Friday, 13 May 2011

(9.30 am)

THE CHAIRMAN: Good morning. Yes, Ms Dunlop.

MS DUNLOP: Sir, we have Dr Perry with us again today. Dr Perry has provided a statement on topic B2 and it's [PEN0160460].

DR ROBERT PERRY (continued)

Questions by MS DUNLOP (continued)

MS DUNLOP: Dr Perry, you begin by talking about self-sufficiency very generally. If we can look at page 2, please, you say that:

"It was accepted that prescribing doctors were free to exercise their own judgment in the choice of either SNBTS or commercial products, preserving the important principle of clinical freedom. Whilst SNBTS and haemophilia directors collectively embraced the goal of self-sufficiency, the use of NHS products was not and could not be enforced by SNBTS."

So I think what you are saying is the bottom line was that if doctors preferred commercial products they were free to use them?

A. Yes, that was certainly very much my understanding at the time, that, although there was this goal of self-sufficiency and there was strong encouragement, I think that the principle of clinical freedom was at

that time really quite a sacred principle that was respected by all parties, I think.

Q. You were speaking as at your arrival in the early 1980s?

A. Yes.

Q. What about --

THE CHAIRMAN: Where did the principle come from?

A. I think this was quite a widely practised principle amongst the medical profession. I think also there was an important acceptance, even at that time, that the manufacturer of the medicine shouldn't be closely involved in specific decisions concerning treatment of patients because that would create a potential conflict of interest, and where the principle of clinical freedom came from, I'm sorry, I probably can't enlighten you too much but it was certainly very prevalent then.

THE CHAIRMAN: Already your answer has complicated the situation by bringing in additional dimensions. I can well understand that the clinician in actually carrying out clinical work could assert -- and it might only be an assertion -- that it was essential for the patient/clinician relationship that the clinician should have complete freedom as to the decisions he took and of course with it, the accountability that complete freedom implies.

But before it can become an aspect of general

practice, it has to be accepted in some way by others and there may be limits that have to be drawn. And in this case I would be very interested, and will be in due course, to know the attitude of government in Scotland to this principle, since from what you have said already, clinical freedom could cut across government policy. So that's one thing we have.

The next element that you have introduced is an assimilation of the position of the national producer with the position of commercial manufacturers and producers of products. So immediately one has a more complex situation emerging.

My role is to try to find out what the reality was, Dr Perry, and I'm not sure that simply saying there was a principle of clinical independence or autonomy, or any of the other expressions we have used, takes me terribly far unless I know the basis on which it was done. Can you help or did you just inherit it?

A. Clearly I just inherited it and whether I can help we will see soon. It was certainly the case that the Scottish Home and Health Department were very strong supporters and proponents of self-sufficiency, that's recorded in a number of discussions, in a number of documents, although the absolute clear policy statement is a little bit elusive.

What they consistently fell short of was demanding that haemophilia doctors would use NHS products, and I think there are a number of references from memory in, certainly the meetings between SNBTS and haemophilia directors, where there was an acceptance that doctors should be free to prescribe products in the best interests of their patients and they wouldn't wish to change that principle.

I'm not sure that takes us forward but that was very much the prevalent position. So my job as a manufacturer was to seek to persuade our colleagues in the haemophilia community that our products were suitable, they were acceptable, there was a reliable supply, so it was a process of persuasion, not a process of instruction.

THE CHAIRMAN: That's something I will have to look at quite closely in your report.

A. Sure.

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Dr Perry, I put to you the proposition that if doctors preferred commercial products, they were free to use them and you agreed with that. I wondered what the position was if the patients preferred commercial products.

A. I think again, from my perspective as a manufacturer,

I don't think I can speak authoritatively on that particular topic.

Q. All I'm trying to get is your understanding of the situation which applied when you arrived in 1981. So the products you were producing, were they really to fill that part of the demand which was represented by doctors who were happy to use your products and patients who were happy to? So if the patients had wanted commercial products, they wouldn't have been using yours. Is that your sense of it?

A. My sense of it when I arrived in SNBTS was that the role of this relatively new centre then in 1981 -- it had only been opened in 1975 -- its job was to meet the demands in Scotland for all plasma products, including Factor VIII, Factor IX, albumin, immunoglobulin and so on, and as I have said on a number of occasions, certainly not within the Inquiry, but self-sufficiency as it was well-known at the time, although perhaps ill-defined, was the only game in town and our job was certainly not to interface with patients but to do everything we possibly could to provide a supply of products for treating patients that were acceptable, obviously to the treating doctors but also to the patients; but we didn't have, as a manufacturer, any direct relationship with the patients. I think that

would have been seen as quite improper.

Q. Right. Just to read on through your statement, you were asked, as were a number of other witnesses, about specific snapshots in the unfolding history in the early 1980s. One of those is the UKHCDO meeting of 13 September 1982, and we do have a note which looks as though it's your note of that meeting. It's [SNB0017431]. Do you recognise that? Does that look like something that you will have prepared?

A. Perhaps if I can see the content, yes.

Q. I suggested to others that sometimes we can tell from the typeface. This looks like a sort of typeface that I have seen on documents for which you were responsible.

A. It could be.

Q. Right.

A. It could be but it might be helpful to see the content.

Q. Certainly. Look at page 3 of [SNB0017431], which is actually the first page of text. Whoever prepared this note has recorded that they were writing down matters of relevance to PFC. There's a bit of mention of preliminary issues and then number 3, the hepatitis working party. We know that Dr Craske presented results of that study that he had been conducting, quite a small study, but if you read on to the following page, 7434, if it's you, you have written a table, drawn a table,

and we can see from the table that from those who had had no previous concentrate, a total of nine people, when they had their first concentrate, all nine of them got non-A non-B hepatitis?

A. Indeed.

Q. You have done a little symbol beside the nine and a note underneath saying:

"Seven out of the nine received NHS concentrate."

A. Yes, my answer to your first question is my best guess, that this is not my document.

Q. Oh, right.

A. And I don't recall attending the meeting. That doesn't mean to say that I wasn't there, and the reason I say it doesn't look as though it's my document is that by the time of that meeting I had only been in post about a year and I think some of the quite complex technical issues that were being discussed here seem to have been very coherently presented in this report, and that may not have been the case had I written the document. I'm not trying to deny any knowledge of it but I don't think this is a report written by myself unless you are going to come on at the end and see my signature on the bottom.

Q. No, we don't have that but I think you were there actually.

A. Okay.
Q. But I don't think anything turns on this, Dr Perry. I was just going to say that if it had been your note, you haven't noted down anything about AIDS. There was a discussion of some sort about AIDS at this meeting but I rather suspected that the person who wrote this note had felt that it wasn't covered by the introductory statement that this note is on matters of relevance to PFC.
A. Okay.
Q. If you didn't write it, you certainly won't remember --
A. It doesn't look like the style in which I would have presented the data with the paragraph numbers, with the margin and so on. It doesn't look like the sort of structure I would have taken for the report but, as I say, I can't be sure but it looks to have much too high a level of really quite technical scientific content for me at that stage in my career in blood transfusion to have competently written.

I think there were probably other people from SNBTS at the meeting. It could well have been written by Dr Foster, for instance. I don't know whether he was at the meeting.

THE CHAIRMAN: Could we see the previous page just briefly?
MS DUNLOP: Yes, certainly. 7433. We listed in the

preliminary report those who attended from Scotland and they were Dr Boulton, Dr Forbes, Dr Ludlam, you Dr Prentice, Dr Sharp and Dr Vosylius. It is not Dr Boulton's note because we have his note as well.

A. No.

Q. That was why it seemed likely that it was yours but it doesn't matter. It was a long time ago, Dr Perry.

A. It is a long time ago and I'm sorry, I can't with any authority remember whether it is my note. It may have been.

Q. Can we go back to the statement in that case, please? That's [PEN0160460] and now that we have mentioned the meeting of September 1982, we can go on to the third page. You have made some general comments about the situation as it stood at that time and you have referred on page 3 to the stated SHHD policy for self-sufficiency. Do you see that reference? It's almost three quarters of the way down the page. This is obviously something that we can ask Professor Cash about and I plan to do that. He is obviously coming today as well.

A. Yes.

Q. But since you have made a brief mention of this already this morning, I just wondered what your recollection was of any formal statements of policy?

A. Well, certainly at that time, I think as a number of other people have suggested throughout the course of the Inquiry, there is no defining moment where a clear policy comes out of the Scottish Home and Health Department that we can, should and will be self-sufficient.

However, there are policies and there are quite clear statements in which both the UK Government and I think SHHD embraced formal statements by bodies such as the World Health Organisation, which stated quite clearly that countries should strive for self-sufficiency in blood and blood products. And I think from memory it wasn't until the late 1980s that a clear statement -- or the mid 1980s or the late 1980s -- that the Scottish Home and Health Department made a very, very clear and unequivocal statement.

I haven't got the reference for that or the detail but I have certainly heard that in discussion with people like Professor Cash that it took that long.

In the meantime, certainly from the perspective as a senior manager in SNBTS, there was absolutely no doubt in my mind, and certainly in the minds of the staff that worked with me, that for all practical purposes self-sufficiency was what we had been set up to deliver and achieve, and indeed there were a number of

references in regular meetings of haemophilia directors and SNBTS directors at their annual meetings, where the importance of self-sufficiency and using NHS products whenever they were suitable and available, was certainly the goal for the Scottish Health Service.

Q. Right. We then asked a question which has been superseded, about who attended various meetings, so we can move beyond that on to the following page, and this is in relation to Dr Galbraith's recommendation to cease importation of American commercial products. You haven't found any evidence that SNBTS directors were aware of the recommendation or its rejection and you go on to say you are not aware of any discussion taking place in SNBTS or SHHD in response to this information:

"This is not wholly surprising since SNBTS had no involvement in or responsibility for importation or use of commercial product. It is highly unlikely that SHHD would have taken a contrary view to DHSS."

I just wanted to ask you about that. Firstly, are you describing something that in practice happened, that SHHD tended to take the same line as DHSS?

A. On this specific topic, I think the whole issue of commercial importation -- this is a licensing issue.

Q. Yes.

A. This is a product licensing issue and product licensing

matters at that time, and still, are based on a UK-wide body, which is now called MHRA, and I'm unclear of any mechanism, any practical or realistic mechanism that SHHD could have used to have taken a contrary view to DHSS. We talk about the DHSS/MHRA but in fact it is a body -- I think the licensing body itself -- I think I'm correct in saying this -- is composed of UK Health Ministers, and that's ministers from Ireland, Scotland, Wales and England, and it's enacted through a secretariat basically, a expert group that happens to be based in London.

Q. Fine.

A. So I can't think of a mechanism where SHHD could have said, "We wish to revoke or remove the licence for these products because we think they are unsafe". They would have been party to the decision that was taken on a UK-wide basis.

Q. Right. I understand the point you make and that relates to the formal situation. I suppose, though, there might have been the possibility of a line, perhaps in a letter from the chief medical officer for Scotland or something like that. I wondered if the comment you are making here went so far as to say that there would be nothing coming from SHHD which differed in any kind of policy sense from what was being said in DHSS. Is that also

the case?

A. I understand the question. Again I can't remember any significant issue where a particular view was taken by DHSS on a very specific topic, such as whether a product should be licensed or used in the UK, and SHHD or the chief medical officer issuing a statement which contradicts the view taken by the DHSS or the CMO in England.

I can't remember any instance of that taking place but theoretically it would have been possible for SHHD to have issued an instruction or a recommendation. It would probably have had to have been a recommendation that, "We no longer wish to use these products in Scotland". Because that would have been contravening the UK licence, and I think that would have created all sorts of difficulties in legal terms and anticompetitive behaviour and so on.

Q. Just thinking in the generality, though, there could on occasions be scope for a different line being taken in Scotland if the situation on the ground was different in Scotland.

A. Sure. Yes.

Q. But in practice you think that that, at least in this context, would have been unlikely?

A. In practice in this context I think it would have been

very unlikely from where I stood. I would have been very surprised to have found SHHD taking a contrary view to DHSS. Whether or not SHHD were aware of the letter from Dr Galbraith and had a separate discussion, which led them to a conclusion which was similar to DHSS, I really don't know.

Q. Just to speak not in the general but in the particular, the different situation on the ground in Scotland, in the early 1980s, was that there weren't the same problems of supply. So if the line in DHSS was being influenced to some extent by shortage of product, NHS product, that would be a condition that wouldn't apply in Scotland, or at least not with anything like the same force.

A. Indeed, had the UK been close to self-sufficiency then there may well have been a different outcome because, as I understand it now, Dr Galbraith was suggesting we cease import of US products and that proposal was rejected on the basis that -- I think it simply says on grounds of supply: that if that were to happen, one would have to wind back all the progress that had been made in terms of home therapy and improved treatment for haemophilia. But I would agree with your proposition that had the wider UK been closer to a degree of self-sufficiency, then it would have been, I think,

a more realistic proposition to have enacted that.

But again, it would have been a licensing authority decision.

Q. You go on to make mention of increasing recognition of the possible causal relationship between AIDS and US commercial products and you conclude that section in which you have discussed the possibility of a ban, which we know didn't happen. You then answered a succession of questions, some of which aren't really relevant to you because they are about clinical treatment of patients. You didn't go to the meetings in Karolinska. On to the next page, thank you.

Do you remember Mr Watt circulating documents round PFC, perhaps copying particular pages he wanted people to read and annotating them?

A. Yes.

Q. Do you remember that?

A. Oh, yes, it was one of the major means of communication.

Q. Right.

A. And very effective in some ways.

Q. Do you remember it particularly in association with this topic, the topic of AIDS and blood products?

A. I don't remember anything specific from that particular topic but it is quite likely, if Mr Watt had been at that meeting, he would have communicated some of the key

outcomes; if there was a report, then he would have annotated it and I would have probably seen it and I don't recall.

Q. You go on to talk a bit more about the Committee On the Safety of Medicines and you tell us in the paragraph beginning, "at this time ..." that Mr Watt's membership was in a personal capacity rather than a representative role of the respective organisations or countries. And the proceedings were conducted under strict confidentiality.

I just wondered if you could explain to us so that we have a complete grasp of what was at stake, the meeting on 13 July 1983, which was considering Dr Galbraith's suggestion that the import of products from the United States should be banned. So there is this proposition that the licence for particular products should be withdrawn because they aren't safe or safe enough. How does confidentiality bite in that context?

A. Well, again from my own experience of sitting on the Committee on Safety of Medicines, I think the confidentiality requirement of all those attending the meeting was an umbrella for all activities and all discussions. I think it applied to -- this would have been an unusual meeting for the Committee On the Safety

of Medicines because their primary goal was to receive licence applications from individual manufacturers, large dossiers of information, and the committee would then discuss whether or not, on the evidence presented, these were suitable for licensing. This was a more policy issue. But certainly from my own experience I think the meeting was always introduced by the chairman and in introducing the meeting, he would certainly emphasise the importance of confidentiality.

I can't remember whether we had to sign on a regular basis that that was the case but we were certainly in no doubt as members of this committee that these discussions were between those four walls and the content of the meeting shouldn't be shared outside it.

Although I wasn't at the meeting obviously, I think that would have applied to this meeting as well. I think primarily for the reason that the committee would have taken the view that any discussion concerning the possibility of withdrawing licences of commercial organisations had a very major commercial component, and was not a matter for discussion outside its committee.

Q. Obviously you can contribute some insight here because you served on the committee between 1986 and 1990?

A. Correct, yes.

Q. Effectively replacing Mr Watt?

A. Yes, I think there was a gap -- I think Mr Watt retired in 1986 and I was asked to participate in the meeting. I don't think it was a direct replacement but I think there was always a wish on the committee to have a reasonable territorial representation from the different parts of the UK and I was seen as somebody who knew something about fractionation and plasma products. So it wasn't a direct replacement.

Q. Indeed Mr Watt had continued to sit on the committee even though he was no longer at PFC.

A. He did.

THE CHAIRMAN: Was membership of the committee published?

A. Yes. My understanding is that although there was no such thing as the Internet then, it would have been in the public domain who actually sat on the committee and what the secretariat was. How easily it would have been able to get that information I'm not sure, but it certainly wasn't a secret.

THE CHAIRMAN: I have some knowledge of committees that are admitted to exist but the membership is kept strictly secret in order to avoid lobbying or any possibility of indirect influence or pressure. It wasn't like that?

A. My best understanding is that the membership was in the public domain, although the discussions were clearly and very explicitly felt to be confidential.

MS DUNLOP: I suspect you now know, Dr Perry, that Mr Watt was at the meeting of 13 July 1983.

A. Yes.

Q. That information has filtered through to you?

A. Absolutely, and indeed, just following on your statement, I certainly have no recollection of Mr Watt coming back and briefing either myself or anybody else on the nature and the content of the discussion.

Q. Dr Perry, you probably know this too, but in the end this is a Scottish Inquiry and we are not examining UK matters, and you said yourself licensing is a UK matter.

A. Sure.

Q. On to the following page, please. You have answered some other questions about international gatherings and your perception, having been around at the time -- and this is section 3.3 -- is that it is an accurate impression to say that there was a strong desire to continue using the products.

A. Yes.

Q. You say that in terms:

"Despite the uncertainty and often conflicting scientific opinion, there was a strong desire to maintain the level and quality of treatment offered by concentrate products."

A. Absolutely.

Q. I wasn't immediately sure what you were meaning but I think, in the following sentence, what you are really saying is there didn't have to be a choice between commercial or NHS concentrate because there was ample NHS material?

A. I think that was the clear implication.

Q. Yes.

A. Unless there was specific patient-related requirements for a different product to that which was supplied by the SNBTS, and I think we have heard from people far more expert than I that occasionally individual patients may have an idiosyncratic reaction to a particular product, in which case the NHS product is not going to be suitable so an alternative would have had to have been found in that circumstance.

Q. Yes. Can we move on to the next page, please?

I wanted to ask you one or two questions about supply, Dr Perry. This looks to have been something you investigated in 1983 and 1984, supply and stock?

