

1 **Thursday, 31 March 2022**
 2 **(10.00 am)**
 3 **SIR BRIAN LANGSTAFF:** Good morning, Dr Perry.
 4 **THE WITNESS:** Good morning.
 5 **SIR BRIAN LANGSTAFF:** Now you are talking not just to the
 6 audience that you see in front of you here, but you
 7 will be talking to others who will be watching online,
 8 I imagine quite a number, probably, from Scotland. So
 9 that is the audience that you have.
 10 You will start your evidence once Mary has
 11 administered the oath and then Ms Richards will ask
 12 you the questions.
 13 **THE WITNESS:** Okay, thank you.
 14 **DR ROBERT JOHN PERRY (affirmed)**
 15 **Questioned by MS RICHARDS**
 16 **MS RICHARDS:** Dr Perry, you have a degree in chemistry
 17 awarded in 1971 and a PhD in chemistry 1975; is that
 18 right?
 19 **A.** That's correct.
 20 **Q.** You are also an accredited qualified person. What
 21 does that mean in practice?
 22 **A.** The qualified person status, I was -- it effectively
 23 applies to, I think, probably all the pharmaceutical
 24 industry, that there was a requirement to have in any
 25 pharmaceutical enterprise somebody who was authorised

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1 the PFC, then, in 1985, the director of the PFC,
 2 a post you remained in until 2003?
 3 **A.** I think it was 1984 that I became the acting director
 4 of PFC.
 5 **Q.** Sorry, that's what I meant to say, yes.
 6 **A.** Sorry, yes. Otherwise that is correct, yes.
 7 **Q.** 2003 to 2004, you were seconded to the role of
 8 personnel director for SNBTS?
 9 **A.** Yes.
 10 **Q.** Then between May 2004 and 2005 you were director of
 11 pharmaceutical and technical projects for National
 12 Services Scotland?
 13 **A.** That is right.
 14 **Q.** In a sentence, what did that entail?
 15 **A.** I think there were a large number, as indeed
 16 throughout the health service, of small regional
 17 pharmacies making special products, products that
 18 weren't available commercially, and there was a view
 19 that that perhaps could and should be centralised into
 20 a single organisation. So I was asked to do
 21 a feasibility study which I carried out on behalf of
 22 National Services Scotland.
 23 **Q.** June 2015 (sic) to January 2007, you were a director
 24 of SNBTS's Better Blood Transfusion programme?
 25 **A.** Yes.

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1 and qualified to release batches of product for
 2 clinical use.
 3 **Q.** Can you just give an outline of the nature of the work
 4 you undertook between 1975 and 1981, so before you
 5 joined the PFC.
 6 **A.** 1975 I was -- I had just finished my PhD and I did
 7 a little bit of teaching during that. I then -- from
 8 my recollection, I joined the water authority in
 9 Wolverhampton or close to Wolverhampton, where I was
 10 an analyst in a laboratory. And after that I moved
 11 on, about -- after about 18 months to become the chief
 12 analyst at an organisation called the Regional Sterile
 13 Supply Unit in Wolverhampton, which was a fairly
 14 large-scale manufacturing organisation for producing
 15 sterile fluids and topical fluids for use in the
 16 West Midlands Regional Health Authority, health
 17 service.
 18 **Q.** Was that the job you were doing immediately prior to
 19 moving to PFC?
 20 **A.** It was, yes.
 21 **Q.** So you joined the PFC in 1981 as quality control
 22 inspector.
 23 **A.** Yes.
 24 **Q.** I will ask you in a few minutes a little more about
 25 that. Then in 1985 you became the acting director of

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1 **Q.** We will come on to that towards the end of your
 2 evidence, Dr Perry, so I won't ask you anything
 3 further about that at this stage.
 4 Since that time, as I understand it, you have
 5 been a self-employed consultant and working with the
 6 International Plasma and Fractionation Association?
 7 **A.** That is correct.
 8 **Q.** What is that association, what does it do?
 9 **A.** The International Plasma and Fractionation Association
 10 was an organisation -- it started out as the European
 11 Plasma and Fractionation Association in 1991, and it
 12 was -- I guess the best way to describe it, it was
 13 a trade association established following the
 14 regulatory development in Europe that plasma products
 15 had to be -- were to be regulated by the European
 16 Medicines Agency as it was then. And the European
 17 Medicines Agency fairly soon, early on in this
 18 development, stated that they didn't want to speak
 19 individually to the not for profit -- all the
 20 not-for-profit organisations in Europe. So there was
 21 a requirement to create an effective and efficient
 22 interface between the not-for-profit fractionators in
 23 Europe with the European Medicines Agency.
 24 **Q.** And what kind of work has your work as a consultant
 25 involved over the last decade or so?

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1 A. I think it has been involved primarily with the
 2 European -- I did little bit of work with the WHO at
 3 one stage, but I think the majority of my work has
 4 been involved in developing documents,
 5 position statements, supporting the members of the
 6 International Plasma and Fractionation Association,
 7 which are -- it is an international organisation and
 8 it has members in Japan, Australia, New Zealand,
 9 Canada, the US and Europe and so on. So it has been
 10 a general role in supporting the activities of that
 11 organisation.
 12 Q. Does that association's membership include
 13 pharmaceutical companies, commercial fractionators --
 14 A. No, it doesn't. It is an association. There is
 15 a comparable organisation that was established around
 16 about the same time as EPFA was established and that's
 17 called the Plasma [Products] Therapeutics Association,
 18 PPTA.
 19 Q. During your career with SNBTS you were involved with
 20 a range of committees and working groups, which you
 21 have listed in your statement. For present purposes
 22 I'm just going to mention three of them. You were
 23 part of the SNBTS directors committee once you became
 24 director of the PFC, is that right?
 25 A. That is correct.

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1 in fact it is 1989.
 2 A. Okay, thank you.
 3 Q. When that became the Advisory Committee on
 4 Microbiological Safety of Blood [and Tissue] for
 5 transplantation, you remained on that committee?
 6 A. Yes, I basically just transferred over to the new
 7 committee. The membership changed but I remained on
 8 it.
 9 Q. That was until around 2004, is that right?
 10 A. That is correct.
 11 Q. We will certainly come back to the decision-making of
 12 the Advisory Committee on the Virological Safety of
 13 Blood at a later stage.
 14 You provided multiple written statements to the
 15 Penrose Inquiry. I'm going to read for the benefit of
 16 the transcript the references to the main statements
 17 you provided, some but not all of which are listed in
 18 your witness statement. That, Dr Perry, is not
 19 because we are going to look at them all, but it is
 20 for the benefit of others so that there is, collected
 21 in a single place, all the relevant reference numbers
 22 for your principal statements.
 23 A. Yes, I understand.
 24 Q. So it is PRSE0001823 on the topic of high-risk donors.
 25 PRSE0003755 on the topic of AIDS.

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1 Q. So that would have involved, amongst other things,
 2 attending regular meetings with SNBTS directors?
 3 A. Yes.
 4 Q. And with Dr Cash?
 5 A. Yes.
 6 Q. You were a member of the Biological Subcommittee of
 7 the Committee on Safety of Medicines from 1986 to
 8 1990, is that right?
 9 A. That is correct.
 10 Q. You took over in fact from Mr Watt who had been on the
 11 committee previously?
 12 A. Mr Watt retired from the SNBTS -- or resigned from the
 13 SNBTS in early 1984, but I think he continued his
 14 membership of CSM for a short period after that. But
 15 then I think there was a view that it would be useful
 16 to have somebody from the fractionation centre in
 17 Scotland to provide expert input into the decisions of
 18 the Biological Subcommittee, so I was appointed to
 19 that committee.
 20 Q. And you were a member of the Advisory Committee on the
 21 Virological Safety of Blood from its inception?
 22 A. That's correct.
 23 Q. I think at one point your statement suggests it was
 24 1991 but -- we will come to the minutes and its
 25 decision-making at a later stage of your evidence --

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1 PRSE0003769, which relates to the infected PFC
 2 batch and the investigation undertaken into that in
 3 late 1984.
 4 PRSE0002178, which looks at issues relating to
 5 AIDS and viral inactivation to 1985.
 6 PRSE0001258, viral inactivation 1985-87.
 7 PRSE0000145, hepatitis C screening.
 8 PRSE0002320, use of concentrates in, I think it
 9 is, '85 to '87.
 10 PRSE0002938, recall of unheated Factor IX, issue
 11 of heated Factor IX.
 12 PRSE0001919, that's a joint statement with
 13 Dr Cuthbertson and Dr Foster on conditions at Liberton
 14 in the '80s.
 15 PRSE0002620, on package inserts and non-A, non-B
 16 hepatitis.
 17 PRSE0003806, which contains communications with
 18 Montagnier.
 19 And PRSE0004392, which contains comments on the
 20 issue of self-sufficiency.
 21 I think you also contributed to a number of
 22 joint or corporate statements on behalf of SNBTS in
 23 the Penrose Inquiry. I'm not proposing to list those.
 24 Then you gave oral evidence to the Penrose
 25 Inquiry on 24 March 2011. PRSE0006011, on the

