permitted to take back --" once it has been issued, you cannot know that it has been kept safely. We took that risk. And I can only say, in my view we were very lucky.

Q. I didn't understand it to be the case that product that was recalled from patients was reheated and reissued.

A. It wasn't the patients, it was in the Edinburgh centre or the haemophilia centre.

Q. Right.

A. It was out, in other words, from our ken.

Q. You say in your answer that you found yourselves alone without active support from SHHD or the MCA. I wondered what you would have had them do?

A. I would have had them do what the chap called Dr Duncan Thomas, in NIBSC, did.

I asked Bob to phone Duncan. He was a good friend of the service. I knew him from my own research very well. He was the senior director of the coagulation section in NIBSC and I asked Bob Perry, "Will you give Duncan a ring and just chat over the whole thing". And what we were looking for -- Duncan kept saying it, "This is not official but in my professional opinion, Bob, it's okay". And he had no formal legal role in there. He was just giving us some moral support, and I had

hoped to get it and I understood the problems around medics and the Scottish Office.

I phoned Bert to see whether -- he said, "I hear what you say, yes, off the record", but he rightly wasn't going to comment and made it very clear.

Similarly, we felt -- and it may be quite wrong -- that because we were in Crown immunity, it had been signalled very clear to us that our contact with the Medicines Control Agency, ie the inspectors, was not to be direct. It was to go through the CSA and, you know, Bob and his colleagues wanted a decision, like, yesterday to get on -- this was in December whatever it was, just before Christmas.

There was a complication, I remember, that PFC was shutting down some time early in 1985 and we were really boxed into a tight situation. So all I said was I felt a bit lonely and exposed. I didn't, stupidly, phone up my medical defence people.

Q. Sir, before I conclude my questioning of Professor Cash, there is something I would like to go and look at. I'm sorry, therefore, that I will need to ask for a short break, if that's possible. We are certainly well ahead in terms of time. So if I can perhaps go and look something up?

THE CHAIRMAN: I don't think I should make it conditional on

being well ahead.

MS DUNLOP: All right, thank you.

(2.25 pm)

(Short adjournment)

(2.38 pm)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Thank you, sir, I'm obliged.

Professor Cash, just before we finish, we did ask a follow-up question on that last answer of yours about finding yourselves alone and unsupported, and you gave a further response, which is [PEN0121909].

Section 1 of this you have called "Background Notes", and I think here you are setting the context really for what follows in section 2.

A. Yes.

Q. And most of your explanation in section 1 is to do with the fact that for a time there weren't manufacturing licences in relation to PFC, and my understanding is that originally a manufacturer's licence was granted in May 1976 for a period of five years and that it was when renewal was due in May 1981 that the position seemed to change insofar as Crown immunity is concerned. Does that accord with your recollection?

A. In effect, yes, that's correct.

Q. I think that's what you are saying in 105, if we could

go a little bit further down. You are saying:

"SHHD announced that the CSA/SNBTS would now operate under Crown immunity and thus outside the regulatory control of the Medicines Act 1968."

Although I think the product licences continued. Is that right?

A. No, the product licensing all lapsed but Bob Perry and his team decided as far as PFC was concerned, they would make an application for product licences for the new products as they came along. The issue arose, which I think is a little clearer now: how on earth can you have a product licence if you have not got a manufacturing licence? And I think that situation is not very healthy.

Q. Well, we do have information that NY was given a product licence in September 1978 for five years, and that that was renewed in September 1983 for a period of five years. And DEFIX, similarly, there was an application for a product licence for DEFIX in October 1978, and that was granted in July 1979 for a period of five years but that one was released under Crown immunity in the period between 1984 and 1989. So a slightly mixed picture with the Factor VIII.

A. But they actually lapsed, and if you take -- I mean, the leader, as far as I was concerned, was IVIGG, in which

Bruce Cuthbertson and his team did a huge amount of work to obtain a product licence in the same manner as the pharmaceutical industry would do. And I vividly remember a lorry coming to pick up the paperwork to go down to London for this. It was huge. And I think in one of the statements I have made, the people in medicines control area told Bob one day that all the PFC product licences were stored in a shoe box. I think I put this in one of my statements.