A. Yes.

Q. Can we have a memo, [SNB0073984], please? We have looked at this already this week, Dr Perry.

A. Yes, I remember it well.

Q. Good. What led to it?

A. I think at that stage my responsibility was still for

quality management and so on. So I did not have a direct role in stock control and so on. That wasn't part of my brief but it was a fairly small team in PFC with the knowledge that self-sufficiency or meeting the needs of the NHS in Scotland was a primary objective. I can't remember exactly what led to it but I remember in the course of signing batches off for clinical use, which was part of my role, I noticed that we seemed to be having an extraordinarily high throughput of Factor VIII in particular and other products, and I then in conjunction with the then production manager, Mr Grant, decided to do a little more detailed analysis. Primarily from the point of view that if stock levels became too high, then product would outdate because the shelf life was only two years. So if you had more than two years' stock you were inevitably making product which was never going to be usefully used.

I can't remember the exact process I used but it was basically using data collected by the production manager, and I thought this was of particular interest to the SNBTS because at that time we were still, I think, issuing product on what I recall was a system called a pro rata system, in which regions of Scotland got back product in proportion to the amount of plasma that they issued. It was my view at that time that (a),

we had more than enough product in Scotland to meet effectively the unconstrained needs of the haemophilia population in Scotland. We had very large stocks, which were growing. But also, with the knowledge that there was a very substantially less degree of self-sufficiency in England and Wales, that there was an opportunity to provide some of this surplus product, which I perceived it to be at the time, to colleagues in England and Wales.

The objective at this time -- certainly in my mind, and of colleagues -- was basically every bottle of product that you could supply, made from UK or Scottish donors in our case, prevented the requirement for importation of product from the US. I think generally the view was that if we did from time to time have a surplus in Scotland, then it was our duty to offer that to wider UK colleagues.

So this was basically doing the sums and making this proposition to the SNBTS, that we had very, very large and substantial stocks and it basically led to the sort of actions that I have described.

Q. Dr Perry, even coming to this topic cold, as it were, as most of us have, one doesn't need to think for very long before realising that there must be quite complicated issues involved in stock of blood products, more

particularly where the stock sits, how much stock should be in each place --

A. Yes.

Q. -- down the supply chain. And by how much stock, I mean in terms of how many months' supply.

A. Yes. Absolutely.

Q. Did PFC have experts on these sort of questions or was it more sort of trial and error?

A. I wouldn't describe them as experts. It was nominally the responsibility of the production manager reporting to the director to manage stock and issue to customers basically. But you are absolutely right, the complexities, I think as evidenced by some evidence that has been given this week to the Inquiry, that there is a reconciling the stock figures against the various data sets that are available was quite difficult at the time, and even within PFC, when you asked what is the stock level within PFC, it's a simple question but often used to give rise to a very complex answer.

I think in this memo I refer to the sausage machine and that implies that the manufacturing process for Factor VIII probably takes, from plasma being entered into process on day one, the product probably doesn't get released for another four months. So at any point in time, the Factor VIII product is at various stages of

release and testing and so on. The stock figures that are often quoted as PFC stock only relate to the product that was held in the warehouse, which was immediately available for clinical use, ie had been released, had been labelled, had been signed off and was ready for dispatch.

But often, certainly during the early 1980s, there were problems of that. We had warehousing problems. We had limited cold storage. So in a period of high productivity, for instance, the sausage machine -- the plasma would still be going into process and through this period we can see that the level of plasma being processed was massively increasing, but we didn't have room to accommodate the product in the finished product cold store at 4 degrees and therefore the intermediate product would build up as a high stock, which was close to the point of being ready to use but wouldn't have actually been entered into finished stock figures.

So one has to exercise extreme caution when we looked at stock figures. We had to then. We were looking at the whole picture and often, for strategic planning purposes, if you were looking at stock and requirements for plasma and so on, you would look at the entire contents of the sausage machine, and that, in fact, is what I'm doing in my memo of November because

there I say there is 7 million units at various stages of processing.

Q. Yes.

A. In addition, as we know, there was stock held at regional transfusion centres, which were effectively the retail outlets for our products. They were the interface with the haemophilia doctors. They supplied the product. So even for a small organisation like SNBTS, you are absolutely right, the whole business of maintaining stocks and controlling stocks and so on was fairly complex and it wasn't computerised.

THE CHAIRMAN: Dr Perry, I'm not sure about the complexity. Branch stock control is not unknown in the commercial world, but I wouldn't have thought it was possible without proper returns and records.

A. Yes.

THE CHAIRMAN: Was there a recording system in place?

A. There was.

THE CHAIRMAN: Did that extend to stocks at the local RTCs?

A. At the regional transfusion centres? In all honesty I don't think the formal system of managing stocks within PFC extended to the regional transfusion centres. It was very simple because we only had five stock centres, which were in the major cities of Scotland. Certainly the reports that I used to see at the time

concerned primarily the stocks held at PFC.

THE CHAIRMAN: Do you have any recollection of stock reconciliation exercises being carried out that would be comprehensive in the sense of including RTCs and stock in the hands of patients?

A. Yes, I think, certainly when I became director in 1984, and of course I would say this, I significantly extended the whole business of surveillance of stocks to include RTC stocks because it was such an important area of stockholding, particularly when we introduced the batch dedication system, for instance, in 1985. That required a significant outposting of stock from a central location in Edinburgh to the individual centres that were feeding the needs of the haemophilia directors.

THE CHAIRMAN: Perhaps we should take it chronologically and Ms Dunlop has not come to that point yet.

A. Sure.

THE CHAIRMAN: But is it implicit in that you found deficiencies in the stock control system when you took over that position?

A. Well, like yourself, sir, I thought that in order to plan the levels of production and the levels of plasma and so on that were required, it was necessary, when looking at stock, to look not just at the stock which was held in PFC but also the stock that was held in the

regional transfusion centres, because that was ultimately all SNBTS stock. So in the reports that I subsequently used to give to directors, it always included the total stock, which included the material held in the so-called retail outlets for SNBTS.

MS DUNLOP: Dr Perry, will there have been notions of what number of months' stock needed to be held in each place? I'm not asking you to remember what they were but you used the term "surplus" so you would be thinking presumably, "We need to have a year's stock or something at PFC", and you would work out that you had more than that. Was that how it operated?

A. Yes.

Q. You did, I think, at this time, prepare some additional documents. One of them is [SNB0073985]. Actually we have been told this is Mr Grant's writing, not your writing.

A. Yes, that's correct. Yes, I believe it is, yes.

Q. If we turn to the next page of this document, this being a document dated 4 November 1983, we can see that there is a note of the stock that was then held in the regional transfusion centres, the five Scottish centres and Belfast.

A. Yes.

Q. That seems to link back into the content --

A. Indeed, and I think this is part of the exercise that I carried out, with significant assistance from Mr Grant, because it was at that point that I thought it was important to find out what the regional transfusion centre stock was. So, yes, this is an early example of capturing stock levels from regional transfusion centres.

Q. Quite interesting to see the Glasgow figure of 900,000 units.

A. Hm-mm.

Q. If we just follow this on a little bit in time, can we look at [SNB0015252]?

This, I think, has a reference to the amount of stock held in Glasgow, at least I'm hoping it does. Can we scroll through it, please? This is 2 February, 1984. We see paragraph 5(i). There is a discussion of the amount of production. If we can go up a little bit, please:

"Trends over the last five years indicated that the SNBTS production of Factor VIII concentrates may be exceeding clinical demand in that current stocks at regional transfusion centres appear to be increasing."

A. Yes.

Q. That certainly seems to have been a perception in the spring of 1984. Then if we look at May 1984, which is

[SNB0074393]. This is one that gives quite a startling figure.

A. Yes.

Q. You have obviously seen this recently too, have you?

A. I have indeed, yes. Yes, I remember it from the time as well because ...

Q. It would be good if you just told us what you remember.

A. Oh, I just remember, as it indicates, this was fairly soon after me taking over as acting director of PFC, and one of the first things that I thought it was necessary to do was, given the, at that time, really quite secure position in terms of product supplies, it seemed to me that we needed to review or we had the opportunity to review the so-called pro rata system and simply issue product in relation to what was required in different regions. We didn't have to have this relationship, in terms of the product we received, we didn't have to have that as a relationship with the plasma that was entered.

So this was part of a process of really speaking to colleagues, and Donald Hopkins was the consultant who was in charge of these stock control aspects in Glasgow, and I asked him for basically clear updated information on what the stock levels were, and I remember, when I got this letter back, following the phone call, I was really quite shocked, surprised and to an extent

delighted that we had so much outposted stock which gave us a great deal of flexibility in terms of planning. It was a very significant piece of information and certainly the stock level in Glasgow was much higher than I would have thought it would have been.

Q. Yes, and enabled you not just to make your forward plans but also to give some of it to patients in England?

A. Oh, absolutely, absolutely. So this was all part of the process of saying, "Look, we don't have to divide up the available product in Scotland according to either a population basis or a pro rata input of plasma, we can simply do it on the basis of clinical need". And I think it was very early in 1984 that we abandoned the so-called pro rata system and simply issued to regional centres on the basis of minimum stock levels.

So we created a fairly simple system which involved regular reports from the regional transfusion centres on a monthly basis, what their stock levels were. We established what the minimum level was and we would then issue on a monthly basis product to ensure that they were always at or above their minimum stock level.

THE CHAIRMAN: Could we look up to see where Dr Hopkins was situated.

MS DUNLOP: He was at Law as well.

A. He was at Law.

THE CHAIRMAN: Do you understand that these returns included the Glasgow Royal Infirmary.

A. No, these just included Law BTS. So to the best of my recollection, these particular returns only included the material held by the SNBTS and the Glasgow Royal Infirmary was basically blood bank stock. So there was a further depot, but I think for practical reasons they didn't hold large quantities of product, but significant quantities. Because if Glasgow Royal Infirmary needed a quick delivery of product, it would be a very simple matter to get it from Law to the Glasgow Royal Infirmary.

MS DUNLOP: We have heard reference, Dr Perry, to a daily order form going from the Royal Infirmary to Law.

A. Hm-mm.

Q. You probably don't recollect very much about what the practical arrangements were.

A. No, except that, because it was issuing blood as well, there was transportation basically shuttling between the centre at Law and the major hospitals in Glasgow. So it would have been perfectly simple and appropriate to issue on a daily or a weekly basis but I'm not sure of the detailed arrangements they had for transferring stock from Law to the Glasgow Royal Infirmary.

Q. Yes. Certainly, as far as concentrates are concerned,

that does sound slightly different from Edinburgh, where Professor Ludlam made reference to the van coming monthly. Do you remember that?

A. Yes. I think what he is referring to is the PFC van.

Q. Yes.

A. Actually it was a lorry and I think, again in the early 1980s I think it was a sort of monthly trip where the van would collect the plasma from the regional transfusion centre on a monthly basis and it would also have a compartment in the van for delivering the products because they were temperature-controlled product.

So I think the deliveries to regional transfusion centres were roughly on a monthly basis. I think subsequently we reviewed that and I can remember a time where I think there might have been weekly deliveries because that was more convenient and required lesser regional stockholding of product.

Q. Did the same truck go to and from Law?

A. Yes, and Inverness and Dundee and Aberdeen. But the transportation from Law to the Glasgow Royal Infirmary was operated by the West of Scotland Blood Transfusion Service.

Q. For all the other centres was it the same convenience of exchange --

A. Yes, absolutely. It was there to collect the plasma and to distribute the finished product. If there was periodically emergency issues of a rare product or a shortage, then obviously we had arrangements where vans could be sent up to any part of Scotland and product delivered, but the standard system, I think, from memory, was roughly a monthly cycle.

Q. Dr Perry, I wanted to ask you some questions about supply to particular hospitals, and I accept that you arrived in March 1981 and it may be that some of these were matters that really were determined before you came on the scene, but it is important to us to try to find out as much as we can about why there was a particular pattern of usage at Yorkhill, to start.

We have quite lot of information about the use of commercial products in Yorkhill, particularly around the turn of the late 1970s and early 1980s. Do you know anything about that? Do you remember anything about it?

A. About the pattern of usage at Yorkhill?

Q. Yes.

A. Probably not. I was aware fairly early on that there were parts of Scotland that were continuing to use commercial products. This was referred to in various meetings and so on. You know, in terms of my level of awareness, certainly up until I took over as director in

1984, I was aware of the fact that there were still some parts of Scotland that were using commercial product, and again I didn't dwell on that too much, it wasn't part of my job to do so. My understanding was that there were some doctors that preferred commercial -- this was my understanding.

I'm not suggesting it is correct or factually accurate, but my understanding and belief was that there were some doctors that preferred commercial product for one reason or another and indeed, in the very early 1980s it was the case that the SNBTS stock levels and supplies weren't as secure as they were two or three years later. I think the early 1980s saw a very substantial ramping up of output and stocks. But I don't remember in detail any discussions or significant reflection on haemo--

Q. Do you think it would be accurate to say that that's something that you just took as a given?

A. I took it as a fact of life but also took it as a target that part of our job was to increase our performance and output so this was no longer necessary. That was the take-home message for me as the operational manager of the fractionation centre, and indeed I think that's certainly the case with the wider SNBTS.

Q. You have already explained a bit about the situation in

the West of Scotland to us and the system that applied, I take it, from your arrival, of allocation back to different regions on the basis of the amount of plasma they had supplied; how much flexibility was there in that if somebody rang up and said, "We are terribly short, we have finished our allocation"?

A. I think it depended very much on what material was available in the central stockpile. I think the pro rata system was designed, from memory, to include not only this pro rata allocation to regions but I think you might call it bottom slicer, a bottom slice of the total output in a period of time was retained as central stock in PFC to meet that sort of circumstance that you described.

The extent to which that flexibility was actually used I don't recall because, as I say, I wasn't directly involved in any detail in the sort of monthly/daily transactions of supply. My job was quality management and quality systems and so on.

Q. Did you visit Law from time to time?

A. Yes, I visited Law quite early on in my career in the SNBTS, yes, but primarily -- and again I recall this quite vividly -- it was to begin the process of introduction of standard operating procedures and quality management systems and so on, but not in

relation to product supplies or pro rata system or product delivery.

Q. That was really what I was meaning. I was wondering if when you went to Law there was some sense in which you were there to discuss any difficulties they might be having or, I suppose, any comments or complaints they might want to relay about the product or the amount of supply.

A. Not at that stage. SNBTS is a fairly small organisation and there were fairly effective, informal systems but I think it's fair to say if there were substantive concerns from any regional transfusion centre about the supply of plasma products or quality issues and so on, they would have been taken up on a director to director basis.

Q. Right. We have heard evidence from Dr Boulton -- and you will know Dr Boulton?

A. Yes, indeed.

Q. We have seen a lot of correspondence as well involving him and it is clear that he was a sort of middleman or a liaison person in Edinburgh between Dr Ludlam in the haemophilia centre and PFC and he was assisting Dr Ludlam to obtain the stock he required for the treatment he wanted to give patients?

A. Yes.

Q. Who was the equivalent of Dr Boulton for the West of Scotland, or was there not one?

A. I think, as Dr Boulton suggested in his evidence -- and I did have a chance to read it very briefly last night -- I don't think there was an immediate or direct equivalent to Dr Boulton. I think Dr Hopkins, who was a consultant in the West of Scotland, was in some ways responsible for managing stock levels and the blood bank and so on, but in terms of the clinical interface, I don't think there was a person in the West of Scotland who worked closely in a clinical sense with the haemophilia doctors.

I think, if there were equivalents it was people like Isobel Walker and John Davidson in Glasgow Royal Infirmary, but they weren't SNBTS staff, they were part of the Glasgow blood bank. The difference, as I'm sure you know, between Edinburgh and Glasgow is that Edinburgh did not only the blood collection and testing and processing and so on, but it also ran the blood bank. In the West of Scotland, it collected the blood, did the processing and testing but the blood bank was run by the health board.

Q. Just lastly, the whole issue of allocation pro rata, who monitored that overall? Was there somebody at PFC whose job it was to do the calculations for plasma --

A. Yes, it was basically the production department. Certainly, when I joined in 1981, it was very clear that that's what they did. I think there were other much more formal arrangements on at least an annual basis. I remember there being meetings of the directors and they were called the pro rata meetings, and part of their function on an annual basis was to look into the future, work out the best requirements for demand, apply the formulas that existed and give colleagues in the wider regional transfusion centres some idea of how much product they might expect in the coming 12 months.

So there were very formal agreements on allocations and how much would be held at central level in PFC and how much would be distributed and on what sort of frequency. So there was a very formal process and that process was chaired by Professor Cash and the regional directors attended that. At the end of that meeting there would be a clear definition of what the plasma intake target was, what the plasma processing target should be, what the product output was likely to be based on yield calculations and so on, and how much regional centres could be expected to receive of not only Factor VIII but Factor IX, albumin and immunoglobulin products. It covered the whole range of products.

Q. Thank you, Dr Perry.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Dr Perry, can I just take you back to a question that you were asked at the beginning about clinical judgment and doctors being free to exercise their own judgment.

I think in your statement the passive voice is used. It says:

"It was also accepted that prescribing doctors were free to exercise their own judgment in the choice of either SNBTS or commercial products preserving the important principle of clinical freedom."

Can I ask you just exactly who accepted that?

A. I think the whole of the senior management of the SNBTS accepted that as a reality of the world that we lived in, and we were not operating a totalitarian system here, that required prescribing doctors to use what they were given basically. And I think that principle was certainly embraced by Professor Cash and certainly embraced by the regional transfusion service directors. And certainly -- I wouldn't say embraced by myself, I'm not a doctor -- but I certainly accepted that that was part of the world in which we operated.

Q. I take it that in terms of when that was accepted, that

was something that when you joined the organisation, that acceptance was in place and continued throughout. Is that correct?

A. It was an acceptance of that principle but in a sense it was a driver for minimising the requirements for doctors to exercise that freedom by obtaining commercial product. Our objective was to make the SNBTS product the product of choice in both quality and quantity, to meet the needs of haemophilia directors. So it wasn't just a complete free-for-all; there were very close relationships between the directors of the Scottish Transfusion Service, whose job it was to collect the plasma and make the product, and the haemophilia directors who were the users. And as we know, there were regular meetings between these groups to plan the future.

Q. How do you reconcile this idea of clinical freedom with the principle of self-sufficiency?

A. It is a difficult reconciliation. That's absolutely right. I think for true self-sufficiency, which I don't think any organisation has truly achieved, for all sorts of technical and clinical reasons, there will always be an occasion when the range of products that you make, certainly in the complex area of blood transfusion and plasma products, won't be the right one for a particular

patient.

So you will never achieve 100 per cent but I think for self-sufficiency to be substantively achieved, it has to be, in my view, an exercise that's undertaken not only by the supplying organisation but by the receiving organisation as well. There has to be a will and a determination to achieve this thing called self-sufficiency or close to it.