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1 question, again, of high-risk donors and particularly
 2 prison donors.
 3 13 May 2011, PRSE0006025 on the topic of
 4 self-sufficiency.
 5 24 June 2011, PRSE0006038 on the implicated PFC
 6 batch.
 7 13 September 2011, PRSE0006045, that was topic
 8 B3, which temporarily escapes me what that was.
 9 28 October 2011, PRSE0006058, that's about viral
 10 inactivation.
 11 23 November 2011, PRSE0006068, hepatitis C
 12 testing.
 13 7 December 2011, PRSE0006074, on the issue of 8Y
 14 and Z8.
 15 I list those so that nobody else has to go
 16 through the exercise of pooling them together.
 17 You have told us in your statement you didn't
 18 give evidence to any other enquiries or
 19 investigations, is that right?
 20 **A.** I think that's correct, yes.
 21 **Q.** So you didn't give evidence to the Lindsay or Archer
 22 Inquiries. Does that mean you weren't involved in
 23 providing evidence on behalf of SNBTS to the Scottish
 24 Executive Investigation?
 25 **A.** I think I was involved in it but I think that role

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1 was not unusual for him to write spontaneously,
 2 because he had something in mind, to ask for a summary
 3 of what happened during this important period. So,
 4 I don't think there was -- anything specific happened
 5 in March 1988 that triggered this other than
 6 Professor Cash just seeking a summary of the events
 7 and what PFC in particular did in response to those
 8 events.
 9 **Q.** We know that there was around this time a piece of
 10 litigation ongoing, which the Inquiry have been
 11 referring to as the "HIV Haemophilia Litigation". Do
 12 you know whether it was in relation to that at all?
 13 **A.** It might have been. I have just noted in the
 14 annotation to go with the litigation papers. So it
 15 may well have been triggered by that.
 16 **Q.** But you didn't have any direct involvement to yourself
 17 with litigation at the time?
 18 **A.** No, I don't recall having any detailed involvement.
 19 **Q.** So, can we then come back to your work at the PFC.
 20 Starting with your role as quality control inspector.
 21 What did that entail?
 22 **A.** The role of quality control inspector -- it was
 23 a curious title, actually, for the job, but it was
 24 a post that was established I think primarily as
 25 a response to the Medicines Inspector's report which

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1 which was basically a lot of data collection and
 2 submission to the Scottish Executive was undertaken by
 3 Dr Foster. But I would have been involved at some
 4 level, yes.
 5 **Q.** Then can we just look briefly at one document. It is
 6 one I will come back to later but it is PRSE0001885.
 7 This is a letter from you to Professor Cash,
 8 14 March 1988. If we look at the text of the letter
 9 it is SNBTS' response to HIV contamination of blood
 10 products:
 11 "Further to your request for details of SNBTS
 12 actions in response to the emergence of AIDS, I have
 13 now assembled the enclosed summary of key events.
 14 "There is much supportive documentation of these
 15 events should this become necessary."
 16 If we just go over the page. As I say, I will
 17 come back to the some of the detail of it, but we can
 18 see there is a chronological narrative and a thematic
 19 narrative set out.
 20 If we just go back to the first page, please,
 21 Sully. Can you recall what the purpose of this was?
 22 Why you had been asked by Professor Cash to pull this
 23 information together?
 24 **A.** No, I can't, I can't recall a specific event or
 25 a specific issue that Professor Cash raised, but it

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1 had taken -- the Medicines Inspector visit and their
 2 quite detailed inspection of the facilities and the
 3 arrangements at PFC which took place in 1979/1980, and
 4 I think there was a view that the organisation needed
 5 to hire somebody with experience in the field, not in
 6 biologicals manufacture but in the principles and the
 7 practice of good manufacturing practice. And I had
 8 obtained that during my work in Wolverhampton at the
 9 sterile supply unit. So I was appointed really with
 10 a quite far reaching role, which I think is why it was
 11 probably called quality control inspector.
 12 I had authority in all parts of the
 13 organisation, because the principle is that everything
 14 that happens in a pharmaceutical manufacturing
 15 organisation can have an impact on product quality and
 16 product safety.
 17 **Q.** What in practice did that entail? In a typical week
 18 in 1982, what would your work have involved?
 19 **A.** In 1982 I think it was fairly -- it was still fairly
 20 on in my career with SNBTS. I think my priorities at
 21 that time were establishing more robust documentation
 22 systems, creating a portfolio of standard operating
 23 procedures which didn't exist when I arrived. It
 24 involved an examination of the facilities and their
 25 compliance with good manufacturing practice and

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1 basically examining the comments and the criticisms
 2 that were made by the medicines inspectors and
 3 beginning to formulate a response to that.
 4 **Q.** If we can just look at a short extract from one part
 5 of your oral evidence to the Penrose Inquiry.
 6 Sully, it is PRSE0006011, please. If we go to
 7 page 93, and pick it up at line 9.
 8 Your evidence had started, just for the benefit
 9 of anyone following on page 89. We can see you were
 10 being asked about your work and you explain at line 9
 11 to 11 you had:
 12 "... no prior experience of blood or plasma
 13 products. This was a completely new area of endeavour
 14 for me."
 15 If we go to page 102, please, top of the page.
 16 Lines 4 to 6 you say:
 17 "I had no knowledge of the plasma fractionation
 18 industry or blood establishments or blood transfusion
 19 services prior to my emigration to Scotland."
 20 So blood fractionation, blood transfusion, was
 21 something completely new to you when you took up your
 22 first post at the PFC?
 23 **A.** Absolutely, yes.
 24 **Q.** Were you provided with any kind of training? You told
 25 us yours was effectively a new post so you weren't

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1 that unexpected?
 2 **A.** No, he'd tendered his resignation. I think his
 3 original plan was to leave a little later but for
 4 reasons I don't think were ever disclosed to me or
 5 others, he left certainly significantly earlier than
 6 was originally anticipated. I think it was meant to
 7 be maybe the middle of 1984 but it turns out he left
 8 at the end of 1983.
 9 **Q.** And so you were -- was it unexpected then being asked
 10 to step up to the role of acting director?
 11 **A.** Well, I had, even though I had only been in the
 12 organisation two or three years by that time, I saw it
 13 as a good opportunity. I was enthusiastic about the
 14 work of the PFC and I applied for the job of director
 15 when the shortlisting took place for that role. So
 16 I think the Common Services Agency and Professor Cash
 17 and others involved thought, well, this is somebody
 18 that could perhaps take on the role of acting director
 19 until the substantive replacement for Mr Watt had
 20 taken place. So I readily accepted that offer.
 21 **Q.** We have heard some evidence of a less than harmonious
 22 relationship between Mr Watt and Dr Lane. Do you have
 23 any understanding or recollection of what the
 24 relationship had been between Mr Watt and Dr Cash?
 25 **A.** They were both powerful strong personalities. Mr Watt

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1 taking over an inherited role. Did you receive any
 2 training or education or assistance in understanding
 3 more about fractionation and transfusion?
 4 **A.** I don't think there was anything that you could
 5 describe as a formal training programme. I think, as
 6 was typical of the time, it was very much on the job
 7 training. Mr Watt, who was my boss, was very open.
 8 He was very generous. I think to an extent he applied
 9 the sort of deep immersion technique and from a very
 10 early stage he allowed me or asked me to go and
 11 deputise for him at national meetings, at local
 12 meetings with the Haemophilia Centres directors'
 13 organisation and also made every effort to ensure that
 14 I could attend international meetings and national
 15 meetings associated with plasma products. So although
 16 there was no formal training, he was very active in
 17 exposing me to all the issues.
 18 **Q.** Then as we established a few minutes ago, you became
 19 director, first acting director and then director,
 20 after Mr Watt left. Now, as I understand it, Mr Watt
 21 tendered his resignation in around the middle of 1983?
 22 **A.** That is correct.
 23 **Q.** And then left in December 1983?
 24 **A.** Yes.
 25 **Q.** Did you have any understanding -- first of all, was

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1 was very innovative and Professor Cash was a very
 2 strong leader in those issues that he felt were
 3 important and I guess the combination of that meant
 4 that they didn't always see eye to eye on every issue,
 5 but I honestly can't recall any major conflict that
 6 caused any disruption to the delivery of services.
 7 **Q.** Now, as director what was essentially your role? What
 8 did you do as director of the PFC?
 9 **A.** I was appointed to be responsible for all the
 10 activities of PFC. The operational activities
 11 primarily. I was an operational manager for the
 12 plasma fractionation centre which was the
 13 manufacturing unit of the SNBTS.
 14 **Q.** And you were accountable to Dr Cash; is that right?
 15 **A.** No, I was accountable to, again, a slightly curious
 16 arrangement but not untypical of its time, I was
 17 responsible to the Committee of Management of the
 18 Common Services Agency, so my boss was a committee.
 19 But subject -- and I think this was stated in my job
 20 description -- to the duties and responsibilities of
 21 Professor Cash.
 22 **Q.** In practice did you have much by way of interaction
 23 with the Committee of the Common Services Agency?
 24 **A.** No.
 25 **Q.** So in practice you would be discussing key issues with

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1 Dr Cash?