The second thing, in actual fact their validity -- it was an excellent product. Their validity, we presumed legally, without a manufacturing licence, was in some doubt.

That's the only point I'm making here.

Q. I see. Can we look at section 2 of this response then, please? You say that particularly then, at that time in December 1984, there were a number of concerns about the heat-treated product which you were about to issue.

A. Yes.

Q. I think perhaps the key paragraph is 2.02. You say:

"Despite a request for SHHD support (through Dr AE Bell, SHHD), the responsibility to permit the release of the first PFC heat-treated Factor VIII was not shared by SHHD or CSA officials, notably the chief pharmacist and/or the medical officer with

responsibilities for regulatory matters, but it was shared by clinical colleagues and, through Dr Perry, informal support was obtained from a senior NIBSC staff member."

A. Dr Thomas.

Q. I see. Is that Howard Thomas?

A. No, Duncan.

Q. Duncan Thomas, right, thank you.

A. Howard is a professor.

Q. I just momentarily wondered if he had had some spell at NIBSC. Anyway, I think perhaps again, Professor Cash, when you say that about looking for SHHD support and it not being shared, the responsibility not being shared by SHHD or CSA officials, what did you have in mind?

A. I think you asked that question before our break.

Q. I did, yes.

A. And I would say much the same thing, that I would have liked what we got from Duncan Thomas, the NIBSC man, that he couldn't speak officially but as a professional he had listened to the data of Bob and his team, and said in his personal view he thought it was okay. And I was looking for more of that from the wider group in the management team, the corporate management team, which included the Scottish Office.

Q. Right. You go on to say, in 2.04, that you even had to

fight for money to send Dr Foster to Groningen in the first place.

A. Yes, it's true. I mean -- I won't go into that. That really was an awful episode for the blood transfusion subcommittee to see, and we were rescued by the Undersecretary letter.

Q. Right. As it turned out, Dr Foster did get to Groningen.

A. And two others.

Q. Yes. And plainly that was a key conference?

A. Absolutely.

Q. So on that, happily, the right thing happened and insofar as the much bigger question of potential liability for these products is concerned, again everything appears to have turned out better than you had feared in that there actually wasn't a comeback against you for any issue of these products?

A. Thus far.

Q. Right. Thank you very much, Professor Cash.

MR DI ROLLO: I have no questions.

THE CHAIRMAN: No.

MR ANDERSON: Sir, for my part I have no questions for Professor Cash arising out of the question of counsel for the Inquiry, but I understand that my learned friend Mr Johnston may have certain questions which may

involve, or may not, putting to him a couple of lengthy documents which were produced this morning.

I wonder in those circumstances, if it might not be more sensible for Mr Johnston to go first and then I can ask such questions as I think are either necessary or suitable thereafter.

THE CHAIRMAN: Yes.

Questions by MR JOHNSTON

THE CHAIRMAN: Are you going to be the proponent on this occasion, Mr Johnston?

MR JOHNSTON: I'm quite happy to be.

THE CHAIRMAN: I think rather than try to make Mr Anderson anticipate what you are going to ask, it would be better to hear from you first.

MR JOHNSTON: Thank you, sir.

Professor Cash, I just have a few questions, the first of them arises out of the supplementary statement you have just been looking at, which you may want to have before you again. It's [PEN0121909]. It's in relation to a paragraph you haven't been asked about, paragraph 1.03, where you explain that the directors sought clarification on who had the legal duty of care with regard to the safety of products and so forth.

Then you explain that this opinion was described by the CSA as preliminary and informal and confirmation was

promised and you say, to the best of your knowledge no CLO follow-up ever materialised.

What I wanted to ask you about was another document, which is [SGH0018906]. You should have there the report of the Blood Transfusion Service subcommittee in February 1982.

