Thursday, 31 March 2022

(10.00 am)

SIR BRIAN LANGSTAFF: Good morning, Dr Perry.

THE WITNESS: Good morning.

SIR BRIAN LANGSTAFF: Now you are talking not just to the audience that you see in front of you here, but you will be talking to others who will be watching online, I imagine quite a number, probably, from Scotland. So that is the audience that you have.

You will start your evidence once Mary has administered the oath and then Ms Richards will ask you the questions.

THE WITNESS: Okay, thank you.

DR ROBERT JOHN PERRY (affirmed)

Questioned by MS RICHARDS

MS RICHARDS: Dr Perry, you have a degree in chemistry awarded in 1971 and a PhD in chemistry 1975; is that right?

A. That's correct.

Q. You are also an accredited qualified person. What does that mean in practice?

A. The qualified person status, I was -- it effectively applies to, I think, probably all the pharmaceutical industry, that there was a requirement to have in any pharmaceutical enterprise somebody who was authorised

and qualified to release batches of product for clinical use.

Q. Can you just give an outline of the nature of the work you undertook between 1975 and 1981, so before you joined the PFC.

A. 1975 I was -- I had just finished my PhD and I did a little bit of teaching during that. I then -- from my recollection, I joined the water authority in Wolverhampton or close to Wolverhampton, where I was an analyst in a laboratory. And after that I moved on, about -- after about 18 months to become the chief analyst at an organisation called the Regional Sterile Supply Unit in Wolverhampton, which was a fairly large-scale manufacturing organisation for producing sterile fluids and topical fluids for use in the West Midlands Regional Health Authority, health service.

Q. Was that the job you were doing immediately prior to moving to PFC?

A. It was, yes.

Q. So you joined the PFC in 1981 as quality control inspector.

A. Yes.

Q. I will ask you in a few minutes a little more about that. Then in 1985 you became the acting director of

the PFC, then, in 1985, the director of the PFC, a post you remained in until 2003?

A. I think it was 1984 that I became the acting director of PFC.

Q. Sorry, that's what I meant to say, yes.

A. Sorry, yes. Otherwise that is correct, yes.

Q. 2003 to 2004, you were seconded to the role of personnel director for SNBTS?

A. Yes.

Q. Then between May 2004 and 2005 you were director of pharmaceutical and technical projects for National Services Scotland?

A. That is right.

Q. In a sentence, what did that entail?

A. I think there were a large number, as indeed throughout the health service, of small regional pharmacies making special products, products that weren't available commercially, and there was a view that that perhaps could and should be centralised into a single organisation. So I was asked to do a feasibility study which I carried out on behalf of National Services Scotland.

Q. June 2015 (sic) to January 2007, you were a director of SNBTS's Better Blood Transfusion programme?

A. Yes.

Q. We will come on to that towards the end of your evidence, Dr Perry, so I won't ask you anything further about that at this stage.

Since that time, as I understand it, you have been a self-employed consultant and working with the International Plasma and Fractionation Association?

A. That is correct.

Q. What is that association, what does it do?

A. The International Plasma and Fractionation Association was an organisation -- it started out as the European Plasma and Fractionation Association in 1991, and it was -- I guess the best way to describe it, it was a trade association established following the regulatory development in Europe that plasma products had to be -- were to be regulated by the European Medicines Agency as it was then. And the European Medicines Agency fairly soon, early on in this development, stated that they didn't want to speak individually to the not for profit -- all the not-for-profit organisations in Europe. So there was a requirement to create an effective and efficient interface between the not-for-profit fractionators in Europe with the European Medicines Agency.

Q. And what kind of work has your work as a consultant involved over the last decade or so?

A. I think it has been involved primarily with the European -- I did little bit of work with the WHO at one stage, but I think the majority of my work has been involved in developing documents, position statements, supporting the members of the International Plasma and Fractionation Association, which are -- it is an international organisation and it has members in Japan, Australia, New Zealand, Canada, the US and Europe and so on. So it has been a general role in supporting the activities of that organisation.

Q. Does that association's membership include pharmaceutical companies, commercial fractionators --

A. No, it doesn't. It is an association. There is a comparable organisation that was established around about the same time as EPFA was established and that's called the Plasma [Products] Therapeutics Association, PPTA.

Q. During your career with SNBTS you were involved with a range of committees and working groups, which you have listed in your statement. For present purposes I'm just going to mention three of them. You were part of the SNBTS directors committee once you became director of the PFC, is that right?

A. That is correct.

Q. So that would have involved, amongst other things, attending regular meetings with SNBTS directors?

A. Yes.

Q. And with Dr Cash?

A. Yes.

Q. You were a member of the Biological Subcommittee of the Committee on Safety of Medicines from 1986 to 1990, is that right?

A. That is correct.

Q. You took over in fact from Mr Watt who had been on the committee previously?

A. Mr Watt retired from the SNBTS -- or resigned from the SNBTS in early 1984, but I think he continued his membership of CSM for a short period after that. But then I think there was a view that it would be useful to have somebody from the fractionation centre in Scotland to provide expert input into the decisions of the Biological Subcommittee, so I was appointed to that committee.

Q. And you were a member of the Advisory Committee on the Virological Safety of Blood from its inception?

A. That's correct.

Q. I think at one point your statement suggests it was 1991 but -- we will come to the minutes and its decision-making at a later stage of your evidence --

in fact it is 1989.

A. Okay, thank you.

Q. When that became the Advisory Committee on Microbiological Safety of Blood [and Tissue] for transplantation, you remained on that committee?

A. Yes, I basically just transferred over to the new committee. The membership changed but I remained on it.

Q. That was until around 2004, is that right?

A. That is correct.

Q. We will certainly come back to the decision-making of the Advisory Committee on the Virological Safety of Blood at a later stage.

You provided multiple written statements to the Penrose Inquiry. I'm going to read for the benefit of the transcript the references to the main statements you provided, some but not all of which are listed in your witness statement. That, Dr Perry, is not because we are going to look at them all, but it is for the benefit of others so that there is, collected in a single place, all the relevant reference numbers for your principal statements.

A. Yes, I understand.

Q. So it is PRSE0001823 on the topic of high-risk donors.

PRSE0003755 on the topic of AIDS.

PRSE0003769, which relates to the infected PFC batch and the investigation undertaken into that in late 1984.

PRSE0002178, which looks at issues relating to AIDS and viral inactivation to 1985.

PRSE0001258, viral inactivation 1985-87.

PRSE0000145, hepatitis C screening.

PRSE0002320, use of concentrates in, I think it is, '85 to '87.

PRSE0002938, recall of unheated Factor IX, issue of heated Factor IX.

PRSE0001919, that's a joint statement with Dr Cuthbertson and Dr Foster on conditions at Liberton in the '80s.

PRSE0002620, on package inserts and non-A, non-B hepatitis.

PRSE0003806, which contains communications with Montagnier.

And PRSE0004392, which contains comments on the issue of self-sufficiency.

I think you also contributed to a number of joint or corporate statements on behalf of SNBTS in the Penrose Inquiry. I'm not proposing to list those.

Then you gave oral evidence to the Penrose Inquiry on 24 March 2011. PRSE0006011, on the

question, again, of high-risk donors and particularly prison donors.

13 May 2011, PRSE0006025 on the topic of self-sufficiency.

24 June 2011, PRSE0006038 on the implicated PFC batch.

13 September 2011, PRSE0006045, that was topic B3, which temporarily escapes me what that was.

28 October 2011, PRSE0006058, that's about viral inactivation.

23 November 2011, PRSE0006068, hepatitis C testing.

7 December 2011, PRSE0006074, on the issue of 8Y and Z8.

I list those so that nobody else has to go through the exercise of pooling them together.

You have told us in your statement you didn't give evidence to any other enquiries or investigations, is that right?

A. I think that's correct, yes.

Q. So you didn't give evidence to the Lindsay or Archer Inquiries. Does that mean you weren't involved in providing evidence on behalf of SNBTS to the Scottish Executive Investigation?

A. I think I was involved in it but I think that role

which was basically a lot of data collection and submission to the Scottish Executive was undertaken by Dr Foster. But I would have been involved at some level, yes.

Q. Then can we just look briefly at one document. It is one I will come back to later but it is PRSE0001885.

This is a letter from you to Professor Cash, 14 March 1988. If we look at the text of the letter it is SNBTS' response to HIV contamination of blood products:

"Further to your request for details of SNBTS actions in response to the emergence of AIDS, I have now assembled the enclosed summary of key events.

"There is much supportive documentation of these events should this become necessary."

If we just go over the page. As I say, I will come back to the some of the detail of it, but we can see there is a chronological narrative and a thematic narrative set out.

If we just go back to the first page, please, Sully. Can you recall what the purpose of this was? Why you had been asked by Professor Cash to pull this information together?

A. No, I can't, I can't recall a specific event or a specific issue that Professor Cash raised, but it

was not unusual for him to write spontaneously, because he had something in mind, to ask for a summary of what happened during this important period. So, I don't think there was -- anything specific happened in March 1988 that triggered this other than Professor Cash just seeking a summary of the events and what PFC in particular did in response to those events.

Q. We know that there was around this time a piece of litigation ongoing, which the Inquiry have been referring to as the "HIV Haemophilia Litigation". Do you know whether it was in relation to that at all?

A. It might have been. I have just noted in the annotation to go with the litigation papers. So it may well have been triggered by that.

Q. But you didn't have any direct involvement to yourself with litigation at the time?

A. No, I don't recall having any detailed involvement.

Q. So, can we then come back to your work at the PFC. Starting with your role as quality control inspector. What did that entail?

A. The role of quality control inspector -- it was a curious title, actually, for the job, but it was a post that was established I think primarily as a response to the Medicines Inspector's report which

had taken -- the Medicines Inspector visit and their quite detailed inspection of the facilities and the arrangements at PFC which took place in 1979/1980, and I think there was a view that the organisation needed to hire somebody with experience in the field, not in biologicals manufacture but in the principles and the practice of good manufacturing practice. And I had obtained that during my work in Wolverhampton at the sterile supply unit. So I was appointed really with a quite far reaching role, which I think is why it was probably called quality control inspector.

I had authority in all parts of the organisation, because the principle is that everything that happens in a pharmaceutical manufacturing organisation can have an impact on product quality and product safety.

Q. What in practice did that entail? In a typical week in 1982, what would your work have involved?

A. In 1982 I think it was fairly -- it was still fairly on in my career with SNBTS. I think my priorities at that time were establishing more robust documentation systems, creating a portfolio of standard operating procedures which didn't exist when I arrived. It involved an examination of the facilities and their compliance with good manufacturing practice and

basically examining the comments and the criticisms that were made by the medicines inspectors and beginning to formulate a response to that.

Q. If we can just look at a short extract from one part of your oral evidence to the Penrose Inquiry.

Sully, it is PRSE0006011, please. If we go to page 93, and pick it up at line 9.

Your evidence had started, just for the benefit of anyone following on page 89. We can see you were being asked about your work and you explain at line 9 to 11 you had:

"... no prior experience of blood or plasma products. This was a completely new area of endeavour for me."

If we go to page 102, please, top of the page. Lines 4 to 6 you say:

"I had no knowledge of the plasma fractionation industry or blood establishments or blood transfusion services prior to my emigration to Scotland."

So blood fractionation, blood transfusion, was something completely new to you when you took up your first post at the PFC?

A. Absolutely, yes.

Q. Were you provided with any kind of training? You told us yours was effectively a new post so you weren't

taking over an inherited role. Did you receive any training or education or assistance in understanding more about fractionation and transfusion?

A. I don't think there was anything that you could describe as a formal training programme. I think, as was typical of the time, it was very much on the job training. Mr Watt, who was my boss, was very open. He was very generous. I think to an extent he applied the sort of deep immersion technique and from a very early stage he allowed me or asked me to go and deputise for him at national meetings, at local meetings with the Haemophilia Centres directors' organisation and also made every effort to ensure that I could attend international meetings and national meetings associated with plasma products. So although there was no formal training, he was very active in exposing me to all the issues.

Q. Then as we established a few minutes ago, you became director, first acting director and then director, after Mr Watt left. Now, as I understand it, Mr Watt tendered his resignation in around the middle of 1983?

A. That is correct.

Q. And then left in December 1983?

A. Yes.

Q. Did you have any understanding -- first of all, was

that unexpected?

A. No, he'd tendered his resignation. I think his original plan was to leave a little later but for reasons I don't think were ever disclosed to me or others, he left certainly significantly earlier than was originally anticipated. I think it was meant to be maybe the middle of 1984 but it turns out he left at the end of 1983.

Q. And so you were -- was it unexpected then being asked to step up to the role of acting director?

A. Well, I had, even though I had only been in the organisation two or three years by that time, I saw it as a good opportunity. I was enthusiastic about the work of the PFC and I applied for the job of director when the shortlisting took place for that role. So I think the Common Services Agency and Professor Cash and others involved thought, well, this is somebody that could perhaps take on the role of acting director until the substantive replacement for Mr Watt had taken place. So I readily accepted that offer.

Q. We have heard some evidence of a less than harmonious relationship between Mr Watt and Dr Lane. Do you have any understanding or recollection of what the relationship had been between Mr Watt and Dr Cash?

A. They were both powerful strong personalities. Mr Watt

was very innovative and Professor Cash was a very strong leader in those issues that he felt were important and I guess the combination of that meant that they didn't always see eye to eye on every issue, but I honestly can't recall any major conflict that caused any disruption to the delivery of services.

Q. Now, as director what was essentially your role? What did you do as director of the PFC?

A. I was appointed to be responsible for all the activities of PFC. The operational activities primarily. I was an operational manager for the plasma fractionation centre which was the manufacturing unit of the SNBTS.

Q. And you were accountable to Dr Cash; is that right?

A. No, I was accountable to, again, a slightly curious arrangement but not untypical of its time, I was responsible to the Committee of Management of the Common Services Agency, so my boss was a committee. But subject -- and I think this was stated in my job description -- to the duties and responsibilities of Professor Cash.

Q. In practice did you have much by way of interaction with the Committee of the Common Services Agency?

A. No.

Q. So in practice you would be discussing key issues with

Dr Cash?
A. Absolutely, yes. He was the National Medical Director at the time. He was very authoritative. He was a very strong leader and I think it is fair to say that I had daily interactions with Professor Cash.
Q. And if we just go back to one part of your oral evidence to the Penrose Inquiry.
PRSE0006011, page 94, please.
From line 3, you are here describing your role and responsibilities as director:
"My responsibilities were effectively the operational management of the fractionation centre of the SNBTS, and my responsibilities covered everything from financial control, operational management to production, quality control, not single-handed, obviously -- I had a staff of about 200/250 people -- and also the research and development of new plasma product that the service wanted to bring into use."
Is that a fair description of your principal responsibilities?
A. Yes, I think that is a good description.
Q. Then your statement tells us that from 1990 your direct accountability was to the SNBTS general manager?
A. Yes, that is correct.

Q. Did the change of management structure in 1990, did it have any particular advantages or disadvantages?
A. I think it was a much more coherent process. As an operational manager of one of the units of SNBTS, my line management reporting and accountability was much clearer than it had been before. So I was still subject to the duties and responsibilities of the National Medical and Scientific Director but I had a clear operational manager in the form of Mr McIntosh.
Q. I want to ask you a little more now about the organisation of the PFC itself. If we take it from your witness statement to start with, so could we have WITN6920001 please, Sully.
If we go to page 7. If we pick it up at the bottom of the page. You explain the departmental structure of the centre. So the first department that you identify, manufacturing, responsible for all aspects of product manufacture from bulk collection of plasma from Regional Transfusion Centres through to -- top of the next page -- return of manufactured plasma products to RTCs. So that's the Department that's doing the core work of the PFC, to take the plasma and turn it into blood products?
A. Yes, I actually think it was probably called the

production department at that time. But that is a good enough title, manufacturing department.
Q. The next department you identify is the quality department and this would be the -- essentially area of activity that you led from 1981 to 1984; is that right, to the end of '84?
A. Yes, that is correct. I think prior to my appointment I think the arrangements in place at PFC were more like a quality control arrangement. It had a laboratory which had a laboratory manager and manufacturing, but there was no single department or person with responsibility for quality across the whole organisation.
Q. And we can see a short description there of the work of this department:
"... Responsible for development and enforcement of Quality Systems, Quality Control laboratory testing of products and intermediates, approval of finished products for use and, latterly, regulatory compliance and product licensing following the removal of Crown Immunity status."
Just pausing there, I will want to come on to ask you about product licensing, interaction with medicines inspectors and so on in due course. But you have said there "latterly, regulatory compliance and

product licensing following the removal of Crown Immunity status", which I think was around 1991?
A. Yes.
Q. Obviously there were attempts at regulatory compliance, there were product licences in existence prior to that?
A. Yes.
Q. Who had responsibility at that point?
A. I think that would probably have been myself. When I took over in 1981, I recall Mr Watt saying that it was very important. Although we operated under Crown immunity I do not think anyone in PFC or the wider SNBTS saw that as a satisfactory arrangement. So the PFC did make attempts, and successful attempts, to obtain product licences from the Medicines Control Agency.
It was always a moot point. What the status of these licences were, given that we were operating under Crown immunity. A good example of that was in -- I think during 1983 we had just developed a new intravenous immunoglobulin product and we were very anxious to establish its safety and its efficacy and its quality prior to entering into clinical trials and I suggested that the best way of doing that would be to submit a full and comprehensive product licence

application for that product, which we did.

I think the Medicines Control Agency, when we submitted it were slightly bemused because they weren't quite sure what to do with it because we were an organisation operating under Crown immunity. But there were certainly strong links that we tried to maintain with the Medicines Control Agency.

Q. I will ask you some more about that in due course. If we continue on this page the next department, research and development, led by Dr Foster, who obviously the Inquiry heard from last week.

Was the research and development department essentially left to set its own priorities, get on with its own work or was it directed from above by Mr Watt or Dr Cash or you?

A. I think probably all of those people that you have mentioned, including myself, had a very close working relationship with the R&D department. Dr Foster was a very able leader. He was very competent. He had an excellent track record of innovation and careful work, but in terms of giving direction to the R&D department, that would certainly have come from people like Mr Watt, Professor Cash and latterly myself when I took over as director.

Q. Would it be right to say you might well have been

involved in discussions with Dr Foster whilst you were quality control inspector, but in terms of trying to give any steer or direction as to how the R&D department should organise itself or prioritise particular projects over another, that wouldn't really have fallen to you until 1984 onwards?

A. No, I would have had an awareness of what Dr Foster was doing. We worked closely together. It was a relatively small centre, the PFC, so we had daily contact and daily conversations I think.

Q. And then we can take I think the remaining three departments rather more quickly. Engineering: so responsibility for all aspects of building, plant and equipment maintenance. Project engineering: responsible for specialist engineering support, IT, et cetera, and then administration and business support services.

Now, you have told us in your statement, and I think we heard elsewhere, that in terms of the PFC's funding, that came through the Common Services Agency?

A. That is correct.

Q. You have said in your statement you don't recall funding being denied for key developments or upgrading. Would it be right to understand you are really talking there of the period from 1984 onwards

when you became director, you wouldn't have had much knowledge or involvement in funding issues prior to that?

A. I might have had some understanding of financial issues. John -- Mr Watt was very open and he involved myself quite closely with his operational managers so you might have expressed frustration about delays in funding and so on but I would not have been closely involved I don't think.

Q. In terms of funding for research and development, was there a particular budget for that to your knowledge?

A. There was not a ring-fenced budget. It was part of the overall PFC operational budget. It had its own staff who were -- so there would have been a staffing budget for the Department but I don't think -- but that would have been a local -- so for instance if we wanted to bring somebody from manufacturing and put them in R&D then that would have been a perfectly legitimate and easy thing for me or Mr Watt to have done.