Q. So in order to sign up to self-sufficiency truly, the clinicians have to sign up too. They have to say, "We are going to use Scottish plasma"?

A. Yes, they have to be part of the process that says, "We understand why we want to be self-sufficient; we realise the advantages of this and we will work as closely with you as we can to make that happen."

So it does require a prescribing doctor to say, "I am part of the Scottish Health Service, I must do the best for my patients, but I am also part of a process which I believe in, which is to do everything we can to avoid the unnecessary use of products which are perhaps less safe than those provided by the NHS".

Q. Scotland is a relatively small community, a small place. All the clinicians that are active in this area and the SNBTS, they all know one another, they all meet together, they all discuss these matters?

A. Indeed, as indeed the SNBTS doctors and the haemophilia doctors did. In fact I think it's a matter of knowledge to most people here that there were regular meetings between the SNBTS directors and the haemophilia doctors to effectively plan for self-sufficiency or at least to work out how best to meet the needs of patients in Scotland.

Q. Can I ask you about the next part of your statement. You are dealing with licensing matters and one of the things you say in your statement is that:

"It is likely and appropriate that ..."

This is on the third page of your statement:

"It is likely and appropriate that this formal position would have informed the policies and decisions of treating doctors."

And what you are referring to there is that the licensing of products -- I think the idea in your statement -- please correct me if I am wrong -- is that the fact that a commercial product was licensed would inform the doctor or the clinician as to whether or not it was appropriate to use that material; in other words, if it was licensed, then it was all right to use it. Is that what you are suggesting?

A. I think that's what the licensing system is intended to achieve. It's intended to give prescribing doctors

clear indications that the product is safe, it's efficacious, its risk/benefit balance has been properly and objectively assessed and it is suitable for use, absolutely.

Q. I have to say that -- and as far as I have heard any evidence -- and I will be corrected if I'm wrong -- I don't hear the directors telling us, the ones that have given evidence, that the fact that the commercial product was licensed actually made any impact on their decision-making at all -- obviously, it's a requirement to use it because you can't use it if it's not licensed, but that that again had an impact in their decision as to whether or not to use it. In fact the reverse appears to be true. Quite a number of doctors have indicated that, notwithstanding the fact that the commercial product was licensed, they chose not to use it because there were specific risks in relation to that?

A. Yes.

Q. Do you want to comment on that?

A. Only to say that at that particular time I think the licensing and the continued licensing of products was part of the confused world that we operated in. I think, as we have discussed previously, the notion of removing licences for these products on the basis of

what we now describe as a precautionary principle would have created so much disruption in the treatment of patients that it was considered an inappropriate thing to do.

I would still take the view that the licensing system was and is set up to establish that products can and should still be used safely in clinical use. That doesn't preclude an individual doctor for a whole number of reasons not using a particular product. But I agree, that there is a slight conflict there. The system, you know, as we now know, was not as effective as it might have been but the consequence of creating a safer environment was to expose patients to no treatment at all, certainly with concentrates.

Q. Do you know if any doctors took the view that the material from PFC should not be used because it wasn't licensed, in the sense that it had Crown immunity?

A. No, I don't recall that being a specific concern. I think colleagues, haemophilia director colleagues, periodically expressed concern, particularly in terms of their liability and the fact that it was a product that was made under Crown immunity and what were their liabilities in case anything went wrong. I think that was an issue and there were some issues, which are well documented, concerning some concerns that people like

Professor Ludlam had in terms of doing clinical trials on behalf of SNBTS and what safeguards were in place for patients and doctors in the event that the clinical trial created a problem or an adverse event for a patient.

I don't recall at any time doctors simply saying -- or haemophilia doctors withdrawing from the process of self-sufficiency, as it were, on the basis that these products were made under Crown immunity and they didn't operate within the UK licensing system.

Q. Not withdrawing but just expressing concern or being worried about that. That wasn't expressed to you at any rate?

A. I don't recall it being a major feature of the landscape. I think what we were trying to do, and collectively, was to do everything that we could to make sure that we maximised the availability of products to treat patients from Scottish plasma, certainly in this period in the early 1980s.

Q. If that's right, then that would possibly tend to suggest that the licensing or otherwise doesn't really come into this decision, clinical decision?

A. No, I think my issue about licensing, informing doctors, would have been primarily, you know, perhaps a more important issue in England and Wales, but also, I think,

just as part of the general background of decision-making, the fact that the UK licensing authority, which has very substantial experts on it -- these are not lay people, these are highly experienced professionals -- if they take the view that a product is safe, then that is a reasonable baseline to start from.

Q. Right. You indicated, I think, at one stage of your evidence that in the early 1980s there was a ramping up of product in relation to performance and output. What I wondered is, are you aware of concerns that were expressed about availability and, more importantly, in relation to quality of PFC material by clinicians? Was that articulated to you?

A. I think there were concerns in the early 1980s. I think there were solubility issues. Yes, I was aware of those.

Q. You were aware of them at the time?

A. I was aware of them at the time and I was also aware that under the leadership of Peter Foster we were doing everything we can to actually improve the so-called quality of the product. But we were aware that our products in some respects were less user friendly -- I think the term has been used -- than some other commercial product.

Q. But, notwithstanding that, certain clinicians were able

to use exclusively NHS product?

A. Absolutely.

Q. Just one point in your statement. Again it's the third page. It's just the page we are on, yes.

Just to emphasise one point, you say:

"However, SNBTS medical and scientific staff would have held personal and speculative views on AIDS and there was periodic informal discussion on the topic but, in the absence of both a formal requirement or responsibility for it to intervene or advise on the use of licensed commercial products and the paucity of scientific information available, it did not, to the best of my knowledge, express a formal view or make any specific recommendations."

I think this is in connection with the issue of decision-making at the beginning of 1983 or just shortly after the beginning of 1983.

A. That's right, yes.

Q. And really what you seem to be saying is that there wasn't a formal requirement for SNBTS at that time to make any specific decision about matters and it didn't have any specific, as it understood it, responsibility to intervene or advise at that time. That's correct, is it?

A. I think it was certainly my understanding at the time

and probably still is, with the benefit of hindsight, that it wasn't any part of SNBTS's job to define the overall -- again this goes back to the clinical freedom issue. Our job, as a collector of blood and plasma and manufacturer of plasma products, was to do just that. Our job wasn't to become the judge and jury on all the products that should be used in Scotland. So it certainly wasn't part of the role of PFC.

Q. So where is this responsibility then? If it's not SNBTS, where do you say it is?

A. In terms of deciding which product is best for each patient?

Q. No, I think really --

A. Whether or not a commercial product should be used?

Q. -- used?

A. I think the responsibility (a), rests with the licensing authority, that's what the system was set up for but also with the prescribing doctor, with any additional information that they have over and above the license status of a product to decide whether it is the best product to use.

Q. What about PFC product? Where is the responsibility there?

A. For using PFC product?

Q. Yes.

A. I think formally that rests with the Secretary of State for Scotland as it was at the time, but also the responsibility for using it rested with the haemophilia doctor on the basis of the status that the product had.
Q. Just two other matters I want to ask you about.
THE CHAIRMAN: Just before you leave that, Mr Di Rollo. You have dealt quite a bit with the use of licensed products. I wondered whether you wanted to ask any questions about the use of products on a named-patient basis, whether Dr Perry might know anything about that.
MR DI ROLLO: I'm quite happy to -- perhaps you would be better to ask the precise question because I don't think I had specifically in mind. So I would be grateful.
THE CHAIRMAN: Are you aware of products being used on a named-patient basis?
A. I'm aware of the system that allows products to be used on a named-patient basis.
THE CHAIRMAN: Would you like to tell Mr Di Rollo what the system was then.
A. What the system was then? I think the system was -- and again, I'm not an expert but I think a clinician or doctor is always free to use a drug to treat a patient whether or not it's licensed if he believes and can justify that that's in the patient's interest. I think the downside to it, which is clearly an issue if you are

a prescribing doctor, is that if you do take that decision, then the responsibility is wholly yours for the outcome and the consequences of that, whereas if it is a licensed product or it's a product in clinical trial you are using, so long as you prescribe the product in the right circumstance and use it in the right way, then the responsibility is very much shared, if not more wholly owned by the licensing authority because they are the people that have taken the expert view that the drug is safe, efficacious and can and should be used.

MR DI ROLLO: I'm grateful for that, chairman.

Just two other matters I want to ask you about relating to the use of PFC product. Just in terms of its manufacture, was there a stage at which package inserts were included with the material which warned of the risk of AIDS from products?

A. Yes.

Q. When was that?

A. I can't remember from memory but it would have been -- I'm sorry, I would need to look those data up but I think the SNBTS has done a lot of work on leaflets and when they were inserted into the particular products but I think it is a matter of record and I'm very happy to come back with the answer to that question.

Q. Somebody is telling me that this is a matter of record so no doubt we can find out, but perhaps we can -- I'm told it's coming.
A. Okay.
Q. The other matter is, was there ever a time, in your knowledge, that there was a surplus in Scotland or even a sort of self-sufficiency before that point was reached, where Scottish material was exported to England?
A. Hm-mm.
Q. There was?
A. I'm sorry, maybe I jumped forward with your question.
Q. Sorry.
A. Was there a period before we had a surplus?
Q. Yes.
A. Where product was exported to England?
Q. That you are aware of.
A. I can't remember that being the case, although that doesn't preclude the possibility that occasionally, maybe not Factor VIII but other products may have been supplied to colleagues in England and Wales.
Q. Thank you very much.
THE CHAIRMAN: I think we know that at one stage PFC did hold plasma that had been sent by England, when the scope of Scottish production was still under discussion.

A. That's right.
THE CHAIRMAN: If we limit Mr Di Rollo's question to a time when product from Scottish plasma might have been sent to England, does that help you to be more particular?
A. Well, I think the English plasma that you refer to was, I think, so-called recovered or outdated plasma and wasn't used for coagulation factor manufacture. I think it was primarily used for albumin. Our generous colleagues in England and Wales said, "We don't necessarily want the product back". But in terms of excluding that from the equation, again I have no immediate memory today of an example of SNBTS exporting significant quantities of plasma products to colleagues in England and Wales. Although periodically that may well have happened. Certainly, as we know, we did in late 1984.
THE CHAIRMAN: Late 1984?
A. Actually in mid 1984 I think the transfer actually took place, and that was roughly 2 million units.
THE CHAIRMAN: Thank you.
MR ANDERSON: I have no questions.
THE CHAIRMAN: Mr Sheldon?

Questions by MR SHELDON

MR SHELDON: Just two matters, if I may.
Doctor, you mentioned that it was perhaps not until

the mid or late 1980s that the Scottish Home and Health Department made a clear, unequivocal statement about self-sufficiency and I just wondered what kind of statement you had in mind there.

A. A clear policy statement from SHHD, that is part of Her Majesty's government in Scotland, that we will be self-sufficient. I can't place that in time. This is actually as a result of a fairly recent conversation I had with Professor Cash, who felt this was the first time that we had a clear statement from the Scottish Home and Health Department on self-sufficiency.

I think until that point, the references to self-sufficiency -- certainly Professor Cash would argue and perhaps myself to a certain extent -- were that it was never absolute government policy -- or it was never clear to us that it was government policy -- that we can and should navigate towards self-sufficiency, although all the indications, all the suggestions, the culture, the meetings, the process that was put in place, indicated that self-sufficiency was the target.

Q. I just wondered really whether you had in mind a public statement?

A. No, just basically a clear written statement that self-sufficiency was part of the Scottish Government's priorities for the service.

Q. Yes. Could we look, please, at a document, it's [SNB0015160]. This is the minutes of a meeting of the SNBTS directors and the haemophilia directors on 21 January. I don't think that you are there, Dr Perry. Certainly not in terms of the list of those who were present.

A. No, I wouldn't have been at that stage. No.

Q. But we see Dr Cash is there --

A. Yes, and Mr Watt, my predecessor.

Q. Indeed. Could we just look, please, at the third page of that document, page 3? In the second paragraph down we see:

"Concern was again expressed about the amount of commercially produced Factor VIII that's still being purchased."

It's perhaps just worth noting that about half way down that paragraph, Dr Ludlam indicates that the reasons for the use of commercial material in Edinburgh were partially clinical and partially a policy of conserving a cushion of NHS Factor VIII. But it's clear that commercial material is still being used.

A. Yes.

Q. Then if we move down the page, I think it's the second last paragraph.

A. Indeed, yes.

Q. We see that the chairman, who I think is Dr Bell of SHHD --

A. Yes, it was Dr Bell, yes.

Q. -- stressed that:

"The SNBTS had been set up to have the capability to cope with all Scottish requirements ..."

Reading short:

"... and that in terms of national policy, the purchase of commercial product should be avoided so far as possible."

So would you agree that really, at least in terms of what I suppose one might regard as a private meeting, as opposed to a public statement, nevertheless it's a fairly clear statement that what SNBTS is about is self-sufficiency and indeed the avoidance of commercial product?

A. I would agree with you. I'm not suggesting that there were never any clues coming from SHHD concerning our status and I would agree, there are a number of other references in meetings of this type where the self-sufficiency requirements are actually mentioned. I think what myself and colleagues were concerned with is, if you then pursue that had a little further and say, "What does self-sufficiency actually mean?" -- because I think, you know, in the real world you are

just saying "self-sufficiency"; it can mean all sorts of different things to different people and from a government perspective, it could be an open cheque book. And Dr Bell was an extremely able and good colleague and friend of the SNBTS, and I would expect him to say this, and he passionately believed in this particular process, but I think if one tried to probe that further and say, "Can we have a clear statement from Scottish Home and Health Department what they actually mean by that, ie what actions arise from that policy, what are our orders in terms of meeting self-sufficiency," I think that always fails to materialise.

Q. Perhaps I could just pursue that a little further then, because I think at one point in your evidence you indicated that whatever the situation about public statements about self-sufficiency and so on, you all felt that that's the goal you were working towards.

A. Hm-mm, absolutely.

Q. I think that perhaps appears from the minutes of this meeting: that everybody perhaps takes on board that self-sufficiency is a desirable goal.

Can I just ask you then: what was the goal that you took yourself to be working towards in terms of self-sufficiency?

A. Meeting most, if not all the needs for plasma products in Scotland, with the exception of occasional rare products, individual patients who had idiosyncratic reactions to the product that we had on offer. We would fully accept that it would certainly be justified to use a non-NHS product.

And I think we quantified it. In the absence of a clear statement -- which in some senses is understandable, but in the absence of that statement we tried to quantify -- because planning self-sufficiency is a quantitative concept not a qualitative one -- and we established targets of 2.75 million units per million population and so on, as navigational systems to guide our activities.

I think the way we generally tried to get a collective agreement on what self-sufficiency was -- and I think primarily through the communications of Professor Cash -- was to offer proposals to the Scottish Home and Health Department, particularly at these annual meetings, and seek their agreement that 2.75 million international units was an appropriate target, and more often than not, Scottish Home and Health Department would agree that subject to availability of funding, of course, but that was broadly how the process would work.

Q. Yes.

A. But as far as I was concerned as an operational manager in PFC, self-sufficiency was about maximising our output and as I've said previously, every bottle of product that we could make from Scottish donors avoided the importation of a product from other sources, which we held and believed were less safe. That was the culture, that was the ethos, that's what drove the team at PFC.

THE CHAIRMAN: We will have a break now. You will bear in mind that there were public statements in 1984 in England and in Scotland in the preliminary report at paragraphs 10.148 and then again at 10.155 to give you the timeframe.

(11.10 am)

(Short break)

(11.31 am)

THE CHAIRMAN: Mr Sheldon?

MR SHELDON: Thank you, sir.

Dr Perry, I wonder if I can just take you to another document. It is [SNB0015252]. I think this is a set of minutes, again of the joint directors, a meeting at which this time I think you were present.

A. Yes.

Q. This is 2 February 1984 and again Dr Bell is in the chair. Perhaps we could look, please, at page 2, the second page of the document. Right at the foot of that

page, we see that Dr Cash is asking members to consider whether, given present SNBTS production of Factor VIII, it was necessary to purchase commercially unless exceptionally a superior product was available. And then over the page there appears to be some discussion about the use of commercial products. Dr McDonald and Dr Hann contribute. Again Dr Ludlam indicates he required to have a small stock of higher purity commercial material for a very few patients.

A. Indeed.

Q. I think we have heard there may be circumstances, where, for example, patients with inhibitors may require particularly high purity Factor VIII. Is that your understanding?

A. Yes, and I think maybe small children, but that's my understanding: a patient that requires large volume treatment. And that would typically be an inhibitor patient who might not be able to tolerate the relatively lower purity SNBTS or NHS product.

Q. We then have a paragraph where Dr Bell emphasises again that the aim of SNBTS and national policy was for Scotland to be self-sufficient:

> "... and although the department would not wish to intervene in what clinicians prescribed, it was not sensible to purchase imported material when suitable NHS

product was available."

A. Indeed.

Q. You have talked a little bit in your evidence about the idea of clinical freedom. Is that an issue which appears to be in Dr Bell's mind in that little passage?

A. Well, I would imagine that's -- knowing Dr Bell as I did, he would choose his words very carefully when discussing these issues. And he, I think, like SNBTS, was a strong advocate of self-sufficiency but he is also, I wouldn't say a strong advocate but he recognised that this so-called clinical freedom issue was an important consideration, and it certainly wouldn't have been a position of the Scottish Home and Health Department to try and force-feed haemophilia doctors and their patients with a product that they didn't want.

So I think, yes, he would have embraced self-sufficiency very enthusiastically but he would have also embraced the important element, that the Scottish Home and Health Department did not wish to intervene in clinical decisions and product choices of haemophilia doctors. So, yes, it's in that sort of difficult zone between the two.

THE CHAIRMAN: At this stage who controlled the budget?

A. The budget for the SNBTS was controlled, effectively by the Scottish Home and Health Department through the

Common Services Agency. The budget for commercial purchase would have been in 1984, to the best of my knowledge, that would have been health boards.

Q. And the health boards received their money from?

A. The Scottish Home and Health Department.

THE CHAIRMAN: Yes.

MR SHELDON: Just thinking a little bit more about issues of clinical freedom and self-sufficiency, doctor, was there any discussion at this meeting, or indeed any other that you can recall, about the extent to which the amount of Factor VIII that haemophilia clinicians prescribed should be or could be reined in or controlled?