2 **A.** Absolutely, yes. He was the National Medical Director

3 at the time. He was very authoritative. He was

4 a very strong leader and I think it is fair to say

5 that I had daily interactions with Professor Cash.

6 **Q.** And if we just go back to one part of your oral

7 evidence to the Penrose Inquiry.

8 PRSE0006011, page 94, please.

9 From line 3, you are here describing your role

10 and responsibilities as director:

11 "My responsibilities were effectively the

12 operational management of the fractionation centre of

13 the SNBTS, and my responsibilities covered everything

14 from financial control, operational management to

15 production, quality control, not single-handed,

16 obviously -- I had a staff of about 200/250 people --

17 and also the research and development of new plasma

18 product that the service wanted to bring into use."

19 Is that a fair description of your principal

20 responsibilities?

21 **A.** Yes, I think that is a good description.

22 **Q.** Then your statement tells us that from 1990 your

23 direct accountability was to the SNBTS general

24 manager?

25 **A.** Yes, that is correct.

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1 production department at that time. But that is

2 a good enough title, manufacturing department.

3 **Q.** The next department you identify is the quality

4 department and this would be the -- essentially area

5 of activity that you led from 1981 to 1984; is that

6 right, to the end of '84?

7 **A.** Yes, that is correct. I think prior to my appointment

8 I think the arrangements in place at PFC were more

9 like a quality control arrangement. It had

10 a laboratory which had a laboratory manager and

11 manufacturing, but there was no single department or

12 person with responsibility for quality across the

13 whole organisation.

14 **Q.** And we can see a short description there of the work

15 of this department:

16 "... Responsible for development and enforcement

17 of Quality Systems, Quality Control laboratory testing

18 of products and intermediates, approval of finished

19 products for use and, latterly, regulatory compliance

20 and product licensing following the removal of Crown

21 Immunity status."

22 Just pausing there, I will want to come on to

23 ask you about product licensing, interaction with

24 medicines inspectors and so on in due course. But you

25 have said there "latterly, regulatory compliance and

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1 **Q.** Did the change of management structure in 1990, did it

2 have any particular advantages or disadvantages?

3 **A.** I think it was a much more coherent process. As

4 an operational manager of one of the units of SNBTS,

5 my line management reporting and accountability was

6 much clearer than it had been before. So I was still

7 subject to the duties and responsibilities of the

8 National Medical and Scientific Director but I had

9 a clear operational manager in the form of

10 Mr McIntosh.

11 **Q.** I want to ask you a little more now about the

12 organisation of the PFC itself. If we take it from

13 your witness statement to start with, so could we have

14 WITN6920001 please, Sully.

15 If we go to page 7. If we pick it up at the

16 bottom of the page. You explain the departmental

17 structure of the centre. So the first department that

18 you identify, manufacturing, responsible for all

19 aspects of product manufacture from bulk collection of

20 plasma from Regional Transfusion Centres through to --

21 top of the next page -- return of manufactured plasma

22 products to RTCs. So that's the Department that's

23 doing the core work of the PFC, to take the plasma and

24 turn it into blood products?

25 **A.** Yes, I actually think it was probably called the

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1 product licensing following the removal of Crown

2 Immunity status", which I think was around 1991?

3 **A.** Yes.

4 **Q.** Obviously there were attempts at regulatory

5 compliance, there were product licences in existence

6 prior to that?

7 **A.** Yes.

8 **Q.** Who had responsibility at that point?

9 **A.** I think that would probably have been myself. When

10 I took over in 1981, I recall Mr Watt saying that it

11 was very important. Although we operated under Crown

12 immunity I do not think anyone in PFC or the wider

13 SNBTS saw that as a satisfactory arrangement. So the

14 PFC did make attempts, and successful attempts, to

15 obtain product licences from the Medicines Control

16 Agency.

17 It was always a moot point. What the status of

18 these licences were, given that we were operating

19 under Crown immunity. A good example of that was

20 in -- I think during 1983 we had just developed a new

21 intravenous immunoglobulin product and we were very

22 anxious to establish its safety and its efficacy and

23 its quality prior to entering into clinical trials and

24 I suggested that the best way of doing that would be

25 to submit a full and comprehensive product licence

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1 application for that product, which we did.
 2 I think the Medicines Control Agency, when we
 3 submitted it were slightly bemused because they
 4 weren't quite sure what to do with it because we were
 5 an organisation operating under Crown immunity. But
 6 there were certainly strong links that we tried to
 7 maintain with the Medicines Control Agency.
 8 **Q.** I will ask you some more about that in due course. If
 9 we continue on this page the next department, research
 10 and development, led by Dr Foster, who obviously the
 11 Inquiry heard from last week.
 12 Was the research and development department
 13 essentially left to set its own priorities, get on
 14 with its own work or was it directed from above by
 15 Mr Watt or Dr Cash or you?
 16 **A.** I think probably all of those people that you have
 17 mentioned, including myself, had a very close working
 18 relationship with the R&D department. Dr Foster was
 19 a very able leader. He was very competent. He had
 20 an excellent track record of innovation and careful
 21 work, but in terms of giving direction to the R&D
 22 department, that would certainly have come from people
 23 like Mr Watt, Professor Cash and latterly myself when
 24 I took over as director.
 25 **Q.** Would it be right to say you might well have been

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1 when you became director, you wouldn't have had much
 2 knowledge or involvement in funding issues prior to
 3 that?
 4 **A.** I might have had some understanding of financial
 5 issues. John -- Mr Watt was very open and he involved
 6 myself quite closely with his operational managers so
 7 you might have expressed frustration about delays in
 8 funding and so on but I would not have been closely
 9 involved I don't think.
 10 **Q.** In terms of funding for research and development, was
 11 there a particular budget for that to your knowledge?
 12 **A.** There was not a ring-fenced budget. It was part of
 13 the overall PFC operational budget. It had its own
 14 staff who were -- so there would have been a staffing
 15 budget for the Department but I don't think -- but
 16 that would have been a local -- so for instance if we
 17 wanted to bring somebody from manufacturing and put
 18 them in R&D then that would have been a perfectly
 19 legitimate and easy thing for me or Mr Watt to have
 20 done.
 21 **Q.** Now, if we could go to page 9 of the statement,
 22 I think it is the next page in fact, bottom of the
 23 next page. You describe the remit of the PFC as
 24 follows in paragraph 29 of your statement:
 25 "At the time of my appointment to SNBTS in 1981

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1 involved in discussions with Dr Foster whilst you were
 2 quality control inspector, but in terms of trying to
 3 give any steer or direction as to how the R&D
 4 department should organise itself or prioritise
 5 particular projects over another, that wouldn't really
 6 have fallen to you until 1984 onwards?
 7 **A.** No, I would have had an awareness of what Dr Foster
 8 was doing. We worked closely together. It was
 9 a relatively small centre, the PFC, so we had daily
 10 contact and daily conversations I think.
 11 **Q.** And then we can take I think the remaining three
 12 departments rather more quickly. Engineering: so
 13 responsibility for all aspects of building, plant and
 14 equipment maintenance. Project engineering:
 15 responsible for specialist engineering support, IT,
 16 et cetera, and then administration and business
 17 support services.
 18 Now, you have told us in your statement, and
 19 I think we heard elsewhere, that in terms of the PFC's
 20 funding, that came through the Common Services Agency?
 21 **A.** That is correct.
 22 **Q.** You have said in your statement you don't recall
 23 funding being denied for key developments or
 24 upgrading. Would it be right to understand you are
 25 really talking there of the period from 1984 onwards