Q. Now, if we could go to page 9 of the statement, I think it is the next page in fact, bottom of the next page. You describe the remit of the PFC as follows in paragraph 29 of your statement:

"At the time of my appointment to SNBTS in 1981

the remit of PFC was to manufacture and supply a range of plasma derived products (Albumin, Coagulation Factor products and Immunoglobulin products as well as anticoagulant and infusion fluids) ..."

Just pausing there, we have heard about albumin, coagulation factor products, of course, and immunoglobulin. Very briefly, what does the reference to anti-coagulant and infusion fluids encompass?

A. I think this was a project which was initiated by my predecessor, Mr Watt, and he felt the facilities that existed at PFC were not only capable of making plasma products but we had the ability and the expertise and the knowledge to make infusion fluids such as sodium chloride injection and just sterile aqueous solutions that are used for patient treatment, but also preparation of specialist anti-coagulant solutions for use in the blood transfusion service.

Q. Then continuing with the sentence:

"... for the treatment of patients throughout Scotland. In the early to mid 1980s this remit was expanded to include bulk collection of plasma from Northern Ireland Blood Service and manufacture and supply to Northern Ireland of plasma products from this plasma."

Then you say in the next paragraph this, which

I just wanted to ask you a little bit more about:

"It was considered (particularly by Professor Cash) an important principle that the distribution to Health Boards, hospitals and Haemophilia Centres of manufactured plasma products should only be via SNBTS (and Northern Ireland) Regional Transfusion Centres, which should be responsible for their onward distribution to Health Board hospitals and Haemophilia Centres. This arrangement was designed to reinforce the role of RTC medical staff for the professional and operational liaison with prescribing doctors in Health Boards. This principle and practice was maintained throughout the period of plasma product supply from PFC."

Why was it that Professor Cash in particular thought this was such an important principle?

A. My understanding, which was quite clear, he was very clear on this point and he often went to great lengths to actually reinforce it, I think his view was that everything to do with blood and plasma products was part of the umbrella term of "transfusion medicine", and we had centres with consultant medics and other medical staff and scientific staff and he felt very much that they should be involved as an interface between the manufacturer and the ultimate users of the

products.

So if there was an enquiry about a particular product, that would go to the regional transfusion centre and that would be fielded by either the director or a nominated medical consultant that was employed by each individual RTC.

Q. So, whatever PFC produced would be distributed by PFC to the Regional Transfusion Centre for onward distribution by the Regional Transfusion Centre to a Haemophilia Centre or to a hospital?

A. Absolutely. That's exactly what happened.

Q. Which -- in practice, would that mean that the PFC had limited ties, directly, then, with the clinicians who were prescribing and using its products?

A. Yes, I think we did have very limited -- I wouldn't call it limited access but the main route of communication on issues associated with plasma products would have always been initially via the Regional Transfusion Centre and the nominated consultant for whatever the product was.

If they felt the need to involve somebody from PFC in responding to that, then we were quite free to do that, but it was a very important principle, underscored by Professor Cash on numerous occasions. And so everything that we produced went through the

Regional Transfusion Centre.

Q. Does it follow from that that at the PFC you would have, again, a relatively limited knowledge and understanding of what the approaches to product usage were in the individual Haemophilia Centres or, indeed, the hospitals utilising your products?

A. Well, the arrangement I described didn't preclude conversations between myself and Haemophilia Directors or anybody else in the PFC, and indeed they took place fairly frequently. Through those channels. But also through the close relationships we had with the Regional Transfusion Centres, both the directors and the scientific and medical staff employed by them, I think we had quite a good idea of the nature of the products we made and what their purpose and use was.

Q. Then, is it right to understand that the PFC itself had no medical staff amongst its employees, apart from Dr Cash as the overall director of -- the national medical director of SNBTS?

A. That is correct, he was the de facto medical adviser or medical director of PFC.

Q. Do you have any recollection as to what proportion of concentrates produced by PFC would end up being distributed to hospitals other than Haemophilia Centres, or is that something you simply wouldn't know

because everything went through the Regional Transfusion Centre?

A. I think we knew -- we knew sufficient for our purposes where the products went. We knew albumin was distributed by the Regional Transfusion Centres to most hospitals because it is used so widely in patient care, for acute emergencies and so on. We would have known where the immunoglobulin products went. And we certainly knew where the haemophilia treatment products were sent and located, and we -- I -- although, as I have said, PFC was very much the wholesaler to the Regional Transfusion Centres, we had a fairly good knowledge, geographical knowledge, of where the products went and how they were used.

Q. In relation specifically to Factor VIII and Factor IX concentrates, did you have any sense of the extent to which they were being used outside of Haemophilia Centres? I don't mean for home treatment, I mean like hospitals other than Haemophilia Centres --

A. Coagulation factor products, I think I knew at a fairly early stage that -- well, Factor VIII would only be used in the context of haemophilia. I don't think there are any other uses for Factor VIII, so I think it was quite clear that that was only used for haemophilia care.

Factor IX -- or the three factor -- the Factor II, IX and X product, DEFIX, I was certainly aware, and others were, that that was also used for anticoagulant reversal therapy in some patients.

Q. Did the PFC ever play any part in the ordering, selecting, storing or distributing of any commercial factor concentrates?

A. No.

Q. Can I then ask you a little about the facilities and the premises of the PFC when you arrived in 1981.

Can you give us a brief tour of what the physical premises comprised?

A. From 1981?

Q. In 1981, when you arrived, yes.

A. It was a facility that had been established and commissioned in 1975. It had been designed at a substantially earlier date than that. So when I arrived in 1981 it was clear that it was technically quite an advanced operation. It had this quite unique method of fractionation, the continuous small volume mixing system which was fairly unique to Scotland, and the associated IT systems that were necessary to drive that. But otherwise I think my early impressions, perhaps informed by the Medicines Inspector's report of the facility in 1979/1980 was that there was

a substantial amount of work required to bring the facilities up to modern GMP standards. And I would say that the modern GMP standards as I've defined were established after the commissioning of the PFC and certainly well beyond the date on which the facility was designed in the late 1960s.

Q. Is that, therefore, your understanding of why, only five years into the life of the building, there was this pretty critical report by the inspectors, which might have been less surprising in a building that had been in existence since the 1950s but might, at first blush, be thought surprising in relation to a Building that opened in 1975?

A. I think the facility as it was established -- in the original design, and I think Mr Watt shared this view and his disappointment that during the phases of building and approval of funding, I think there were economies that were required to bring the cost of the facility down and what suffered was storage facilities, general pharmaceutical manufacturing areas, but they were all cut down to a minimum size. And I think the consequence of that was that very soon, very early on, particularly as plasma supply began to increase in the 1980s, that they were found to be inadequate to meet the needs of a modern

pharmaceutical facility.

Q. If we pick matters up with the second visit from the Inspectors. So a visit that took place by the time you were in post.

A. Yes.

Q. So it is BNOR0000572. It is not the clearest document to read but we can see at the top of the page it refers to an "Inspectorate report on the current status at the Protein Fractionation Centre, Edinburgh as of October 1 1981". So you were in post at this point in time?

A. I was, yes.

Q. If we go over the page. We can see under the heading "General Comments", the bottom half of the page, there is reference to your appointment and that there had been "progress towards a" -- and then we miss a word, perhaps "fully integrated Quality Assurance system", and that had been progressed.

If we just go, please, to page 7, and the "Conclusions". Again, we can see if we pick it up under the heading "Conclusions" at the top of the page it says:

"Progress towards implementing necessary standards of CHP in general Quality Assurance matters including provision of standard process documents and

standard operation procedures is generally acceptable.

"A major effort regarding those aspects is now coming to fruition."

So that was the work you were focusing on in 1981?

A. That is right. I think that's where my initial focus was applied, because it was something that could be done without additional funding or building modifications and so on.

Q. Then there are two major exceptions to that noted. Then 4.2 then turns to deficiencies regarding buildings and facilities. It says:

"Firm proposals to remedy those deficiencies regarding buildings and facilities as reported in the first inspection are still awaited, with dates of implementation."

Then paragraph 4.3 -- if we can go down a tiny bit, Sully:

"The present buildings and facilities continue to fail to reach minimum standards of GMP, and a licence would not be recommended for an industrial equivalent unless agreed upgradings agreed upon as a matter of urgency."

So, that would tend to suggest that the response to the first inspection had been -- I'm not suggesting

this was necessarily the only thing done but your appointment focused on the quality assurance matters, but there were still a number of problems identified in the first inspection regarding buildings and facilities that hadn't been addressed and that the Inspectorate hadn't even had proposals for addressing. Was that your understanding?

A. I think that's probably right. This was October. I think you --

Q. October '81, the first inspection having concluded in January 1980. So over 18 months on.

A. Absolutely. Well, when I arrived in 1981 I don't think there was any action being taken in response to the Medicines Inspector's report. It was the beginning of a fairly long road to get the -- to identify the operational solutions to the criticisms to get the funding, to create the necessary close down periods, shut down periods at PFC to implement these.

I think by then I would have had a fairly good idea on what needed to be done, and I think there may have already been some work in progress for areas where simple changes could be made, like labelling and packaging areas and so on, but I think one of the first things I did was to improve the arrangements. But I don't think this happened in October 1981. But

by that stage I will have identified the need for an automated bottle and vial dispensing and sterilisation and dispensing facility, because those activities were entirely manual in 1981 and that was a clear and outstanding requirement to be rectified.

Q. Now, we understood from Dr Foster's evidence that the original manufacturing licence, when it came to expire in the early 1980s, was not renewed or -- in the sense that a further application for a manufacture's licence was not submitted on the basis of advice to or from SHHD in reliance upon Crown immunity.

A. Yes.

Q. What's your understanding of the position and why that happened?

A. My understanding is similar to Dr Foster's. I think SHHD were, at that time -- I think through the chief pharmacist of SHHD -- were very anxious that we didn't step outside our authority, which was granted by the Secretary of State for Scotland. So his view was that we had the authority to do what we did directly from the Secretary of State from Scotland and there was no requirement to go through central licensing and processing systems. We thought this was an appalling idea but it was what SHHD's position was at the time.

Q. Is it right to understand that from the point of

expiry of the first manufacturer's licence -- and I'm afraid I don't have the precise date, but presumably around 1981, I think it was a five-year --

A. I think it was earlier than that, the first -- oh, the manufacturing licence?

Q. The manufacturing licence.

A. I'm sorry, yes. Yes.

Q. So whatever the precise date, which I am sure we can establish, from that point until, would it be then, the early 1990s, PFC did not have the manufacturer's licence, it relied instead on Crown immunity?

A. I think that is correct.

Q. In practical terms, and in relation to the deficiencies that the Inspectors had identified with regard to buildings and facilities, to what extent were those addressed and when?

A. They were addressed throughout the 1980s. It was a continuous process, involving numerous refits to the organisation -- which had to be done in small pieces of activity because we couldn't afford to close the facility down for a year to do a complete rebuild and refit of the organisation. So it was a progressive requirement.

And although I've said I didn't think funding generally inhibited the activities of PFC, it was

quite a sustained battle, I think, with SHHD and CSA to get the necessary funding at the right time. Eventually it came through but that process probably took -- and it was a continuous process and carried out through the 1980s until the early 1990s, where there was a very substantial investment in the centre to increase warehousing and various other essential buildings.

Q. And there was a shut down for around three months at the end of 1984 --

A. That is correct.

Q. -- for building works. Was that the longest period of shut down up until that point or had there been earlier periods of shut down for --

A. I think there would have been earlier periods of shut down and they may have been shorter, but they may have been around about the same time. We were able to do it in 1984 because we had such good stocks of product.

Q. Yes. We will certainly be coming onto the issue of the surplus or stockpile and how that was built up and what was done with it. Just on the conditions at the PFC. If we could look at one of the written statements please to the Penrose Inquiry on this topic. PRSE0001919.

We can see this is a statement entitled,

"Conditions at PFC, Liberton during the 1980s", and it is a joint response prepared by you, Dr Foster and Dr Cuthbertson, and we can see the context of it from the first main paragraph. You had been asked -- well, I'm not sure whether you had been asked to or whether you were addressing because you wanted to, comments that Professor Cash had made in a letter in July 1988 which we looked at I think in earlier Inquiry hearings.

For present purposes can we just turn to page 3, paragraph 1.2, where the joint response says this:

"Since 1980 and in particular following the [Medicines]] Inspection of 79/80 (by Mr John Flint and Dr John Purves), the PFC had consistently identified, documented and communicated its concerns (to the CSA and the SHHD) regarding facilities and staffing arrangements at the PFC. In particular, the inescapable requirement for a major building extension in the light of anticipated major increases in plasma throughput to meet self-sufficiency targets, a wider product portfolio and increasingly complex manufacturing processes. The requirement for these developments and investments was reinforced by comments and reports from (informal) [Medicines Inspectorate] inspections and visits."

A. I think good examples are, I think others have mentioned this had as well, that -- well, first of all, I think we were blessed with having people like Dr Foster and Dr Cuthbertson who were basically committed to the National Health Service and the work we were doing in PFC. So we weren't looking to replace people like that. They were perfectly -- well, they were more than fit for purpose, as it were. But I think in many other areas of activity of PFC, particularly employing people, skilled, trained operators who had experience within a pharmaceutical manufacturing environment, simply didn't fit the definitions the Whitley Council prescribed. Because the Whitley Council prescribed the qualifications and the experience you needed to become a medical laboratory scientific officer, and we didn't need medical laboratory scientific officers. We needed pharmaceutical operatives and so on.

Q. Then just continuing:

"By 1987, little progress had been made in gaining recognition by either the CSA or the SHHD of the need for further substantial investment at PFC."

Then you go on to refer to a letter you wrote which we can look at I think at a later stage if we need to, in October 1987, setting out your concerns.

Just pausing there. Is it right to understand from the reference there in brackets to informal, that although you had no manufacturing licence at PFC in the early 1980s, there was a degree of further involvement on a voluntary informal basis?

A. Yes, we had quite a good and constructive and almost collegiate relationship with the inspectors and they were certainly as enthusiastic as we were to assist in developing the facilities and fixing the problems that still existed.

So we I think from my memory of those years, I think we very much welcomed the continuous and the continued involvement of the inspectors in our activities.

Q. Then picking it up:

"Between 1980 and 1987 significant improvements and investment in equipment, facilities and quality systems had been made, but on-site storage facilities remained too small and the Centre was constrained in its ability to recruit appropriately skilled and qualified staff by the rigid application of NHS Whitley Council staff employment Regulations."

Again, just pausing there. In what areas of the PFC's activities were you having difficulties of recruitment?

We will look at the extent to which the PFC, notwithstanding the constraints described here, was able to increase production, essentially achieve self-sufficiency in domestic products for Scotland. And indeed build up a surplus which was distributed in part as I understand it to BPL. But would it be right to understand, looking at this, that had there been further substantial investment in terms of both facilities and staff in the PFC, that could presumably have resulted in even more by way of production of factor concentrates and other plasma products?

A. I think probably the answer is yes, it would have needed a fair degree of planning and building up stocks, because one of the key underlying principles of operation of the PFC and the SNBTS was that there would be continuous supply of products from voluntary donors from Scotland. We didn't have the option of closing down for a year and not supplying because that would have been a failure, so I think even in an ideal world we would have had to have done it as a progressive programme of work. I think the main -- one of the main constraints was about staffing arrangements and this was a dominant theme throughout the 1980s because it was always envisaged that the PFC would run on a continuous basis using the continuous

small volume mixing system, and to do that sensibly. And to run the downstream processes following the initial fractionation, we were constrained by the requirement to shoehorn those into an eight-hour working day and sometimes manufacturing processes don't usefully fit. So it constrained our activities. It actually constrained some of the development programmes as well because they had to be adapted to basically fit the Whitley Council employment conditions for staff working at the facility.

Q. If we then just go to your statement to this Inquiry, WITN6920001, page 24. I just want to look briefly with you at the range of products produced by the PFC.

This is specifically in relation to factor concentrates. So if we just zoom in please on the table. Again, just so that we understand what was and wasn't being produced, you have got there:

"1956, Factor VIII concentrate (Cohn fraction I), freeze dried.

"1966, Cryoprecipitate ...

Then, 1968, the first freeze-dried Factor IX concentrate, is that right, being produced by SNBTS?

A. Yes.

Q. Referred to as PPSB?

A. Yes.

Q. Then 1971 we see DEFIX. Is it right to understand DEFIX remained the Factor IX concentrate then that the PFC produced over the following years?

A. It did, yes. That's right, yes.

Q. Then 1974 we have the first Factor VIII concentrate being produced; is that right?

A. That's my understanding, yes.

Q. NY?

A. Yes.

Q. Then NY remained the name of SNBTS' Factor VIII product until we get to Z8 in the second half of the '80s?

A. Yes, that is correct.

Q. We can see that just at the top of the next page. Obviously there was then heating.

A. There was heat treatment programmes, yes.

Q. If we go to the next page.

So then we can see that the dry heated DEFIX referred to as "modified DEFIX", and the "modified NY", and then the production of Z8, April 1987.

Then I don't think I need to ask you about any of the later products, such as Liberate or HIPFIX.

Can I turn -- sorry, we can take that down, thank you -- to ask you a little bit about the PFC's relationship with other organisations and bodies.

So, starting with the regional transfusion services in Scotland, is it right to understand that PFC was essentially an equal partner in terms of the structure of SNBTS with each of the regional transfusion services?

A. I think that's correct, yes. The director of PFC always sat with the other directors at the director's meetings, the coordinating group meetings, the meetings of Haemophilia Centre Directors and so, yes, it was a fully integrated and I think although it did -- the nature of this work was quite different to an RTC, it was a fully integrated part of the management systems within SNBTS.

Q. With Professor Cash as the -- or Dr Cash, later Professor Cash, as the National Medical Director, essentially in overarching control and to whom the directors of the regional transfusion services and then the director of the PFC could all report?

A. It wasn't quite like that and this was always a frustration for Professor Cash and I think to an extent Regional Transfusion Centre directors, that I think each of them were like myself responsible to the Committee of Management of the Common Services Agency.

So in many senses they were -- they had

an independent -- they could have operated an independent -- independently of Professor Cash. In practice they never did and Professor Cash I think often expressed his concern and frustration that he didn't have this line management authority. But I think he was a highly consultative individual and sought to get agreement and 99% of the time did get agreement with Regional Transfusion Centre directors and the PFC director on key issues that emerged from time to time.

Q. Now, obviously, PFC's relationship with the regional transfusion services in Scotland was, as you described it, was different from the relationship between BPL in England and Wales and its relationship with the regional transfusion services of England and Wales.

Were there particular advantages or disadvantages to the system in Scotland in your mind?

A. Well, as it operated, certainly in the 1980s and perhaps for the duration of my employment, it always seemed to me to be the sensible way to run an organisation. I think in the early 1980s, it wasn't quite a truly national service. Individual centres had some freedom to act under the direction of the medical directors for the individual regions but for the large part, 99% of the time, it did operate

and function very much as a national service.

And I think that provided the opportunity and the ability to develop the programmes it did and the reason, for example, in 1984, that the SNBTS had managed to develop large product stocks was that -- the basis for that was set in the mid-1970s, when Dr Cash as he was then was director of the Southeast Scotland Blood Transfusion Centre and he instituted a major programme to convert doctors and clinicians and surgeons to the use of packed red cells instead of whole blood. I know it is a long distance between that and self-sufficiency but it is the fundamental building block, or it was in the 1980s, for self-sufficiency.