A. No, I think during this period we were -- well, I can perhaps only speak for myself, but from a PFC perspective, our understanding at that time, that demand for plasma products was and would continue to increase. And part of the challenge was to actually respond to the quantitative increase in product requirement and also the qualitative increase in product requirement, ie introduction of heat treatment and all these other safety factors that were being considered.

So I don't think there was any discussion in these meetings to try and control the activities of haemophilia directors to fit the product that was available. The discussion was primarily about how we

could meet our ambition to be largely or as self-sufficient as possible in the supply of coagulation factor products to treat patients in Scotland.

I think there were periodically discussions about increased usage, and I think haemophilia doctors were perhaps not called to account but they were asked to explain why the demand for Factor VIII was rising on a year on year basis, but I don't think it was with the specific intention, either from SHHD or anyone else, to say that too much was being used. But I think they were putting a mark down that we are interested in quantitative increases for the reasons that I have discussed. Self-sufficiency, if not defined and scoped out, is basically an open-ended process with a potentially infinity sum of funding required. So it was --

THE CHAIRMAN: Dr Perry, at the end of paragraph 5 there is a paragraph:

"It was also pointed out that an accurate assessment of future need could only be made if commercial purchases were fully identified and taken into account."

Do you remember who made that point?

A. Dr Bell -- no, I don't remember, no.

THE CHAIRMAN: It's a fairly obvious point.

A. It's a fairly obvious point and it could well have been

made by Dr Bell and perhaps what Dr Bell -- if it was him and it reads as though it was him -- he would have been certainly familiar with the important requirement of understanding what the total usage of Factor VIII was including commercial product, knowing that that was a problem or an issue.

MR SHELDON: Can I just finally, in relation to this document, ask you for your recollection, if any, of the context of that discussion. Was that discussion about commercial products and the use of commercial products, a discussion in the context of cost or a discussion in the context of risk?

A. I think it was a discussion -- from memory -- and this is one of perhaps a number of occasions where this type of discussion would have taken place, and I think typically it would have been led by Professor Cash who was the national medical director, we would have had information. It might not have been accurate but we knew that whilst SNBTS had substantively achieved its goal of making enough product quantitatively for treating patients in Scotland, there was still commercial purchase, and our view, as I have described, was certainly that one vial of NHS product made avoids the importation of a less safe US product. And so I think it was probably risk-driven but also financially

driven.

I think Professor Cash -- I think he did lead this particular discussion -- was challenging, I think, his colleagues, haemophilia director colleagues, to effectively justify the use of commercial product when there was a suitable NHS product available, but that would have been also trying to establish whether there was any particular problem with the SNBTS product.

Q. Thank you. Just one final matter.

You mentioned some issues about the licensing of medicines and so on and indicated that that appeared to be a UK matter. The possibility was floated, I think, by Ms Dunlop about a letter or recommendation from SHHD about the use of imported concentrates. You have given some evidence about clinicians' attitude to the licensing system and so on, and I just wondered -- and if you don't feel comfortable answering this question please do say -- I just wondered what the reaction might have been if we had a Scottish letter or Scottish recommendation saying, "Don't use imported concentrates", in circumstances where in fact there was a valid UK licence?

A. Well, I think it would be highly speculative of me to comment. (a) I can't imagine the circumstances, either legal or otherwise, in which such a statement could have

been made, given that the UK licensing authority was the UK licensing authority, and for Scotland to declare UDI and to have a separate offline process, which is second guessing the CSM, in itself is difficult.

Having said that, if that curious process could have been achievable, I'm not sure what the reaction would be. I think if there was very substantive evidence -- I think colleagues, certainly haemophilia doctors and perhaps even SNBTS, would have wanted to see the evidence for that particular decision to be clearly laid out. Although, at that time, the SNBTS and patients in Scotland were in substantially better position in terms of NHS supplies than they were in England. So I guess in a sense it would have been manageable. I just can't conceive of the circumstances in which such a statement might or could have been made, in my experience. That's not to say that there isn't a mechanism there for doing that. But a CMO letter, for instance, second guessing the views and decisions and clear position on the Committee on Safety of Medicines, I think would have caused some chaos in the system actually.

Q. All right, thank you.

A. Certainly for the licensing authority.

THE CHAIRMAN: It is not necessarily a bad thing.

A. But I speculate.

THE CHAIRMAN: Yes. I don't think I want you to speculate too much further on that. There are constraints but of course, as you have pointed out yourself, there was a very different factual position in Scotland as against England, which perhaps shouldn't have influenced the Committee On the Safety of Medicines.

Ms Dunlop?

Further Questions by MS DUNLOP

MS DUNLOP: There was one other question I wanted to ask Dr Perry and I forgot. May I ask it?

THE CHAIRMAN: Certainly.

MS DUNLOP: Dr Perry, this is about licensing, and if you don't know or don't remember, please just say so. You were asked a bit about named patient usage of a product and that it's also possible to get a product for clinical trials in advance of its having been licensed.

A. Correct.

Q. If however, a product has gone to -- well, then it would be the Committee on Safety of Medicines -- and actually a licence application has been refused, does that change things or is that product still available for use on a named-patient basis or for trials?

A. It could still be available on a named-patient basis or the clinical -- or the refusal of the licence could be, for instance, that the Committee On the Safety of

Medicines wants more clinical data. So the fact that a licence has been -- unless it's on very clear safety line, ie, "You are transmitting disease to patients as a result of this product" -- in which case I don't think the licence application would go to the Committee On the Safety of Medicines. But there are a number of examples of products being submitted for licence and the licensing authority saying either, "We want more clinical data" or, "We want more validation data" or, "We want more pharmaceutical data" and so on. Or simple things like, "We want your product information leaflet to be changed". So there are a whole range of scenarios in which a product can be refused a licence and continue to be used, either on a named patient basis or in a clinical trial, with a view to the submission being made at a later date.

Q. Right. If the grounds for refusal had related in some kind of way to safety -- say, the committee had thought unjustified claims were being made about the product or something like that -- in a practical sense that might put doctors off using it.

A. Yes, that would -- and it's certainly directly applicable to the applications for heat-treated Factor VIII in 1984. I wasn't on the committee at that time but my understanding was that the Committee On the

Safety of Medicines took the view that the apparent claims for safety, improved safety of the products, were not justified by data. I think they would have had in their mind also their concern about, as I think has been rehearsed a number of times by people far more knowledgable about this area than I, that the downside of heat treatment was unknown. So without any evidence of upside risk or upside reduction in risk in terms of virus safety, there was this genuine concern about the downside risk of damaging the product and creating inhibitors.

Q. So formally it would still be available --

A. Absolutely.

Q. -- but on the ground it might have altered the way in which the product was seen?

A. Absolutely. Or they could simply be asked to reduce or modify their claims. So if you submitted a licence application and said, "This product is better than product Y because it reduces the risk of hepatitis", to say that you would need to give clear evidence, and I think they were perhaps suggesting that it reduced the risk of hepatitis in their applications but the data didn't support it.

Q. Thank you.

THE CHAIRMAN: Ms Dunlop, I'm slightly concerned that there

may be some loose ends at the moment about the productive capacity of PFC over this period when stocks appear to have been rising dramatically. Is this something you will be coming back to at some stage?

MS DUNLOP: You mean the 83/84 period, sir?

THE CHAIRMAN: Yes.

MS DUNLOP: I wasn't proposing to, sir, because I don't see it relating to the circumstances in which anyone acquired infection.

THE CHAIRMAN: Well, it doesn't but we have now had quite lot of evidence about very large stock build-ups over this period and I just want to be clear, if there is a sort of physical explanation for that, we get it, but I will do it myself. Don't worry.

Dr Perry, we know that there was a very significant investment in England in 1982 at Elstree and I have also seen a programme of developments in Scotland. Could you pinpoint, just in a few sentences, what was happening that might have had a bearing on productive capacity in 1982 through to 1984?

A. I think there was a programme of investment. We were installing major new dispensing equipment, product filling equipment, to meet modern standards. That's one example. We were restructuring the production department, relocating, labelling and packaging,

improving the storage capability within the envelope of the building we had. So there were a range of improvements, structural improvement's, that were going on within the centre, probably primarily in response to the so-called Flint and Purves advice, Medicines Inspectors' report in 1979 and 1980 and the subsequent visit by Messrs Ayling and Haythornthwaite.

So they are the two immediate very substantive exercises that spring to mind. It was basically a restructuring of the production department to make the flow better and you can't manufacture pharmaceuticals in a building site. So it required quite significant periods of closedown, which in itself required to build stocks to cover those periods, because I think the key feature of self-sufficiency is that you can't have it this month and then abandon it next month. It is for ever.

THE CHAIRMAN: But there was nothing in that answer to suggest that the actual throughput would have been significantly increased once the modifications had been made.

A. No. These were mainly quality improvements to improve standards of good manufacturing practice and so on.

I think there were some elements of improved productive capacity, for instance automated filling

lines and so on gave you the opportunity to slightly increase batch size and reduce the labour component of sterile dispensing and so on. But they weren't designed to increase volume throughput.

THE CHAIRMAN: So the apparent dramatic increase from 900,000 units to 4.5 million units in storage in Glasgow certainly wouldn't be explained by changes in the productive capacity of PFC.

A. Well, I think part of the dramatic improvement in stocks -- and it was quite dramatic -- over a relatively short period of time was a combination of more plasma, still within our capability at the time, quite dramatic improvements in yield as a result by Dr Foster. And I think the combination of those two factors led our production to fairly quickly, over a period, 1981 to 1984, exceed the then current clinical use of our particular product, and that's what led to the stock build-up which has been discussed in 1984.

THE CHAIRMAN: One of the contributions made by Dr Foster was eventually persuading people that the quality of plasma sent to PFC was important in relation to yield.

A. Yes, it was a ten-year process, I seem to remember. I don't think it was a one-off event.

THE CHAIRMAN: Thank you. Dr Perry, thank you very much.

A. Thank you.

MS DUNLOP: Our next witness is Professor Cash, sir.

(11.52 am)

PROFESSOR JOHN CASH (continued)

Questions by MS DUNLOP (continued)

THE CHAIRMAN: Good morning, Professor Cash.

MS DUNLOP: Good morning Professor Cash. I think it's still good morning.

A. Yes.

Q. I want to ask you some questions about the topic that we call B2. You have provided a statement for us in relation to that topic and you have also provided a sheet of supplementary comment.

I want to go back to the 1970s and to ask you about risks of concentrates generally, which in the 1970s, as we understand it, really meant hepatitis, as a perceived problem.

This is a version of your statement which has some handwritten questions on it but I think for ease of reading everything that comes after, we need the questions too. It's [PEN0150273]. Can we go to page 2?

Towards the bottom of the page we can see some response from you and it's in bold. You say in a paragraph numbered 2 that you think the first public warning in the UK concerning the potential dangers of commercial concentrates came from the SNBTS, and you

refer to what is actually your letter. Perhaps we could have that. That's [LIT0010245].

When you were here before, Professor Cash, I think you wondered if the television programme might have been a response to the suggestions of the danger, but it actually looks as though your letter was in response to the television programme because it was December 1975 and here is your letter on 24 January, I think it is. 24 January 1976.

You have no doubt looked at this letter again recently?

A. Yes, some months ago, yes.

Q. Right. I just wanted to ask you particularly about the sentence which we see at the top of the right-hand column, so we need to go up again. It's that sentence about the level of a potentially lethal virus into the whole community being deliberately increased.

One or two witnesses have wondered about the use of the word "deliberately". I wondered if on reflection you didn't really mean "deliberately" but perhaps "knowingly", or do you want to stick with "deliberately"?

A. I personally wouldn't see much difference between "knowingly" and "deliberately" but perhaps lawyers would. But there is no doubt in my mind that the policy

that was coming through into England and Wales, that this wasn't by accident, it was a very deliberate policy that was being developed, and so I'm pretty relaxed about changing it from "deliberately" to "knowingly", but I don't personally see any difference. The people that knew were the civil servants and there is evidence of that that we have.

Q. Sorry to jump about but can we go back down to get the bit immediately before that. So back down to the bottom of the page.

A. Yes.

Q. "... no doubt that the import into the UK ..." We can read on for ourselves about that being an unequivocal pathway. Then if we read up to the top, the level of a potentially lethal virus into the whole community was being increased.

Given what happened in the early 1980s, when an actually lethal virus was introduced, when you looked back at the letter, did it seem to you that you had been something of a prophet?

A. I wouldn't dream that I'm a prophet. I would simply say that, looking at the word -- I'm aware that people have talked about that I suggested it exaggerated -- the programme, and I think I would say without any shadow of doubt, it was an exaggeration and I can explain why that

was so.

But I wouldn't see myself as some prophet, a prophet of doom. I just think if you have a process -- I'm not sure whether -- in 1969 I did my own World in Action. I had a WHO travel fellowship and spent three and a half months in the States looking very carefully at all aspects of their transfusion service, made a lot of hugely important friends over there, that were immensely important in the later years. And one of the things I did when I was in California was to go into the Cutter -- it was Cutter, not Hyland -- skid row area, and this is in San Francisco, as I recall, and -- I mean, I thought the film was pretty gentle on that. What I saw was just obscene. It was just obscene.

So the film didn't surprise me. I thought it had exaggerated because if you ask, "Did that reflect the total input of commercial plasma into the US system," it did not. Indeed, as John Prothero, in the second disc of that programme, who was in the Haemophilia Society, said, there were companies -- and there were companies -- who claimed -- and I actually believed them at the time -- that they didn't use these sort of donors at all, that they used university campus people. And if you look at the latest, which is many years later, PCR Hepatitis C studies on old batches of commercial

concentrate, to my astonishment -- these were held in NIBSC -- some of them were negative. And that does indicate that there were sources of the commercial that in fact may be on a par, in terms of safety, with the voluntary paid donor. So I felt the programme did exaggerate the point. It was also very dominated by Ari Zuckerman, whom I knew very well. He was very much a B virus man.

Q. Yes, I think we appreciate the point that much of what was being discussed and what was being used as an example of the problems that might occur was actually Hepatitis B rather than non-A non-B. But I think perhaps you have partly answered my next question, which was going to be what you meant, if you can remember, by saying that the absolute magnitude of the problem was exaggerated and overdramatised?

A. Well, very briefly I'll repeat that they were suggesting that all plasma that was used in commercial concentrates was coming from skid row. That wasn't true.

Q. Okay. I think some people who have read the letter, and it has obviously been scrutinised a lot recently, but some people have thought that you were referring to the numbers of people who would get hepatitis.

A. No.

Q. And as we look back now --

A. No, no, no. I cannot claim that --
Q. -- there was a suggestion of that in the programme, that doesn't count as an exaggeration?
A. Quite.
Q. That wasn't what you were getting at --
A. No, it was the skid row.
THE CHAIRMAN: Could I just ask you about your reference to recent studies? We have heard about a study reported by Minor. Is that what you have in mind? It is suggested that five out of 46 --
A. It could be Phil Minor but Peter Simmonds and Chris Ludlam I think were engaged.
THE CHAIRMAN: I have done it too.
A. And I think it's Lancet, sir, and it's a beautiful study.
PROFESSOR JAMES: There was a Minor letter, which perhaps is the one you are referring to, in 1990, that we saw a couple of days ago, where from memory, they tested 46 American pools and found four or five of them negative for HCV by the very early tests of 1990.
A. Right. Certainly I think Phil Minor -- he is NIBSC, is Phil.
PROFESSOR JAMES: Yes.
A. And I think he obtained the samples for Peter Simmonds to do the PCR.

PROFESSOR JAMES: Very possible.
A. I think he did the first, but I think he was doing antibody. I think he was doing ELISAs and picked them up that way. But Peter Simmonds is deemed -- did PCRs --
THE CHAIRMAN: If you can give us references later to your sources, that would help.
A. Could somebody chase me on that? I shall forget.
MS DUNLOP: Can we go back to Professor Cash's statement, please. The other reference you make in paragraph 2 is to work at the end of the 1970s and to there being a need for prospective studies. Just to clarify for the record that the reference seems to be the published proceedings of the symposium on unresolved problems in haemophilia.
A. That's correct, in Glasgow.
Q. Yes, and I think we can actually bring up the reference concerned. It's [DHF0030649]. You, Professor Cash, surmise that perhaps the book, which I happen to have here -- but the book wasn't published until 1982 and that would seem to be correct but the actual symposium was 1980.
A. Yes.
Q. And I think we have confirmed that your reference is actually to the first paper in the book, which is the

work of Dr Craske. In your supplementary paper you agreed that that is correct. And we can see your words, the words that you quote on page 7 of your version. If we could go to page 7. I think it might be page 11 in the book but if we go to page 7.

At that point, Dr Craske was thinking that there was an increased risk from commercial Factor VIII compared with NHS Factor VIII. No firm conclusion could be drawn until prospective studies had been carried out. So by prospective studies, presumably, looking at ideally previously untreated patients and monitoring them from the time of their first administration of concentrate onwards.

A. Yes, and may I say -- and I am very interested in seeing, I haven't read it all -- Chris Ludlam's transcript. Very interesting. I think it's probable that Ludlam was sitting on -- I say "probable" because I wasn't clinically involved -- sitting on a population of haemophiliacs in the UK that were relatively unique, ie they had not been exposed to commercial concentrates at all. And doing prospective studies, you would need either to have this very slow -- the PUP concept of previously untransfused patients and/or you could add in a group of patients that had not had commercial, and my view -- I didn't feel strongly about this -- of

John Craske's conclusion is that was a really tough nut to expect the haemophilia directors to go on and do a prospective study.

That was a conclusion. And I'm just pointing out that that was as late as 1980, that there was caution among the clinical teams and John Craske was really, although not a clinician, very closely involved with the haemophilia doctors in the UK, that they were saying -- and later they clearly, when AIDS came, they were reticent to ascribe too much danger of the commercial concentrates versus the non, whereas I have to say, because I think it was pretty evident, I was at the other extreme end of that.

Q. Just to round off this point for the moment, because I think we will need to come back to it when we are looking in more detail at Hepatitis C, but there is quite a lot of material from the first half of the 1980s, including Dr Craske's own work, to show that the attack rates for non-A non-B with NHS concentrates were very high as well. Can we look particularly at a letter, [SNF0012890].