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1 the remit of PFC was to manufacture and supply a range
 2 of plasma derived products (Albumin, Coagulation
 3 Factor products and Immunoglobulin products as well as
 4 anticoagulant and infusion fluids) ..."
 5 Just pausing there, we have heard about albumin,
 6 coagulation factor products, of course, and
 7 immunoglobulin. Very briefly, what does the reference
 8 to anti-coagulant and infusion fluids encompass?
 9 **A.** I think this was a project which was initiated by my
 10 predecessor, Mr Watt, and he felt the facilities that
 11 existed at PFC were not only capable of making plasma
 12 products but we had the ability and the expertise and
 13 the knowledge to make infusion fluids such as sodium
 14 chloride injection and just sterile aqueous solutions
 15 that are used for patient treatment, but also
 16 preparation of specialist anti-coagulant solutions for
 17 use in the blood transfusion service.
 18 **Q.** Then continuing with the sentence:
 19 "... for the treatment of patients throughout
 20 Scotland. In the early to mid 1980s this remit was
 21 expanded to include bulk collection of plasma from
 22 Northern Ireland Blood Service and manufacture and
 23 supply to Northern Ireland of plasma products from
 24 this plasma."
 25 Then you say in the next paragraph this, which

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1 I just wanted to ask you a little bit more about:
 2 "It was considered (particularly by
 3 Professor Cash) an important principle that the
 4 distribution to Health Boards, hospitals and
 5 Haemophilia Centres of manufactured plasma products
 6 should only be via SNBTS (and Northern Ireland)
 7 Regional Transfusion Centres, which should be
 8 responsible for their onward distribution to Health
 9 Board hospitals and Haemophilia Centres. This
 10 arrangement was designed to reinforce the role of RTC
 11 medical staff for the professional and operational
 12 liaison with prescribing doctors in Health Boards.
 13 This principle and practice was maintained throughout
 14 the period of plasma product supply from PFC."
 15 Why was it that Professor Cash in particular
 16 thought this was such an important principle?
 17 **A.** My understanding, which was quite clear, he was very
 18 clear on this point and he often went to great lengths
 19 to actually reinforce it, I think his view was that
 20 everything to do with blood and plasma products was
 21 part of the umbrella term of "transfusion medicine",
 22 and we had centres with consultant medics and other
 23 medical staff and scientific staff and he felt very
 24 much that they should be involved as an interface
 25 between the manufacturer and the ultimate users of the
 25

1 Regional Transfusion Centre.
 2 **Q.** Does it follow from that that at the PFC you would
 3 have, again, a relatively limited knowledge and
 4 understanding of what the approaches to product usage
 5 were in the individual Haemophilia Centres or, indeed,
 6 the hospitals utilising your products?
 7 **A.** Well, the arrangement I described didn't preclude
 8 conversations between myself and Haemophilia Directors
 9 or anybody else in the PFC, and indeed they took place
 10 fairly frequently. Through those channels. But also
 11 through the close relationships we had with the
 12 Regional Transfusion Centres, both the directors and
 13 the scientific and medical staff employed by them,
 14 I think we had quite a good idea of the nature of the
 15 products we made and what their purpose and use was.
 16 **Q.** Then, is it right to understand that the PFC itself
 17 had no medical staff amongst its employees, apart from
 18 Dr Cash as the overall director of -- the
 19 national medical director of SNBTS?
 20 **A.** That is correct, he was the de facto medical adviser
 21 or medical director of PFC.
 22 **Q.** Do you have any recollection as to what proportion of
 23 concentrates produced by PFC would end up being
 24 distributed to hospitals other than Haemophilia
 25 Centres, or is that something you simply wouldn't know
 27

1 products.
 2 So if there was an enquiry about a particular
 3 product, that would go to the regional transfusion
 4 centre and that would be fielded by either the
 5 director or a nominated medical consultant that was
 6 employed by each individual RTC.
 7 **Q.** So, whatever PFC produced would be distributed by PFC
 8 to the Regional Transfusion Centre for onward
 9 distribution by the Regional Transfusion Centre to
 10 a Haemophilia Centre or to a hospital?
 11 **A.** Absolutely. That's exactly what happened.
 12 **Q.** Which -- in practice, would that mean that the PFC had
 13 limited ties, directly, then, with the clinicians who
 14 were prescribing and using its products?
 15 **A.** Yes, I think we did have very limited -- I wouldn't
 16 call it limited access but the main route of
 17 communication on issues associated with plasma
 18 products would have always been initially via the
 19 Regional Transfusion Centre and the nominated
 20 consultant for whatever the product was.
 21 If they felt the need to involve somebody from
 22 PFC in responding to that, then we were quite free to
 23 do that, but it was a very important principle,
 24 underscored by Professor Cash on numerous occasions.
 25 And so everything that we produced went through the
 26

1 because everything went through the Regional
 2 Transfusion Centre?
 3 **A.** I think we knew -- we knew sufficient for our purposes
 4 where the products went. We knew albumin was
 5 distributed by the Regional Transfusion Centres to
 6 most hospitals because it is used so widely in patient
 7 care, for acute emergencies and so on. We would have
 8 known where the immunoglobulin products went. And we
 9 certainly knew where the haemophilia treatment
 10 products were sent and located, and we -- I --
 11 although, as I have said, PFC was very much the
 12 wholesaler to the Regional Transfusion Centres, we had
 13 a fairly good knowledge, geographical knowledge, of
 14 where the products went and how they were used.
 15 **Q.** In relation specifically to Factor VIII and Factor IX
 16 concentrates, did you have any sense of the extent to
 17 which they were being used outside of Haemophilia
 18 Centres? I don't mean for home treatment, I mean like
 19 hospitals other than Haemophilia Centres --
 20 **A.** Coagulation factor products, I think I knew at
 21 a fairly early stage that -- well, Factor VIII would
 22 only be used in the context of haemophilia. I don't
 23 think there are any other uses for Factor VIII, so
 24 I think it was quite clear that that was only used for
 25 haemophilia care.
 28

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

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

8 A. No.

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

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

13 A. From 1981?

14 Q. In 1981, when you arrived, yes.

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

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1 pharmaceutical facility.

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

5 A. Yes.

6 Q. So it is BNR0000572. It is not the clearest document
7 to read but we can see at the top of the page it
8 refers to an "Inspectorate report on the current
9 status at the Protein Fractionation Centre, Edinburgh
10 as of October 1 1981". So you were in post at this
11 point in time?

12 A. I was, yes.

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

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

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

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

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

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

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1 standard operation procedures is generally acceptable.

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

4 So that was the work you were focusing on in
5 1981?

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

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

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

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

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

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

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1 this was necessarily the only thing done but your
 2 appointment focused on the quality assurance matters,
 3 but there were still a number of problems identified
 4 in the first inspection regarding buildings and
 5 facilities that hadn't been addressed and that the
 6 Inspectorate hadn't even had proposals for addressing.
 7 Was that your understanding?
 8 **A.** I think that's probably right. This was October.
 9 I think you --
 10 **Q.** October '81, the first inspection having concluded in
 11 January 1980. So over 18 months on.
 12 **A.** Absolutely. Well, when I arrived in 1981 I don't
 13 think there was any action being taken in response to
 14 the Medicines Inspector's report. It was the
 15 beginning of a fairly long road to get the -- to
 16 identify the operational solutions to the criticisms
 17 to get the funding, to create the necessary close down
 18 periods, shut down periods at PFC to implement these.
 19 I think by then I would have had a fairly good
 20 idea on what needed to be done, and I think there may
 21 have already been some work in progress for areas
 22 where simple changes could be made, like labelling and
 23 packaging areas and so on, but I think one of the
 24 first things I did was to improve the arrangements.
 25 But I don't think this happened in October 1981. But

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1 expiry of the first manufacturer's licence -- and I'm
 2 afraid I don't have the precise date, but presumably
 3 around 1981, I think it was a five-year --
 4 **A.** I think it was earlier than that, the first -- oh, the
 5 manufacturing licence?
 6 **Q.** The manufacturing licence.
 7 **A.** I'm sorry, yes. Yes.
 8 **Q.** So whatever the precise date, which I am sure we can
 9 establish, from that point until, would it be then,
 10 the early 1990s, PFC did not have the manufacturer's
 11 licence, it relied instead on Crown immunity?
 12 **A.** I think that is correct.
 13 **Q.** In practical terms, and in relation to the
 14 deficiencies that the Inspectors had identified with
 15 regard to buildings and facilities, to what extent
 16 were those addressed and when?
 17 **A.** They were addressed throughout the 1980s. It was
 18 a continuous process, involving numerous refits to the
 19 organisation -- which had to be done in small pieces
 20 of activity because we couldn't afford to close the
 21 facility down for a year to do a complete rebuild and
 22 refit of the organisation. So it was a progressive
 23 requirement.
 24 And although I've said I didn't think funding
 25 generally inhibited the activities of PFC, it was