So those programmes he was able to -- and when he became National Medical Director he reinforced those programmes and I think was very instrumental and successful in moving Scotland into an area where it used predominantly packed red cells and whole blood became a very rare product and it was that that created the ability for PFC to build the stocks that it did during the early 1980s.

Q. You as director of PFC, Mr Watt as your predecessor, attended regular meetings with the other SNBTS directors; is that right?

A. Yes.

Q. Were they quarterly, roughly?

A. I think they were quarterly or as required there would have been *ad hoc* meetings called of -- well, there were, I think from memory they were -- the directors meetings, of which the representatives from SHHD would attend, usually the medical officer, I think they were quarterly. I think they were more regular coordinating group meetings and, as the title suggests, the coordinating group was designed to allow the National Medical Director to coordinate and, where necessary, standardise the activities of all the Regional Transfusion Centres.

Q. There was something called Scot Blood which I understand to be an annual conference?

A. Yes.

Q. Who organised that and what kind of issues in the early '80s would it look at?

A. I think the genesis of the Scot Blood meeting was with the scientific staff of SNBTS felt, I think it was probably as far back as in the 1970s, that it would be a good idea if they organised an annual conference or an annual meeting, probably not a conference then, but an annual meeting where all the scientists in the SNBTS throughout Scotland could get together and have

basically a mini conference with the scientific and senior technical staff. I think latterly that became a fixed activity and it developed into -- initially, it was run by the scientists themselves with the blessing of Professor Cash and regional doctors and so on.

It subsequently turned into a combined scientific meeting but also a social gathering for SNBTS staff. It was usually held at weekends and individuals, just to give some measure of the importance of it, I think individuals were required to pay to go to it actually. But it was a very important annual meeting of the whole of the SNBTS team.

Q. Then in terms of the involvement of Northern Ireland, Dr McClelland, Dr Morris McClelland, once the arrangement with Northern Ireland was established, he effectively joined the SNBTS directors meetings; is that right?

A. Yes.

Q. What about the relationship between the PFC and the SHHD? First of all, in practical terms, what was the nature of the relationship? How often were there interactions with the SHHD?

A. It varied over time. I think certainly throughout my tenure within SNBTS there were annual meetings of the

annual SNBTS and Haemophilia Directors' Group which was very instrumental in driving forward the programme for provision of haemophilia -- a product for treating haemophilia. And that was always either chaired or certainly attended by senior medical staff and other officials from SHHD.

From that group a coagulation factor working party I think it was called, this is different from Professor Cash's coagulation factor study group, this was an annual -- the working party was established to take forward some of the output from the annual meeting and develop it into operational activity.

And I think, as I say, during my tenure I think it was Professor Ludlam who chaired that and that would have also been attended by medical staff from SHHD. So they were closely appraised of what was happening within SNBTS with respect to the provision of haemophilia treatment products.

Q. In the course of the 1980s who were the officials from SHHD that you recall having dealings with on --

A. Dr Bell, Dr Burt Bell, who was a great enthusiast for self-sufficiency, I recall. And I think he was partly instrumental in setting up the annual meeting of haemophilia directors and SNBTS directors. There were a number of other -- Dr Forester, who was not

associated with us for very long but he was the SHHD person, and I think latterly throughout the 1980s it was Dr Keel. Dr Aileen Keel from SHHD. There may have been others but ...

Q. And do you have any particular recollections of the relationship between SHHD, whether it is any of those individuals you have identified or others, and Dr Cash and whether there were any difficulties in the relationship there?

A. Well, there was frequent contact between Professor Cash and SHHD at a fairly senior level and I think, in truth, they didn't always agree. There was -- I think Professor Cash was always trying to drive the service forward, particularly in terms of self-sufficiency and introduction of donation testing and issues like that. And there was -- not often but occasionally they had slightly -- they were facing in different directions. And I think this became evident during the late 1980s, early '90s, for the introduction of hepatitis C testing, so -- where I think SHHD were quite clear this had to be implemented on a single date for the whole of the UK and I think others, including Professor Cash, thought maybe that's not the way forward.

Q. We will certainly pick up that particular issue at

a later stage of your evidence.

Just more generally in relation to SHHD, can I ask you to look at PRSE0004392. This is one of your multiple written statements to the Penrose Inquiry. If we go to the second page. I just want to look at your -- question numbered 4 towards the top of the page. You were asked the question:

"Was it your experience that SHHD policy normally mirrored that of DHSS?"

Then we can see your reply:

"In my experience on matters relating to blood safety, product licensing and professional practices SHHD policy mostly, if not always, reflected that of DHSS."

Then you refer to the role of the licensing authority committee on the safety of medicines and decisions taken in that capacity applied equally to all UK territories.

Now, given your experience that the SHHD policy largely or mostly reflected DHSS policy, would it follow that notwithstanding the quite regular interaction that you describe between SNBTS and SHHD, the scope for SNBTS to influence national policy in Scotland and indeed in the wider UK or to influence matters on a national level may have been quite

limited, if essentially the expectation was that SHHD would follow the DHSS's line?

A. As my statement says, that is my recollection. I can't recall any situations or circumstances where SHHD took a different approach to a product safety -- a blood safety issue. They were always step in step with DHSS. Where they did diverge was the policy approach to self-sufficiency throughout the 1970s and 1980s where SHHD were always quite explicitly committed to I think what we would regard as the true definition of self-sufficiency, which was meeting all the needs of patients in Scotland for products from voluntary non-remunerated donors. That was the target. It wasn't to balance commercial supplies and so on, so there was a divergence of policy there.

So far as influencing the UK position, I think my recollection is that the SNBTS directors and senior scientific and medical staff were quite influential in those -- and there were many UK fora in which issues, particularly of blood safety and testing techniques, testing regimes, introduction of hepatitis C testing, and SNBTS were always well represented and always quite vociferous and quite influential in those meetings, so it's not correct to say we didn't have the ability to influence, I think we did, but it would

still be within a UK context.

Q. Just before we break, you rightly observe that there were SNBTS directors on a number of national committees, the Advisory Committee on the Virological Safety of Blood obviously being an example of that?

A. And SACTTI and the Standing Advisory Committee on Transfusion Transmitted Disease and so on.

Q. SACTTI I think was later, 1989, probably -- well, in fact, I think they were both later. In any event, is it correct that when you sat in those committees you were there in, as it were, a personal capacity? You were not there as a representative of SNBTS or PFC?

A. Oh, this is my role in respect of ACVS --

Q. Yes.

A. Yes, it was, to start with. My understanding is, yes, I was there in a personal capacity. I was not there to represent the SNBTS, but I was only there because I had skills and experience gained whilst in the employment of SNBTS. And the same is true of my membership of the Committee on Safety of Medicines Biological Subcommittee. I was there as an individual and forbidden, for obvious reasons, to divulge anything outside of that meeting that may have occurred.

MS RICHARDS: We will come back to that issue of the

confidentiality of those types of meetings at a later stage.

Sir, perhaps we could take the morning break?

SIR BRIAN LANGSTAFF: Yes, we will do that and come back at 11.50 am.

Now this is the first break. Let me say to you what I say to all witnesses either at the very beginning of their evidence or at the first break, and it is this: you are giving evidence, you must not discuss the evidence you have given or, for that matter, any evidence which you think you may later be asked to give with anyone, whoever that anyone is. But you can talk about anything else you like.

A. Thank you, I understand.

SIR BRIAN LANGSTAFF: 11.50 am.

(11.20 am)

(A short break)

(11.50 am)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Perry, still on the topic of the PFC's relationship with other bodies, I wanted to ask you next about the relationships with BPL.

First of all, on a personal level, we have heard evidence about the relationship between Mr Watt and Dr Lane, do you have any particular recollections of

the relationship between Dr Cash and Dr Lane?

A. Not a great deal. I think there was some -- they had conflicting views which I think probably arose from the discussions that took place in the 1970s and perhaps early '80s about how the overall supply of UK plasma should be fractionated in Scotland versus at BPL.

But I attended meetings where they were both present and there was always a constructive dialogue. I don't think they agreed on all issues but, as I said about Mr Watt, they were both strong personalities and had clear views on certain topics.

Q. Then we have heard evidence that at an informal level, and I have in mind the written evidence of Dr Smith and then the written and oral evidence of Dr Foster and Dr Snape, that there were good informal links and communications between, for example, those working on research and development in PFC and those working on research and development in BPL.

What was the nature of your own interactions with BPL? Who did you tend to have dealings with?

A. I had dealings with Dr Snape, Dr Smith, Dr Smith's co-worker, Dr Winkelman, Dr Lane. Although probably more frequently with Dr Smith and Dr Snape than Dr Lane. But I had fairly regular, though not

frequent, contact with Dr Lane and of course I met him periodically at meetings and we would always have constructive discussions I think.

Q. Now, if we just go to your statement to this Inquiry, so WITN6920001, and if we go to page 15, bottom half of the page. You say in paragraph 46 -- sorry, let me pick it up in paragraph 45. You say there:

"... PFC ... considered its relationship with BPL to be very important, although as separate units under different UK jurisdictions there were few, if any, mechanisms or fora for regular formal liaison and collaboration. However there was a regular and productive scientific collaboration."

Then if we go to the next paragraph, please, Sully. You reiterate in the opening sentence of paragraph 46 you don't recall any formal liaison mechanisms between BPL and PFC:

"... although Professor Cash was a consistent and strong advocate for closer and more formal cooperation between UK Blood Services concerning the development of safer NHS products."

Then if we look at the last sentence on that page you say:

"I am not aware of or cannot recall any formal mechanisms being established by DHSS/SHHD or the Blood

Services for formal cooperation concerning joint product development programmes."

Then if we just go over the page. You then set out, I don't need to go to any particular paragraph, but you talk about your own relationships with BPL personnel and communications in particular between Dr Foster and Dr Smith.

If we go to the next page then, please, Sully, and just look at paragraph 52. You say:

"There may have been some merit in a joint approach for the development, production and supply of plasma products for the UK wide NHS (particularly for providing increased benefit of scale for PFC) but this did not apparently enjoy the support of DHSS or SHHD to the extent of serious consideration or study."

Can you just assist us first of all with what you mean by the passage in brackets, referring to providing increased benefit of scale for PFC?

A. I think it was simply that the PFC, as it became set up for Scotland and Northern Ireland, was a relatively small fractionator in international terms. They were -- certainly compared to BPL and certainly compared to some of the larger units in France and the Netherlands and so on. And as with most endeavours of this type, increased scale creates greater efficiency.

So, I think PFC always felt, certainly during the 1970s and 1980s, that it would benefit not only PFC but the UK as a whole to have a more equitable split of plasma to supply to both PFC and BPL.

But by the time I'd arrived I think that discussion -- I don't think it was concluded or it was over, but it was certainly well advanced to the stage where it seemed to me that Scotland would pursue its programme of self-sufficiency for Scotland and with the prospect of Northern Ireland coming on stream as well.

Q. You have said in one of your Penrose statements -- I am not going to put it up on screen but the reference is PRSE0001258, page 11 -- you observed that it would be difficult to argue against a case for the closest possible collaboration between two UK NHS services engaged in identical and unique activities.

But as the statement we have just got on screen explains, your sense appears to be that there wasn't the support of either the Scottish Home and Health Department or the Department of Health in London for formal closer collaborative endeavours?

A. No, I think that was my sense when I joined the PFC, that these discussions had been going on some time. And I think there was the shift experiment that was

done to still establish whether or not PFC could increase its throughput and so on, but I -- I have actually thought about this, and the first point I would make is I think the arrangements that we had, the "informal arrangements" as they are called, were highly productive. And it may well have been, in the context of haemophilia product development, that a more formal arrangement for collaborative working between BPL and PFL and PFC may not have improved the outcome, for example, and I am sure we will come on to it, heat treatment.

I think at BPL and PFL, under Dr Jim Smith's leadership, they chose to go down a dry heat treatment route and we, in the early stages of our heat treatment programme, wanted to do pasteurisation because we thought that was the best technology to adopt in terms of non-A, non-B hepatitis.

I think it is possible to speculate that had there been a formal arrangement, then, it could well have been that both organisations might have chosen to simply pursue pasteurisation because that was -- I think Dr Jim Smith has mentioned this in his witness statement, that that was -- I think there was quite a strong consensus between PFL, BPL and PFC that that was the preferred technology if the target virus to be

inactivated was non-A, non-B hepatitis.

It may well have been that in a more formal structured arrangement those involved in the discussions of the technology to choose may well have chosen pasteurisation, in which case I think the outcomes in terms of the speed with which both BPL, PFL and PFC developed their dry heat treated products would have been much slower.

Q. If we leave aside the research and development element, and I understand your answer in that regard, but look at what the benefits might have been of a more formal, liaison in other terms, a more formal liaison or arrangement between Scotland, England and Wales and Northern Ireland might have resulted, might it not, in increased overall production of domestic concentrates?

A. Yes, I'm not absolutely clear in my mind whether the constraint on BPL's output was capacity or plasma supply or perhaps a combination of both. But I think PFC certainly took the view that it did have spare capacity or it could -- spare capacity could have been developed fairly quickly with additional resources, freeze dryers and so on, but the central processing technology had the capacity to produce more product. So, yes, I think, is the answer to that question.

Q. And did you ever get the -- any sense of what underpinned the lack of enthusiasm on the part of SHHD and DHSS that you described for a closer joint collaborative exercise?

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

Q. Can I move then to relationships with fractionators beyond BPL and PFL.

First of all, to what extent did PFC have links with fractionation centres outside of the United Kingdom?

A. It had -- well, I think Mr Watt set up -- who set up the PFC and commissioned it and so on, he made it his business to appraise himself of the work of many fractionators. These were predominantly not-for-profit organisations in Europe but there were commercial organisations that he had dialogue with as well.

So that extended into my tenure as well and we had really quite excellent relationships with the Dutch Red Cross, the Finnish Red Cross, I think latterly the French fractionation facilities under the CRTS, as it was then. So, yes, quite an extensive network of contacts, predominantly in the not-for-profit sector.

Q. In terms of the full profit sector, the commercial

fractionators, the pharmaceutical companies producing their Factor VIIIs and so on, to what extent was there any relationship, formal or informal, between PFC and those pharmaceutical companies?

A. I think we knew who the commercial companies were and I think we knew some of the key, particularly scientific staff involved in those activities.

I don't recall there ever being a free exchange of information. I think, as so many others have said, the commercial sector kept their processes and their know-how very closely guarded secrets, for obvious commercial reasons. So although we would have dialogue, we had a broad general understanding of what they are doing but we never -- I don't think we ever accessed at any deep level a scientific understanding of their processes and how they made them work.

Q. It might be said, having regard of Dr Foster's evidence, that a picture emerged of being able to glean bits and pieces here and there at international conferences on a -- small pieces of a jigsaw?

A. Yes.

Q. It would presumably, in principle, have been enormously helpful if there had been a more extensive or formal process for the exchange of information?

A. Kind of global co-operation.

Q. Yes.

A. Well, yes. But I think, for reasons that I have described -- the not-for-profit sector was much more like a family in Europe. They weren't competing. The national services in France, Finland, Holland, the UK, weren't competing with each other for markets so there was a much freer exchange of scientific information and co-operation.

The commercial sector were fiercely competitive with each other and still are. So they guarded their proprietary information and know-how, as I say, very closely. They were closely kept secrets. So there was never in my view any real prospect of accessing their information and if we did -- if one did then more often than not it would be patented. So not accessible for the public sector to utilise.

Q. Now, moving then back to England and Wales but now the regional transfusion services in England and Wales. Is it right to understand that at the PFC you didn't have much by way of dealings or interactions with the Regional Transfusion Directors in England and Wales?

A. I think that's a fair summary, yes. I think we knew many of the regional directors and they knew us but these were informal contacts met at conferences and meetings.

Q. Did you ever for example get the minutes of the meetings of the Regional Transfusion Directors of England and Wales?

A. I think I probably did see them, yes.

Q. Would that have been through Professor Cash?

A. That would have been through Professor Cash.

Q. Can I then turn to relationships with Haemophilia Centres and Haemophilia Centre Directors. We have obviously touched on that in relation to Scotland because of your earlier evidence about Professor Cash's principle of everything going through the Regional Transfusion Centres.

Did you have a closer relationship with a degree of interaction with the Haemophilia Centre in Edinburgh for reasons of geography, geographical proximity than other services or was there no real difference in Scotland?

A. I think it is probably true to say we did have a slightly closer relationship with the Centre in Edinburgh. It was adjacent to the transfusion service in Edinburgh and it was literally five miles from the PFC. And Professor Ludlam was the chair of the Coagulation Factor Working Party. So, yes, we did have a close working relationship. But that wasn't to the exclusion of other haemophilia directors.

Q. In relation to the Haemophilia Centres in England and Wales, we will come on to Northern Ireland in a moment, there was no particular tie or, as I understand it, regular degree of interaction other than through a degree of PFC attendance at the annual meetings of the UK Haemophilia Centre Directors?

A. I think that is correct. I think that's true.

Q. And I think we see you attending UKHCDO meetings fairly early on in your PFC career, October 1981, and you were there again, I think, in '82 and '83?

A. Yes.

Q. What was the thinking behind having PFC represented at those meetings?

A. I think Mr Watt, who I reported to, felt it was a good idea that I should be exposed to these meetings because, in the absence of a formal training programme, this was a very good way of learning what the issues were and what the priorities were and what the -- what was happening in haemophilia care. So these were very important meetings.

I don't think I probably contributed greatly to them but I certainly listened carefully and learnt a great deal, at a personal level. But they were UK meetings. So they were there to represent the Scottish haemophilia directors and the Northern

Ireland haemophilia directors as well.
Q. Then, specifically in relation to Northern Ireland, you had contact with Dr Morris McClelland, as the Regional Transfusion Director, through his attendance at SNBTS meetings once the arrangement with Northern Ireland was established.
What about the Haemophilia Centre in Northern Ireland and the Haemophilia Centre Director, Dr Mayne, to what extent were there any interactions between the PFC and Dr Mayne or her centre?
A. I never went to a Haemophilia Centre in Belfast but I think as soon as PFC started processing Northern Irish plasma and supplying them coagulation factors, albumin and immunoglobulin products back, Elizabeth Mayne, I think it is correct that she joined the annual meeting of Scottish Haemophilia Centre Directors and Transfusion Directors, but she certainly attended the Coagulation Factor Working Party on a regular basis. So we had quite a close relationship with Dr Mayne. She was a good colleague.
Q. Can I then come on to some aspects of regulation. We have obviously touched on the issue relating to the manufacturer's licence. Just in relation to that, is it right to understand that Dr Cash and Mr Watt, neither of them agreed with the decision not to renew

the manufacturer's licence?
A. This would have been prior to 1984?
Q. Yes.
A. I think as I have said previously, I think both Mr Watt and Professor Cash felt that formal regulatory approval of PFC was an important objective, but I think certainly following the inspection by Flint and Purves in '79 and '80, I think there was probably a view taken by both Professor Cash and Mr Watt that it would unlikely -- an application for a manufacturer's licence would have been unlikely to have been granted at that stage.
So the absence of the manufacturing licence became an important -- I guess I would call it an important tool to try to get the funding that we felt we needed.
Q. Just for the benefit of others and the transcript, there is a reference to the views of Mr Watt and Dr Cash and their disagreement with the decision not to renew the manufacturer's licence in a document put together by Mr McIntosh for the Penrose Inquiry. I am not going to go to it given that it predates, I think, your involvement. PRSE0002556, page 16 is the reference for that.
But before I ask you a little about the process

in relation to product licences, I just want to ask you about interactions with another regulatory body, NIBSC, so the National Institute for Biological Standards and Controls. Have I got that right?
What interactions did PFC have with NIBSC?
A. We had, I guess in some senses, a formal relationship with the NIBSC, as the national control authority, whose responsibility, amongst many other things, was to approve batches for release. I think latterly in our relationship to do virological testing, to test product batches for potency and so on. So that was the formal relationship and it was very close and mirrored very much other organisations that had products on the market in the UK.
But there was also a -- I guess you would call it a more informal relationship between scientists in PFC, and the wider SNBTS, with scientists at NIBSC. For example, Dr Cuthbertson was quite closely involved with NIBSC in developing assay techniques for testing for virological markers in plasma products and adapting test systems that were available and designed for single donation use to assay systems that would be sufficiently sensitive for testing plasma product. So that is an example of the sort of collaboration.
And I think NIBSC set up various working

parties. I think there was -- I have seen documents that have been sent to me, and I certainly recall, of an AIDS scientific working party that was established by NIBSC.
So NIBSC, I think, part of its vision, certainly in the early 1980s by its then director, Geoffrey Schild, was to become much more integrated in the work of the transfusion service, and the best way to do that was to set up working groups on scientific issues.
Q. Can we just look at your statement to this Inquiry.
WITN6920001, page 13, please, Sully.
I just wanted to ask you a little bit more about paragraph 40. You described the PFC as being:
"... required to submit samples of finished products, intermediates and plasma pools for control testing and batch release to NIBSC as the national control laboratory."
Can you just help us understand a little more about how that process worked. So what samples would be submitted to NIBSC and at what point in the -- or what stage in the life cycle of a product would that take place?
A. I can certainly explain what it meant, and what I can't give you is a timescale for the various

changes that took place. But in the very early stages of this, I think samples of PFC product would be submitted to NIBSC for Factor VIII potency testing, for example, to check that the potency that we were assigning to the product matched their determination. And that was important because finding assays that were suitable for plasma products was not always easy. So there was an ongoing collaboration in that area.