This is a letter from you to Dr Forbes. Slightly frustratingly we haven't been able to find any response to the letter or any written record of Dr Forbes' data, but the letter does give us a hint as to what was in the

information, when it says:

"You advised the working party that you had data which indicated that the results from the Oxford study were identical to yours."

The Oxford study, I think, is a reference to Dr Craske's work in which he looked at 26 patients --

A. I think so.

Q. -- and found that all nine treated with concentrates for the first time acquired non-A non-B hepatitis, and that included all of those who were given NHS product. But just perhaps to take it shortly for the moment, do you still think that it was possible that the Scottish product had a lower infectivity than the commercial products for non-A non-B?

A. I wonder if -- I will "if" and "but" a lot in a moment -- but I wonder if I can just remind you what I said on my previous appearance and that is that one of the things that struck me throughout this period was our clinical colleagues -- and John Craske, for instance, although that's not strictly true -- took no cognisance of the notion that the viral load -- and I would like to stress "load", the amount of virus per syringe or whatever -- could be a significant factor in the final outcome. Certainly from my physiology days when I did an extra degree, dose response curves were very

important. I'm retired and I have little access now to libraries and time, but I am aware, and I have papers that will demonstrate that in the HIV context viral load is absolutely critical as to whether you pass on -- whether the recipient will in fact get it.

I never escaped the conclusion that -- when the haemophilia directors said and John Craske said, when you get to a pool size of NHS product, you will get the same infectivity, and what that tells us is that the NHS product probably had two viruses per ml and the commercial had 2,000 viruses per ml. Yes, indeed, they would both produce evidence of hepatitis.

The real question is -- and I never came to any conclusion about this -- was the clinical pathological outcome of having a mild attack of hepatitis with just two viruses versus 20 or 200 -- was it any different? And I don't think those studies were ever done.

Q. Right.

A. And thus, I think, viral load -- I don't see it appearing in the preliminary report or anything so far -- as being an issue in relation to the commercial concentrates.

Don't forget -- I shouldn't say this -- but a lot of the commercial stuff was from plasma phoresed. So if you had a group of people who were HCV or HIV positive,

you would be stacking in a bigger volume of contaminated material. This is nothing to do with pool size at the moment. So load, I think, is an issue which needs to be explored and considered.

Q. Thank you.

I wanted to turn, Professor Cash, to ask you about questions of policy, in particular self-sufficiency. The first reference I wanted to take you to, just to sketch the background, is Hansard, which I think is at [PEN0120185]. In the end I think it was three references we looked at from January and February 1975, where there was a statement by Dr David Owen in the House of Commons, and we can see that at the bottom of that page. He says:

"I believe it is vitally important that the National Health Service should become self-sufficient as soon as practicable in the production of Factor VIII ..."

We know too that there were international statements, particularly the Council of Europe, but I think your position is, in short, that there wasn't a formal policy statement for Scotland. What would we be looking for, because I notice that the way it was expressed by Dr Owen was that it was the NHS, the National Health Service, that was to become

self-sufficient. He perhaps was very careful not to say England or the UK. He said the National Health Service. That surely meant and was understood as meaning the whole of Britain?

A. Yes, I wouldn't -- being an Englishman, I would demur from that, but you then have to say, "What's on offer?" -- if he said, "I believe we must get to the moon tomorrow," you then say, "How are we going to do that?" And if he has an aeroplane with a rubber band to run it and a propellor, clearly it doesn't mean very much. We were in a situation -- and I think I wrote about it at the time -- in which David Owen's statement, when you looked at what they were going to do to achieve their self-sufficiency -- and I was reminded in this World in Action thing that I had a look at again -- Sir William Maycock is on the second disc. He was signed up to the notion at the time of the World in Action that by 1977 they would be home and dry. Anybody that had the remotest knowledge would have known that, forgive me, there wasn't a cat in hell's -- they were clearly not on the same planet, as my friend, Graham Scott, used to say.

Q. I think you made that point in your letter, your 1976 letter?

A. Is that right?

Q. Yes.

A. So I would presume, because we may be coming to this later, that what the Secretary of State for Health said in London applied to Scotland. However, in Scotland we knew that -- well, by then we were way past, even by then -- which we can talk about at another time. But by 1975, we had taken off in terms of motoring. Our friends south of the border hadn't woken up. They didn't know anything was happening.

What I wanted as a Scottish national medical director was an assurance -- and it's a long saga, I am afraid -- an assurance from my colleagues in the Scottish Office that don't worry about David Owen, we are past that, but really are we going to get sorted out and become seriously nationally self-sufficient in Scotland. That became a major issue, which, as far as I'm concerned, the Scottish Office did not declare their hand until late 1988.

Q. Well, because you have made these points in your statement, Professor Cash, we did do a bit of research so that we could try to assemble as complete a picture as possible. Can we have firstly our letter, the Inquiry team letter, which is [PEN0150051]?

Obviously, we are asking people who weren't around at the time to do some research on this. So no doubt

it's like a form of archaeology that they had to do, going back and digging out files and searching, but just to let you see the letter. Two questions were posed in this letter to the Scottish executive and we have the reply, which is [PEN0150100]. Now, for the moment, I just want to look at the first part only, the first paragraph:

"Blood policy files from 1974 to 1989 have disclosed one document."

Just to look at it to show that really it's not perhaps the answer to the question, at least not an entire answer to the question. It's [SGH0027195]. It is issued from the Scottish Office in -- I think it must be 1986, although it seems to be number 169 of 85 but given that it gives results up to the end of December 1985, that would suggest it was issued in 1986.

The context of it is that screening of donated blood for antibodies to HTLV-III has been in place for three or four months. This is Norman Fowler making reference to the results of the first few months and saying that he wants to emphasise a need for a steady increase in blood donations in 1986 as part of the drive towards achieving self-sufficiency in blood products.

So would you accept that this is a reference to an

aim of self-sufficiency but it seems to be 1986, and it's a joint statement from Norman Fowler on behalf of all the health ministers in the UK?

A. Yes. I have a problem, to be absolutely honest. In 1977, June thereof, I was in New York at the World Federation of Haemophilia congress. I had been invited over there by Louis Aledort -- his name appears a lot in these documents -- to give a talk on really the subject that I had presented in 1975, I think in Helsinki. The basis of this was that the notion of self-sufficiency, national -- was a runner, we could do it, and this is what you needed and so on and so forth. And this was in fact in New York, a repeat, with an update.

This is a rather dramatic tale but only once in my life I have been elbowed off the rostrum in the middle of my talk. The person who did this was the chief executive of Immuno, Dr Eibl.

Q. E-I-B-L. I've seen that name before.

A. He is about six foot four in his socks and he bounced me off the rostrum and with his finger pointing to this huge array, vast auditorium of haemophilia patients -- a significant number I subsequently discovered were from the UK -- doctors, scientists, carers, social workers and so on and so on, made it very clear that what I was saying was nonsense, and I won't go into that, but the

last thing he said was:

"And we can assure you ..."

Meaning the commercial sector:

"... that the UK Government does not accept that the WHO commitment to self-sufficiency is a runner, and what John Cash is saying is a load of nonsense -- and then came the runner -- and the UK Government, we know, does not support him."

I was bundled off, went out and had a coffee and coming next to me while I was having a coffee came a man who introduced myself as John Prothero, whom we saw, who was a haemophiliac. And he was a senior guy in the UK haemophilia centre and John and I had a lot of interesting chat and he brought me back to reality and he finally said:

"You need to know, John, that what Eibl said out there actually we believe, that is the UK Haemophilia Society, that is there isn't a cat in hell's chance that the NHS will get anywhere near, in England and Wales, self-sufficiency."

And he said:

"We now know that we have to have Factor VIII. So what we are doing is pursuing the government to let us have it, commercial sources."

So despite all the talk in England and Wales of

self-sufficiency, if you looked at what they were doing and you go through the blood transfusion advisory committee papers, they just weren't in the hunt, and they were told this. I wrote to Ed Harris. You have them on your big database, this.

So nothing was new. They just didn't come to Scotland to really look and see how it was being done, not that they should do, but they just weren't that interested. So, yes, you can bring me -- I'm sure there are far more papers than this. I'm sure I have some which -- "We are committed to self-sufficiency", but again, when you look at what they are proposing and what's on the ground, it just doesn't add up and didn't.

Q. All right. You are drawing a distinction, which we understand, between words and deeds. I suppose some might say that for Scotland the words might be missing but the deeds were there, and there does seem to have been an awareness among all those working in the field that self-sufficiency was what was being sought. Indeed, Dr Perry used the phrase, "The only game in town".

A. That's right.

Q. Can you have a look please, firstly at [SNB0104452]. This is a congress in Budapest in 1982 and this is actually Dr Foster's report of proceedings, but you were

there too.

A. Hm-mm.

Q. And if we look at page 10, we see your name. There is a paragraph numbered 4:

"Other Factor VIII presentations."

It says:

"In discussing the problem of achieving self-sufficiency from an all voluntary blood donor programming, Cash gave details of the SNBTS programme to meet clinical demands into the 21st century."

We have that, and I also just wanted to show you what Dr Foster said to us. Can we go to the transcript, please, for 10 May, at page 44? I think we need to go down towards the bottom of the page. In fact the context of this passage, Professor Cash, is that we were imagining the attempt to achieve self-sufficiency as being like a runner in a race, who is chasing the person in front and never even managing to draw alongside because just as you nearly do, the runner pulls ahead. And it becomes more elaborate when you start to think that the person behind is running uphill all the time as well.

A. Absolutely.

Q. Anyway, no doubt it is not a particularly original analogy. You will see that towards the bottom of this

transcript it is said that:

"It might be difficult to find express statements of a policy of self-sufficiency for Scotland by politicians or by Government."

There doesn't seem to be any doubt that everybody knew that that was the aim for Scotland, and Dr Foster said at the 1981 meeting -- I think this is the joint meeting:

"There seemed to be quite a consensus and complete agreement that that was the objective we were all working towards."

So I suppose my question is: if the words weren't there for Scotland, did it matter because everyone was just getting on with trying to achieve it?

A. It mattered hugely, and when we get to the realisation that in 1982 I submitted a paper to the CSA, the blood transfusion committee, saying "Look --" I mean, I have a picture, this amazing picture we produced of our predictions that took us to 1997. I don't know whether you are aware of the picture.

Q. Well, I don't know if you mean literally a picture. You mean a graph?

A. Yes, a graph. I have a picture of our predictions and then from Peter's stuff, Peter Foster's, what actually happened. And it's very interesting to see that. But

the point I'm making is that in 1982 it was already clear to me and my colleagues that if we were going to stay in the self-sufficiency mode -- and we were moving in 1982 into a surplus for a period of time -- but we saw ourselves as the thing -- like any other, we needed to warn the Scottish Office that we needed other sources of plasma. And our first port of call at that stage -- although I was aware of the work of Claus Hogman in Uppsala, which was optimal additive solutions. Our first port of call until that arrived was to introduce a plasmapheresis programme. And all I can tell you is that if you take that request -- and it was in the public expenditure survey, the request that we made -- it was ignored until 1988. And in 1988 we fell off the cliff because our plasma -- we needed to boost our plasma.

So although the directors -- and Bob Perry with his no other show in town routine he used to tell us about -- were all working their socks off. So we had within a service a clear policy that we were running for. The real question is, it was never very clear to me at least whether, when the chips were down, my mates in the Scottish Office shared that vision. And I took a view, which may be completely wrong, that one of their fundamental problems was here in St Andrew's House, that

down the road in London was an organisation that by any standards was a disaster, and this, in my view -- and I had some evidence for this -- was becoming a increasing embarrassment and was quite tough for the Scottish Office people.

Q. Which was the disastrous organisation in London?

A. The National Blood Transfusion Service in terms of plasma supply and their fractionation setup. Yes. They were not delivering. 60 per cent plus of the needs of their patients was having to come from commercial sources.

Q. There were some formal statements towards the end of the 1980s. You were referring to that and --

A. What, you mean in Scotland?

Q. Yes, for Scotland.

A. Yes, indeed.

Q. Just to put in front of you a paper. You may have seen it recently or you may not. It's a paper that you enclosed with a letter, [SNB0061686]. We need to go to the first page in, please. Although it is the next page, it must have a separate reference, [SNB0061687]. No.

THE CHAIRMAN: Try the one ahead.

MS DUNLOP: Well, this page is definitely 1687 and I had assumed that, given it's the enclosure with the letter

it would follow, but that was obviously a fallacious assumption.

THE CHAIRMAN: I am just suggesting 85 because sometimes when they are loaded they are adjacent but in reverse chronological order.

MS DUNLOP: I have printed it out, sir, and it has the number on it so that must be its number. It's just it's not there. We will come back to it.

There was a Department of Health statement in 1990 -- and we have looked at that this week, Professor Cash. When we have loaded in our document we will look at what you were saying around about 1990. Just to look at what the Department of Health were saying, that's [SGH0050501], in October 1990.

A. Yes, that's the chief medical officer.

Q. Yes.

A. And as my recollection goes, because I wrote in the BMJ about it or something, this was a document on its way to the UK Haemophilia Society.

Q. Well --

A. It's from the CMO, England.

Q. That definition of self-sufficiency, the one that we see in the last sentence, when you saw that, did that surprise you?

A. No.

Q. You had better explain.

A. I don't wish to be too contentious but I think what emerged in the 1980s is that the commercial sector -- I mean they told me this, that they could be absolutely assured that the market in England and Wales would remain one in which they played major roles, and it was my understanding -- and I can give you some reasons for this -- that this was a comfortable position from the point of view of government. This is forgetting about AIDS or anything like this, but this is taking us into the early 1980s. So the notion of the public sector, down there, BPL, up here, PFC, dominating the scene down there, not only was not happening but actually politically was not something that people were comfortable with.

As a consequence of which the commercial people envisaged they would retain a significant amount of the market for Factor VIII, despite all the talk, all the letters, all the statements made by Sir George Young, now a member of the current cabinet, in 1980. Despite all this, this was the belief.

And in due course, the chief medical officer came out with this and by then the clinicians down there were -- there was lots of other evidence: the Galbraith decision and so on and so forth -- that they were

absolutely hooked to the commercial stuff, despite the fact that they said -- and I think they did, the clinicians -- "We want NHS stuff", they weren't going to get it.

So there is no doubt that this came as no surprise, not only because what he was saying, the overriding factor is clinical freedom, and I took a view -- and I wrote about this -- that when the chips are down, the overriding thing is about money, and clinical freedom will take a second seat.

So I was not surprised when I saw this and I wrote about it and said I was, however, dismayed.

Q. Was the sort of notion that we see encapsulated in the last sentence on the screen ever your understanding of self-sufficiency, as you were pursuing it in Scotland in the late 1970s and early 1980s?

A. No. I felt we had a moral obligation -- this is the transfusion service -- to deliver what I saw -- Charlie Forbes said when he puts his hand up, whenever, at any time of day or night, like a surgeon waiting for a.

Q. At the drop of a hat, I think he said.

A. He wanted it, just there. And my view was that was got to be our job, our goal. If you look at the UK haemophilia directors' minutes, you will see time and time again, every two or three years or every year

sometimes, they would issue recommendations on the products that they would recommend people using. And every time, until about 1989, I think, they said, "Our number one priority is from products that come from unpaid donors". They then later wanted heat treatment and so on and so forth. And that was their clinical choice in terms of a corporate body and the government just didn't deliver. There is no doubt whatsoever that the CMO London's comments in 1990, in my view -- I was very distressed about it because I believed they reflected clearly the reality -- and I knew Harold Gunson was very distressed by it too, I might add, very distressed by it -- they reflected the problem they were in.

Q. Professor Cash, I wanted to change the subject now, although we will obviously, when we have the full paper into court book, which will be very shortly, go back and look at it. But if I could change the subject and ask you about Yorkhill, more particularly about the choice of product with which to treat children with haemophilia at Yorkhill.

You will know, I'm sure, that we have discovered a position whereby Yorkhill hospital in Glasgow was using large amounts of commercial concentrate and even in 1980 it looks as though, from the usage reported by

UKHCDO to us, usage that was reported to them and they have passed on to us, that in 1980 only about 20 per cent of what they were using was from PFC. They were using a lot of a product, Factorate, made by Armour.

A. Yes.

Q. Can we go to your statement again, please, page 6. We asked you about this and you give us some information in paragraph 2 there. That was your recollection, that the haemophilia centre director at Yorkhill preferred commercial concentrates to the PFC NHS product.

You did suggest that we asked Dr Aileen Keel about this, and we did try to find out about Dr Keel but Dr Keel's work at Yorkhill was between July 1981 and January 1983, when she was employed there as a leukaemia research fund fellow. So our understanding is that work was in connection with leukaemia.

Just to put this in context to explain why we are asking about it, it looks from the statistical information that we have as though 21 boys became infected with HIV through their treatment at Yorkhill, possibly in the very early 1980s. Doing the best one can to interpret the data, there does seem to be a connection with this use of commercial product.

So questions for the Inquiry involve matters such as

when Dr Willoughby -- for it's Dr Willoughby we are talking about -- made the choice to use commercial product, why he made it and why he wasn't using PFC product.

So can I start by asking you just a little bit about Dr Willoughby? He wasn't at the joint meeting on 30 January 1981. We have the minutes of that, we have looked at that several times. He was represented at that by Dr Pettigrew. There doesn't seem to have been any discussion specific to Yorkhill. How well did you know Dr Willoughby?

A. Not at all, really.

Q. How many times did you meet him?

A. I'm not sure I ever did. But that's my recollection at the present time. But I have read some of the transcripts and his colleagues seem to think he was a very energetic and good doctor, but I have honestly no recollection of meeting him but I may be quite wrong. You are now going to show me a letter, I imagine, from 1972, are you? I have no recollection and I apologise, sir, for having no recollection.

Q. Sadly for us but it will be a relief to you, we don't have anything of that nature.

A. That's very disappointing.

Q. We have looked very thoroughly in our database for

information that might shed some light on all of this. Most of the material that we have about Dr Willoughby -- and we don't have much -- seems to show his involvement in matters to do with anti-D and cell separators. There is one exchange, however, which is interesting, an exchange of correspondence from 1977. Can we look first at [SNB0071075], please?

This is a Dr Easton, a senior registrar. Can we look right at the top, please, just so we can see the heading.

A. Thank you.

Q. It's the haematology department at Yorkhill.

A. Yes.

Q. And on 22 February 1977 Dr Easton is writing to Mr Watt and he tells Mr Watt that they are trying the effect of:

" ... administering Factor VIII concentrate prophylactically to a few severely affected haemophiliacs. These are patients who would probably go on to home therapy at a later stage."