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1 by that stage I will have identified the need for
 2 an automated bottle and vial dispensing and
 3 sterilisation and dispensing facility, because those
 4 activities were entirely manual in 1981 and that was
 5 a clear and outstanding requirement to be rectified.
 6 **Q.** Now, we understood from Dr Foster's evidence that the
 7 original manufacturing licence, when it came to expire
 8 in the early 1980s, was not renewed or -- in the sense
 9 that a further application for a manufacture's licence
 10 was not submitted on the basis of advice to or from
 11 SHHD in reliance upon Crown immunity.
 12 **A.** Yes.
 13 **Q.** What's your understanding of the position and why that
 14 happened?
 15 **A.** My understanding is similar to Dr Foster's. I think
 16 SHHD were, at that time -- I think through the chief
 17 pharmacist of SHHD -- were very anxious that we didn't
 18 step outside our authority, which was granted by the
 19 Secretary of State for Scotland. So his view was that
 20 we had the authority to do what we did directly from
 21 the Secretary of State from Scotland and there was no
 22 requirement to go through central licensing and
 23 processing systems. We thought this was an appalling
 24 idea but it was what SHHD's position was at the time.
 25 **Q.** Is it right to understand that from the point of

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1 quite a sustained battle, I think, with SHHD and CSA
 2 to get the necessary funding at the right time.
 3 Eventually it came through but that process probably
 4 took -- and it was a continuous process and carried
 5 out through the 1980s until the early 1990s, where
 6 there was a very substantial investment in the centre
 7 to increase warehousing and various other essential
 8 buildings.
 9 **Q.** And there was a shut down for around three months at
 10 the end of 1984 --
 11 **A.** That is correct.
 12 **Q.** -- for building works. Was that the longest period of
 13 shut down up until that point or had there been
 14 earlier periods of shut down for --
 15 **A.** I think there would have been earlier periods of shut
 16 down and they may have been shorter, but they may have
 17 been around about the same time. We were able to do
 18 it in 1984 because we had such good stocks of product.
 19 **Q.** Yes. We will certainly be coming onto the issue of
 20 the surplus or stockpile and how that was built up and
 21 what was done with it. Just on the conditions at the
 22 PFC. If we could look at one of the written
 23 statements please to the Penrose Inquiry on this
 24 topic. PRSE0001919.
 25 We can see this is a statement entitled,

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

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

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

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

19 Q. Then just continuing:

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

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

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

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

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

15 Q. Then picking it up:

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

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

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

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

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1 small volume mixing system, and to do that sensibly.
 2 And to run the downstream processes following the
 3 initial fractionation, we were constrained by the
 4 requirement to shoehorn those into an eight-hour
 5 working day and sometimes manufacturing processes
 6 don't usefully fit. So it constrained our activities.
 7 It actually constrained some of the development
 8 programmes as well because they had to be adapted to
 9 basically fit the Whitley Council employment
 10 conditions for staff working at the facility.
 11 **Q.** If we then just go to your statement to this Inquiry,
 12 WITN6920001, page 24. I just want to look briefly
 13 with you at the range of products produced by the PFC.
 14 This is specifically in relation to factor
 15 concentrates. So if we just zoom in please on the
 16 table. Again, just so that we understand what was and
 17 wasn't being produced, you have got there:
 18 "1956, Factor VIII concentrate (Cohn fraction
 19 I), freeze dried.
 20 "1966, Cryoprecipitate ...
 21 Then, 1968, the first freeze-dried Factor IX
 22 concentrate, is that right, being produced by SNBTS?
 23 **A.** Yes.
 24 **Q.** Referred to as PPSB?
 25 **A.** Yes.

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1 So, starting with the regional transfusion
 2 services in Scotland, is it right to understand that
 3 PFC was essentially an equal partner in terms of the
 4 structure of SNBTS with each of the regional
 5 transfusion services?
 6 **A.** I think that's correct, yes. The director of PFC
 7 always sat with the other directors at the director's
 8 meetings, the coordinating group meetings, the
 9 meetings of Haemophilia Centre Directors and so, yes,
 10 it was a fully integrated and I think although it
 11 did -- the nature of this work was quite different to
 12 an RTC, it was a fully integrated part of the
 13 management systems within SNBTS.
 14 **Q.** With Professor Cash as the -- or Dr Cash, later
 15 Professor Cash, as the National Medical Director,
 16 essentially in overarching control and to whom the
 17 directors of the regional transfusion services and
 18 then the director of the PFC could all report?
 19 **A.** It wasn't quite like that and this was always
 20 a frustration for Professor Cash and I think to
 21 an extent Regional Transfusion Centre directors, that
 22 I think each of them were like myself responsible to
 23 the Committee of Management of the Common Services
 24 Agency.
 25 So in many senses they were -- they had

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1 **Q.** Then 1971 we see DEFIX. Is it right to understand
 2 DEFIX remained the Factor IX concentrate then that the
 3 PFC produced over the following years?
 4 **A.** It did, yes. That's right, yes.
 5 **Q.** Then 1974 we have the first Factor VIII concentrate
 6 being produced; is that right?
 7 **A.** That's my understanding, yes.
 8 **Q.** NY?
 9 **A.** Yes.
 10 **Q.** Then NY remained the name of SNBTS' Factor VIII
 11 product until we get to Z8 in the second half of the
 12 '80s?
 13 **A.** Yes, that is correct.
 14 **Q.** We can see that just at the top of the next page.
 15 Obviously there was then heating.
 16 **A.** There was heat treatment programmes, yes.
 17 **Q.** If we go to the next page.
 18 So then we can see that the dry heated DEFIX
 19 referred to as "modified DEFIX", and the "modified
 20 NY", and then the production of Z8, April 1987.
 21 Then I don't think I need to ask you about any
 22 of the later products, such as Liberate or HIPFIX.
 23 Can I turn -- sorry, we can take that down,
 24 thank you -- to ask you a little bit about the PFC's
 25 relationship with other organisations and bodies.

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1 an independent -- they could have operated
 2 an independent -- independently of Professor Cash. In
 3 practice they never did and Professor Cash I think
 4 often expressed his concern and frustration that he
 5 didn't have this line management authority. But
 6 I think he was a highly consultative individual and
 7 sought to get agreement and 99% of the time did get
 8 agreement with Regional Transfusion Centre directors
 9 and the PFC director on key issues that emerged from
 10 time to time.
 11 **Q.** Now, obviously, PFC's relationship with the regional
 12 transfusion services in Scotland was, as you described
 13 it, was different from the relationship between BPL in
 14 England and Wales and its relationship with the
 15 regional transfusion services of England and Wales.
 16 Were there particular advantages or
 17 disadvantages to the system in Scotland in your mind?
 18 **A.** Well, as it operated, certainly in the 1980s and
 19 perhaps for the duration of my employment, it always
 20 seemed to me to be the sensible way to run
 21 an organisation. I think in the early 1980s, it
 22 wasn't quite a truly national service. Individual
 23 centres had some freedom to act under the direction of
 24 the medical directors for the individual regions but
 25 for the large part, 99% of the time, it did operate

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1 and function very much as a national service.
 2 And I think that provided the opportunity and
 3 the ability to develop the programmes it did and the
 4 reason, for example, in 1984, that the SNBTS had
 5 managed to develop large product stocks was that --
 6 the basis for that was set in the mid-1970s, when
 7 Dr Cash as he was then was director of the Southeast
 8 Scotland Blood Transfusion Centre and he instituted
 9 a major programme to convert doctors and clinicians
 10 and surgeons to the use of packed red cells instead of
 11 whole blood. I know it is a long distance between
 12 that and self-sufficiency but it is the fundamental
 13 building block, or it was in the 1980s, for
 14 self-sufficiency.
 15 So those programmes he was able to -- and when
 16 he became National Medical Director he reinforced
 17 those programmes and I think was very instrumental and
 18 successful in moving Scotland into an area where it
 19 used predominantly packed red cells and whole blood
 20 became a very rare product and it was that that
 21 created the ability for PFC to build the stocks that
 22 it did during the early 1980s.
 23 **Q.** You as director of PFC, Mr Watt as your predecessor,
 24 attended regular meetings with the other SNBTS
 25 directors; is that right?