I think as time went on there was a requirement for -- following the introduction of HIV testing and probably hepatitis B testing, we were required -- or we did -- perhaps we weren't required because we were under -- we were operating under Crown immunity, but we took the view that we should engage and integrate our activities with -- in common with the commercial sector and anyone else who is putting products on the market in the UK.

So the -- NIBSC, as I say, would determine whether or not our assay systems -- so we would send a sample of a batch of Factor VIII, for example and we had already tested it and we found it negative for HIV and negative for hepatitis B surface antigen. That finished product vial would go to NIBSC and they would test it and confirm the result.

And I think when this system operated, we

wouldn't have released the product until we had confirmation from NIBSC that they too had found the product to be negative in their assay systems.

Then I think it further developed into a phase of requiring plasma pool testing. So, we would take a sample of the plasma pool -- actually, strictly speaking, it was the cryosupernatant, not the plasma pool. There was a cryosupernatant, and that would be tested by PFC for virological markers, and a frozen sample to be sent to NIBSC and they would do -- they would test it for HIV, hepatitis B surface antigen, and eventually hepatitis C, in the early 1990s, when that test was introduced, and, similarly, the pool would be released.

Although, because of the nature of the process, we couldn't delay the processing of the pool until we got the result back from NIBSC, because the turnaround time was sometimes a fortnight, but it -- the pool would have to have been found negative for the finished product batch associated with the pool to be released for use.

Q. And the reference to "intermediates", what's that a reference to, samples of intermediates?

A. It could well have been that at some stages intermediate fractions, like Fraction II -- this would

have perhaps been -- or maybe -- well, it talks about plasma pool, so it might have been part of a more informal collaboration on a scientific level. I don't -- on reflection, I don't recall there being any specific regulatory requirement submitting intermediate fractions for testing by NIBSC but we may well have done that as part of a scientific collaboration.

Q. In terms of the contribution of NIBSC to virological safety, its ability to contribute really depended upon the availability of screening tests or tests for markers of a virus?

A. Primarily virological markers, but it also had this important role of standardising Factor VIII assays. NIBSC, amongst the other things it did, it did create international standards for Factor VIII and it was always a matter of concern when a new international standard was coming out because at a stroke a change in the international standard could have reduced the measured yield in PFC products -- and this problem would have applied to BPL as well -- by as much as 20%.

So they had this very important role of creating Factor VIII reference standards against which operational routine standards would be calibrated.

Q. Then, can we look at a letter that you wrote in late 1987. It was referred to in one of the extracts to your Penrose evidence that we looked at before the break.

It is at PRSE0000712, please, Sully.

So this is a letter you wrote 21 December 1987 to Mr Donald, the general manager at the Common Services Agency. It is headed "Product liability/personal liability". You say, picking it up in the second sentence:

"... I note that the Agency has not (and perhaps cannot) provided an absolute assurance that it will underwrite the activities of its employees at the Protein Fractionation Centre. I am also aware that professions such as pharmacists and doctors can arrange personal indemnity insurance. Unfortunately, the professions represented at PFC (including my own) do not have access to such facilities and thus I must conclude that in the face of existing rules of negligence and the new consumer protection laws, I (and my senior colleagues) remain exposed and vulnerable in an area of product manufacture which attracts considerable public attention."

Then just continuing with the next paragraph:

"Perhaps my sustained anxieties stem mainly from

the fact that the manufacturing activities of the Centre are at a level substantially above that for which the Centre was designed and there exist major breaches of GMP in our day to day activities as a consequence which can only be resolved by the provision of additional buildings. One might argue therefore that I am professionally negligent in allowing such activities to continue. However, I continue to do so in the interests of self-sufficiency and, in my opinion, in the public interest. The Agency is aware of this position but to my knowledge has never explicitly instructed me to continue with a policy of growth. I am therefore knowingly operating the Centre above its capacity and I am ever conscious of recent disasters elsewhere whereby the corporate body and individuals are subject to criminal proceedings. As the captain of this particular ship, I find the analogy too close for comfort."

Then over the page you conclude:

"Clearly, I am not implying an imminent disaster at PFC since we continually make strident efforts to compensate for deficiencies at the Centre but I believe it is appropriate (and reassuring for myself and senior staff) that we clarify unequivocally that

the Agency is aware of the deficiencies at the Centre and has authorised the continuation of activity at the present level. I recognise that this amounts to an instruction to carry out our professional duties outwith minimum standards required of the pharmaceutical industry but in the circumstances, such an instruction will at least relieve some of the anxiety felt by myself and senior colleagues."

Now, that doesn't read like a letter that would be written lightly, Dr Perry?

A. No, no, I remember. I do remember this letter.

Q. What were the particular concerns that drove you to write in those terms in 1987 to the CSA?

A. I think the background to this particular letter was an increasing level of frustration that we were not getting approval or agreement by SHHD or the Common Services Agency for that matter, although they would have got the money from SHHD, for what was required at PFC, which was a fairly major building programme, involving cold rooms, storage areas, increased and improved processing areas, new sterile filtration areas and so on. So this was really, I think, part of a process and I think you showed the letter from Professor Cash, this slightly pre-dated that and Professor Cash was responding to this letter.

I think this was my attempt to do pretty much what it says in the letter, which is if I am -- and I was committed at the time. I didn't write this letter with any prospect of closing PFC down. That wasn't my intention. But it was to try and raise personal and I think they were legitimate concerns at the time, that I was responsible, I would have been considered responsible and I didn't have recourse to things like medical defence unions or the associated body for pharmacists to protect me in the event that there was some litigation that was directly attributable to the circumstances. So I was actually asking for the CSA to understand the issues and underwrite the activities of PFC, and also to try and force funding, to be crude, yes.

Q. And did you get a response from the CSA at any stage?

A. I think there was a response. I don't think it was a satisfactory response because that's what provoked Professor Cash to write his letter, and the response was from the SHHD. I don't think the CSA really understood what the issue was because they very seldom engaged in details such as this in their activities. But SHHD I think responded by saying, "In our view, the PFC is perfectly suitable for its purpose", and I think that's what promoted Professor Cash to write

his letter. Which in some senses was underpinning and emphasising the points that I was making, but in his typical way he went a little bit further.

Q. We can take that down, thank you, Sully.

I want to ask you next a little bit about product licences. I'm specifically focusing on obviously Factor VIII, Factor IX products.

First of all, at the PFC, whose job was it to make the applications for the product licence or have any ongoing interaction with the medicines division of the licensing authority?

A. I think that was probably assigned to me when I joined in 1981. I think that was one of the portfolio of activities, and I think, as I briefly mentioned before, one of the major tasks that I undertook in 1983 was to assemble a comprehensive product licence application which was an enormous undertaking at the time for our newly developed intravenous immunoglobulin product.

Q. What did you understand the purpose of the product licensing system to be?

A. It was -- I guess, effectively, a peer review system. That we felt that self regulation, particularly in the area of complex biological manufacture, we felt it was professionally appropriate that we should submit our

studies, our processes, and their intricate designs to peer review. And the only peer review system that existed was product licensing. And that, for example, was the rationale I made for applying for a product licence for intravenous immunoglobulin in 1983.

I did get a response when the SHHD discovered that I had submitted this licence to the MCA. I think the chief pharmacist he expressed his concern that I had, I think, in his words, usurped the authority of the Secretary of State.

Q. I'm just going to ask you to look at part of your evidence to the Penrose Inquiry on the licensing system in broad terms, PRSE0006025.

So this is an extract from your evidence -- or this is the transcript, sorry, of your evidence on 13 May 2011. If we go to page 42, please. We can pick it up I think at line 16. This is in a question that was being asked to you. It says:

"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?"

Then we have your answer:

"I think that's what the licensing system is intended to achieve. It's intended to give prescribing doctors [top of the next page] 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."

Then there is a question -- sorry, if we go back to the whole page -- or an observation put to you along the lines that the evidence the Penrose Inquiry had heard was that licence didn't make any particular impact on the clinical decision-making of Haemophilia Centre Directors.

Then if we go to the bottom of the page you were asked if you wanted to comment on that and at line 21 you said:

"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."

Sorry, can we have the rest of the first half of the page, Sully, because it is not in fact that point I want to ask you about at this stage. It is the next bit. You continue:

"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."

Now, I'm showing you that for present purposes really just to understand what you thought the purpose of the product licensing system was. It was intended, is this right, to provide a degree of external assessment of the safety of the product?

A. Yes, before you showed me that I was going to clarify that that was the other major reason and prescribing doctors, although they understood the status of PFC, they had a reasonable expectation to understand what

measures we had taken to assure the safety of these products. And the only system that exists for doing that is the licensing system.

Q. If we then turn to the question of the product licences for factor concentrates at the PFC. We will see, probably this afternoon when we look at some of the examples of package inserts and product warnings, we will see that licence applications were submitted in I think 1978, designed by Mr Watt, for product licences for Factor VIII and Factor IX, so the NY and for DEFIX. So that was I think in 1978 and they would therefore have come up for renewal in around 1983?

A. Yes, that is right.

Q. As far as you can recall, were those licences renewed in 1983 for the factor concentrates?

A. I think they were but I would have to check on individual products and so on but I believe there was an attempt made to -- or perhaps a successful attempt to get them re-licensed and their licences extended.

Q. Now --

A. I would add that the original licence application in 1978, although it was written carefully, it probably wasn't as substantive as the type of licence application that would have been required by a commercial manufacturer to submit. But the key

information was included and the licensing authority took the view that it should be licensed.

Q. Now, during the lifetime of a product licence, so in relation to PFC's product licence, if you were to say from 1978 to 1983, at least in relation to the first licence, were there any particular reporting obligations or reporting practices undertaken by the PFC in terms of, for example, adverse reactions, instances of hepatitis, jaundice?

A. Yes.

Q. Would those, in the life of the licence, be reported to the licensing authority or would they be reported elsewhere, do you know?

A. Certainly latterly it was quite carefully prescribed when the licences became substantive, following the removal of Crown immunity, any significant adverse reactions, and there would be a definition what significant meant. They certainly would be reported or in regular post-marketing surveillance studies and so on, not necessarily on a one by one basis but they would be collected together and submitted to a licensing authority.

I think in the early 1980s, it was certainly the case that Regional Transfusion Centres were encouraged to have a close liaison with the users of the products

and if there were any adverse reactions they would be reported directly to PFC.

So I think we had a fairly good idea. I would not call it a fully developed pharmacovigilance system as one witnesses nowadays, but it was certainly a link between individual patients. I think interestingly though it may have been the case that Factor VIII infusions to patients so frequently caused elevations of ALTs and perhaps even jaundice, I don't know the clinical details, but that was prescribed as an expected adverse effect. So that wouldn't necessarily have to be recorded, so we didn't get routine reports. This is before introduction of heat treatment, of patients seroconverting for non-A, non-B, for example. But we would have got reports of a hepatitis B transmission.

Q. This may be a hypothetical question because I don't know if it happened, but if you got reports of a hepatitis B transmission reported to you at PFC, do you know whether in the period really leading up to the mid-80s or indeed beyond that, the period when there was Crown immunity, did that get reported by PFC or by SNBTS more generally to the licensing authority?

A. I can't be sure of that. I can't be sure of that. It would certainly have been reported to the PFC. PFC

would have carried out an investigation and the appropriate outcome implemented, which would have ranged from no action to a complete recall of the batch.

Q. Then can you recall, and if you can't obviously please say so, whether information on pool sizes was part of the information that PFC would submit to the licensing authority when applying for a licence?

A. I think it was actually, yes. I think there would have been a requirement to state -- it was a measure of the scale of activity which was an important parameter I think. I don't know whether it is expressed in kilos, litres or individual donations but one or all of those would have been used to measure it. I think that's the case, yes.

Q. Then during the lifetime of the licence, you have got your licence granted for five years, you don't have to renew for five years. During that period of time, if there are changes that might have a bearing on risk, for example, increase in pool sizes or the development of knowledge that non-A, non-B hepatitis is a more serious condition than hitherto believed, or the development of knowledge that non-A, non-B hepatitis is -- the belief that it is an inevitable consequence of a first dose with NHS concentrates. If that the

kind of information that might have a bearing on risk comes to light in the course of the duration of a product licence, do you know whether there was any obligation on the licence holders to notify the licensing authority? Or was that just something that would be picked up at the next renewal?

A. I think the licensing authority were interested in adverse events which fell outside the recognised adverse events which -- like slight haemolysis or even transmission of hepatitis viruses. The licensing authority would have regarded those as fairly frequent and not remarkable.

We now know that they were extremely remarkable but at the time it was, as we now know, a significant and severe problem with the products.

Whether -- so -- I do recall one example of a Factor VIII infusion taking place, for example, in Glasgow and the patient developed a significant reaction to his treatment and that was reported and thoroughly investigated. And I believe actually a medicines inspector came up to look at that. It turned out that it was as a result of a too fast infusion by the patient. I think it was finally determined to be an issue of citrate toxicity rather than a problem with the product batch.

But that was reported to the licensing authority because it was unusual and I think we hadn't seen it before so we felt it was appropriate to report it. But, as I say, the pharmacovigilance systems that we have now are much more significant and robust.

Q. Just so that you understand, Dr Perry, the purpose of these questions is to really try and get a sense of how in practice the product licensing system operated. We have looked in earlier hearings at some of the legal requirements. We have looked at some of the applications from commercial companies, but it is really the extent to which the -- once the licence was granted, the extent it was an ongoing dialogue with the licensing authority at this period, late '70s, first half of the '80s, that prompts the questions.

A. I think it wasn't fully developed either because the licensing authority -- I talked in my Penrose -- I think you showed it in the Penrose, and it was a confused area. I think it was confused not only for PFC and the SNBTS but it was confused for the licensing authority as well. They weren't quite sure how to deal with an organisation submitting product licence applications when actually they operated under Crown immunity, so the status of that relationship was a little bit confused.

Q. If we take the example of increased pool sizes. Do you think it is more likely than not that that -- that that wouldn't have been reported by PFC to the licensing authority during the lifetime of the licence? Or are you just --

A. I think it would have been an unusual event. It is difficult to define what a small change and a large change might be. But a small change in pool size would have been considered not of consequence, of sufficient consequence, to notify the licensing authority because they would simply note the position bearing in mind that most of the products that they were licensing, which was sensitive to pool size were commercial concentrates with pool sizes orders of magnitude larger than the PFC. So if the PFC had submitted a licence application or an amendment to the a licence application saying we have changed the -- we have modified the pool size from 500 litres to 1,000 litres, I don't think they would have taken much notice of that. I think they would have said, well, that's still orders of magnitude less than the size of -- or substantially less than the size of, for example, commercial pools.

Q. Then the example of developing knowledge in relation to non-A, non-B hepatitis. Would it be right to

understand from your earlier answers, and please correct me if this is not right, that a growing awareness of the seriousness of non-A, non-B hepatitis would not be something PFC would necessarily report to the licensing authority because post-transfusion hepatitis was already a known risk?

A. No, I think we would have assumed or I would have assumed that this was a well known phenomena by the licensing authority and they didn't need reminding from one manufacturer that that was the case.

Q. Can I then just ask you a little about PFC's involvement or I think more accurately lack of involvement in issues relating to donor selection. If we pick it up again in one of your Penrose statements.

PRSE0001823, please, Sully. If we go I think to page 3. Second paragraph. Top of the page, please. Thank you Sully.

You say in the second paragraph:

"Latterly during this period PFC and Regional Centres worked more closely on the development of quality systems and standard operating procedures for the processing and testing of plasma but this did not extend to issues of donor selection which, at that time, would have been accepted as the exclusive responsibility of Regional Directors and their medical

staff. This situation remained largely unchanged until reorganisations of the service in the 1990s. In its original Licence Applications to DHSS Medicines Division for Factor VIII information on donor selection practice or policy was neither supplied by PFC/SNBTS or requested by the UK Licensing Authority."

So, as I understand it, two points essentially emerging from that part of your statement. First of all, in submitting your licence applications, you were neither asked to provide nor volunteered information about donor selection practices in SNBTS?

A. I think that -- my understanding is that that's the case yes.

Q. Then, secondly, your broader point is that the approach to donor selection was not something that PFC got involved with. It regarded that as -- the term used here -- the "exclusive responsibility" of the Regional Transfusion Service?

A. I think that is correct as well. That subsequently changed as the quality systems developed -- and PFC was also -- I was personally instrumental in trying to expand the concept of quality systems throughout the Regional Transfusion Centres, driven by the need for PFC to have a modern and mature quality system in place. But I think it was still the case that the

detailed considerations for donor selection were -- I think personally and I think generally were considered to be the exclusive responsibility of Regional Transfusion Centres.

That is not to say that I was excluded from an interest in that but certainly in the early 1980s that would have been a given that the plasma coming to PFC had been subject to suitable donor exclusion and testing procedures.

SIR BRIAN LANGSTAFF: May I ask, on whose behalf was the application made for what would in other -- what was originally, and would, after the mid-80s, possibly, had you been a commercial organisation -- who made the application; SNBTS or PFC?

A. Well, neither actually, sir. It was made, I think -- and I'm not sure when this changed, but maybe never, it was made on behalf of the Committee of Management of the Common Services Agency.

SIR BRIAN LANGSTAFF: And they managed both SNBTS and -- the Regional Transfusion --

A. They were the umbrella organisation that managed the SNBTS and many other organisations.

SIR BRIAN LANGSTAFF: So this was one organisation which was responsible, albeit vicariously, for donor selection as it was responsible for the information

that you were capable of giving it. So why wouldn't the information about donor selection have been given to the licensing authority?