What's perhaps slightly puzzling is the reference to cost because it wouldn't have cost anything to Yorkhill to use PFC product, as I understand it.

A. No.

Q. So do you think that he is thinking about cost in general terms, taking into account the cost of launching

this form of treatment?

A. I have to say I have no idea but if you look carefully at, for instance, the UK haemophilia directors organisations' minutes -- you need to look very carefully -- there are occasions when somebody has leapt up and said, "I'm opposed to this public sector, let's move everything out into the private sector and really create a marketplace". I have to say that that was not a view that was not in Scotland. Some of the tensions -- and I wonder, when I read that now, was this a poor senior registrar being hounded by a chap -- I had never met Dr Willoughby -- that was very concerned about public sector, civil servants, costing an arm and a leg: "It would be much cheaper to the nation if we went and bought it."

I'm not for a moment suggesting that's relevant to Willoughby. By jove, it was not an unknown view among some individuals in that area. So I wouldn't wish to comment about that at all as far as ...

Q. Just for the record, because we are interested in this, you did get a reply, which I think took the letter at face value and answered the questions. It's [SNB0071083]. So the letter is engaging on ideas of cost --

A. Yes.

Q. -- albeit, as Mr Watt says, it's difficult to be precise.

A. Can I just interject and say -- this reminds me, seeing this, that it doesn't appear in the preliminary report at all; no reference to what I regarded as absolutely critical work we did on what I called "value for money".

What we did was -- not "we" did; we brought in independent financial people, to simply ask the question: would it be cheaper for the NHS in Scotland to purchase all this stuff we are making or would it be more expensive? I'm not sure whether you are aware of this story. There is a lot of data in the -- I think you call it the "court book", is it, the large database, in which they demonstrated that in fact if you looked at the bottom line, the work we were doing saved the Scottish Health Service £7.5 million a year. That was in, whenever it was, the mid 1980s.

One of the astonishing things was, when these papers were produced and lodged with the CSA, they didn't get discussed by the Blood Transfusion Service subcommittee. If you look at your court book, you will see I sent copies of the outcomes to the Scottish Office. I had anticipated getting warm letters of, "Well done chaps, you are doing a magnificent job." But absolutely no response whatsoever.

So the whole area of costing, we regarded, if you will allow me to say, as hugely important, and I'm sure John Watt at this date was struggling to make up the figures. We eventually had a group of experts that came in and did it for us and there are a large number of documents which were the outcomes of their work. In 1989/1990, the procedure was -- there was a very good reason why this was repeated -- was repeated and instead of 7.5 million, our profit then, it was still there but it was about 1.2 million. There is an interesting story there.

Q. All right. Can we just finish looking at this letter? It's quite complicated in its thinking.

THE CHAIRMAN: Sorry, could I just have a second before --

MS DUNLOP: Well, yes, all right. I have something else --

THE CHAIRMAN: -- you go on or are you coming back to this?

MS DUNLOP: I'm coming back to what Professor Cash has just said, sir, but for coherence I would like to finish looking at this letter if we might.

THE CHAIRMAN: It might be difficult to achieve --

MS DUNLOP: Well, right. Can we finish looking at the letter, please? Can we go on to the next page, please? We can see Mr Watt has gone into quite a bit of detail here about cost.

A. I see.

Q. And the frustrating thing is there doesn't seem to be any more correspondence, nothing else coming from Yorkhill about this. You know, "Well, in the light of what you say, we would like to proceed with PFC product," or anything like that. So I am afraid it's just a bit of a straw in the wind.

A. I suspect he is a young senior registrar and Watt has done his classic: he blows you away with a vast amount of information. Busy clinicians, you know, "For goodness sake," you know, and that's how we all are.

Q. Right. I do have one letter. It's slightly before the exercise that you were describing a moment ago but I think it may be part of what you were alluding to. I think it's in court book. It should be; it's not on the list. [LIT0010394]. You see, this is a letter that Mr Watt sent to the Lancet in 1979.

A. Yes.

Q. It's about this topic. It does contain some interesting information about costings and it's obviously been sent in response to an editorial criticising the fractionation centres. We can see that on the top of the right-hand side, criticising the fractionation centres for their economic performance and not providing a realistic pricing for NHS Factor VIII concentrate. He goes on to say:

"For the past 18 months the cost of Factor VIII concentrate produced from this centre has been 2.4p per activity unit."

Then at the end of that paragraph he has got the lowest priced commercial product now available in the UK, which costs 9.5p. Is this the sort of material you were thinking of?

A. No, it's very interesting. No, no, I'm being very unkind to my late old friend, John. I'm impressed with the numbers but I'm not at all sure as to the validity of the methodology he has done to get it to that. But, no, we brought in -- please, I can provide you quite easily with the "Value For Money" file if you don't find --

Q. We have a lot of documentation, Professor Cash. I'm not at the moment convinced we need more.

A. That's fine but all I am saying is these numbers are not part of the study I'm referring to.

Q. Right. So I think we have your evidence that work was done, and indeed there is a whole file, the Value For Money file, which records the results?

A. It's "Value For Money" -- called that in my filing system.

Q. I understand.

THE CHAIRMAN: Professor Cash, I'll make my position clear:

The preliminary report could never be comprehensive and in part it was intended to be provocative. If it has provoked you into the recollection of something that I have missed entirely, then what I would ask you to do is just send us a note of the title headings, so that we can have a look at it. We need not take time with it now but I will look at it in due course.

A. Can I say, sir, that I thought the preliminary report was quite outstanding.

THE CHAIRMAN: It may have been but equally it may have been holed below the water line. So if you can provide this data, it will be followed.

A. Thank you, sir.

MS DUNLOP: Thank you, sir.

Returning, Professor Cash, to the theme of Dr Willoughby's reasoning, which is what I was trying to get at, we have seen -- and if you have been keeping up with the transcript, no doubt you have noticed this -- that Dr Willoughby made one of, I think, very few interventions that we have found at a UKHCDO meeting, when he referred to the chance of having adults who weren't crippled. Have you seen that in the transcript?

A. I think I have.

Q. Just for the record, can we have a quick look at it? It's [SNB0017296]. It's actually the Glasgow meeting.

A. Oh, the 80, yes.
Q. Yes. Can we look at page 6, please. It's perhaps difficult to square this with the letters we just looked at from 1977, where, no doubt on instructions from the consultant, Dr Easton was writing and asking what's the cost of all this going to be because here, as I read what Dr Willoughby says, he is really saying this is priceless.
A. I think having an adult with no painful joints and serious deformities is priceless. I should say, I don't think -- and again I don't wish -- there weren't doctors who were saying this wasn't worth it. We were really saying, "Do we get the best value for money by going for the public or the commercial people?" This is before we got very worried about viruses and so on.

My interpretation of this statement here is that Willoughby is saying from a clinical point of view there is no price that you can put on doing this work; from a taxpayer's point of view there should be a price and there may be a cheaper way of achieving the same end.
Q. Did you go to the Glasgow meeting yourself?
A. Do you know, I'm fairly sure I did but I can't recall it.
Q. Let's just look at the front of the minutes and see if you are shown. Can we go back? It doesn't look like

it. Go on to the following page.

A. There are the apologies, and I haven't even apologised in that list of names, which is not very good.

Q. It is actually not as long a list as many of these meetings.

A. Oh, indeed, but the good news is, all you know is, that I haven't apologised. So, in answer to your question, I may have been.

Q. Right. One of the pieces of evidence that we have about why the decision was made to use so much commercial product at Yorkhill comes from Dr Pettigrew. Look at the transcript for 5 May, please, and go to page 18. Thank you. Just to let you read that. (Pause)

A. Yes.

Q. I deduce from everything you have said, Professor Cash, that you are not really in a position to comment on this either.

A. Not really, beyond the fact -- as I say, I never met Willoughby. I'm actually not sure -- I'm sure you may come to it but we had really in Scotland great difficulties in getting information -- we had information on the commercial purchasers. This became quite a contentious issue for a while. I actually don't recall myself being aware of what was going on in Yorkhill until I see the preliminary report, and it's

very interesting -- or at least I don't recall that.

But I think it needs to be appreciated that there were on occasions -- and problems of solubility of the PFC early products, and there is no doubt in my experience that some clinicians reacted, I was about to say, "violently" -- that would be quite wrong -- but reacted very much more strongly about this than others, who seemed very much more relaxed.

Certainly, if you ask about the speciality of paediatrics in the 1980s, it was in a very -- just paediatrics, forget haemophilia at the moment -- it was in a very interesting development stage and it would come as no surprise to me, not knowing the guy, that the paediatricians were extremely twitchy if it didn't dissolve quickly or whatever, whatever, it really wouldn't.

So I could well see somebody like Dr Willoughby deciding -- and I'm also certain that he clearly thought that home therapy -- and I don't think he mentions prophylaxy at this point because that was the next big... But home therapy was critically important to hitting these very early, as soon as they thought they were bleeding. It was very important.

Q. Yes. Of course, there are two different possible problems, aren't there? There is, "I want to use this

product and I can't get enough of it, there isn't a reliable supply chain."

A. Yes.

Q. Or, "I don't want to use this product because I don't like its quality," and it's a little difficult to work out which it is.

A. Yes. I don't think we can work it out, at least I can't, because I never met Willoughby, we didn't discuss it. I'm simply saying that there could be what I would say was a fairly benign reason -- I may dispute it -- a benign reason why in fact Willoughby went down this track.

Q. Just, I think, before we stop for lunch, because it's also from the early 1980s, can we look at the minutes of the joint meeting in January 1981? That's the meeting at which I said Dr Willoughby was represented by Dr Pettigrew. It's [SNB0015055]. You can see there she is in the list of those present.

A. Yes.

Q. Then we go on to supply and demand. We scroll down. And then on to commercial purchases:

"The data provided for 1979 and 1980 show that a significant and apparently increasing quantity of commercially produced Factor VIII was being used and the reasons for this were discussed."

What's interesting about it is that there is no mention of where. It doesn't look as though the meeting probed which particular hospital this might be, or which hospitals. So you are saying that you didn't really have an awareness that this was particularly true of Yorkhill?

A. I didn't, and I'm not sure -- I mean, I saw something -- was it Dr Pettigrew or someone -- in the transcripts, that at that time they only had three patients, or was that Chris Ludlam?

Q. In 1980 they had 55.

A. I beg your pardon. I can't remember now but I know because it was minuted, there was great -- Arthur Bloom said he was very unhappy about giving the transfusion service information on concentrates, it's minuted, because this would lead to comparisons between practices of doctors and centres and so on and so forth, and in my view at the time, the views of Arthur Bloom at that time on this issue, spread right across and up and into Scotland, and we had difficulty in getting figures. And if you ask me: did you get them from individual hospitals or whatever, whatever, whatever? I actually now couldn't be certain. It is just possible -- and it rings a bell -- that we were only allowed to get them from, say, Chris Ludlam. In other words, he gathered

them together and gave us the total figures. That rings a bell, but I think you would need to confirm that with Chris.

Q. I think it's slightly beyond that, Professor Cash, because there does seem to have been awareness from various minutes around this time that there were a lot of purchases in the West of Scotland. So I suppose it would really only have been a choice of two: it would either be Glasgow Royal Infirmary or Yorkhill.

A. Yes.

Q. I just wondered, it might not have been minuted but maybe it was something actually that everybody knew?

A. I can't honestly recall, I really can't.

Q. The other thing that we should note as we look at these minutes is the reference to cryoprecipitate. You were emphasising the important part cryoprecipitate could play in haemophilia treatment. Actually, what happened to your suggestion is apparent to us all.

A. Well perhaps I can just ameliorate some of the pain of my mates. The reason I floated this -- and I wrote about it. I wrote a paper about it, and it went down like a load of lead. And I completely understood this position.

May I say, sir, just as an interjection. In the 1960s I did a PhD and the man who supervised that was

a man you know well in your papers, Howard Davies.

Q. Oh, yes.

A. And dear old Howard used to insist that on Friday afternoon, if he was going to supervise my PhD research, that I went round with him and looked at haemophilia patients, and I did. It must have been the early 1960s, and I was appalled by what I saw. Apart from the fact that there were a large number of patients on pethidine and had become addicted to opiates because of pain control, they didn't have enough Factor VIII. And I saw very clearly that as cryoprecipitate arrived, that produced an immense revolution, but then when the concentrates -- in terms of clinical practice, this produced.

As a person responsible for self-sufficiency, so I thought, I was drawing attention to my colleagues, not just saying, "Keep going with cryoprecipitate, chaps", but cryoprecipitate was much higher yielding than John Watt's PFC's concentrates, and that applies across the world. So if you switched fast from cryoprecipitate to concentrate, from the point of view of self-sufficiency, you were going to need a lot more plasma to stay still. And I actually suggested we gave just a thought before we rushed down that track, and that's all that that was really about.

If you want to know where that actually took place, talk to a Pim van Aken, because the Dutch did exactly that.

Q. We have certainly seen reference to continuing use of cryoprecipitate in Belgium, and at the joint meeting in 1983 you yourself made that point, that there was a lot of cryoprecipitate still used in Belgium.

A. Yes. So in other words, from the point of view of plasma yields -- and again the preliminary report doesn't go into this in great detail -- but it was a massive issue in its own right, the whole question of: how on earth do you get the plasma in the volume and quality we needed to do whatever we were going to do? And this was just an effort.

In actual fact, it was killed, was cryoprecipitate. (A), the clinicians didn't want to know, and they weren't unique in Scotland. You can argue they made a grave error of judgment, but they were our customers. But what really, really killed it was the medicines inspectors came in and closed the freeze-drying plant in the West of Scotland that we were going to use for cryoprecipitate, if that's the way the clinicians wanted to go.

Q. Sir, I think that would be a convenient moment at which to stop.

THE CHAIRMAN: Yes. I might just remind you that you did make a contribution at a joint symposium of the Royal Society of Edinburgh and the College of Physicians in 1972, when I think you spoke about cryoprecipitate, and perhaps were not entirely comfortable with the knowledge of fractionation becoming a dominant factor. It is not in the preliminary report --

A. No, can I say, yes, I came from the background of the plasma suppliers; I was a centre director. And I became increasingly alarmed that we couldn't cope with the needs of plasma and also the yields of fractionation.

THE CHAIRMAN: We will get to these things at an appropriate time.

A. But I was a great supporter of the practice.

(1.06 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: Yes, Ms Dunlop?

MS DUNLOP: Sir. In the interval it has become possible for us to turn the page of that document, so we should just, I think, to finish off the discussion, look at [SNB0061687].

The date of this, Professor Cash, appears to be the beginning of 1990, and I'm guessing from the numbers on the bottom left of the page it looks as though that

might mean some sort of drafting date or draft as at 15 January 1990. Does that look like --

A. Yes, I think so.

Q. -- the way one should understand that --

A. I think that's right.

Q. -- footer there?

Just to pick up your views on the whole self-sufficiency question as at 1990. Obviously, this is beyond the period that we are really looking at in this topic but I refer to it really only because it makes some reference to matters in retrospect.

So you are referring, I think, in the first paragraph to the fact that there wasn't a policy statement when SNBTS wanted one in the early 1980s. Is that right?

A. Yes, yes. I don't know whether there is any paperwork to prove that but, yes, that's clearly what I'm saying.

Q. Whereas you want to say in July 1989 --

A. Yes.

Q. -- there was a sort of policy alert, that SHHD wished the SNBTS to develop a programme of self-sufficiency.

A. That's the letter from Hamish Hamill I referred to this morning.

Q. I'm sorry, the letter from ...?

A. Hamish Hamill, who was the undersecretary.

Q. The other reference that you make to matters in the past occurs later in the paper. It's actually page 9. You say:

"Self-sufficiency was made our operational policy by the SNBTS directors in isolation in 1980. We achieved our objective in 1984 without any targeted additional resources, particularly staff resources."

So again it seems to me you are recording that, even in the absence of formal policy statements in the 1980s, it hadn't stopped you from getting on with matters on the ground.

A. Absolutely, absolutely.

Q. Yes.

A. And there are a number of technical ways we did this which I won't bore you with.

Q. We certainly had a very full explanation from Dr Foster of a lot of technical contributions that were made to achieving self-sufficiency, whatever quite that means.

A. Well, I would just briefly add -- because Peter probably wouldn't be aware of it so much -- the pigtail blood bag proved to be -- and it's published and so on -- proved to be critically important in giving us the kick-start which convinced the Scottish Office that we could do it. This was in 1979, 1980, 1981.

Q. How did the pigtail blood bag help?

A. The pigtail blood bag was a single bag with a pigtail sticking out that you could plug into a giant bag. You just plugged them in, squeezed them and the plasma came out. Without the pigtail system, you would have double and treble bags, all linked together, that you purchased. When you purchased these bags -- and they were very expensive, the double bags and triple bags. Vast amounts of these bags at very expensive cost were cut and thrown away because they weren't used.

We in Edinburgh -- it was developed in Edinburgh during the time I was a doctor there -- developed the pigtail bag system initially with Baxter Travenol to do this work and it meant we could have a single bag for every donation and have the facility to say, "What do we want to use this for?" "Plug it into there". "What do we want to use this for?" "Plug it into there." It really cut our costs. If it had been introduced into England and Wales, everybody worked out it would have saved them about £1.5 million a year.

Q. Right. Can we go back to another joint meeting? This is the one that took place in 1983. The minutes are [SNB0015160]. I don't think, Professor Cash, that we can gain any illumination from the minutes of this meeting on the topic we were discussing before lunch, which is the pattern of usage at Yorkhill. It does

looks as though this is rather late in the narrative, as far as Yorkhill is concerned anyway, because the use of commercial concentrate seems to have peaked several years before this --

A. Yes, that's true.

Q. -- and in fact have been declining at this point and in the course of being overtaken by use of PFC product. We also note that in fact there was no representation from Yorkhill at this meeting. Dr Willoughby sent his apologies but we know that that was just at the time of the changeover from Dr Willoughby to Professor Hann.