A. Yes.

Q. Have you seen this recently?

A. Yes, I have.

Q. If we just glance at it for a moment, you will see that in the first paragraph it said that it was agreed that steps should be taken to clarify the legal position of the scientific director at the PFC. And then number 2:

"Subsequently the views of the legal adviser were sought and he advised that the legal opinion is that health authorities in Scotland enjoy Crown exemption ..."

And so forth.

Then there is a reference later on in that paragraph to a circular, and then just reading on down paragraph 3:

"There is no doubt that the licence holder in respect of the licences which are held is the management committee of CSA. Another part played by the scientific director is that he has been designated in the licence

as the person who, on behalf of the management committee, is responsible. The legal adviser goes on to say that the primary responsibility is that of the management committee as licence holder."

Then just moving to the next sentence:

"On this basis, the legal adviser thinks it's inconceivable that the scientific director would face any prosecution under the Act for carrying out these duties assigned to him in a reasonable and competent manner."

And so forth. Then finally:

"This opinion has been discussed at a meeting attended by the Convenor, the National Medical Director, the Scientific Director ..."

And so forth:

"... when it was concluded that the assurances given by the legal advisers were satisfactory."

I just wondered if in light of that document, do you wish to qualify what you put in your supplementary statement to the effect that you never did get adequate legal advice?

A. Well, no, is the answer. I'll explain why.

First of all, I confirm when we got the initial thing we said, "That seems okay", and as the weeks went by and we began to think about it, we, the team, began

to wobble about it and indeed, in due course we went back again, this time with not just the PFC director but the regional transfusion directors for the whole of the service, and there is plenty of bits of paper in the archives that confirm that.

The more we began to think about it -- and this became extremely important, not weeks later -- is that the management committee, as licence holder, which means manufacturing licence, is the legal point. If, in fact, the central government says to the management committee, "We are taking away -- you don't have to have a manufacturing licence, you are Crown immune," then what is the position? And I say this because that, we now know, was evident to the CSA as they were discussing this. It was evident to the department.

The real question is -- and I'm not a lawyer, sir, as you well know -- that if, in fact, the government decides it is the management committee as licence holder that is responsible, our view eventually, within weeks of this -- well, if there was no licence, you are not a licence holder, then who is actually responsible? Forgive me but that's very simple medics stuff about law, for which I apologise.

Q. Thank for that.

A. So having been content -- "Okay, that looks okay" -- we

began to get the wobble, and then a big wobble come January 1983, when we got a formal letter from the Scottish Office saying we are into Crown immunity, having been total, "No, no, no, you will comply fully with the Medicines Act," we were told this in 1975.

Q. I see. But I think, just looking at the paragraph I started with in your statement, where you said, to the best of my knowledge, no CLO follow-up on legal advice ever followed, on the face of that, that's incorrect, isn't it, because there was this follow-up that we have just looked at?

A. I would need to look at the -- I beg your pardon. An opinion was given and then there was, as I understand it -- it was such a long time ago -- there was a PS, "This is our preliminary view. We will come back to you later."

I may have mixed it up. I don't think so.

Q. Right.

A. And I apologise if I have.

Q. But I think we can see at the end of this document you have in front of you that you were at a meeting at which it was concluded that the assurances given were satisfactory.

A. Yes.

Q. That was the position at that time?

A. Yes.
Q. All right. I think we will leave that for the present, thank you.
One point I wanted to raise with you in your principal statement, which is [PEN0121912] on page 1923, this is the question where you were discussing the management of PFC.
A. Yes.
Q. The only point that I want to ask about is in 22.2, where you are suggesting that it's a failure by SHHD officials to address the issue that led to a number of avoidable management crises within PFC.
I think before lunch you saw the document that explained the lines of management for PFC and various others including yourself. I just wonder, against that background, what is it that you were expecting SHHD officials to do?
A. Oh, I was expecting them to use the management structure that worked.
Q. Well, I think we have seen that the PFC was within the CSA, so was it not properly an issue that you should take up in the first instance there?
A. Oh, I did, okay? I did.
Q. You did?
A. And they passed it on to the department.