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1 basically a mini conference with the scientific and
 2 senior technical staff. I think latterly that became
 3 a fixed activity and it developed into -- initially,
 4 it was run by the scientists themselves with the
 5 blessing of Professor Cash and regional doctors and so
 6 on.
 7 It subsequently turned into a combined
 8 scientific meeting but also a social gathering for
 9 SNBTS staff. It was usually held at weekends and
 10 individuals, just to give some measure of the
 11 importance of it, I think individuals were required to
 12 pay to go to it actually. But it was a very important
 13 annual meeting of the whole of the SNBTS team.
 14 **Q.** Then in terms of the involvement of Northern Ireland,
 15 Dr McClelland, Dr Morris McClelland, once the
 16 arrangement with Northern Ireland was established, he
 17 effectively joined the SNBTS directors meetings; is
 18 that right?
 19 **A.** Yes.
 20 **Q.** What about the relationship between the PFC and the
 21 SHHD? First of all, in practical terms, what was the
 22 nature of the relationship? How often were there
 23 interactions with the SHHD?
 24 **A.** It varied over time. I think certainly throughout my
 25 tenure within SNBTS there were annual meetings of the

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1 **A.** Yes.
 2 **Q.** Were they quarterly, roughly?
 3 **A.** I think they were quarterly or as required there would
 4 have been *ad hoc* meetings called of -- well, there
 5 were, I think from memory they were -- the directors
 6 meetings, of which the representatives from SHHD would
 7 attend, usually the medical officer, I think they were
 8 quarterly. I think they were more regular
 9 coordinating group meetings and, as the title
 10 suggests, the coordinating group was designed to allow
 11 the National Medical Director to coordinate and, where
 12 necessary, standardise the activities of all the
 13 Regional Transfusion Centres.
 14 **Q.** There was something called Scot Blood which
 15 I understand to be an annual conference?
 16 **A.** Yes.
 17 **Q.** Who organised that and what kind of issues in the
 18 early '80s would it look at?
 19 **A.** I think the genesis of the Scot Blood meeting was with
 20 the scientific staff of SNBTS felt, I think it was
 21 probably as far back as in the 1970s, that it would be
 22 a good idea if they organised an annual conference or
 23 an annual meeting, probably not a conference then, but
 24 an annual meeting where all the scientists in the
 25 SNBTS throughout Scotland could get together and have

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1 annual SNBTS and Haemophilia Directors' Group which
 2 was very instrumental in driving forward the programme
 3 for provision of haemophilia -- a product for treating
 4 haemophilia. And that was always either chaired or
 5 certainly attended by senior medical staff and other
 6 officials from SHHD.
 7 From that group a coagulation factor working
 8 party I think it was called, this is different from
 9 Professor Cash's coagulation factor study group, this
 10 was an annual -- the working party was established to
 11 take forward some of the output from the annual
 12 meeting and develop it into operational activity.
 13 And I think, as I say, during my tenure I think
 14 it was Professor Ludlam who chaired that and that
 15 would have also been attended by medical staff from
 16 SHHD. So they were closely appraised of what was
 17 happening within SNBTS with respect to the provision
 18 of haemophilia treatment products.
 19 **Q.** In the course of the 1980s who were the officials from
 20 SHHD that you recall having dealings with on --
 21 **A.** Dr Bell, Dr Burt Bell, who was a great enthusiast for
 22 self-sufficiency, I recall. And I think he was partly
 23 instrumental in setting up the annual meeting of
 24 haemophilia directors and SNBTS directors. There were
 25 a number of other -- Dr Forester, who was not

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

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

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

25 **Q.** We will certainly pick up that particular issue at
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1 limited, if essentially the expectation was that SHHD
2 would follow the DHSS's line?

3 **A.** As my statement says, that is my recollection.
4 I can't recall any situations or circumstances where
5 SHHD took a different approach to a product safety --
6 a blood safety issue. They were always step in step
7 with DHSS. Where they did diverge was the policy
8 approach to self-sufficiency throughout the 1970s and
9 1980s where SHHD were always quite explicitly
10 committed to I think what we would regard as the true
11 definition of self-sufficiency, which was meeting all
12 the needs of patients in Scotland for products from
13 voluntary non-remunerated donors. That was the
14 target. It wasn't to balance commercial supplies and
15 so on, so there was a divergence of policy there.

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

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1 a later stage of your evidence.

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

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

10 Then we can see your reply:

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

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

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

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1 still be within a UK context.

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

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

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

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

14 **Q.** Yes.

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

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

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1 confidentiality of those types of meetings at a later
 2 stage.
 3 Sir, perhaps we could take the morning break?
 4 **SIR BRIAN LANGSTAFF:** Yes, we will do that and come back
 5 at 11.50 am.
 6 Now this is the first break. Let me say to you
 7 what I say to all witnesses either at the very
 8 beginning of their evidence or at the first break, and
 9 it is this: you are giving evidence, you must not
 10 discuss the evidence you have given or, for that
 11 matter, any evidence which you think you may later be
 12 asked to give with anyone, whoever that anyone is.
 13 But you can talk about anything else you like.
 14 **A.** Thank you, I understand.
 15 **SIR BRIAN LANGSTAFF:** 11.50 am.
 16 (11.20 am)
 17 (A short break)
 18 (11.50 am)
 19 **SIR BRIAN LANGSTAFF:** Yes.
 20 **MS RICHARDS:** Dr Perry, still on the topic of the PFC's
 21 relationship with other bodies, I wanted to ask you
 22 next about the relationships with BPL.
 23 First of all, on a personal level, we have heard
 24 evidence about the relationship between Mr Watt and
 25 Dr Lane, do you have any particular recollections of

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1 frequent, contact with Dr Lane and of course I met him
 2 periodically at meetings and we would always have
 3 constructive discussions I think.
 4 **Q.** Now, if we just go to your statement to this Inquiry,
 5 so WITN6920001, and if we go to page 15, bottom half
 6 of the page. You say in paragraph 46 -- sorry, let me
 7 pick it up in paragraph 45. You say there:
 8 "... PFC ... considered its relationship with
 9 BPL to be very important, although as separate units
 10 under different UK jurisdictions there were few, if
 11 any, mechanisms or fora for regular formal liaison and
 12 collaboration. However there was a regular and
 13 productive scientific collaboration."
 14 Then if we go to the next paragraph, please,
 15 Sully. You reiterate in the opening sentence of
 16 paragraph 46 you don't recall any formal liaison
 17 mechanisms between BPL and PFC:
 18 "... although Professor Cash was a consistent
 19 and strong advocate for closer and more formal
 20 cooperation between UK Blood Services concerning the
 21 development of safer NHS products."
 22 Then if we look at the last sentence on that
 23 page you say:
 24 "I am not aware of or cannot recall any formal
 25 mechanisms being established by DHSS/SHHD or the Blood

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1 the relationship between Dr Cash and Dr Lane?
 2 **A.** Not a great deal. I think there was some -- they had
 3 conflicting views which I think probably arose from
 4 the discussions that took place in the 1970s and
 5 perhaps early '80s about how the overall supply of UK
 6 plasma should be fractionated in Scotland versus at
 7 BPL.
 8 But I attended meetings where they were both
 9 present and there was always a constructive dialogue.
 10 I don't think they agreed on all issues but, as I said
 11 about Mr Watt, they were both strong personalities and
 12 had clear views on certain topics.
 13 **Q.** Then we have heard evidence that at an informal level,
 14 and I have in mind the written evidence of Dr Smith
 15 and then the written and oral evidence of Dr Foster
 16 and Dr Snape, that there were good informal links and
 17 communications between, for example, those working on
 18 research and development in PFC and those working on
 19 research and development in BPL.
 20 What was the nature of your own interactions
 21 with BPL? Who did you tend to have dealings with?
 22 **A.** I had dealings with Dr Snape, Dr Smith, Dr Smith's
 23 co-worker, Dr Winkelman, Dr Lane. Although probably
 24 more frequently with Dr Smith and Dr Snape than
 25 Dr Lane. But I had fairly regular, though not

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1 Services for formal cooperation concerning joint
 2 product development programmes."
 3 Then if we just go over the page. You then set
 4 out, I don't need to go to any particular paragraph,
 5 but you talk about your own relationships with BPL
 6 personnel and communications in particular between
 7 Dr Foster and Dr Smith.
 8 If we go to the next page then, please, Sully,
 9 and just look at paragraph 52. You say:
 10 "There may have been some merit in a joint
 11 approach for the development, production and supply of
 12 plasma products for the UK wide NHS (particularly for
 13 providing increased benefit of scale for PFC) but this
 14 did not apparently enjoy the support of DHSS or SHHD
 15 to the extent of serious consideration or study."
 16 Can you just assist us first of all with what
 17 you mean by the passage in brackets, referring to
 18 providing increased benefit of scale for PFC?
 19 **A.** I think it was simply that the PFC, as it became set
 20 up for Scotland and Northern Ireland, was a relatively
 21 small fractionator in international terms. They
 22 were -- certainly compared to BPL and certainly
 23 compared to some of the larger units in France and the
 24 Netherlands and so on. And as with most endeavours of
 25 this type, increased scale creates greater efficiency.

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1 So, I think PFC always felt, certainly during the
2 1970s and 1980s, that it would benefit not only PFC
3 but the UK as a whole to have a more equitable split
4 of plasma to supply to both PFC and BPL.