A. I was going to say, yes.

Q. I wonder if we can juxtapose Professor Cash's statement as well, please. Can we go back to the statement at page 3?

(Pause)

Professor Cash, while we are waiting, I was going to take you to the part that says that you were the one who ensured that the topic of HIV/AIDS was discussed at the joint meeting on 21 January 1983. Just to flesh that out a little bit -- and if it helps, we can do this with the actual minutes of the meeting, Professor Cash. Can we go on through the minutes, please, and look at the discussion of AIDS, which is on page 7. You were drawing members' attention to recent articles in the

United States and also in the Observer and the Lancet.

For reasons of economy and looking at documents one at a time, perhaps we will finish looking at the minutes before we look at something else and just note that in these minutes there is also another mention of cryoprecipitate. I mentioned this before lunch. This is where you refer, on page 3, to the successful clinical trial of freeze-dried cryo in the West but, because of the closure of the plant at Law --

A. That's right.

Q. -- it was a project that wasn't going any further. Is that right?

A. That's right. It would have needed massive investment.

Q. Yes. I think we can leave the set of minutes and look at what is in Professor Cash's paper, [SNB0137601]. Was it your practice, Professor Cash, to do a paper before a meeting of this nature?

A. This is the joint?

Q. Yes.

A. Yes. I should perhaps say that the joint meeting was created by myself, in the sense that I felt very strongly in -- I don't know, 1980/1981, I think it was -- that there needed to be a forum whereby the clinicians and ourselves could work closely together. This was established and welcomed and in the event it

fell upon me to meet Bert Bell, who was the chairman from the Scottish Office, to discuss what we would have on the agenda and the content. I suggested initially to him that I produced a document for everybody to look at and, yes, to the best of my knowledge, every meeting I produced a document. The meeting changed later but in this critical period I think you will find there is a document for each meeting.

Q. You mentioned AIDS in it. Could we go to 7607, please? That must be page 7. You are drawing the attention of the haemophilia directors to this problem and you say:

"The information contained in appendix 6 has been sent to Professor Bloom."

I think it was actually in the context of looking at Professor Prentice's statement we realised that --

A. I can't remember.

Q. Well, when we looked at it in the Inquiry, we hadn't actually identified quite what was before everybody at the meeting on 21 January 1983, when you were discussing AIDS. The answer to that question comes with this paper. In particular now, looking at appendix 6, which begins on page 14, we can see that this is the July 1982 MMWR.

A. Yes.

Q. We are now quite familiar with that. If we go on to

page 15, this is the December MMWR. So the answer to which MMWRs were circulated before the meeting on 21 January 1983 is that it was both of these ones from 1982.

A. I noticed they are my copies. I don't know who circulated them.

Q. So could we go back to the statement then, please, and read what Professor Cash is saying in his statement? This is paragraph 3 at the top of the page.

A. Yes.

Q. The question we tried to focus on when we asked for statements was whether there had been discussion of any possible connection between AIDS and blood products at that meeting and you don't think that the minutes reflect the extent of the discussion that took place. Do you actually remember that meeting?

A. No, to be honest, absolutely not.

Q. Right. Okay.

A. But I think I said, when I was here before, that minutes don't always well reflect the quantity or the quality of discussions.

Q. Yes.

A. I reported a sense of dark foreboding, I see. That to me would mean at least it was fairly extensively discussed.

Q. I don't think we need to go into paragraphs 4 and 5 but paragraph 6 of your statement on that page.
A. Oh, yes.
Q. You say that around this time you had asked Dr Bell:

" ... whether the CMO ... might ... issue a letter to Health Boards, prescribing physicians and patient interest groups, drawing attention to the increased risk of virus infections in patients receiving commercial plasma products and advising that whenever possible the safer SNBTS products should be preferred."

I think we can just take that paragraph as read and the next paragraph also. Read paragraphs 8 and 9 on the following page. (Pause)

Professor Cash, we did ask whether there was any record that we could look at about these discussions, and that was the other paragraph that was covered in the letter from the Scottish executive. Perhaps we can just go back and look at that. That's [PEN0150100]. It's paragraph 2.
A. Hm-mm.
Q. It's 28 years ago and it has, I think, been difficult to find any documentation of this but it's plainly something you remember quite clearly, is it?
A. Very clearly actually, yes.
Q. Are you thinking particularly of when you spoke to the

CMO directly?

A. Yes, absolutely.

Q. Right.

A. Yes.

Q. Can we go back then, please, to the statement at paragraph 9. What was your understanding as to Dr Reid's thinking?

A. Well, it's difficult. Years have gone by and this was a fairly seminal moment, and all I can say is that in the process by which I was appointed national medical director I had a whole series of conversations with Dr Graham Scott, who was then the deputy chief medical officer.

My problem was that I had a superb job as director of the Edinburgh centre and I was not at all anxious to leave that, and when the post was advertised after the death of Hugh Jeffrey, I didn't apply, and it was readvertised and I didn't apply. And at that point I was summoned to the department to talk to Graham Scott and this I did, and he prevailed upon me to give it careful consideration, and I did. And slowly but surely I decided: okay, but there will be certain conditions. And there was a number of conditions.

One of the conditions was that the Scottish Office would back us in terms of national self-sufficiency.

I discovered in these discussions -- and these discussions were in 1979 -- that this was a problem for Graham, and I had the distinct impression, no more than that, that there was certain pressure from London in which the interpretation of self-sufficiency -- we talked about this this morning -- was different from ourselves. And Graham was initially very uncomfortable that he could guarantee this to me and so on and so forth.

But we met again and he had obviously had further chats with some of his colleagues and he gave me an assurance -- it wasn't policy -- he gave me a personal assurance that they would do their damnedest, and I was delighted and so I took the job on. This was the second moment, after I had taken the job on, that I had serious doubts that I had made the right decision and switched from coming out of Edinburgh. What was behind my concern was, I began to feel -- not for the first time, I have to say -- that behind the department in Scotland -- and this is pre-devolution, don't forget -- was a powerful Secretary of State for Health down in London. I look at it now and I sometimes think I was very naive to go and see the chief medical officer, "Could you write a letter to all the chaps in Scotland". And I now, more than ever -- I didn't appreciate it

sufficiently then -- understand the position that he said he wasn't able to do that.

I should point out, I have since learned that John Reid came from London, the DHSS, to the big job up here. So he knew his colleagues very well down there.

Q. So you are saying that really the possibility of taking a different line from the DHSS was not open?

A. It didn't seem to me open. And when you say what proof did I have that London were -- it was just a feeling, it was just conversations. There were other conversations with Harold Gunson -- but not related to this topic; they occurred on other occasions.

Q. What you were looking for was something of that sort, a letter from the CMO --

A. It is really quite common in the health service, in which the CMO writes a "Dear Doctor" letter, copies it to health boards and whatever it is. Yes, it was just a "Dear Doctor" letter in which he was pointing out these things. What they would have signaled, I argued, perhaps naively, that this was the Department of Health in Scotland putting its shoulder behind what we were doing in the SNBTS.

Q. Right. Professor Cash, in a different context, it does look as though you were quite grateful that SHHD weren't too closely involved. If we look at [SNB0125017], the

context of this is leaflets. This is a letter from you in December 1990 to the then Dr K Calman, and you are saying that you have always advised SHHD of what you were doing but you had had no requirement for SHHD clearance:

"... the issue being regarded as a professional matter, the significant advantage of this approach is the speed at which the SNBTS can introduce change."

Then you return to that in the third paragraph. You say:

"Scotland consistently introduces change many months ahead of England and Wales."

How should we understand this, Professor Cash? Is it that there were some issues where it was better not to have SHHD involvement and some issues where it was better to have such involvement?

A. Yes, but I would simply say, where we were looking for SHHD involvement is the whole area of self-sufficiency. That's a big, big -- as we discussed this morning -- policy issue, impacting on a lot of other doctors, you know, on the health service in general.

The topic with Ken Calman is about an internal functional bit of business within the SNBTS, ie the whole business of developing donor self-exclusion leaflets; in the AIDS era that was hugely important.

All I'm saying is that what happened there is -- and I don't know whether we are going to come to this -- we became very dismayed at the speed in which the London department -- this has nothing to do with what we have just been talking about -- the speed the London department was in fact responding to the AIDS crisis in the context of blood transfusion.

Q. I --

A. And this was an area where we took off on our own and the Scottish Office very kindly said, "That's fine, guys". Because traditionally, donor exclusion leaflets were the work of the DHSS. If you ask: did they say, "Carry on chaps" in terms of donation testing; no they didn't. Donation testing in the HIV and HCV remained unequivocally -- and Archie McIntyre referred in some of his letters -- the area for DHSS. This was an area in which we were allowed to get on ourselves.

Ken Calman didn't appreciate it but I was asked to write this letter by Harold Gunson because they were getting increasingly concerned at the difference between the donor self-exclusion programmes north and south of the border because of delays.

So, yes, there would be things that were internal that we were managing. I was delighted if we didn't have to touch base with our colleagues in the

Scottish Office. There are other things that we felt would be very helpful.

Q. Right. We certainly see you using the expression in this letter, "a professional matter". So as a professional matter this was something that you felt was appropriately left to you to get on with.

A. Yes. Yes.

Q. But you wouldn't say the same about trying to increase the production of blood product concentrates, Factor VIII concentrate; to you there was a wider policy context --

A. I would have thought wider policy, managerial, pigtail bags -- there was nothing medical about pigtail bags for instance -- and things like that. This was what we eventually called "Jack Gillon's country". Although at that time, HIV, Brian McClelland did all the work. Wonderful.

Q. Thank you. Just to ask you some questions about the actual supply of concentrates.

I think the position we have reached so far in our evidence is that, to start with Edinburgh, commercial concentrates, if they were needed, when Dr Ludlam arrived, the system that applied -- and that continued to apply for another couple of years -- was that all the commercial products were ordered via the regional

transfusion service.

Can we just have [PEN0150480] please? This is the letter from Dr Ludlam in April 1983, where there is a change taking place. But you see he says that in relation to the ordering and storing of non-NHS produced therapeutic materials, to date this has been arranged by the Blood Transfusion Service. He was taking that over. So that seems to be the piece of the jigsaw that relates to commercial products in Edinburgh.

In April 1983 Dr Ludlam was cutting out the involvement of the regional transfusion centre and ordering material directly via the pharmacy. We understand from his evidence that the products, once obtained, would be stored in the SNBTS blood bank, I think until 1983. And then from this change in 1983 they were stored in and issued from the pharmacy.

Commercial products in Glasgow, if we think about firstly the situation that a specific product was needed for a specific patient, which we have heard happened from time to time, it's a little more difficult to work out whether that was obtained by a doctor ordering through the hospital pharmacy or by the doctor ordering through the Blood Transfusion Service at Law. Do you have any recollection of what would happen there?

A. I have no detailed recollection but I do know -- I mean,

I have written odd papers that are in the main database, in which I have said I have reason to believe that in Edinburgh and Glasgow, the West of Scotland, the purchases are done by the pharmacy. I can't date those documents, I am afraid, at the moment, out of my head. Whereas I had the view -- and I may be quite wrong but I said it -- that Aberdeen, Dundee and Inverness, any orders were done through the regional transfusion centre.

Q. Yes. You do say in your statement that SNBTS had no involvement in any part of the purchasing process for commercial products for the two big centres, Glasgow and Edinburgh.

A. Yes.

Q. But I'm just saying that from this letter of Dr Ludlam's, it does look as though they did until 1983.

A. Oh, yes. Can I say, the issue, which is what we have just seen, of Chris Ludlam moving out, we were all very unhappy with. The only reason that we were unhappy is that, from that moment on we became very uncertain that the data we had on commercial purchases was accurate. I think looking back, we exaggerated all that because it remained very small, but we were very worried that perhaps behind all this -- in which we had now been excluded from seeing the data as it was being purchased

and so on -- there may be something bigger than we had imagined. I think that wasn't so but from a planning point of view, we became very anxious.

Q. Right. As far as commercial products at Yorkhill were concerned, Dr Pettigrew thought, in her evidence, that the material would be ordered by a technician at Yorkhill. In fact she named an individual, a Mr Jewel, a senior chief technician. But I don't suppose you are in a position to offer --

A. That will be the local haematology and it will be the blood bank section, I imagine. And he probably did it through the hospital pharmacy.

Q. As far as general stock goes, if we think of Edinburgh, thinking of material coming from PFC, we have heard Dr Perry describing -- it is not a van, Professor Ludlam called it a van. Dr Perry says it is more of a lorry, it's a vehicle. It came to the Royal Infirmary very conveniently delivering and uplifting.

A. Yes.

Q. It was refrigerated, a refrigerated truck.

A. Sure, sure.

Q. So I think we understand that. The stock from PFC in the Royal Infirmary, once it had arrived at the Royal Infirmary, Professor Ludlam said that Drs Boulton and McClelland held it in a cupboard for him. No doubt he

means something cold, but they stored it in the blood transfusion centre in the Royal Infirmary. Then general stock for Glasgow, as we understand it, the same truck would take that to Law and deliver it to Law.

A. I think that's right.

Q. Then it becomes slightly more mysterious because the material has to get from Law to either the Royal Infirmary in Glasgow or Yorkhill, and there is some reference to daily ordering from the Royal Infirmary to Law. Then presumably, once Yorkhill start to use PFC material they must have had some kind of ordering system too.

A. Yes.

Q. Do you have any recollection of the personnel in the West, who were helping to make self-sufficiency a practical reality, people who were assisting the users in the West of Scotland to get the product they needed from PFC, making things easier for them perhaps, taking any comments or compliments/complaints back to PFC?

A. Yes.

Q. Who was involved in that?

A. There is no doubt Ruthven Mitchell, the director, was very hands-on in that region. But I would imagine the two guys who were doing the sort of thing you are really interested in in terms of doctors would be Bob Crawford

and -- for goodness sake, I have just forgotten --

Q. Was it Dr Hopkins?

A. Thank you. The irascible Dr Hopkins, who I saw a brilliant quote in one of the transcripts.

Q. Right.

A. Yes.

Q. Is this prompted by what you have read in the transcripts?

A. No, Bob Hopkins was --

Q. I don't mean his irascibility, I mean his involvement.

A. Oh, I see, yes. He was involved. And I think if the late John Davidson was with us, who was the haematologist operating on behalf of George McDonald in the blood bank area in the Royal Infirmary, he would confirm he had quite a lot of fun with Dr Hopkins. Yes, that would be the pathway.

Q. Can we go back to the statement from Professor Cash, please, on to page 5. Thank you.

There isn't very much else that we need to cover, Professor Cash, because we have discussed most of it already.

We clarified -- and this is evident from the handwritten question that we can see on page 5 -- that there seems to have been a bit of debate about Glasgow and Edinburgh becoming reference centres; that being

rather different from ordinary membership of UKHCDO.
A. I apologise. I initially got it quite wrong.
Q. No. I should also explain, sir, that the reason for the handwritten questions is because originally we only had the statement as a PDF and it seemed like the best way to put some questions on the statement to Professor Cash.
A. It was very helpful.
Q. I'm glad it worked as a solution.
A. Oh, yes.
THE CHAIRMAN: I have seen a later reference, which I'll no doubt in due course draw Ms Dunlop's reference to, in a letter from the DHSS, saying that Glasgow and Edinburgh were perhaps not strictly reference centres but were rather centres of excellence. Do you remember that coming into the --
A. Yes, I do. I saw Dr Ludlam -- because Ludlam's comments about it -- and I thought he was pretty laid back with you the other day -- it was quite tetchy, quite tetchy, and we supported Chris and the Glasgow boys strongly.
MS DUNLOP: I'm certainly happy to look at that. It is [DHF0017665]. Is it pejorative?
A. I honestly don't know. Professor James may have a view on this. Senior civil servants in London regarded Scotland as a place like the northeast and Newcastle and

the notion of having two of these people on the UK was too much. They had no idea of not only the sensitivities and rivalries, but -- I was reading a letter this morning about a superregional centre at the Royal Free hospital, and the notion of having two from Scotland was really irksome, and the arrival, for instance, of five Scottish regional transfusion directors down into England was regarded as just outrageous. We just needed one. "You will do, John," was the comment.

Q. Certainly --

A. And that's another culture. It's all about the culture.

Q. Of course, Professor Cash. I'm not saying the Inquiry team doesn't notice these things too but the chairman has reminded us of this letter. There is another letter which says words to the effect, "Of course, they have to have two," meaning there has to be one in Glasgow and one in Edinburgh?

A. Absolutely.

Q. And that's a whole different topic, which I don't think we should even think about opening up.

THE CHAIRMAN: Certainly not at this time on a Friday afternoon.

A. Thank you, sir.

MS DUNLOP: No. But just the reference to Scotland having

two haemophilia centres, which perhaps are regarded more as centres of excellence than reference centres, one wouldn't want to be oversensitive. Perhaps it wasn't meant to be pejorative at all. I daresay we will never know.

Can we just look at the heading please? I don't think we know who said it.

A. I'm pretty sure it wouldn't be Arthur Bloom.

Q. No, it's a DHSS letter.

A. Yes, very gentle.

Q. We have enough information that I can tell you who occupied that room in 1983, but that really would be speculating to say that the same person was in that room in 1985.

Can we just look at the end of the letter, please? There we are. Absolutely no illumination there.

Now, we were in the statement. Can we go back to the statement, please? There really isn't much else I need to put to you at all. You don't think that at the time you knew about Dr Galbraith's proposals. That's at the bottom of page 5.

A. Yes.

Q. And then on to the next page. We have discussed this, the different considerations that applied to supply in England.

A. I don't want to delay the weekend for you but the Galbraith thing is hugely important --

Q. Quite.

A. -- in my view. First of all, I was absolutely dismayed and quite angry that I knew nothing about it until I read the papers of this Inquiry. What I can tell you is that I discovered quite by chance that John Watt was on the Committee on the Safety of Medicines biological subcommittee -- quite by chance -- by going over to see him in 1980 and falling over these sacks of documents that these chaps get with all evidence. He told me he was on this committee. I said "Excellent," because what we want to do with that committee is persuade them to up the ante in terms of safety of the commercial products coming into the United Kingdom.

John asked me to produce an A4 list of suggestions that they might do to improve the safety and when I took it back, he was now of a different mind, that (a) he was working under state secrets (inaudible) and couldn't divulge to me or anybody else the business of this particular committee and furthermore he was very anxious that he might be accused of conflicts of interest, ie he was the public sector and he was making comments about the private sector.

I do not know, to be absolutely honest, because he

never came back to me, whether John in fact took these proposals, but they were really quite important proposals, that I had hoped -- you know, when the Galbraith thing finally arrived in 1983, I would have hoped that committee, which John was on, would have said, "Okay, we can't abandon the American stuff, but can we make it any safer?" And there is no doubt that they could have, and they took no action at all, and I was pretty concerned about that, I must say, when I read the Galbraith story here.