A. I think it probably would nowadays. But I think if the period that we are talking about is the early '80s or the late 1970s, it is the case that the licensing authority didn't seek this information. Nor, incidentally, I imagine, did they seek the specific information of those commercial suppliers of Factor VIII in terms of their donor selection procedures and so on. So it didn't have that -- the focus of attention which we now know it should have done.

SIR BRIAN LANGSTAFF: Yes. Thank you.

MS RICHARDS: We can just see the first page of a licence application if we go to PRSE0002726.

Just to confirm -- if we go to page 5, I think, Sully -- the answer that Dr Perry just gave. Can you go on five pages, Sully? There we are.

So if we look at -- zoom in on the top half of the page, we can see this is the Factor VIII product licence application. Then we can see the proposed licence holder is the Committee of Management, Scottish Health Service Common Services Agency.

A. Right.

Q. Then:

"Trading style to be shown on licence if different from above: Scottish National Blood Transfusion Service Protein Fractionation Centre."

Then if we go just to the bottom of the page we can see that this was the licence application submitted by Mr Watt in March 1978.

A. On behalf of the management committee.

Q. On behalf of the management committee. We will come back to that document for different purposes at a later stage, Dr Perry.

Just sticking, however, with the issue of donor selection just for a moment. Do you recall whether the PFC ever did its own audit or assessment or checks on the donor selection policies and practices that were being implemented by the different transfusion centres in Scotland?

A. I don't think it would have considered itself competent to identify -- to go into the detail of donor selection procedures but it would have checked and audited against the need to have donor selection. And standard operating procedures for donor selection would have been the sort of working title. So the PFC would have taken the view that it wasn't competent to judge specifically what the exclusion criteria might

be, but we would check to make sure there was a documented system in place and that was operated.

Perhaps not in -- certainly not in the 1970s or in the early '80s, but that developed over time. The whole concept of PFC auditing Regional Transfusion Centres as a supplier of a raw material, I can't remember the date on which -- in which it emerged and developed, but it was sometime in the 1980s, I think.

Q. I want to move to the topic of self-sufficiency next and get started on that before we break for lunch.

If we look at PRSE0006011. Again, this is an extract from the oral evidence given to the Penrose Inquiry, 24 March 2011. I want to go to page 94. We looked at one passage on this page earlier. I want to look at a different passage now.

So you were being asked here about your arrival at and your role at the centre. I just want to pick it up at line 11 onwards. You say:

"I think the preoccupation at that time -- and there was absolutely no doubt in my mind that this was the case when I joined in 1981 and certainly strengthened as the 1980s moved forward, that the dominant goal and target was self-sufficiency. It was very clearly evident to everyone who worked in it that, in terms of plasma products, the goal and the

aim was to make Scotland self sufficient in plasma products and in particular coagulation factors.

Does that remain, first of all, your recollection of the position?

A. Yes, a very, very clear recollection. And that became very clear to me very soon after I started in 1981. It didn't take long for me to understand why the PFC was there.

Q. Do you recall -- if we keep this up on screen in a moment because we are going to go to a different page in a moment. Do you recall gleaning or gaining an understanding of why self-sufficiency was this dominant goal for the PFC?

A. Yes. I think the complexity of the answer to that developed over time, but initially it was very clear to me that there was a view that plasma derived from voluntary non-remunerated donors and used as a raw material for plasma products was a lower risk material than plasma or products obtained by the commercial sector.

So the object of self-sufficiency was to effectively eliminate the need for commercial products to be used in Scotland. That was the stated aim. It was quite clear, it was unambiguous. And clearly -- and I believe everyone that I came into contact with

understood that.

Q. The reason for asking, Dr Perry, is there might be a number of reasons why it is said self-sufficiency is a good goal. It might be, for example, the elimination of commercial concentrates because ultimately that would be cheaper for the State. That's why I wanted to pick up on your understanding for the reasons for it.

If we could go on in this transcript to page 118. Picking it up at line 5, you come back to your understanding about this being a goal:

"My understanding at the time when I joined the service, as a new person to the blood service, was that this was a goal or a policy that had been set by the Scottish executive at the time, that we wanted to meet the WHO recommendations for self-sufficiency. But I think also it became very clear that one of the prime justifications for self-sufficiency was a belief, which was based on fairly good evidence, that imported products from the USA, which were the alternative source of products, were much higher risk products than those that would be produced from voluntary non-remunerated blood donors from one's community. So it was a target which was aimed at creating a sufficiency of supply from our own

community but also a target which sought to reduce the risk to haemophilia patients of transmission of disease from other countries."

So that remains your evidence, does it, that one of the prime motivating factors or was it the prime motivating factor was the issue in relation to safety?

A. I think was the prime motivating factor. I don't believe there was ever a comparison of what the cost saving is. It certainly wasn't driven by a perceived lower cost. I'm not sure it was lower cost to produce one's own products rather than buy commercial products. So I think that was the clear justification.

And it was a goal set well before my arrival in SNBTS by SHHD, who -- I don't think there's any formal grand statement by SHHD that, "We will become self sufficient", but it was a concept that they clearly supported, and funded, because collecting -- collecting increased levels of plasma required significant injection of revenue funding for blood bags and the consumables and so on associated with this.

Q. Then in terms of your understanding of what self-sufficiency meant, I think it is probably in the same document at page 57, please, Sully. No, it's

not. Sorry, wrong reference.

Can we go to PRSE0006025. Then page 57 of that document.

So this is your evidence to the Penrose Inquiry on 13 May 2011. We don't need to go to it but the bottom of the previous page you had been asked what was the goal that you took yourself to be working towards in terms of self-sufficiency.

Then this is your answer:

"Answer: 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."

Do I understand that last sentence to mean: justified to use a non-NHS product in the exceptional circumstance that you described in the previous sentence?

A. If an individual patient had an acute reaction or a severe reaction to our product, if it was a haemophilia product and the haemophilia director judged that his or her patient needed an alternative product, then I'm not sure that the PFC or the SNBTS would have had any involvement in that. If that's

what the haemophilia director in Scotland decided was the case, they would have purchased it and I think periodically that did happen.

Q. But leaving aside what you describe as an exceptional category of cases, you understood self-sufficiency for Scotland as meaning the production of sufficient factor concentrates to provide for treatment at a level to be determined by the Haemophilia Centre Directors for all haemophilia patients in Scotland?

A. Yes, I think that is correct. There were some very, very rare coagulation deficient patients, Factor XIII deficient or maybe even Factor V, and I don't think PFC ever had an aspiration to make every product for every patient. So we had -- as we have talked earlier about the productive relationship we had with BPL, I think from PFL, Dr Smith had available products Factor XIII products, Factor X perhaps, and if we needed those products or if haemophilia directors needed those products they could readily obtain them from BPL.

Q. So this would encompass producing and therefore providing enough factor concentrates at least in terms of Factor VIII and Factor IX for home treatment needs for patients?

A. For all the estimated needs and I think part of the

SNBTS self-sufficiency planning or work up to it was work that was carried out by Professor Cash and other senior haematologists in Scotland in the '70s and '80s and they sat down and they identified in some considerable detail how much Factor VIII would be needed for the haemophilia population of Scotland.

And the figure that sticks in my mind, I think it started out lower than this but the figure they arrived at was 2.75 million units per million population. I think if one reads the minutes of the annual meeting of haemophilia directors and transfusion directors, you will see that every year that figure, that aspirational figure or that target figure was underlined and agreed to by haemophilia directors by SHHD and others attending the meetings. So it wasn't just a blind aspiration to be self sufficient. There was actually -- there were numbers placed on this.

MS RICHARDS: Sir, I have got a number of other questions relating to self-sufficiency but perhaps we can pick those up after the lunch break.

SIR BRIAN LANGSTAFF: Yes, let's do that.

May we come back at 2.00 pm. 2.00 pm, please.

(1.01 pm)

(The short adjournment)

(2.00 pm)

MS RICHARDS: Dr Perry, I'm going to ask you to look, still on the topic of self-sufficiency, at a short passage from one of your Penrose statements. PRSE0003755.

If we go to the very bottom of the page we can see it says:

"At this time [so this is the last two lines] self-sufficiency was an accepted goal for Scotland which dominated its planning throughout the 1980s. 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. Therefore 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."

Now if we just leave that on screen -- please, Sully -- you also elsewhere, in your Penrose oral evidence I think, referred to the principle of clinical freedom as being quite a sacred principle at the time. The reference for that, we don't need to go to it, is PRSE0006025, pages 1 to 2.

When you say here it was "accepted that doctors were free to exercise their own judgment ...

preserving the important principle of clinical freedom", accepted by whom?

A. I think it was accepted by the Scottish Home and Health Department and the medical staff inside that, it was accepted by SNBTS colleagues, certainly medical colleagues who understood the importance of this principle, and I think they certainly internalised that as an important principle. I think in the case of Professor Cash, I think his view was always that we needed -- he had no authority to impose SNBTS products on doctors and so on, so his approach was always one of persuasion, perhaps slightly bordering on coercion occasionally but that was in the spirit of not exposing patients to commercial products when SNBTS products were available.

So, yes, it was a -- I think, from my perspective -- I didn't deal with patients directly, for reasons that are perhaps self-evident, but he certainly took the view that he would try to do everything he could to enable prescribing doctors to avoid the use of commercial products. And to do that, the products that SNBTS provided had to be of a quality and specification that would be considered the product of choice by SNBTS doctors, including the fact that they were derived from voluntary

non-remunerated donors, which at this time was still an important safety parameter.

Q. Do you know what, if any, particular steps were taken, whether by Dr Cash or by SNBTS or specifically by the PFC, to try to persuade, influence clinicians to use SNBTS products rather than commercial products?

A. I think there was a regular process, at least once a year, where the prescribing doctors, the Haemophilia Directors and the SNBTS directors, including the PFC directors and SHHD officials, which was the annual meeting of directors, I think Professor Cash and myself always sought to influence or just illuminate the availability of SNBTS products and -- just to make sure that they absolutely understood what was available from SNBTS and that, in the absence of any good clinical reason, took the view that these products should be preferred over commercial products.

But it wasn't a position that was forced on Haemophilia Directors. They would have taken part in those discussions, there might have been discussions about their need for commercial purchase, but that was the regular forum in which I think the whole idea and concept of self-sufficiency was born.

But collectively, I think, and going back even to the 1970s, haemophilia doctors and SNBTS directors

and the SHHD had collectively signed up to the concept of self-sufficiency, I think even as early as the 1970s. They understood the benefits of that in terms of product safety and I think largely were supportive of the actions and the efforts that SNBTS was making.

Q. Did you ever get reported back to you -- I'm really thinking of the first half of the 1980s, any particular concerns being expressed by haemophilia clinicians about the nature or quality of PFC products, any reasons why they were using commercial products in place of SNBTS products?

A. Yes, there was. We occasionally got reports. I think there were issues certainly in the early '80s about product solubility and convenience. I think it was a larger dose volume than commercial products. And I think there may have even been a preference expressed by some patients that this was a more convenient product: it dissolved more quickly, there was a lower infusion volume and they could do their home therapy much more conveniently with commercial products. But set against that was the -- it was more than a perceived risk, it was a known risk, as far as the SNBTS was concerned, that these products were less safe than SNBTS products.

Q. We can take that down now, thank you, Sully.

Do you recall it being drawn to your attention or coming to your attention that at Yorkhill Hospital there was significant use of commercial concentrates?

A. Yes, I did know that. I don't know when I knew it or where the information came from but I was aware that there was a significant use of commercial factor concentrates in Yorkhill. I don't know the reasons for that, and certainly that changed quite abruptly when, I think it was, Dr Gibson became the paediatric haemophilia director for Yorkhill and the paediatric service in general for haemophilia.

Q. Do you know, and I appreciate you probably can't speak to the time before you joined PFC, but do you know whether there was any contact made by the PFC or, more broadly, by SNBTS or Dr Cash with Dr Willoughby at Yorkhill to explore why there was this very significant use for children of commercial concentrates?

A. I don't know, is the honest answer. I think one of the problems SNBTS had, certainly during the 1980s and perhaps through the 1980s, we didn't have a clear understanding of the pattern of usage throughout Scotland. We knew what was being used of SNBTS products but we didn't have any regular data from either individual hospitals or Haemophilia Centres on

their use of non-SNBTS products.

Q. Would you have expected someone to be gathering that data, not necessarily PFC, because PFC essentially is a producer of its own products --

A. Sure yes.

Q. -- but someone, again SNBTS or SHHD, to be -- in order to achieve self-sufficiency, to overcome the obstacle created by the sacred principle of clinical freedom, to find out what commercial concentrates were being used and why, so that there could be a systematic approach to reducing that usage?

A. I think Professor Cash made efforts to understand the pattern of usage in Scotland and to understand the reasons why non-SNBTS products were being used in certain circumstances. I'm not sure that SHHD took any specific action. I suppose, in a sense, from my perspective, they could have done, and indeed the annual meeting of SNBTS directors and haemophilia directors could have collectively agreed to undertake that analysis. And I think these data did slowly begin to emerge and maybe the overriding organisation, the umbrella organisation, the UKHCDO organisation was in a position and, I believe, did collect certain data on the use of NHS products and commercial products but it didn't break it down into individual hospitals or

individual prescribing doctors.
Q. Yes. It might be said in relation to the latter organisation, you are right, they might be well placed to know what was being used, but they are the very clinicians who might be jealously guarding the principle of clinical freedom?
A. Yes, but they wouldn't necessarily jealously guard the information. I think they were collectively signed up to openness and transparency, and I have no reason to believe that individual Haemophilia Directors withheld or certainly falsified information for that reason. I have no reason to believe that was the case. So there were efforts.

It took some time to better understand the use of commercial -- the reason for commercial products, but it all -- the use of commercial product, other than in very few and perhaps rare circumstances -- I was never aware of what particular circumstances it would be appropriate to use a commercial product, but by 1983/84 the use of commercial product had all but disappeared, I think as a result of the collective efforts of both haemophilia doctors and SNBTS staff to address that particular issue.
Q. Did Scotland achieve self-sufficiency, in your view, in the 1980s, and if so, approximately when do you say

that was achieved?
A. I think it was probably achieved in 1983, early 1984. And I think it was -- it depends how you define self-sufficiency, of course, and I think that was sustained until perhaps 1987/1988, when I think the organisation faced the sort of collective headwinds of increased demand, loss of yield, as a result of introduction of heat treatment and virus inactivation procedures, and I think in 1988 there was a requirement for some commercial purchase. That was a big disappointment.
Q. To what do you attribute Scotland achieving self-sufficiency by late '83, early '84?
A. I think I alluded this morning to the fact that it set out fairly early on, on the road to eliminating the use of whole blood transfusions, and therefore being able to collect the plasma which could be used for fractionation. And that process began in the 1970s and certainly progressed in the 1980s, and by 1983/84 I think whole blood was very seldom used in transfusion in Scotland, which inevitably meant that there was more plasma available for fractionation, which could increase the output from PFC.

The other factor was the work undertaken by Dr Foster to improve process yields at PFC, with the

introduction of his fairly unique technology for the continuous thawing of plasma. And that yielded very substantial increases in product yield at that time.
Q. Did the pro rata system as operated in Scotland have any particular role to play?
A. I think it was originally designed -- if my understanding is correct, the pro rata system was based on the pro rata supply of products in proportion to the amount of plasma that a particular region supplied. There might have been a population bias in that as well but I think it was primarily introduced to incentivise regions to increase their plasma output, because that meant that the regions in which they operated and their respective health authorities would have had reduced costs associated with commercial purchase. So it was -- I think it was done to incentivise plasma collection and to provide some basis for an equitable supply of product.
Q. Now, in terms of the PFC's ability to fractionate plasma collected other than in Scotland or Northern Ireland, so plasma from England and Wales, what's your understanding of why that did not happen?
A. In England and Wales?
Q. So why the PFC was not used to fractionate plasma collected in England and Wales.

A. In all honesty, I do not think I know the answer to that question. We certainly took the view that we could and perhaps should have done. I'm not familiar with the timeline in England and Wales in terms of the availability of plasma or the capacity of BPL or their building programmes. It may well have been that the plasma simply wasn't available. It could have been a plasma shortage, in which case the fact that PFC had capacity to process more wouldn't have actually improved matters in England.

But I think, from my perspective, certainly when I took over as director, it was always my view that had we been approached to process plasma then we would have done our utmost to adjust our activities and our processes and procedures to accommodate that.
Q. Had you had any involvement or any direct knowledge of the shift working trial in late 1981?
A. Yes, I was in post then and I was involved in it, from a quality perspective, because at that stage I was responsible for all issues associated with quality, so I had an overview from a quality perspective on the process. So, yes, it was undertaken, as I recall, from basically outdated plasma. It wasn't fresh plasma. And I think its primary purpose was to establish the capacity of its -- of the PFC's central

processing system, that's the CSVM, to operate continuously and to demonstrably be able to process more plasma than it could.

And I think it achieved that objective. I think it proved over the two or three-week experiment that was undertaken that it could do that.

But, it didn't encompass all the downstream processing associated with albumin or immunoglobulin and certainly not coagulation factors, because they weren't prepared from that plasma.

So it was a partial success in that sense. I don't think it proved the ability of the PFC to instantly process all the plasma to finished product but it demonstrated that its core technology was capable of doing more than it did. Certainly with shift working.

Q. Did you have any involvement or direct knowledge of any of the discussions relating to shift working or funding that might need to be made available to enable PFC to fractionate English or Welsh plasma?

A. Not in the early '80s, but when I took over as director that was still an ongoing -- yes, I will call it a fight. It was an ongoing fight to get recognition and understanding that the PFC was fairly unique in -- not special -- the health service and it

needed alternative arrangements for paying its staff in ways which we could put in place a shift working process. So it -- and that was necessary not only for coagulation factors but for the -- all the other products as well, that we were constrained by the 8-hour day.

Q. And was that a fight with the SHHD or the CSA? Who was the impediment to progress in that respect?

A. I think it was the Whitley Council. But to answer your question more directly, I think it was an inability between the CSA and the Scottish Home and Health Department to recognise this requirement and make what was seen as a fairly substantial variation order to the Whitley Council. Because that's how these things were done. If you wanted to employ somebody -- and we had to do this routinely -- if you wanted to employ somebody that didn't meet the criteria for a medical laboratory scientific officer, then you had to apply for a variation order. And they sometimes took some time. So, in a sense, it was a failure of CSA and SHHD to collectively, in my view, provide a solution to that.

That changed in the early 1990s. I think it was one of the initial projects that Mr McIntosh engaged on, and we did succeed, eventually, in getting

a bespoke collection of systems for remunerating staff and paying shift premiums and so on. But it took ten years.

Q. It might be said that the failure to use PFC's fractionating capacity more fully, so as to fractionate plasma from England and Wales, was a lost opportunity for the UK as a whole. Would you agree with that?

A. I think from my perspective, yes, it was. Yes. I think others might disagree and might say the correct solution was the solution we had then, which was to rebuild BPL for the whole of England and Wales. But I think a joint approach to providing the capacity for fractionating products for the UK would have been more quickly met and more efficiently met by a joint approach.

And I think it would have been more secure as well. As it was, BPL were processing at least 90% of the plasma for the UK and the PFC was only producing 10%. Now, in any sensible organisation you wouldn't have that imbalance. You would say: in order to secure the long-term security of supply, or at least a minimum level, something closer to a 50/50 split would be appropriate.

Q. In relation to Northern Ireland, your arrival in 1981,

essentially coincided with the introduction of the arrangement with Northern Ireland for the fractionation of plasma collected in Northern Ireland. Do you know why it wasn't something that was undertaken earlier? Do you have any knowledge of that?