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

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

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

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

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1 inactivated was non-A, non-B hepatitis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 fractionators, the pharmaceutical companies producing
 2 their Factor VIII and so on, to what extent was there
 3 any relationship, formal or informal, between PFC and
 4 those pharmaceutical companies?
 5 **A.** I think we knew who the commercial companies were and
 6 I think we knew some of the key, particularly
 7 scientific staff involved in those activities.
 8 I don't recall there ever being a free exchange of
 9 information. I think, as so many others have said,
 10 the commercial sector kept their processes and their
 11 know-how very closely guarded secrets, for obvious
 12 commercial reasons. So although we would have
 13 dialogue, we had a broad general understanding of what
 14 they are doing but we never -- I don't think we ever
 15 accessed at any deep level a scientific understanding
 16 of their processes and how they made them work.
 17 **Q.** It might be said, having regard of Dr Foster's
 18 evidence, that a picture emerged of being able to
 19 glean bits and pieces here and there at international
 20 conferences on a -- small pieces of a jigsaw?
 21 **A.** Yes.
 22 **Q.** It would presumably, in principle, have been
 23 enormously helpful if there had been a more extensive
 24 or formal process for the exchange of information?
 25 **A.** Kind of global co-operation.

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1 **Q.** Did you ever for example get the minutes of the
 2 meetings of the Regional Transfusion Directors of
 3 England and Wales?
 4 **A.** I think I probably did see them, yes.
 5 **Q.** Would that have been through Professor Cash?
 6 **A.** That would have been through Professor Cash.
 7 **Q.** Can I then turn to relationships with Haemophilia
 8 Centres and Haemophilia Centre Directors. We have
 9 obviously touched on that in relation to Scotland
 10 because of your earlier evidence about
 11 Professor Cash's principle of everything going through
 12 the Regional Transfusion Centres.
 13 Did you have a closer relationship with a degree
 14 of interaction with the Haemophilia Centre in
 15 Edinburgh for reasons of geography, geographical
 16 proximity than other services or was there no real
 17 difference in Scotland?
 18 **A.** I think it is probably true to say we did have
 19 a slightly closer relationship with the Centre in
 20 Edinburgh. It was adjacent to the transfusion service
 21 in Edinburgh and it was literally five miles from
 22 the PFC. And Professor Ludlam was the chair of the
 23 Coagulation Factor Working Party. So, yes, we did
 24 have a close working relationship. But that wasn't to
 25 the exclusion of other haemophilia directors.

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1 **Q.** Yes.
 2 **A.** Well, yes. But I think, for reasons that I have
 3 described -- the not-for-profit sector was much more
 4 like a family in Europe. They weren't competing. The
 5 national services in France, Finland, Holland, the UK,
 6 weren't competing with each other for markets so there
 7 was a much freer exchange of scientific information
 8 and co-operation.
 9 The commercial sector were fiercely competitive
 10 with each other and still are. So they guarded their
 11 proprietary information and know-how, as I say, very
 12 closely. They were closely kept secrets. So there
 13 was never in my view any real prospect of accessing
 14 their information and if we did -- if one did then
 15 more often than not it would be patented. So not
 16 accessible for the public sector to utilise.
 17 **Q.** Now, moving then back to England and Wales but now the
 18 regional transfusion services in England and Wales.
 19 Is it right to understand that at the PFC you didn't
 20 have much by way of dealings or interactions with the
 21 Regional Transfusion Directors in England and Wales?
 22 **A.** I think that's a fair summary, yes. I think we knew
 23 many of the regional directors and they knew us but
 24 these were informal contacts met at conferences and
 25 meetings.

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1 **Q.** In relation to the Haemophilia Centres in England and
 2 Wales, we will come on to Northern Ireland in
 3 a moment, there was no particular tie or, as
 4 I understand it, regular degree of interaction other
 5 than through a degree of PFC attendance at the annual
 6 meetings of the UK Haemophilia Centre Directors?
 7 **A.** I think that is correct. I think that's true.
 8 **Q.** And I think we see you attending UKHCDO meetings
 9 fairly early on in your PFC career, October 1981, and
 10 you were there again, I think, in '82 and '83?
 11 **A.** Yes.
 12 **Q.** What was the thinking behind having PFC represented at
 13 those meetings?
 14 **A.** I think Mr Watt, who I reported to, felt it was a good
 15 idea that I should be exposed to these meetings
 16 because, in the absence of a formal training
 17 programme, this was a very good way of learning what
 18 the issues were and what the priorities were and what
 19 the -- what was happening in haemophilia care. So
 20 these were very important meetings.
 21 I don't think I probably contributed greatly to
 22 them but I certainly listened carefully and learnt
 23 a great deal, at a personal level. But they were UK
 24 meetings. So they were there to represent the
 25 Scottish haemophilia directors and the Northern

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1 Ireland haemophilia directors as well.
 2 **Q.** Then, specifically in relation to Northern Ireland,
 3 you had contact with Dr Morris McClelland, as the
 4 Regional Transfusion Director, through his attendance
 5 at SNBTS meetings once the arrangement with Northern
 6 Ireland was established.

7 What about the Haemophilia Centre in Northern
 8 Ireland and the Haemophilia Centre Director, Dr Mayne,
 9 to what extent were there any interactions between the
 10 PFC and Dr Mayne or her centre?

11 **A.** I never went to a Haemophilia Centre in Belfast but
 12 I think as soon as PFC started processing Northern
 13 Irish plasma and supplying them coagulation factors,
 14 albumin and immunoglobulin products back,
 15 Elizabeth Mayne, I think it is correct that she joined
 16 the annual meeting of Scottish Haemophilia Centre
 17 Directors and Transfusion Directors, but she certainly
 18 attended the Coagulation Factor Working Party on
 19 a regular basis. So we had quite a close relationship
 20 with Dr Mayne. She was a good colleague.

21 **Q.** Can I then come on to some aspects of regulation. We
 22 have obviously touched on the issue relating to the
 23 manufacturer's licence. Just in relation to that, is
 24 it right to understand that Dr Cash and Mr Watt,
 25 neither of them agreed with the decision not to renew

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1 in relation to product licences, I just want to ask
 2 you about interactions with another regulatory body,
 3 NIBSC, so the National Institute for Biological
 4 Standards and Controls. Have I got that right?

5 What interactions did PFC have with NIBSC?
 6 **A.** We had, I guess in some senses, a formal relationship
 7 with the NIBSC, as the national control authority,
 8 whose responsibility, amongst many other things, was
 9 to approve batches for release. I think latterly in
 10 our relationship to do virological testing, to test
 11 product batches for potency and so on. So that was
 12 the formal relationship and it was very close and
 13 mirrored very much other organisations that had
 14 products on the market in the UK.

15 But there was also a -- I guess you would call
 16 it a more informal relationship between scientists in
 17 PFC, and the wider SNBTS, with scientists at NIBSC.
 18 For example, Dr Cuthbertson was quite closely involved
 19 with NIBSC in developing assay techniques for testing
 20 for virological markers in plasma products and
 21 adapting test systems that were available and designed
 22 for single donation use to assay systems that would be
 23 sufficiently sensitive for testing plasma product. So
 24 that is an example of the sort of collaboration.

25 And I think NIBSC set up various working

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1 the manufacturer's licence?

2 **A.** This would have been prior to 1984?

3 **Q.** Yes.

4 **A.** I think as I have said previously, I think both
 5 Mr Watt and Professor Cash felt that formal regulatory
 6 approval of PFC was an important objective, but
 7 I think certainly following the inspection by Flint
 8 and Purves in '79 and '80, I think there was probably
 9 a view taken by both Professor Cash and Mr Watt that
 10 it would unlikely -- an application for
 11 a manufacturer's licence would have been unlikely to
 12 have been granted at that stage.

13 So the absence of the manufacturing licence
 14 became an important -- I guess I would call it
 15 an important tool to try to get the funding that we
 16 felt we needed.

17 **Q.** Just for the benefit of others and the transcript,
 18 there is a reference to the views of Mr Watt and
 19 Dr Cash and their disagreement with the decision not
 20 to renew the manufacturer's licence in a document put
 21 together by Mr McIntosh for the Penrose Inquiry. I am
 22 not going to go to it given that it predates, I think,
 23 your involvement. PRSE0002556, page 16 is the
 24 reference for that.

25 But before I ask you a little about the process

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1 parties. I think there was -- I have seen documents
 2 that have been sent to me, and I certainly recall, of
 3 an AIDS scientific working party that was established
 4 by NIBSC.

5 So NIBSC, I think, part of its vision, certainly
 6 in the early 1980s by its then director,
 7 Geoffrey Schild, was to become much more integrated in
 8 the work of the transfusion service, and the best way
 9 to do that was to set up working groups on scientific
 10 issues.

11 **Q.** Can we just look at your statement to this Inquiry.