Q. Can we just look at page 3 of Professor Cash's statement? In the paragraph which has the number 4 you have made a reference to -- actually this is UKHCDO and their conclusions being difficult to challenge, where almost 60 per cent of the concentrate used was sourced commercially. Certainly, the meeting on 13 July 1983, that considered Dr Galbraith's papers, appears to have been strongly influenced by considerations of supply. You say that yourself on page 6.

You have obviously thought about this recently. One question that one could pose about that debate on 13 July 1983 is: if one has a little of a product or a lot of a product -- so the product is either scarce or plentiful -- how does that affect a judgment as to whether or not it's safe?

A. I'm sorry, I am not quite with you. I think it's the nature of, not the amount.

Q. It's perhaps a slightly tongue in cheek question, Professor Cash. It does seem that the discussion very much centred on the supply: is this scarce or plentiful? And the answer was it was scarce, but the topic for the meeting looks to have been the safety of the product, and I'm wondering if you can see how the fact that something was scarce or plentiful would impact on whether or not it was safe.

A. No, I can't but the dead hand of the DHSS, whether it's their supplies division or in other departments, on the work of the Committee on the Safety of Medicines -- if you look at the Medicines Act and what's around it, the CSM is supposed to be totally independent and so on, and there is absolutely no doubt that the chairman of that committee on the day, I knew very well -- and Joe was not independent, he was very influenced by policy-makers and DHSS, and it would not surprise me, I mean, I wouldn't criticise this, that in fact that committee met and the chairman already had been given the steer as to where he was to take the thing and it was about supply. Forgive me but it was about supply in the end and I'm absolutely certain that ministers would have been extremely concerned if a bunch of experts had said,

"It's dangerous, take it out, just walk away from it," which is what Dr Galbraith in fact was recommending.

Some people -- and I would have to share that view -- would have regarded that view as irresponsible. But there was a middle way and it was not even considered and that's the thing that distressed me. It might in my view -- and it sounds outrageous -- have saved a lot of lives.

Q. Professor Cash, much of what's in the rest of your statement is either material that we have already covered or that you say is more relevant for haemophilia clinicians to answer.

I think the only section that we should look at -- you can perhaps take the intervening pages as read and look at page 9, just to look in particular at the views express in the paragraph numbered 2.

The question that is being asked is in relation to the early part of 1984 but how should we understand the timeframe to which you are referring in paragraph 2, particularly your comment that:

"NHS products were viewed by many haemophilia centre directors as intrinsically unreliable, both in terms of supply and quality of product."

What timeframe are you speaking of?

A. Oh, as best recollected, it would be pre-high purity.

Q. So up until when?
A. That would be 1988-ish.
Q. Right.
A. If you ask me were these views justified, I would unequivocally say no but I think there was great anxiety by the prescribing clinicians throughout the United Kingdom that if we let the public sector, which is run by civil servants and politicians -- "Not by you, Cash," they would tell me, and rightly so -- we may get into trouble in the future.

I think I have said it somewhere in one of my witness statements: in Scotland we eventually fell from -- I call it fell from grace. By 1988 we had run short of plasma. We had signalled the need and the funding had not come. There were a lot of clinicians who were very keen to have NHS stuff but they regarded -- for reliability and indeed quality. We had problems with research, we had problems with optimising yield so that we remained self-sufficient, whereas all our commercial mates didn't have these problems, they just charged the money or whatever costs. So it was a difficult task to manage.

Q. Yes. But there are some positive comments --
A. Oh, yes.
Q. -- really throughout the minutes of meetings in the

early 1980s too, for example 21 January 1983. I don't want to go back to it but Dr George McDonald was complimenting the SNBTS directors and PFC on the quantity and quality of Factor VIII concentrate.

A. George was not a clinician and I don't think, if you read -- I'm sure you have -- Charles Forbes' comments, they would necessarily mirror that. So there was an area of difficulty and we were aware of it.

Q. Yes but even if he wasn't a clinician, Dr McDonald was presumably going on what people were telling him at that time?

A. I can't tell you. He was a dear friend.

Q. Right. Not a big point. We did suggest to you there was a word missing in paragraph 4. It's not a big point at all. I think we just wondered if the phrase at the end, "rather to retain some sort of the marketplace", means just to retain some sort of involvement in the marketplace.

A. "Some sort of." There's a "the", I think, that probably shouldn't be there.

Q. Okay, it is not a word missing, it is a word too many?

A. Yes.

Q. Right. Just, in conclusion, look at your supplementary comments. I think again we have covered most of these. [PEN0150362]. I think we have covered everything on the

first page.

Then the second page. Apart from one or two textual corrections, the biggest point, obviously, on the second page is in relation to exactly that issue; that's the question 6 in the statement, the paragraph we have just looked at about the views of haemophilia centre directors. You have said you basically are adhering to the views expressed in your statement. I think we should just read for ourselves what you say about your doubts as to whether the haemophilia centre directors or SHHD were fully committed. (Pause)

Some at least of this, Professor Cash, does relate to a period beyond the period we are examining at the moment, which is primarily the use of concentrates in the early 1980s.

A. I think the big change came in 1988/1989 with the EU Directive 381, with the now Lord Forsyth coming into my office and having chats and walking out leaving a cheque for £4 million in effect. That produced a huge change, that allowed us -- and we abandoned Crown immunity, we invested very heavily and so on, and for certainly the period that I was there, until I retired in 1997, there was a complete change. I was conscious -- and the attitude of my mates and colleagues in the Scottish Office -- for whatever reason we seemed to

have, I thought, detached ourself from London.

Q. Well, Professor Cash, a speaker should, I gather, leave his audience always wanting more. So perhaps with your reference to being left a cheque for £4 million, we can conclude for today.

A. Thank you very, very much.

THE CHAIRMAN: Mr Di Rollo?

Questions by MR DI ROLLO

MR DI ROLLO: Professor Cash, there was one document which I would like to put to you. It's [SNF0010178]. Can it just be put up on to the screen? I think this is in the context of certain remarks you made about Yorkhill this morning. If you go to page 3 of the document, under (e), "Purchase of commercial blood products", we will see that there is a paragraph there:

"During a full discussion, in which it was acknowledged that the Glasgow Western Infirmary Royal Hospital for Sick Children appeared to be the last remaining hospital to use substantial quantities of commercial Factor VIII in the West of Scotland, it was agreed that Dr Mitchell should write to the consultants concerned to enquire why they needed commercial products. In addition, Dr Cash would include the matter in a document which he was preparing concerning planning for self-sufficiency in clinically safe products."

It does appear from that that there was obviously some involvement by you and some knowledge on your part in respect of the situation at Yorkhill and Glasgow Western Infirmary and their use of commercial products at the time. Do you agree with that?

A. I have not checked the dates but I take your point and apologise for misleading this morning. I do not remember that.

Q. Just dealing with the point generally, my learned friend was asking you about the use of commercial material at Yorkhill, and it does appear that that was something that was going on. You said today that you didn't ever meet Dr Willoughby and you are not really able to tell us why it was that he may have been using commercial product to the extent that he was and certainly seems to have been doing more or less to the exclusion of NHS product. You can't really help us with that?

A. No, forgive me. I did make some suggestions as to why he might.

Q. Yes, but you do not know?

A. I don't know.

Q. It was never discussed with you at the time?

A. No, no.

Q. You would assume, I suppose, that it was for good clinical reasons.

A. Of course, yes.
Q. There wouldn't be any other reason to choose commercial over NHS, something to do with marketing or a better relationship with the company they were dealing with rather than with PFC Limited or anything of that nature? You are assuming that it's a clinical reason rather than anything else?
A. No, no, it's a clinical reason, yes. As I said this morning, it might be he had strong views about solubility, about the volume that he could get compared to the volume he could get our doses in. There were all sorts of potential reasons that I could see a paediatrician ...
Q. As I understand it, you think that it's important that the clinicians should have a choice. Is that what you are saying?
A. Oh, yes. Forgive me, yes.
Q. So if, for example, government had dictated to you that you will only use NHS product, would you have said, "No, no, we can't have that because the clinician must have a choice"?
A. No, I'm simply saying that clinical freedom has got some very significant advantages. Situations may arise when clinical freedom has to take second place and we see this today, we have seen it for decades, ie the

financial manager in the Royal Infirmary in Edinburgh tells the doctor there is no money for that patient with cancer: Good night and good bye, and he has to accept -- that's the only point.

Q. At what point in the self-sufficiency drive do you say that the physician gives up his clinical freedom? That's what I'm trying to get to. Obviously, you can't have self-sufficiency if the clinicians are free to choose commercial products.

A. Well, I'm not convinced by that. I can take you to documents in which the clinicians are saying, "We want NHS products of that quality and that amount and if you deliver that, great stuff. That's all we want." To deliver that -- and we have never got down to talking about it yet -- is really quite complicated, it isn't just about money. But I have always taken the view that if we could have delivered, and our mates south of the border could have delivered, quality compared to the commercial, quantity and delivered on time, it would have naturally meant that the clinician would have said, "That's great, we will have it." Why? It's NHS, and as Ms Dunlop has said, in Scotland -- not England, but in Scotland it didn't cost them anything to their budgets, the hospitals.

Q. Did you feel they did get there in Scotland at a certain

point, in your view?

A. No. We had surpluses of the product in 1983/1984 that we produced, and we sent a lot of that surplus down to England, but in my view, in discussion with clinical colleagues -- and I was well aware of this when I worked in the Edinburgh centre -- there was the odd patient, haemophilia patient, you put in the NHS stuff and they reacted to it.

Q. Yes, but --

A. And you had an odd patient for the commercial, same.

Q. -- leaving aside those kinds of cases. We are not really talking about that; we are talking about the sorts of situations where one is as good as the other in terms of -- you do actually genuinely have a choice. Then did they reach self-sufficiency in Scotland at any point, leaving aside the reactions of patients or that kind of thing?

A. Yes, I think the moment we were surplus and handing it down to England we were self-sufficient. However, in the real world, if the clinicians were not picking it all up and were for some reason using alternatives because ours in their view was not appropriate to give ...

Q. It's a question of their view, though --

A. Yes, of course.

Q. -- it is a question of how you control or affect or influence their view.
A. Yes.
Q. And what I'm saying to you is it can't presumably just be a question of the government doing it because if it was the government doing it, then the medical profession would react against that and say, "You are not going to tell us what we do in terms of prescribing material."
A. Well, we are getting into another area about self-sufficiency. In my view, if you are going to be really self-sufficient, you need the government, the civil servant's team, you need the transfusion service and you need the clinicians to be working very closely together.
Q. Surely.
A. And if you have listened to half of today, as far as I'm concerned, you will have realised that that didn't happen quite as well as we had wanted. You can say that was the clinicians but there were other people involved. All of us have got motes in our eye. We didn't quite get our act together. But I will tell you internationally we did a hell of a lot better than any other country I know actually.
Q. Can I just ask you about one more matter, again arising from the questions you were asked earlier.

You referred in the context of Dr Galbraith's intervention, the decision that had to be made by the committee in relation to what to do at that point. You said there was a middle way in relation to that. What's the middle way that you are suggesting, I'm not entirely sure?

A. There are a number of options and we haven't enough time to go into this in detail but it is a recorded fact -- and I know Ms Dunlop doesn't want any more paper for this Inquiry and I appreciate that, but if you are at all interested, and if you are into Douglas Starr -- which I see you are and I'm delighted -- there is another series of publications of all papers, the Philadelphia Inquirer -- which you may laugh but it is actually a very serious paper -- that ran a series of major investigative articles on the bad blood business in the US of A.

I became aware of these articles because, in 1969 when I visited the States, I made a great friend -- a number of them -- but one of them was Lieutenant Colonel Tom Zuck of the US army, and in 1984/1985 he was seconded to the FDA. And the reason he was seconded -- and I was very close to him and knew all about this -- is that the FDA inspection area for blood banks and plasma centres was a disaster area, and if you

want to see this in detail, read the Philadelphia Inquirer. There was a major Douglas Starr investigation of it. At the time we are talking about, the regulation of the blood industry, in its broadest sense, in the US just went out of the attic. Primarily because, they say, Mr Reagan did what Mrs T did, had a massive cut in the -- and the staff of the FDA were halved overnight.

So at the crucial period, when the -- and my argument was the Committee on the Safety On Medicines should know -- I knew that, John Watt my old friend knew that. The Committee of Medicines should be saying, "We are importing theses materials from the US of A; what's going on in terms of regulation?" And almost certainly -- because I asked them -- the inspectors from London of the MCA, I thought they went and inspected these -- they didn't, they didn't have the resources.

So we were importing stuff from the USA from set-ups that were not being inspected at all. And if you want the gory detail, I'll tell you. Have a look at the Philadelphia Inquirer.

You say: what could we have done? First of all, introduce some inspection. Secondly -- and I don't know whether this is on -- there were certain companies, and if you look at the World in Action, John Prothero, the

haemophiliac in the second disc, super guy, he actually says, "I'm very amazed by this documentary" because he says, "I know of some companies that claim they don't use skid row at all". It's part of their marketing, and certainly I did -- I'm not going to name the one -- and they claimed, "If you get your stuff from us, we can guarantee it is not coming from there. We can guarantee it's of the highest quality in terms of plasma." One of the companies claimed it would be just as safe as ours.

We could have actually then said to supplies division in DHSS -- when I say "we", the Committee on the Safety of Medicines -- then what we should be doing is getting our contracts from these companies that have approval. "That company, that company" -- the Committee of Medicine -- "doesn't have our approval". Whether that was politically on, I don't know, but it was a middle way.

Q. Thank you. Thank you very much, professor.

MR ANDERSON: I have no questions.

THE CHAIRMAN: Mr Sheldon?

MR SHELDON: Briefly, sir, please.

Questions by MR SHELDON

MR SHELDON: Professor Cash, I wanted to ask you about your proposal to the Scottish CMO that a letter be issued. I really just want to ask you this: why did you feel it

necessary to suggest or request that such a letter be issued by the Scottish CMO?

A. Because I was not certain in my mind that our clinical colleagues were at all impressed that the SNBTS had the fullest support of the Scottish Home and Health Department in that context.

The main evidence for that came, for them, when we said, "Could we have full data on purchases of Factor VIII, and therefore, if the best way of getting that is if we issue it, you tell us what to buy, we will buy it for you and we will issue it," the directors of the haemophilia centres did not like that, the supplies in England.

DHSS went to the UK haemophilia doctors making that request and it was turned down, and after that I wanted an assurance from the Scottish Office -- that was communicated to hospital pharmacies, to regional pharmacies -- that the purchases of commercial Factor VIII in Scotland should be very carefully considered.

Q. We looked this morning at a couple of minutes of joint directors' meetings, one in January 1983 and one in February 1984, where really that very point is made, that purchases of commercial products should be kept to a minimum. This is in the context of a discussion about

the risks associated with imported product. The impression that was given really, from the minutes of those meetings is that there was substantial consensus among those present, ie the transfusion directors, the haemophilia directors and representatives of SHHD, that commercial purchases should be restricted and NHS products preferred.

Is that a fair way of characterising it?

A. Yes, but I think the concern that we had, as I explained an hour or so ago, is that we were not entirely certain that the data we were getting on commercial purchases was accurate.

Q. I'm not quite sure that I follow that. Is the concern that there were purchases being made by haemophilia directors, for example, which weren't being declared or which weren't being talked about at these meetings?

A. Yes.

I'm not suggesting that -- they could have been mistakes or whatever but until -- I think in the preliminary report, comments have been made about the work of Bob Stewart. And the great strength that Bob Stewart had when he joined the organisation -- that clearly the regional pharmacy people had been instructed then, finally, in 1989/1989, to provide us with the information, and they did and it was magnificent.

Q. Is it your recollection that your concern about the amount of commercial concentrate being purchased in Scotland was shared by officials within SHHD?
A. Yes, but I think there is a statement made by Bert Bell at one point that the department does not wish to interfere with the autonomy -- I think that's right, sir -- the autonomy of the regional health authority.
Q. Perhaps we can just look at that, in fairness to Dr Bell. We have already looked at it briefly. It's [SNB0015252].

This is the minute of the meeting of 2 February 1984. Could we look, please, at page 2. If we look to the bottom of that page, we can see the context which is you asking members to consider whether it's necessary to purchase commercially. If we look over the page.

A. This is 1984, is it, this one?
Q. That's right, 2 February, 1984.
A. Thank you.
Q. Over the page, there is clearly some discussion: Drs McDonald, Hann and Ludlam make contributions, and Dr Bell emphasises that the aim of SNBTS and national policy was for Scotland to be self-sufficient, and although the department would not wish to intervene in what physicians prescribed it was not sensible to

purchase imported material when suitable NHS product was available.

So is Dr Bell really there trying to negotiate the line, or walk the line between affording freedom to clinicians but also saying that, "If possible, you shouldn't be buying commercial product"?

A. Yes. I welcomed that and I welcomed also the statement he made, I think, in the 1983 meeting. And all I was doing was to get, in a sense, the CMO to say the same thing.

I have to say to you -- and I'm sure you will appreciate -- that a relatively junior medical officer -- and he was not a junior in terms of experience but in terms of position -- saying something in a committee -- a very small group of a committee -- "That minute won't be seen by regional pharmacies", and so on and so forth, "and chairmen of health boards, whereas a CMO letter will". So I notched it up on -- I think I was pretty naive in doing that -- but that was the purpose of it certainly.

Q. Thank you, sir. Nothing further.

THE CHAIRMAN: Yes, thank you.

Ms Dunlop, are you content to stop at that?

MS DUNLOP: Yes. I have no other witnesses for today, sir.

THE CHAIRMAN: Professor Cash, thank you very much once

more.

A. Thank you, sir.

THE CHAIRMAN: I think it's merely an instalment.

A. Oh, dear. Thank you very much.

THE CHAIRMAN: Yes?

MS DUNLOP: I wonder, sir, I think it's perhaps a good time for a five minute break. I have been going for an hour and 20 minutes. I think, in terms of discussing whether we should do anything else today, it might be useful to take a five minute break.

(3.19 pm)

(Short break)

(3.30 pm)

(The Inquiry adjourned until 9.30 am on Tuesday, 17 May 2011)

I N D E X