Q. What did you actually ask? Are these specific requests for anything or just general --
A. I think you have seen the document. I wrote to Mr Mutch, the secretary of the CSA, because we began to think about it --
Q. I see. So that's --
A. Yes, and saying, "Look, we need to get a decent line management structure, if we can do that." And I'm quite certain there are documents in which Mr Mutch touched base with the chaps in the department and then came back to us.
Q. All right. So that's the document we should have in mind when reading this paragraph?
A. Certainly, yes, indeed, sir.
Q. All right, thank you. There are just two other documents I want to touch on briefly. The first of them is [SGH0034925]. Have you had a chance to look at this document recently?
A. About 1 o'clock this morning.
Q. I see, that's quite recently. I don't want to take you into the detail of this at all but we can see what you are concerned with is writing to the Scottish Home and Health Department, Dr Moir, and you are commenting on the Medicines Inspectorate activities and their impact on Blood Transfusion Services.

A. Could I come in and say that there was -- and this is a matter of record -- that in the first tranche of medicines inspectors and the first dummy runs into the regional transfusion centres, the Scottish Office colleagues took grave exception to what the medicines inspectors were up to.

We have not actually mentioned it in the prisons episode. We got a view that the medicines inspectors had no right to be making -- whether this is true or not -- no right to be interfering in that area. And the really contentious area for the medicines inspectors for our regional transfusion centres was the area of the quality of the plasma we were picking up from individuals, whether they were from prisons or whatever.

And our mates in the Scottish Office said they have no right to be there, and I huffed and puffed. And the man who communicated this to us was Boyd Moir, a first-class bloke.

And eventually -- I huffed and puffed and eventually Boyd wrote me a letter and said, "All right, John, can you actually provide me with just a draft of where you think the inspectors then should be interfacing with the whole picture in the regional centres." And this letter -- I just want to fill this in -- was a response to a request, and it wasn't in any way attempting to

say, "must" or "thou shalt". It was just, in fact, a list of areas of activities that I guessed from my experience and from our interface with the inspectors, were legitimate, okay, in the debate about what should be done. And ultimately this finished up with money, ie if you can't do that, then it put pressure on the department. So everybody's interest was appropriate.

And this was me simply saying as a professional, "If you want to know, I think they should be in that area and that area and that area". When I say "should be in", they don't take control of it. They are coming in and inspecting against specifications and saying "good" or "not so good" or "bad". That's all.

Q. I suppose the consequence of their inspecting and saying "not so good" is that they make a direction which will lead ultimately to money being provided by you?

A. Exactly. So Boyd Moir, whom I knew very well, very legitimate saying, "Well, look, let's look at the worst case scenario. Where do you think they should be because this is of huge interest to the treasury and goodness knows what". Absolutely right.

Q. So in essence is it fair to say your notion, as we see it set out in this five-page letter, is that the Medicines Inspectorate should have a pretty broad role to play, which would involve making recommendations in

many areas of interest to --

A. Wherever I felt, and that's -- I should add that historically -- this is very historical -- by 1988 all this came to pass.

Q. Right.

A. Okay? So it's a little bit boring in that sense.

Q. Yes.

A. But, yes, I simply said, "Look, from my professional point of view, those are the areas". And as I have said before, medicines inspectors have no control like that. They are there -- they first of all advise the CSM and they come up with suggestions, they can close a centre or -- if you are really -- you know -- I mean, really bad. But they are not controlling, they are actually -- and as we will see later in the Inquiry, the problem these guys had, the medicines inspectors, they didn't have a book, a little red book, to say, "Show me this and I want to just see". They knew nothing about blood transfusion. And as a consequence, in 1988 we began the Red Book, which emerged, published in 1991. So the inspectors could now go around and audit the place. That's all they are entitled to do.

Q. I see, right. But as I said before, the effect of an audit by them is that you --

A. No question. And I understood very well that if the

people who are writing the rules upon which they -- in other words, the specifications on which they will inspect -- are the very guys in the regional centres, I could well understand people in the departments of health -- it wasn't just in Scotland because I went down to see Dr Hilary Pickles and talk about all this, and she said, "You are like turkeys, you lot, writing dossiers against Christmas". And she said, "We can't have, in the Department of Health, doctors, professionals --" they are actually technical scientific staff -- "writing prescriptions for more money. You are out of control." So I understood the problem. Eventually it was resolved.