A. No. My understanding is that Northern Ireland had some of their plasma processed but it was mostly outdated plasma by BPL, and they presumably got some -- and I'm not sure what the transfer arrangement, whether it was a cross-charging arrangement or a contract fractionation arrangement. But I don't know. I think it came as a result of the culmination of discussions about UK capacity and the final decision that BPL would be redesigned and rebuilt to process for England and Wales, and Scotland would manage the interests and the needs of Scotland and Northern Ireland.

Q. I think you were involved in the quality audit that was undertaken in advance of the plasma actually beginning to be shipped and fractionated at the PFC?

A. Yes.

Q. In broad terms, what did that entail?

A. I think it was an arrangement where both myself and, I recall, Dr Cuthbertson were -- basically went to

Northern Ireland centre, I can't remember how long we spent there, but we did a basic audit of their facilities for the collection, the separation of plasma, their environmental conditions and so on. But, importantly, their testing arrangements, their arrangements for virological testing of the plasma. And I think as has been recorded, there was a problem with that initially with the sensitivity of their hepatitis B assay. So plasma didn't come to PFC until that matter was resolved. But thereafter I think there was subsequently subsequent audits of the Northern Ireland centre by PFC as well as the Scottish centres.

Q. If we could look at your witness statement to the Inquiry.

WITN6920001, please. If we go to page 55, please, Sully, bottom of the page.

Just picking it up at the very bottom of the page, you refer to information about product usage being submitted to the Penrose Inquiry. You then say this:

"These details do not include products used in Northern Ireland, for which no information was sought or presented. To the best of my knowledge there was no information held by SNBTS on the breakdown of

product use in Northern Ireland, except for the understanding and knowledge from conversations with Dr Morris McClelland (Northern Ireland BTS) that supplies of PFC products were insufficient for all patient needs and accordingly were supplemented with commercial product purchase."

Do you know why it was the case that the amount of PFC product going to Northern Ireland was insufficient and thus there was still a lot of commercial concentrate being used in Northern Ireland?

A. Yes, it is quite simple: they didn't provide enough plasma for us to be able to reward them with an increased level of product. The product they got from PFC was in direct proportion to the amount of plasma that they supplied.

Q. It was a feature of the pro rata system?

A. It was -- and that remained in place for Northern Ireland because they were separately funded, they came under a different jurisdiction, and so it was always -- it was always the case, even after I dismantled the pro rata system, that Northern Ireland would only get back products as a proportion of the amount of -- in relation, in direct relation to the amount of plasma that was supplied.

Q. Do you know, and it may be that this is not something

you'd have expected to have knowledge of, do you know if issues like that were raised on behalf of Northern Ireland with SNBTS or SHHD or the CSA to see whether there was a way in which Northern Ireland could receive a greater quantity of PFC product?

A. I don't think there was. I think there was -- certainly Dr Morris McClelland, who regularly attended our meetings, understood the arrangements that were in place and, in a sense, he knew what needed to be done if he wanted to increase the supplies of NHS products for haemophilia patients in Northern Ireland.

I guess, in 1984, when we did decant what we considered to be excessive Factor VIII to England and Wales, it would have been possible, maybe we did this, to have supplied additional quantities to Northern Ireland as well.

Q. Can I then ask you next in broad terms about pool sizes.

We can take that down, thank you, Sully.

I don't think I need trouble you with looking at what the data is in relation to each individual year. It is captured in a number of documents, it is captured in documents from the Penrose Inquiry and you will know this Inquiry has attempted to capture it in its own presentation reports.

Broadly speaking, it is right, isn't it, that there was an upward trajectory in terms of increase in pool sizes?

A. There was, yes.

Q. I think the figure Dr Foster gave the Penrose Inquiry -- which was -- I think somewhere in your evidence also you endorsed -- was around 4,000 donations?

A. That was -- certainly during the later 1980s, I think it went up to about 900 to 1,000 litres or kilograms of plasma, which would have equated to 4,000 donations roughly.

Q. How were decisions taken at PFC and by whom were they taken to increase pool sizes?

A. I think it would primarily taken as a result of discussions between manufacturing managers, the PFC director and probably would involve Dr Foster as well if there were issues associated with scaling up and so on. He would have been an important -- have an important input into those decisions.

But I think also, in our regular, both formal and informal, briefings with Professor Cash, he would have been aware of the kind of pool sizes that were being used.

But the requirement to increase pool sizes, as

I think I mentioned in my witness statement, was driven by the need to increase capacity. And you could either do that by increasing the number of batches that you made, which wasn't immediately accessible to us. You need more freeze dryers, a different configuration of manufacturing facilities, or you simply increased the batch size. And I think we felt that the increase in batch size -- it wasn't taken unilaterally, it was taken after discussion -- was justified because, even with our increased batch size, up to 4,000 donations, that was still substantially less certainly than commercial producers were using and certainly substantially less than the pool sizes used by BPL.

But then BPL were dealing with more plasma. So that's not a criticism of BPL. It is simply a reality associated with the scale of manufacture.

Q. I think the way you put it at one point on your witness statement is not increasing pool sizes would have exposed patients to greater risks. Am I right in understanding that's on the assumption that the alternative then for those patients is the use of commercial concentrates?

A. If we hadn't increased pool size to increase our manufacturing capacity, then we wouldn't have kept

pace with demand, and the only alternative then would have been for Haemophilia Directors to buy commercial product, which would have been the worst of all outcomes.

But I have thought about this some more since the 1980s and reduced pool size. The pool size is an important parameter, there is no question of that, but it is mostly important when you only have a single use or occasional use of a product. For those patients who are on lifelong therapy using Factor VIII, simply keeping small pool sizes would mean that those same patients would be subject to the same amount of donors because the individual batches wouldn't last as long.

So you don't necessarily, in the long-term, get a reduced exposure to patients over a period of a year or a lifelong treatment for haemophilia. So it would only be a transient benefit, certainly so far as non-A, non-B hepatitis was concerned. And I think that was our thinking as well. Although pool size was important, smaller batches certainly constrained capacity but didn't necessarily -- in terms of chronic exposure to factor concentrates -- necessarily reduce the overall donor exposure over a significant period of time.

Q. One question I have been asked to ask you in relation to Factor IX production is whether smaller pools could have been used to prepare Factor IX due to the fact that far less was required by way of Factor IX concentrates?

A. Yes, but I think the same principles apply to Factor IX as they do to Factor VIII. Although it was a lower output product, it did consume manufacturing capacity of PFC. So had we increased or decreased the pool size for Factor IX, or kept it at a very low level, that would have consumed our freeze-drying capacity and our downstream processing capacity, which would have limited our ability to make Factor VIII. So both Factor VIII and Factor IX, which drew upon freeze-drying resources, were interlinked as well.

Q. Is it right to understand, if one is looking at a much bigger picture, what you are talking about is the decisions that were made constrained by PFC, as it was, with the capacity, the size, the number of freeze dryers, the storage facilities, the production lines, the staff it had --

A. Yes.

Q. -- rather than it not being possible to devise a system whereby smaller pools could be used?

A. I think had you -- had the plasma supply continued to

increase in the way that we wanted it to increase, and indeed it did increase, and we hadn't increased the pool size, then we would have had to have completely reconfigured the manufacturing activities at PFC. It would have become effectively not a large scale but a small scale manufacturing unit with multiple process streams going on simultaneously and it is highly expensive, it is highly inefficient.

Also, the smaller the pool size, there is a thing called a "line loss" during the manufacturing process. As you go from one step to another, you also lose some material because it's residues in tanks and so on. And QC sampling, the size of product loss through QC sampling, for example, can start to become very, very substantial. The smaller the pool size becomes, you could be losing 10 or 20 per cent of your batch, just through QC sampling, because the number of samples that you need to take for QC testing is fixed. And these become -- when you put them all together, they become very substantial losses in output.

Q. Can I just ask you to look at one letter, it is from Dr Cash to you, just to see if you can help us understand what he was referring to. It is PRSE0003102. It is a letter of 7th December 1984 to you. I just wanted to -- it is headed "batch

dedication", and I will come later to the question of batch dedication, but I just wondered if you could help us with the second paragraph:

"Any moves directed towards restricting donor pool size (designated plasma pool for each donor) must be discussed by all directors before implementation. It is an exciting option but I suspect will have colossal cost and operational implications. There's much to be done before we need to consider this option."

Do you know what Dr Cash was referring to there?

A. Yes, I do. I didn't remember this letter until it was provided to me by the Inquiry and it was a response to a suggestion by Dr Crawford for a system of restricting or creating individual donor pools, and I have to say that I never really understood at the time what he was actually proposing. But it did seem to me, and it certainly seemed to Professor Cash at the time, that it might have been horrendously expensive and operationally extremely complex. So he was simply saying, "We have arrangements in place to control donor pool size". What was the date of this?

Q. December '84.

A. December '84. By then we had agreed to introduce a system of batch dedication to control patient

exposure to donors and this, however exciting, was extremely complicated and should not -- and Professor Cash's view, and I think probably mine as well, was that it was not really a viable option.

Q. Is it right to understand it received no further consideration?

A. Oh absolutely none, no. Well, that's not fair. There was no further discussion on this as an option.

Q. Freeze dried cryoprecipitate; we know from documentation that the Inquiry has already looked at and indeed evidence, oral evidence that the Inquiry has heard, a little of what happened in relation to the freeze dried cryoprecipitate production at the Law Hospital?

A. Yes.

Q. I think you have seen in the materials provided to you documents that suggest it is something that Mr Watt certainly was not keen on, describing it as a step back in history and a "suitable product perhaps for Turkey but not Scotland" I think were his words?

A. Yes, they were.

Q. And I think you'll also have seen some exchanges between Mr Watt and Dr Cash on it. As I understand the chronology, it was essentially abandoned in January 1983. Did you have any involvement in the

decision-making relating to the use of freeze dried cryo seen here?

A. I don't recall having any detailed discussions about it. I think it is by 1982 I would have been aware of this but perhaps primarily from a historical perspective. I think by the time I arrived at PFC, I think, as far as I was concerned, the discussion and debate about this was all but over. There was still the option, and it hadn't been formally abandoned as an option, but for all the reasons that have been provided, freeze dried cryoprecipitate was, I think, formally put to bed, as it were, in early 1983.

In addition, I think my view at the time was that such an activity would have required a complete redesign of the manufacturing facilities. It was a completely different process. It was small-pool, multiple small-pool manufacture. We didn't have the environments in which to do that, the sterile handling environments and so on, and at that time I was in the middle of a process of redesigning facility for large-scale manufacture. So my view would have been this can't be done.

Q. At the PFC?

A. At the PFC from a quality perspective.

Q. But you didn't have any involvement in the question of

whether it could or should be done elsewhere?

A. No. No.

Q. Can I then come to it the stockpile or surplus that was built up. I want to look at a handful of contemporaneous documents with you in a moment.

But what was -- how was it that by the end of 1983 and into 1984 that PFC had built up this significant quantity of product?

A. I think it was a consequence of increased throughput, plus, and probably more importantly, the rewards from the work that Dr Foster did in terms of increasing process yield for Factor VIII at that time.

And I can remember discovering that we had this large quantity of Factor VIII and doing some simple calculations and concluding that unless we took some action, then this product would outdate, and I communicated that to Mr Watt, and Mr Watt subsequently communicated it to Professor Cash. Is my understanding of the events.

Q. What I wanted to do is look at a couple of those communications from '83 and then look at a couple of communications in '84 with BPL and then explore it a little more generally with you.

So if we start by looking at PRSE0001576.

This is a memo from you to Mr Watt and others,

18 November 1983. It says:

"A recent survey ... of the stock levels of FVIII concentrate both at RTCs and within the PFC 'sausage machine' indicates the development of some important and interesting trends which I feel should be examined as a matter of urgency by the SNBTS so that appropriate action (if any) can be taken".

Then you refer to the stock levels here. I don't, I think, need to read out that second paragraph.

Then looking at the third paragraph you say:

"Looking back at the SNBTS annual statistical sticks for 1982/83 the SNBTS issued [approximately] 25,000 vials of Factor VIII. Assuming this rate of usage is maintained present stocks represent 1.4 years supply. If this stockpile continues to grow at the present rate (ie 10,000 vials/year) then we will soon be in a position of manufacturing Factor VIII which will inevitably outdate."

Then you conclude:

"However, I have a feeling that we may already be in a position where other existing material or future batches will outdate."

Then you suggest trying to "gain a more accurate picture of where we are holding". We can see there

you and Mr Grant have done some form of stock exercise?

A. Yes. I can't remember whether it was initiated by Mr Grant or maybe just in terms of my routine sort of surveillance of the centre, I noticed we had very, very large quantities of Factor VIII and perhaps asked Mr Grant, who was the manufacturing manager, to do a stock take and find out some details of what product existed, what its expiry dates were and so on.

And I remember being quite shocked at the outcome that we had accumulated that amount of material whilst still operating a pro rata distribution system. But we may come on to that.

Q. Your concern was that you were going to have more than you needed to issue and you were essentially going to be left with outdated concentrate that couldn't be used?

A. It's not so much --

Q. It would be wasted or --

A. Well, yes, in a sense, but the concern that I and certainly Professor Cash had, and others, was that this was valuable material, the UK was short of Factor VIII, certainly NHS Factor VIII, and it would have been a shocking waste of material if this was not usefully used for haemophilia care in the UK. So it

was the waste of product in terms of haemophilia care that was shocking and, in a sense, having a surplus product in itself is not a problem, you can destroy it, but that would have been a criminal act I think.

Q. Then if we go to PRSE0001537.

This is Dr Cash to Mr Watt, 29 November 1983, copied to you or referred to you as well, as we see from the stamp. If we just look at the first paragraph to start with:

"Recent correspondence with colleagues at PFC and odd comments gleaned from others has indicated that we may be genuinely moving near to a national (SHS) surplus of factor VIII."

SHS, is that Scottish health service?

A. Scottish health service, yes.

Q. "It would be imprudent to make any rash moves at the moment -- we will take the opportunity of examining the position together in the near future.

"There are two points I would wish to make at this time."

Then the first:

"Outdating

"It would be a very serious matter if product outdated when patients South of the border continue to be exposed to commercial material."

So that is the point I think you were just making?

A. Yes.

Q. "I have a gut reaction (but we need this corroborated by PFC) that supplies may be sufficient for us to pull out RTC deposited product that has 6 months shelf life left and offer it to the NBTS."

Then he asks Mr Watt to provide him with certain information.

Then we go over the page, just so we don't need to come back to this document, we can see there the second point is:

"Batch issue to individual patients

"I have long dreamt that this might eventually be introduced (even gradually) -- to reduce the number of donor exposures. I would be most grateful for your thoughts on how this would be introduced in your region."

Then the PS:

"An answer to (a) is more urge lit required than (b)."

So we will come back to the issue of batch issue or batch dedication --

A. This letter was, I think, almost certainly sent to regional directors as well, because he is asking them

for data on the amount of product that they had in their centres.

Q. So that is end of November 1983, the existence of this surplus or stockpile appears to have been clearly identified, a little work being done to ascertain exactly what was held and to consider options and to deal with it:

A. Yes.

Q. We then move, I think -- in terms of the documents I'm going to ask you to look at, and then I'm going to see if you can help fill the gap -- to June 1984.

CBLA0001850.

Now, of course, that was -- the document we just looked at was 29 November 1983. Mr Watt left soon after in December 1983. You took over in the beginning of '84 as acting director, and this is sent by you in your capacity as acting director to Mr Pettet at BPL, 8 June. If we go to the text of the letter:

"I understand that agreement has been reached between Dr Cash and Dr Lane that excess stocks of PFC Factor VIII are to be decanted to CBLA for subsequent distribution to Regional Transfusion Centres in England and Wales. Dr Lane has also indicated that you are the most appropriate person to liaise with

PFC ..."

Next paragraph:

"You will appreciate that a regular supply commitment cannot be made but our best estimate is that the a total of 7-9 x 10 [to the power of] 6 IU [I think that says] could be decanted to England and Wales within the current financial year."

SIR BRIAN LANGSTAFF: It is 7 to 9 million, isn't it?

A. It is 7 to 9 million units, yes.

MS RICHARDS: "I am now most anxious to establish the necessary arrangements for product supply.

"We will supply the product in our standard package ... and I would suggest that a quarterly collection would be the most practicable arrangement.

"Perhaps you could let me know when you will be in a position to receive and distribute this material and no doubt you will contact me if you require any further information from this end. Our interest in the material once it has been sent to CBLA will be restricted to arrangements for product recall in the event of a product defect/adverse reaction. In such an event, I believe it would be most sensible if you acted on our behalf."

So that's you writing to BPL, 8 June '84. Then if we go to CBLA0001882. This is a further letter

from you, 7 September 1984, to Mr Pettet. It says:

"Following our telephone conversation I can now confirm that 2,123,500 a IU of ..."

A. The "a" is a typographical error.

Q. "... of Factor VIII Concentrate will be delivered to your centre on Friday, 14 September."

You explain it is equivalent to 8,320 vials.

Then the next paragraph:

"It is difficult at this stage to assess how much will be available in the next quarter (December '84) ..."

Then you give an estimate of what the surplus may be but say that:

"... you shouldn't plan on this being available!"

Now, having looked at that correspondence, can you help us understand, first of all, why, on the basis of this correspondence, it looks like it took until the middle of 1984 for the arrangement to be made to supply surplus to BPL?

A. Yes.

Q. Do you know why that couldn't have taken place more quickly?

A. No, I think there was one parallel activity that was going on at the time, at the beginning of 1984, when

I took over as acting director from Mr Watt, and that was the dismantling of the pro rata system and putting in its place a supply arrangement based on clinical need, on a truly national distribution system, irrespective of the amount of plasma that was coming on. And that decision was proposed and agreed by directors on the basis of the stocks that had been built up.

So I think -- I'm trying to reconstruct what might have happened and -- which will have caused this -- I wouldn't call it a delay -- why we didn't actually formalise the arrangement until June, and that was we were waiting to see what impact that arrangement would have on stock levels and so on. Or maybe it was no more complex than wanting to reconfigure our supply arrangement in Scotland and then move on to this as a separate topic.

I don't think we perceived it as an urgent activity.

Q. And then --

SIR BRIAN LANGSTAFF: Just on that last point, the letter from John Cash of 29 November 1983, where he spoke about the need to reduce it and asked for an answer to two points, point (a) and point (b). He said, in effect, point (b) can wait but point (a) can't and

point (a) was this. So if it wasn't urgency, it must have been the next best thing.

A. I think Professor Cash was making the point it was urgent from a SNBTS perspective to establish exactly what the stock level was at the Regional Transfusion Centres as well as the PFC. I do not think he was implying that there was an urgent requirement to decant the product, other than its imminent outdating. So he was simply saying we need to fix this problem first because we cannot be seen to be allowing Factor VIII to outdate on our shelves. That would be a shocking dereliction of duty, I think his view was and I think I shared that view.

MS RICHARDS: Do you know what else was done with the surplus? Was this supply to BPL essentially the answer to the issue identified by you, by Dr Cash?

A. Well, it was envisaged at that stage to be an initial step. I think I made -- I was quite surprised when I reviewed this correspondence to see that I had estimated 7 to 9 million units. That would have clearly been over a long period of time and I think, with hindsight, it probably didn't take account properly of losses on heat treatment which were coming in and increased demand and so on. So it was probably a slightly exaggerated, or at least over-optimistic,

view of how much could be supplied to England and Wales.