Q. So in essence that makes the point I was trying to suggest to you. The advantage to you is the Medicines Inspectorate would give some legitimacy to the prescription you wrote to yourselves and that is probably why the department was less keen on this?

A. The advantage to me, as national director, I could sleep at night. To the Brian McClellands of this world, actually running a ship with a team down there, hugely important, every day.

Q. Okay. Could we just go to the last page of this letter, which is the fifth page? Skimming over the various points of detail, which you have suggested it would be

appropriate that might be covered by the Medicines Inspectorate, and then you enter into a section called "How do we cope?" Then you set out various problems as you see them. Just looking briefly at the last paragraph of the letter, you say you have just re-read it and you wonder whether it's a bit too hard, and you then make some points about management. Then you say tomorrow you will have the courtesy to convey your sincere thanks for the genuine efforts that colleagues are making. I don't suppose you remember whether you did do that the next day?

A. I don't remember, but what I can tell you for sure is that this man, Dr Boyd Moir in the Scottish Office, played a major role -- I'm not sure if he recognised it but he did -- in the creation of the red book and the specifications. He played a huge role. So I can imagine that the Scottish office might have been very distressed by this letter of mine, as you say, for the reasons of funding, but in actual fact I discovered that Boyd Moir completely agreed with me and in due course, about two years later, he saw the opportunity to me to get on to the NIBSC board and begin to influence and change the whole scene.

So he takes a lot of credit and he is a civil servant. They are not all baddies.

Q. Interesting.

Just one last point on this letter. If we go right to the bottom of that page. I don't know if you recognise the handwriting. We are assuming that it's Dr Bell's handwriting. I don't know if --

A. I honestly don't but I have seen other things from Bert and it looks like -- but I honestly do not know. It is certainly not mine, it's far too good.

Q. No, it doesn't look like yours. If I read out what I think it says, if you could just tell us whether you agree with it. It says:

"There is a case [is this what he is trying to say?] for widening the scope of authority and extending the timetable to ensure priorities more rationally but as it is, the medicines inspectors have to operate the existing statutes within timescales. SHHD has no practical alternative but to order priorities by the existing rules."

Can you understand that as a sensible response by Dr Bell to the points you make?

A. Only that I don't know what the existing rules are.

Q. Well, the existing rules will be those set out in the legislation?

A. Yes, well, that's the legislation of what Act?

Q. The Medicines Act is the one that you have been

referring to --

A. Irrelevant to us, isn't it?

Q. -- throughout your letter?

A. Irrelevant to us. We are in Crown immunity.

Q. Do you accept that final sentence, that in practice all the department can do is order priorities by the existing rules; if the priorities are to be changed, then the rules will need to be changed?

A. Yes, (inaudible) I think.

Q. One last document then, which is [SGH0034922]. Again, I should say I only want to look at a couple of points in this with you, if I may.

You have there a memo addressed to Dr Moir and it's written by Dr Bell, as we will see at the end. You see at the beginning, it says:

"Dr Cash has sent me a copy of his letter to you of 1 June. I thought it might be helpful to me if not to you to record spontaneously some of my reactions."

We have, in the author's own words, a spontaneous setting out of the points that have occurred to him in reading through your proposals in relation to the Medicines Inspectorate. The only points I wanted to ask you about are on the last page, page 3, where, in the second last paragraph, he raises the question:

"What are the problems?"

And he suggests that the issues to be considered are being blown up into problems largely because of the attitudes of the SNBTS:

"No one would dispute the need to identify levels of appropriate priority but there are different approaches to this. Ours is to define closely those obligations which are inescapable because of their statutory force and which, because of that, can make legitimate claims for special financing."

I think one could read that as a reference, for example, to the funding provided in order to meet the upgrading suggested by the Medicines Inspectorate. Would you agree with that?

A. Yes, sure.

Q. Dr Bell goes on to say:

"Personally I would not necessarily accept that some matters covered by the application of the Medicines Act need take precedence over other developments, such as the heat treatment of Factor VIII, which, in terms of public need, are possibly more urgent."

Would you agree with Dr Bell on that?

A. Absolutely.

Q. So is it fair to say that -- well, we saw this morning a great disagreement in funding in relation to the Medicines Inspectorate and then we saw that heat

treatment came to be treated separately. Ultimately, did you and Dr Bell differ much on the priorities that were important at the time that we are looking at?

A. I have a problem in responding. First of all I have read this document from top to bottom very carefully, although it was rather late at night, and you may be surprised to know, as I think I alluded to earlier, that Bert Bell -- if any of the directors were here today and had read this document, they wouldn't believe it. I can assure you of that. Bert Bell was highly regarded. He was very much one of the team, although he was in the Scottish Office. He was immensely supportive. He was an absolute rock in a very difficult period.

He is the only civil servant that I have worked with that, when he retired, we had a dinner, all of us together, to wish him well on his retirement, and that night Bert Bell said some really very nice things about us and I like to think we reciprocated.

You have raised just a sentence. If you look at the whole of this document, I actually must tell you I can't believe that Bert wrote it. I mean, it sounds silly. There are attitudes, there are accusations, there are silly things like -- they are just misinformation.

But, I mean, the attitude of hostility that comes out in this letter is extremely worrying and, I find,

very distressing, and for me -- and I'm being very specific -- it's one of the most important documents in this Inquiry I have seen so far because it reveals some fundamental problems that we all had. I have never had a problem -- and you have just alluded -- you said that we -- he says we blew it all up. I mean, we didn't. And indeed, as I have said to you, if I take you just four years later, everything that Bert is worrying about -- platelet concentrates versus penicillin, do you remember, in the first paragraph? He is wrong. And the one guy that knew that in the Scottish Office was Boyd Moir because Boyd worked with the NIBSC.

So we never had a problem with Bert. That's the awful thing. I have to tell you of that. And all my directors, if you mention Bert Bell, "Oh, those were the days." If you read this letter -- well, I can't believe it. So your question, did I have a major disagreement? No. Did he always deliver what I wanted? No, because he has a job to do.

Q. All right. I was trying to avoid going into the ins and outs of this memo but it seemed to us --

A. I think this document is --

Q. -- important for you to see it?

A. This document is sick.

Q. Would it not be fair to say you characterised the letter

we looked at a moment ago as a cri de coeur, where you were --

A. Yes.

Q. -- perhaps unburdening yourself of the issues that you were bothered about. Could one not say the same of this from Dr Bell's perspective?

A. It was, yes. I would have to say that if this document had a different signature on, another medical person in the Scotch office, I would have said, "Yes, yes, that's what you would expect." But not Bert. He was a man of great integrity as far as I was concerned and I'm astonished that if he was really thinking these things, some of it didn't in fact, you know, trickle through to me in some way. But it didn't.

Q. But in fact it didn't?

A. It honestly didn't.

Q. All right, thank you very much, that's all I wanted to ask you.

THE CHAIRMAN: Mr Anderson?

MR ANDERSON: In the event, sir, I have no questions.

THE CHAIRMAN: Do you have any follow-up?

MS DUNLOP: I don't have any further questions, thank you, sir.

THE CHAIRMAN: Professor, thank you very much.

A. Thank you, sir.

THE CHAIRMAN: Are we seeing the professor again?
MS DUNLOP: Yes.
THE CHAIRMAN: So it's au revoir and not good bye.
Yes, Ms Dunlop?
MS DUNLOP: I have no further witnesses lined up for today, sir, so it's tomorrow morning with Professor Ludlam, and I should say I'm anticipating that that will be fairly brief as well.
THE CHAIRMAN: Well, I might hope it would. You may have noticed that I'm not at my best and if I deteriorate further, I'll need a very short day.
MS DUNLOP: We will aim to deliver on that, sir.
(3.11 pm)
(The Inquiry adjourned until 9.30 am the following day)

I N D E X