SIR BRIAN LANGSTAFF: Just on that point, in this letter that's currently on the screen, the quarter in which 14 September falls, 2 million. The quarter in which December falls, 2 million. That's a rate of 8 million a year.

A. Yes, I don't think the intention was to do it on a continuous basis at 8 million a year. I think the surplus that had been built up had been built up over a number of -- well, not a large number of years but maybe '83 and '84 we had built this stockpile and I think it was simply -- I think in some ways it was demonstrating proof of principle, that it was possible and appropriate to transfer products from one part of the NHS in Scotland to another part of the NHS in England and Wales. I don't think it was ever envisaged as an on-going arrangement. It was a mutually agreed and satisfactory and, I think, appropriate thing to do in the circumstances, because product -- I think this was quite unprecedented. I know that sounds quite surprising in today's world. But it was unprecedented at the time that product from Scotland should be transferred to England or vice versa. They were administratively quite separate

units and where there was, as we've said before, high degrees of co-operation, there was never large-scale transfer of product.

MS RICHARDS: Was consideration given by you or by Dr Cash or anyone else, to your knowledge, to providing some of the stockpile to Northern Ireland given the relationship that already existed with Northern Ireland and the difficulties that Northern Ireland faced in terms of the effect of the pro rata system?

A. I don't know that I've got a clear memory or recollection of that. I don't recall there being discussions but I think, as I mentioned before lunch, that would have been an appropriate thing to do.

Q. Then this letter envisaged that there may be a further supply in December 1984.

A. Yes.

Q. Did that ever happen or did that get overtaken by events --

A. That was overtaken by events.

Q. Is it right to understand -- and obviously we will come on to this -- the surplus that was held by PFC was then effectively heat treated --

A. Yes.

Q. -- to enable supply of the heat-treated product to patients in Scotland?

A. Correct, yes.

Q. Can we just look before we leave this topic at a discussion in your oral evidence to the Penrose Inquiry.

Sully, it should be PRSE0006025, please.

If we go to -- sorry, page 28 I think it might be. This is in the course of a series of questions and answers about the surplus and what was done with it, but I just wanted to ask you about the exchange here. So you refer towards the top of the page of importance of finding out -- this is lines 4 to 5 -- what the Regional Transfusion Centre stock was, which is what I think you referred to a few minutes ago. Then there is a reference to the Glasgow figure.

If we just go further down the page -- I'm sorry, there is a passage that I'm -- yes, sorry, top of page 30. My apologies. Yes, you pick up in your answer in relation to the Glasgow figure and you talk about -- this is lines 4 to 5:

"Certainly the stock level in Glasgow was much higher than I thought it would have been."

Can you recall anything about that now, the particular detail in relation to the level of stock held in presumably the Glasgow Regional Transfusion Centre?

A. We're really talking about 1984 -- mid-84 now, aren't we --
Q. Yes.
A. -- or certainly late '83 when you were carrying out this exercise.
Q. Yes.
A. Yes, I think all of these observations and narratives actually contributed to my -- one of the first things I did when I became acting director which was to dismantle the pro rata system and build in a system which was based on supplying Regional Transfusion Centres with product based on their stock levels and their estimated clinical need and, built into that system from early 1984, was a requirement for Regional Transfusion Centres to feed back on a monthly basis what their stock levels were and then PFC could, as the central unit responsible for supplying products, would have a much better overview of the overall stock position in what I described earlier as a sausage machine.
Q. You can take that down, thank you, Sully.

I want to move next then to the topic of hepatitis and specifically your knowledge of hepatitis and what was understood about hepatitis at the PFC. At the time you took up your role in 1981, what, if

any, knowledge did you have of hepatitis?
A. Of hepatitis? Very little indeed. I think in my witness statement I described I spent a very informative and interesting year working as a biochemist in the Royal Postgraduate Medical School in Hammersmith in the chemical pathology unit, and I guess that's where I first came across hepatitis because samples were supplied for analysis in yellow tubes and, when I asked what the yellow tubes meant, they said that's coming from a patient that is suspected of having hepatitis, and we were told to be very careful with it. That was probably the extent of the intervention that occurred.

But beyond that, and from discussions with colleagues and doctors that worked in the unit in Hammersmith, I had some understanding of what sort of patients that material would come from. But beyond that, I had no knowledge of its pathology and its clinical sequelae to becoming infected with hepatitis. So it was very rudimentary understanding.
Q. Then you've said in your witness statement to this Inquiry that you became aware of the association between hepatitis viruses and blood and blood products within weeks of joining SNBTS. You describe it as a knowledge that was superficial initially but

deepening with time through discussion with PFC colleagues and wider SNBTS colleagues.

So, going back to, I think, a question I asked you earlier, would it be right to understand that there was no formal training that you received about risks of viruses or hepatitis in particular?
A. No. I had no formal training. I think, without wishing to be too immodest, I think I learnt very quickly from the regular and detailed discussions and correspondence and meeting with doctors and visiting Regional Transfusion Centres and so on, but it was not a formal structured programme to educate me in issues associated with hepatitis.
Q. Do you recall learning relatively quickly or otherwise about non-A, non-B hepatitis?
A. Yes, it was the first time I'd heard of such a thing when I joined the SNBTS but, as I say, again, within weeks I was educated in what this actually meant at a very superficial level. You know, there is hepatitis B which I was familiar with -- well, I was aware of but I had never heard of non-A, non-B hepatitis before I joined the Blood Service in Scotland.

But, as I say from discussions with colleagues and basically the work of PFC and from Mr Watt as

well, I think my learning curve was quite steep in respect of non-A, non-B hepatitis.
Q. And in terms of the nature of non-A, non-B hepatitis, do you recall what the prevailing view was in PFC that was being shared with you about the nature of it or the seriousness of it or its potential for long-term sequelae?
A. At the beginning of the 1980s?
Q. Yes.
A. I think it probably reflected the wider perspective on non-A, non-B hepatitis, which was it wasn't properly understood. I think, to be honest, the view that was conveyed to me or the view that I took away from discussions and conversations with colleagues was that it was a mild, self-limiting disease -- undesirable; you wouldn't want to catch it -- but it's not a major issue. That was at the beginning of the 1980s. Now, as we know, I think that particular view that I'd picked up developed quite quickly into a better recognition of what this disease caused and what its long-term sequelae was.

But I only -- I learnt these -- I got my perspective from discussing with colleagues in the SNBTS and attendance at -- and particularly when I became acting director and I attended regional

directors' meetings, RTC or SNBTS directors' meetings, the topic of non-A, non-B hepatitis was discussed frequently. So that was a useful and important learning experience as well.

Q. Can I just ask you to look at one paragraph in your statement on this issue and see if you can help illuminate it a little further. It's WITN6920001, please, Sully, page 31. Three zeros.

So paragraph 87 is you saying that you became aware of the association between hepatitis viruses, blood and blood products within weeks of joining SNBTS, and then you explain how that deepened through time with discussion, in particular, following appointment as acting director.

Then it is the next paragraph I wanted to ask you about. You say:

"Also, at this time, Professor Cash was increasingly expressing his view during informal discussions and conversations that manufacturers (including PFC) should begin to address the challenge of producing non-infective (with respect to hepatitis) products and that a prevailing view amongst haemophilia care providers and the fractionation industry that risks of infectivity were greatly outweighed by the benefits of increased treatment

would not be sustainable in the longer term."

Two matters arising out of that paragraph, Dr Perry. First of all, if we just have 87 and 88 on the screen, please, Sully.

Are you able to be more specific about what "at this time" refers to?

A. I think -- my earliest recollection of this type of conversation with Professor Cash was a lunchtime discussion. We often met at lunch because we went to lunch at the same time and we spent the lunchtime discussing non-A, non-B hepatitis. I think that would have been probably in maybe late 1981 or 1982. The view that was expressed to me by Professor Cash was that we really can't sustain a product supply which is transmitting non-A, non-B hepatitis to all its recipients. We just saw that as it might be nowadays seen as a blinding glimpse of the obvious, but at that time he was simply saying that this is not sustainable, even measured against the perceived benefit of clotting factor concentrates in haemophilia care. He found that, I think, genuinely, deeply uncomfortable and that's why he created the Factor VIII study group in 1982.

Q. Did you understand Professor Cash to be articulating that view because it reflected a deeper understanding

that non-A, non-B hepatitis was not this mild, self-limiting condition?

A. I don't think he necessarily -- I wouldn't necessarily infer that from his conversation. He was simply saying we know that there is something contaminating the blood supply and that is finding its way into coagulation factor concentrates. That, in itself, is a justifiable reason for taking action. I don't think he was either giving me or whether he concluded himself that non-A, non-B hepatitis was a much more serious condition than had once been thought. It was simply the fact that a pharmaceutical product that was injected into patients should not be infective for anything.

Q. Then just still sticking with the end of 1981, if we look at CBLA0001464. These are the minutes of a meeting of the UK Haemophilia Centre Directors, 9th October 1981. If we go to the third page, we can see you're in attendance. You are the sixth name down or thereabouts, Dr Perry.

A. Yes.

Q. So this would have been the first time, obviously, you attended a meeting of UKHCDO because it's the first year of your employment at PFC.

A. Yes, I think this was part of my unstructured training

programme, although I think it said I was attending on behalf of Mr Watt but ...

Q. If we just go to page 19, please, Sully. We can see there the heading "Reports from Working Party Chairman", and the first report is in relation to hepatitis:

"Dr Craske presented the report which he had pre-circulated to all Haemophilia Centre Directors."

Then there's a discussion recorded in the minutes. Do you know whether the reports of the working parties were circulated to other attendees who were not Haemophilia Centre Directors?

A. I do not think they were confidential documents. I think they enjoyed quite wide circulation is my understanding. Does it provide a clue to that on the heading?

Q. No, that's why I was asking. It says it was pre-circulated to Haemophilia Centre Directors. I'm just wondering whether you were, as it were, able to go home from the meeting with copies of Dr Craske's reports to share amongst colleagues in SNBTS or PFC?

A. Well, it might not have been in a written report. It might have been a verbal report that he delivered and -- but I have no memory that, in the introduction to these meetings, it was stated that they were

confidential or anything like that. And indeed, on the occasions that I did attend these meetings, I would often write a report and circulate it to colleagues. It was part of the collegiate discussions that the transfusion services had with haemophilia directors. I don't think they would have served any purpose if they had been confidential.

Q. No, I wasn't suggesting that they were confidential, Dr Perry. It is really just a question as to whether you can recall whether -- we know Dr Craske did produce written reports. I was simply --

A. He did indeed.

Q. -- wondering whether they were made available beyond Haemophilia Centre Directors?

A. Well, they would have been circulated -- if I had received such a report from Dr Craske at the meeting, then as soon as I got back to Edinburgh I would have circulated that to colleagues. It would have been photocopied and posted out.

Q. Then if we just move forward, perhaps before the break, to the second UKHCDO meeting you would have attended.

So PRSE0000185, please, Sully.

So this refers to the Haemophilia Directors' annual meeting, 13 to 14 September 1982. These are

not the minutes. This is a note taken by someone in attendance.

If we go to -- I think it's probably page 3. Is this your note, do you think?

A. I have seen this. And I have tried to work out myself whether -- in a sense it could be. It sounds like it might have been written by me, but it might have been written by somebody like Dr Chris Prowse, who was very familiar with coagulation factor products.

It seems to have a fair amount of high level scientific and clinical data in it for me, at that stage in my career, to have competently written this, but some of the phraseology does sound familiar to me.

Q. In any event, whether it was written by you, it would appear from the very top of the page, where it says "Notes (On Matters of Relevance to PFC)", it was written by someone associated with PFC for the purpose of sharing with the PFC, is that a fair inference?

A. Absolutely, yes, yes. Yes. This would have been circulated throughout the SNBTS I think.

Q. Then I just want to ask you briefly about something at page 5.

You can see -- you don't need to look at the top of the page, but there is a discussion about liver disease in haemophiliacs. Then it is the bottom half

of the page I just wanted to ask you about.

So there is a reference to a presentation, it would appear, by Professor Zuckerman on non-A, non-B hepatitis. Then a presentation by Dr Snape, which is described as containing no revelations. But then it says:

"It was the declared policy of BPL in (in the future) to establish a system whereby all incoming plasma would be quarantined for 6 months in order to enable reports of post-transfusion hepatitis from centres to be traced to plasma donations or pools."

Do you know whether a similar system was -- or policy operated at PFC?

A. No, we did not operate that policy.

Q. And do you know whether any consideration was given to whether -- one that should be adopted on receipt of this?

A. I don't know. This was 1982, wasn't it?

Q. Yes, September '82.

A. If we had done that, that would have required the express consent, approval and support of Mr Watt and Professor Cash to do that. And removing effectively six months' supply of plasma would have severely affected our ability to maintain our output and so on.

I'm not absolutely sure whether BPL did actually

implement this, because the same -- there would have been the same downside for BPL to -- it's basically post-transfusion surveillance.

Q. Then if we see there is a reference there to a policy in relation to infrequent uses of Factor VIII and IX. Then over the page in relation to regular users. I just wanted to ask you about the first of those. We can see the second, "Selective Vaccination", the third, "Heat Inactivation - currently being investigated". The first:

"Improvements in donor screening and pool security."

Do you know what's meant by that?

A. No. Can we go back a page, please?

Q. Yes. It is the bottom of the previous page.

A. Is that -- or is that just the heading?

Q. Yes.

A. "Removal of Viral Contaminants ..."

What is that?

Q. It is a note of Dr Snape presenting BPL policy in relation to infrequent users and then, over the page, regular users?

A. Yes, okay.

Q. It is just the reference to -- obviously donor screening is, I think --

A. "Improvements in donor screening and pool security."

I'm not quite sure I can explain what that means.

"Selective Vaccination" is fairly obvious. That's perhaps infecting -- injecting susceptible haemophilia patients with hepatitis B vaccine, because that was the only vaccine that was available for hepatitis viruses at the time.

And "Heat Inactivation".

But, no, I can't -- unless Dr Snape was suggesting that you could do some more to reduce the viral burden in plasma pools by changes to donor screening. And I'm not sure what pool security meant, but ...

Q. Just before we leave this topic and break, if we can go back to your witness statement at WITN69290001, page 33, please.

A. I would say, having just read that last document, that I'm fairly confident that it was written by myself now.

Q. Thank you. I think there was a prolonged debate during your oral evidence to the Penrose Inquiry whether it was or wasn't. So one mystery solved hopefully.

Then if we just look at paragraphs 94 and 95.

94 you say this:

"In any event it became clear to me at an early stage in my employment in SNBTS that the transmission of NANB to eg haemophilia patients, was an unacceptable state of affairs -- thus the decision to establish a SNBTS FVIII study group."

That is picking up on a concern expressed by Professor Cash?

A. Yes, it is part of that.

Q. Then, I just wanted to ask you about 95:

"Notably, in the early 1980s research was conducted in SNBTS with the objective of identifying specific candidate markers and tests for NANB hepatitis."

What particular research did you have in mind there?

A. It wasn't being undertaken at PFC, it was being undertaken in Dr Brian McClelland's centre by -- and I do remember his name -- his name was Bob Hopkins, and his project -- was he spent a considerable amount of time, I think measured in years, in searching for appropriate markers that you could measure that would be indicative of non-A, non-B hepatitis infection. I think despite his best efforts, and he was a very good scientist, I don't think it had a successful

outcome. But it was a process in place in SNBTS.

MS RICHARDS: Sir, I note the time and I'm moving to a different topic, so perhaps a good moment --

SIR BRIAN LANGSTAFF: Yes. We will take a break now until 3.50 pm.

(3.23 pm)

(A short break)

(3.50 pm)

MS RICHARDS: Dr Perry, I'm going to move to ask you now a little bit about AIDS and your knowledge of AIDS.

Do you recall roughly how or when you learnt about AIDS for the first time?

A. No, I can't put a precise date on it, but my guess would be some time in 1982, perhaps, from discussions with Mr Watt and just general surveillance of the literature and so on. But I can't -- I think my very early discussions with Mr Watt was one of the ideas he had that it was CMV infection, it was a consequence of CMV infection, but that was pure speculation.

Q. We know that in July 1982 there was reported cases of AIDS in haemophiliacs in the States, July 1982. And then later, I think December 1982, further reports in the MMWR report of a transfused baby or toddler in California. Would you have read the MMWRs or had them brought to your attention, do you recall?

A. Yes, I would have either read it or appropriate abstracts from it would have been photocopied and circulated. That was part of the SNBTS document sharing before internet existed. That's how information was circulated around the SNBTS. So I regularly saw MMWR, yes.

Q. So in the second half of 1982, not necessarily immediately they were published, but those publications would have come to your attention?

A. I can't guarantee that but it was certainly a regular feature of my background reading, as it were.

Q. And do you recall, in general terms -- I'm not asking here about specific meetings or specific dates, but do you recall how and when it became apparent that there might be a link with blood or blood products and an issue of potential significance for SNBTS and, indeed, for fractionators?

A. No, I think I would be guessing if I pretended that I did know exactly when that happened. But it would perhaps have been around late 1982, early 1983, that there was increasing -- I don't think there was ever a key event, a single event, that triggered the complete understanding of AIDS and its aetiology and epidemiology but it would have been around that time. I think the view that it was a blood-borne virus was

hardening up, I think.
Q. Then if we look at your witness statement, WITN6920001. If we go to page 28 and look at the bottom of that page, I think you say at paragraph 79:
"I do not recall any specific practical actions being undertaken by PFC in response to early reports concerning AIDS other than paying close attention to emerging UK, international and regulatory (particularly FDA) opinion."
Then, over the page, you refer in the second line at the top of the page to:
"SNBTS and PFC staff regularly attended UK and international meetings and conferences in which AIDS increasingly featured in the scientific programmes and discussions."
So I think it is right to understand from your statement that, at this point in time, late '82 into 1983, there was nothing in particular PFC did as a response to the emerging and increasing knowledge about AIDS.
A. I'm not sure when -- I think the answer to that is no, we didn't do anything in particular. I'm not quite sure when -- I can't remember, although it's been discussed recently at the Inquiry, when the first leaflets were proposed to be sent to donors and so on.

Q. Yes, and that's a little later in 1983 --
A. That's a little later, yes.
Q. -- so we see discussions emerging or taking place certainly in Scotland in May of 1983.
A. Yes. My recollection -- what we did do (but it wasn't in response to AIDS, it was in response to non-A, non-B hepatitis) which was establish the SNBTS coagulation factor study group under Professor Cash and, of course, had that been -- had early success, then it would have been applied to HIV risk as well as non-A, non-B risk.
Q. We heard from Dr Foster about his attendance at the World Federation of Haemophilia conference in Stockholm in the middle of 1983. Did you attend that conference?
A. No, I don't remember going to that, no.
Q. Now, a meeting you did attend, and which you refer to in your statement, is the meeting of Haemophilia Centre Directors in October 1983. If we can look at the note that I think you made, or someone from PFC made, about that meeting, it is at PRSE0000040 please, Sully. We can see it is entitled:
"Notes on the Fourteenth Meeting of UK Haemophilia Centre Directors at Oxford RHA 17th October 1983."

Looking at this now, is it your belief that this was your note?
A. I think it is, yes. I think so.
Q. Then we can see it records:
"Major points of interest emerging from the morning session were brief discussions on BPL ATIII concentrate ..."
Is that antithrombin III?
A. Yes, antithrombin III.
Q. And then:
... 'non-infective' FVIII concentrates."
A. Yes.
Q. Then there's an account about what Dr Snape was saying about ATIII?
A. Yes.
Q. If we go to the bottom half of the page, we can see there the heading "Heat-treated Factor VIII concentrate" and it records Dr Snape seeking haemophilia directors' views on two options regarding heat-treated Factor VIII products. The first option is dry heat, and you record:
"No technical details were presented ...
"Subject to demand, Terry Snape indicated that such a product could be available within 2-3 months ... would be available on the basis that it is no

worse than the existing product."
Then this records, assuming this is your note, you asking whether any viral inactivation data was available on the process, to which Terry responded by saying that:
"... such data may be available in due course but would probably follow the general availability of the product and therefore be retrospective."
Do you have any recollection of that issue being discussed and explored?
A. I can't remember the actual question and answer exchange, but clearly I asked the question about -- this would have been model viral inactivation data, not patient data, or this would have been spiking samples with model viruses and I think that's what I was probing Dr Snape about.
Q. Then we see the second option identified is "pasteurisation". Then if we go over the page, I just want to pick up the first main paragraph on the page. It says:
"In general discussion of above options Dr Craske pointed out that limited experience (Travenol) of heated dry product was not encouraging. There also emerged a general fear and fateful acceptance that the production of non-infective

products would lead to reduction in availability of NHS concentrates (i.e. loss of yield). Terry seemed to reinforce this view quoting figures of up to 25% loss in yield over the existing product. I pointed out that, while hard data was not yet available, developments relating to other aspects of the overall manufacturing process upstream of any heating process may partly or fully offset any yield inherent in pasteurisation. I quoted, in particular, Peter's publication on zinc and calcium."

That's presumably Dr Foster?

A. Yes.

Q. "Neither Dr Boulton, Dr Ludlam or myself considered it appropriate to discuss publicly the details of our current 'clinical trial' on heat treated Factor VIII."

So just pausing there, can you assist, first of all, with the general fear and fateful acceptance that production of non-infective products would lead to a reduction in availability of NHS concentrates. What was the issue or the concern there? Who was expressing fear or fateful acceptance? Was that the general attendees at the meeting?

A. I would imagine it would have been the Haemophilia Centre Directors who were already suffering from shortages of NHS product, and perhaps also, I think --

and it says that Terry seemed to reinforce this view. So I think Terry, representing BPL, reinforced that view that the output of BPL, if they were to heat treat their products, would fall by a further 25%.

So it was -- and the inevitable consequence of that would be for increased purchases of commercial products, whether heated or unheated, which would not have been a good outcome.

Q. Then why was it, looking at the last sentence of that paragraph, that you, Dr Ludlam and Dr Boulton didn't think it appropriate to discuss publicly what was happening in terms of PFC's trial of heat-treated Factor VIII?

A. Sorry, what was the date of this?

Q. It is 17 October 1983.

A. Oh, okay. I think it was -- because clearly the details of our -- what is described there is our clinical trial, I think this was the ZHT -- the PFC pasteurised product. Details of that had already been shared with BPL, but amongst -- only within -- between BPL and PFL. And I think Dr Boulton, Ludlam and myself thought it was neither ready or appropriate to discuss this in a wider public forum. I don't think -- I am not sure whether the trial at that stage had taken place or whether it was in planning.

Q. Then the note continues:

"Despite the unvalidated nature of BPL's short term solution there seemed to be a general feeling in favour of a heated dry product since such a solution would 'do no harm'. It was suggested that BPL manufacture a limited scale batch of heated dry product with a view to conducting a small clinical trial in virgin haemophiliacs (or at least those with no previous exposure to concentrates and who have normal LFTs)."

That appears to suggest the mood of the meeting favouring dry-heated product over a pasteurised product. Is that the right way to read this note?

A. I think it was simply reflecting that the dry heat treated product, without really any evidence that it would be effective against non-A, non-B or any other unknown viruses, because we don't know their nature, would have -- it would have been quicker, so in a sense if there was any favour shown to the dry heat treated product, I think it was simply the timescale for its introduction. I think, certainly from where I sat, most people felt that a pasteurised product was likely to be more efficacious in terms of virus kill over a wide range of viruses than quite modest dry heat treatment.

Q. And is it right to understand that this meeting didn't lead to any change of approach or direction on the part of PFC's work? You continued -- when I say "you", I mean PFC -- continued with its pasteurisation project?

A. Yes.

Q. Then if we go to the bottom half of the page we can see the "Afternoon session". It says:

"Comprehensive written reports were circulated (attached)."

I think that probably answers my earlier question to you about obtaining copies of the written reports.

Then there is a reference to the situation in relation to the States. We can see towards the bottom it says:

"... total of 21 cases of transfusion associated AIDS in the USA."

Then if we go to the top of the next page it says:

"Crude interpretation of these figures provides the following risk statistics.

"Transfusion -- 1 in 500,000 at risk.

"Haemophiliacs -- 1.2 in 1,000 at risk.

"Conclusion -- Serious disease in haemophiliacs

a low possibility??"

I don't know whether you can, at this distance of time, say, Dr Perry, but is that your interpretation of what -- the figures that have been delivered or is that you recording a discussion at the meeting about numbers at risk and the extent to which serious disease --

A. I think this is -- they are certainly not my figures. I don't think I would in -- been in a position to do those calculations. I think these were -- the data that was presented. I have to say it was a -- in many senses, as we know now, they were wildly off the mark, and simply because they were just taking numbers of known patients with AIDS and dividing that by the total population and, in a sense, projecting that as a risk, which clearly completely underestimated the number of patients that seroconverted to HIV but had yet to be detected.

SIR BRIAN LANGSTAFF: It wasn't dealing with risk at all, was it? It was dealing with perceived incidence.

A. It was an incidence calculation, you are right, yes.

MS RICHARDS: There's then a summary of the UK situation and reference to details of haemophiliac cases A1 and A4. That, I suspect, is a reference to the individuals that we have referred to as the Cardiff

case and the Bristol case, or Cardiff patient and Bristol patient. In any event, do you have any recollection of discussions within PFC or within SNBTS about the fact that by October 1983 there were cases in haemophiliacs in the United Kingdom? Do you remember that being a subject of discussion and concern at SNBTS?

A. There were two cases, weren't there, in haemophilia patients?

Q. Yes.

A. That's right. I can't remember whether -- I'm pretty certain it will have been discussed. This was a report that went out to all my colleagues in PFC and certainly colleagues in RTCs. So it would have provoked discussion. I can't remember what that discussion was or what the outcome of that discussion might have been.

Q. Then if we just look at the bottom of this page, we have got the heading "Hepatitis":

"NHS material is no better than commercial product, with respect to disease transmission.

"In a small study using an 'accredited donor' pool, manufactured by BPL, one in eight recipients have so far developed signs of NANB hepatitis. So far this study is of two months duration and unfortunately

BPL cannot determine the pool size used to make the batch."

Now, that first paragraph under the heading "Hepatitis":

"NHS material is no better than commercial product, with suspected disease transmission."

Would be a fairly fundamental piece of information, would it not, for PFC, whose raison d'être, as you've described it, has been very much "domestic NHS concentrates are safer than commercial concentrates". Can you recall the discussion about that issue?

A. I think this relates to -- unless my timing is wrong, but to the really quite key and sentinel publication by Dr Kernoff, who did detailed studies in patients on NHS product and on commercial product, and he found that I think -- I think something like 8 out of 9 patients on NHS product developed symptoms of non-A, non-B hepatitis, 100 per cent for commercial product, and I think it is referring to that. So in my note this is simply a shorthand referring to an appendix. So maybe there is more detail in the appendix but I can't remember what that appendix actually contained.

But if this meeting is from late 1983, I think

it was certainly known by then that NHS products were not free from the risk of non-A, non-B hepatitis. They were believed, certainly in the early studies, to have lower severity of disease and the clinical symptoms were shorter lived. Whether that turned out to be a valid observation, I don't know, so there were differences but the idea that NHS products were safe was simply discounted as a result of this.

Q. Can I then just ask you to look briefly at the formal minutes of the meeting, rather than your note.

We will find those at PRSE0004440.

We have got the date there again, 17 October 1983, and your attendance is recorded on the second page.

If we go to, I think it should be page 9, first of all, Sully.

I don't have a question for you in relation to this, Dr Perry, but I'm going to flag up that if we look at the penultimate paragraph on the page, it says:

"In reply to a query Dr Snape said that BPL hoped that not more than 10-15% of the factor VIII yield would be lost in the making of the virus free products."

I just draw attention to that, because I think

your note had recorded a possibility of up to 25%. It may not be inconsistent but I just wanted to draw that out.

A. Okay.

Q. If we go to the next page, there is a discussion under the heading "Any Other Business", and this is a passage the Inquiry has looked at on a number of occasions, but it refers to Dr Chisholm, who was the Haemophilia Centre Director in Southampton, identifying a problem of patients not wanting to take up commercial Factor VIII and a discussion about reversion to cryoprecipitate. And Professor Bloom's response:

"... no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were a cause of AIDS."

Then Dr Chisholm is recorded as saying she can get unlimited supplies of cryoprecipitate, other directors report the same. And then it records an agreement that:

"... patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive the NHS or commercial concentrates in their usual way.

Now, that is a debate perhaps of most direct interest to haemophilia clinicians, but is it one that you have any recollection of, that part of that meeting?

A. No, I don't recall the detail of the meeting, I'm afraid. I think -- I was certainly aware subsequently that this was beginning to be the case, but, I'm sorry, I can't elaborate on that at all.

Q. Can I then just pick matters up at PRSE0001885.

We looked earlier at this letter from you to Dr Cash in March of 1988, attaching the summary of events. I just want to ask you about a couple of passages now in the summary itself.

So if we go to page 2, please, Sully.

Under the heading "Summary of SNBTS response to HIV contamination of PFC coagulation factors", which is the heading, if we can zoom in on the top half of the page. What we have got identified there under the heading "[Factor] VIII heat treatment developments" is as follows:

"Early 1982. In response to known hepatitis risk of [Factor] VIII concentrates, PFC initiated development programme for solution heating of Factor VIII ..."

I'm not going to ask you further about that at

the moment. You then say:

"BPL (Elstree) were exploring dry heat as an option on a collaborative basis with PFC."

In terms of 1982, what is the reference there to collaboration with PFC? What was it that PFC was contributing to BPL's dry heat work?

A. I think we were simply sharing information. I don't think there was a jointly agreed research programme. I think it was simply an observation that PFC and BPL, or PFL, were exchanging information, particularly in terms of BPL's success or otherwise with their dry heat treatment programme. And likewise the PFC with its pasteurisation process.

Q. Then the next item that you record, "1983/1984":

"International debate as to causative agent of AIDS. Consensus view that causative agent was an infectious agent (virus) emerged in mid-1984."

Now, why were you identifying the consensus view emerging in mid-1984, as you put it, as the next significant item here?

A. I don't really know. I think what I was reflecting was that there were other -- at that time, perhaps, maybe a little earlier than mid-1984, that there were other putative explanations in terms of T cell abnormalities and repeated infusion of high quantities

of protein through regular infusions and so on. And Professor Ludlam, he didn't advocate these. He simply suggested that these might either contribute or could conceivably -- or there was evidence that they could conceivably be the case. I think I'm simply reflecting there from my own personal knowledge that by that time it was absolutely clear.

Q. The next entry is October '84. That's the "Report from SEBTS of seroconversion of haemophiliac cohort", which we will come on to in due course.

Then October '84 still refers to PFC examining tolerance of the unheated stock to withstand dry heat. And then we have reference to the Groningen conference.

Can you just assist in unpicking this. It says:

"Present at conference (Groningen) ..."

Were you present at that conference?

A. I was, yes.

Q. "... where first virus inactivation results were announced (US) from CDC/Cutter study within one day of results being obtained."

Is that saying that the announcement in the conference was within a day of CDC/Cutter having that data?

A. It was. I think CDC had been invited to the meeting

to give a presentation but it was really presented as breaking news. They had literally had those data passed to them from the US and they took the opportunity to basically announce this really quite important finding.

Q. If we just go back and look at the first half of that page as a whole. And bearing in mind this is what is being described as -- I think it says "SNBTS response", but it is, I think, really reflecting PFC's work, is it not, because we know SNBTS were doing other things such as the AIDS leaflet and so on.

A. Yes, of course. Yes, yes.

Q. It might be said this gives a picture that PFC itself didn't really focus upon any matters relating to AIDS until October 1984, when there was this combination of factors -- Groningen, the discovery of the infected PFC batch -- and it is only at that point that PFC then focused upon the possibility of adapting its work to respond to the risk of AIDS.

Is that a fair inference?

A. I think that's a reasonably fair summary of the position. We were still moving forward in the hope that the pasteurisation process would develop fairly quickly and be implemented routinely. It turned out that that wasn't the case.

Q. I'll come back to the events of autumn 1984, Dr Perry, tomorrow. What I want to do, just before we finish for the day, is start looking with you at a topic relating to product warnings and labels. We won't, I think, finish that in the next ten minutes but I think it's worth starting.

You can take that down, please, Sully.

So, in terms of the PFC products that were issued to Regional Transfusion Centres for onward issue to Health Boards and to Haemophilia Centres, what were the different categories of information that accompanied that project? There'd be a label, was this right, on the vial itself?

A. Yes.

Q. And there'd be what's I think sometimes described as a "leaflet" or sometimes described as an "insert". Are they the same thing or were they different things?

A. Yes. Certainly in the early 1980s, there would have been a leaflet or a product insert included with each product which was typical of the industry generally and it still is.

Q. And was there anything else? Was there anything else external or by way of informational packaging?

A. There was key -- if the products were contained in an outer carton, which they often were, because for

instance the Factor VIII product was -- I think it latterly was supplied as ten vials of Factor VIII and ten vials of water for reconstitution in a single container (a multi-dose, as it were, container) but even when it was supplied as a single product, there would have been really mandated by pharmacopoeia monographs and regulations that there was certain minimum information that you had to put on the label, on the outer packaging and in the product insert leaflet.

I'm sure you'll explore it more but the product insert leaflet at that stage was primarily directed at professionals, not patients.

Q. Yes and certainly we're going to explore all these issues.

In terms of a responsibility at PFC, whose responsibility either in terms of department or individual was working out what information should be included on the insert or the leaflet or on the vial?

A. That would have been -- the quality department would have been responsible for that, not necessarily for its procurement, but the procurement would have been done, I think at that stage in the early '80s, by the manufacturing department as part of its responsibility for procuring raw materials and so on.

I think also Professor Cash, acting as medical director or adviser, would have been asked, either formally or informally by Mr Watt in the early 1980s, and subsequently by myself, to sign-off the precise text. Although, it was largely informed by -- I noted I was provided with a series of pharmacopoeia monographs here and labelling on vials is often prescribed by the pharmacopoeia monograph.

Q. Yes, and we'll certainly look at that and that really leads to the next question I wanted to ask you which is, what was the decision-making process, as far as you can recall, about what should be included on the vial of the leaflet? I appreciate you joined in 1981, so you wouldn't have been around in 1978 when the licence application was first submitted and the text of an insert or leaflet was identified.

In terms of your own knowledge from 1981 onwards, can you recall what the process was? Was it just a case of looking at the pharmacopoeia and using that language or --

A. I think it was the pharmacopoeia and other regulations that existed that prescribed -- for example, when you submitted a licence application, an important part of the licence application was what you were going to put on the label. So the precise wording, and even the

size of the respective messages, were authorised as a result of being granted a marketing authorisation.

So we would have gone through that process and you're right to say that when I joined in 1981 I'd had no impact -- or input into that. But I think -- I can't remember exactly when, maybe 1982 -- I did a review of the packaging, particularly for coagulation factors, and within that review I would have certainly reviewed the precise wording and made any changes that were necessary, and had that approved by the PFC director and his medical adviser, who was Professor Cash.

Q. We'll look at the language of the pharmacopoeia in the morning rather than now.

Just in terms of the input or involvement of the licensing authority, would it be right to understand that what happened is PFC would submit its application which would contain, as you say, draft wording, contain -- and we will look at an example in the morning -- a leaflet or insert which had certain information about hepatitis on it?

A. Yes.

Q. But it would be submitting that as part of the product application process?

A. Yes.

Q. It might or might not then be approved. But the licensing authority didn't itself come up with a required form of wording; is that right?

A. Periodically, they may have -- in response to any manufacturer submitting a licence application, there might be some form of words, particularly to do with the product inserts where different companies take -- use different wording. It's not standardised, it's not one size fits all and they may well come back and ask for changes or a different emphasis and so on.

I think our product inserts were fairly simple and fairly straightforward and -- but it is the case that the licensing authority could come back and ask you to change something.

Q. Yes, I accept that. I think my question was a slightly different one. The licensing authority didn't itself produce a form of wording for use on Factor VIII concentrates.

A. No.

Q. It would respond to what was being submitted to it by PFC or BPL or Armour or whoever it might be?

A. That's right. But if we -- and we did, we called our product "human anti-haemophiliac product BP", so that would automatically trigger the licensing authority to look at the BP monograph and check whether our wording

complies with the monograph.

Q. Then just in terms of who the audience was for the inserts or the labels on the vials and so on, can I just ask you to look at an extract from your evidence to Penrose. PRSE0006038.

If we start -- so this is your evidence on 24th June 2011. If we start on page 95 -- I just want to pick it up from the bottom half of the page from line 14 onwards. You were asked essentially the same question that I'm asking you: who were those pack inserts designed for? Was it for the doctors, the patients or who. And this is your response:

"It's a good question. Certainly nowadays you have a thing called a 'product information leaflet' and a 'technical information leaflet' and they have different target audiences and they are written in completely different ways."

Just pausing there, Dr Perry, do you know when that particular change or --

A. I think it was the early 1990s.

Q. Then you say:

"At that time, I think the answer to your question is they were targeted in the way they were written, certainly at prescribing doctors. They gave some basic characteristic but also some of the

information was very accessible to lay people in terms of how you reconstituted the product, how you used it and so on."

A question was:

"Was part of the purpose of the package insert to give information about the possibility of there being risks of viruses being transmitted through the product?

"A. The package inserts that we had in common with the rest of the industry certainly included warnings that -- I think we were very general in our warnings saying, 'this product, although the plasma is tested for hepatitis B it cannot be assumed to be free of infectious risk', or words to that effect. So, yes, it was designed to give a warning to both patients and certainly to doctors, but doctors already knew this."

And then we continue with your answer at 16 that:

"... these products carried a risk associated with them. So the document that was included with each vial was really part of that process but also to satisfy our essentially legal obligations within the pharmaceutical industry ... even then the industry was required for prescription medicines to have some sort

of information leaflet associated with them."

It would appear from that answer you're suggesting it's, is this right, predominantly aimed at doctors but also with a view to providing information to patients?

A. I think they were designed and designed primarily for doctors and, indeed, pharmacists. I think the whole product insert leaflets at that time were there to inform not only the prescribing doctor but if there was a pharmacy -- for our products, that wasn't the case because they weren't supplied through pharmacies but, as a general principle, these leaflets were there to provide important information to both prescribers and pharmacists who were fulfilling prescriptions.

I think I always took the view, and I think others did, that these products were supplied with the product and patients on home therapy would have been supplied with the whole package, so that they would have had the leaflet and many of them may well have read it. But I think the precise wording was prescribed by the requirement to satisfy the professional requirements for the product, rather than the individual patients. Those leaflets came later.

MS RICHARDS: Perhaps we can pick that up in the morning by looking at the actual wording, which will take

a little time so I won't embark upon it now.

SIR BRIAN LANGSTAFF: Yes. We will take a break now, then, until 10 o'clock in the morning, if you please. So 10 o'clock in the morning.

(4.31 pm)

(Adjourned until 10.00 am on Friday, 1 April 2022)

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