12 WITN6920001, page 13, please, Sully.

13 I just wanted to ask you a little bit more about
 14 paragraph 40. You described the PFC as being:

15 "... required to submit samples of finished
 16 products, intermediates and plasma pools for control
 17 testing and batch release to NIBSC as the national
 18 control laboratory."

19 Can you just help us understand a little more
 20 about how that process worked. So what samples would
 21 be submitted to NIBSC and at what point in the -- or
 22 what stage in the life cycle of a product would that
 23 take place?

24 **A.** I can certainly explain what it meant, and what
 25 I can't give you is a timescale for the various

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

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

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

25 And I think when this system operated, we
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1 have perhaps been -- or maybe -- well, it talks about
 2 plasma pool, so it might have been part of a more
 3 informal collaboration on a scientific level. I
 4 don't -- on reflection, I don't recall there being any
 5 specific regulatory requirement submitting
 6 intermediate fractions for testing by NIBSC but we may
 7 well have done that as part of a scientific
 8 collaboration.

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

13 **A.** Primarily virological markers, but it also had this
 14 important role of standardising Factor VIII assays.
 15 NIBSC, amongst the other things it did, it did create
 16 international standards for Factor VIII and it was
 17 always a matter of concern when a new international
 18 standard was coming out because at a stroke a change
 19 in the international standard could have reduced the
 20 measured yield in PFC products -- and this problem
 21 would have applied to BPL as well -- by as much as
 22 20%.

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

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

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

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

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

24 **A.** It could well have been that at some stages
 25 intermediate fractions, like Fraction II -- this would
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1 **Q.** Then, can we look at a letter that you wrote in
 2 late 1987. It was referred to in one of the extracts
 3 to your Penrose evidence that we looked at before the
 4 break.

5 It is at PRSE0000712, please, Sully.

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

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

24 Then just continuing with the next paragraph:

25 "Perhaps my sustained anxieties stem mainly from
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1 the fact that the manufacturing activities of the
2 Centre are at a level substantially above that for
3 which the Centre was designed and there exist major
4 breaches of GMP in our day to day activities as
5 a consequence which can only be resolved by the
6 provision of additional buildings. One might argue
7 therefore that I am professionally negligent in
8 allowing such activities to continue. However,
9 I continue to do so in the interests of
10 self-sufficiency and, in my opinion, in the public
11 interest. The Agency is aware of this position but to
12 my knowledge has never explicitly instructed me to
13 continue with a policy of growth. I am therefore
14 knowingly operating the Centre above its capacity and
15 I am ever conscious of recent disasters elsewhere
16 whereby the corporate body and individuals are subject
17 to criminal proceedings. As the captain of this
18 particular ship, I find the analogy too close for
19 comfort."

20 Then over the page you conclude:

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

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

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

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

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

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

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

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

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

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

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

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

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

12 A. I think that was probably assigned to me when I joined
13 in 1981. I think that was one of the portfolio of
14 activities, and I think, as I briefly mentioned
15 before, one of the major tasks that I undertook in
16 1983 was to assemble a comprehensive product licence
17 application which was an enormous undertaking at the
18 time for our newly developed intravenous
19 immunoglobulin product.

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

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

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1 studies, our processes, and their intricate designs to
 2 peer review. And the only peer review system that
 3 existed was product licensing. And that, for example,
 4 was the rationale I made for applying for a product
 5 licence for intravenous immunoglobulin in 1983.
 6 I did get a response when the SHHD discovered
 7 that I had submitted this licence to the MCA. I think
 8 the chief pharmacist he expressed his concern that
 9 I had, I think, in his words, usurped the authority of
 10 the Secretary of State.
 11 **Q.** I'm just going to ask you to look at part of your
 12 evidence to the Penrose Inquiry on the licensing
 13 system in broad terms, PRSE0006025.
 14 So this is an extract from your evidence -- or
 15 this is the transcript, sorry, of your evidence on
 16 13 May 2011. If we go to page 42, please. We can
 17 pick it up I think at line 16. This is in a question
 18 that was being asked to you. It says:
 19 "And what you are referring to there is that the
 20 licensing of products -- I think the idea in your
 21 statement -- please correct me if I am wrong -- is
 22 that the fact that a commercial product was licensed
 23 would inform the doctor or the clinician as to whether
 24 or not it was appropriate to use that material; in
 25 other words, if it was licensed, then it was all right

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1 disruption in the treatment of patients that it was
 2 considered an inappropriate thing to do."
 3 Sorry, can we have the rest of the first half of
 4 the page, Sully, because it is not in fact that point
 5 I want to ask you about at this stage. It is the next
 6 bit. You continue:
 7 "I would still take the view that the licensing
 8 system was and is set up to establish that products
 9 can and should still be used safely in clinical use.
 10 That doesn't preclude an individual doctor for a whole
 11 number of reasons not using a particular product. But
 12 I agree, that there is a slight conflict there. The
 13 system, you know, as we now know, was not as effective
 14 as it might have been but the consequence of creating
 15 a safer environment was to expose patients to no
 16 treatment at all, certainly with concentrates."
 17 Now, I'm showing you that for present purposes
 18 really just to understand what you thought the purpose
 19 of the product licensing system was. It was intended,
 20 is this right, to provide a degree of external
 21 assessment of the safety of the product?
 22 **A.** Yes, before you showed me that I was going to clarify
 23 that that was the other major reason and prescribing
 24 doctors, although they understood the status of PFC,
 25 they had a reasonable expectation to understand what

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1 to use it. Is that what you are suggesting?"
 2 Then we have your answer:
 3 "I think that's what the licensing system is
 4 intended to achieve. It's intended to give
 5 prescribing doctors [top of the next page] clear
 6 indications that the product is safe, it's
 7 efficacious, its risk/benefit balance has been
 8 properly and objectively assessed and it is suitable
 9 for use, absolutely."
 10 Then there is a question -- sorry, if we go back
 11 to the whole page -- or an observation put to you
 12 along the lines that the evidence the Penrose Inquiry
 13 had heard was that licence didn't make any particular
 14 impact on the clinical decision-making of Haemophilia
 15 Centre Directors.
 16 Then if we go to the bottom of the page you were
 17 asked if you wanted to comment on that and at line 21
 18 you said:
 19 "Only to say that at that particular time
 20 I think the licensing and the continued licensing of
 21 products was part of the confused world that we
 22 operated in. I think, as we have discussed
 23 previously, the notion of removing licences for these
 24 products on the basis of what we now describe as
 25 a precautionary principle would have created so much

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1 measures we had taken to assure the safety of these
 2 products. And the only system that exists for doing
 3 that is the licensing system.
 4 **Q.** If we then turn to the question of the product
 5 licences for factor concentrates at the PFC. We will
 6 see, probably this afternoon when we look at some of
 7 the examples of package inserts and product warnings,
 8 we will see that licence applications were submitted
 9 in I think 1978, designed by Mr Watt, for product
 10 licences for Factor VIII and Factor IX, so the NY and
 11 for DEFIX. So that was I think in 1978 and they would
 12 therefore have come up for renewal in around 1983?
 13 **A.** Yes, that is right.
 14 **Q.** As far as you can recall, were those licences renewed
 15 in 1983 for the factor concentrates?
 16 **A.** I think they were but I would have to check on
 17 individual products and so on but I believe there was
 18 an attempt made to -- or perhaps a successful attempt
 19 to get them re-licensed and their licences extended.
 20 **Q.** Now --
 21 **A.** I would add that the original licence application in
 22 1978, although it was written carefully, it probably
 23 wasn't as substantive as the type of licence
 24 application that would have been required by
 25 a commercial manufacturer to submit. But the key

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1 information was included and the licensing authority
 2 took the view that it should be licensed.
 3 **Q.** Now, during the lifetime of a product licence, so in
 4 relation to PFC's product licence, if you were to say
 5 from 1978 to 1983, at least in relation to the first
 6 licence, were there any particular reporting
 7 obligations or reporting practices undertaken by the
 8 PFC in terms of, for example, adverse reactions,
 9 instances of hepatitis, jaundice?
 10 **A.** Yes.
 11 **Q.** Would those, in the life of the licence, be reported
 12 to the licensing authority or would they be reported
 13 elsewhere, do you know?
 14 **A.** Certainly latterly it was quite carefully prescribed
 15 when the licences became substantive, following the
 16 removal of Crown immunity, any significant adverse
 17 reactions, and there would be a definition what
 18 significant meant. They certainly would be reported
 19 or in regular post-marketing surveillance studies and
 20 so on, not necessarily on a one by one basis but they
 21 would be collected together and submitted to
 22 a licensing authority.
 23 I think in the early 1980s, it was certainly the
 24 case that Regional Transfusion Centres were encouraged
 25 to have a close liaison with the users of the products

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1 would have carried out an investigation and the
 2 appropriate outcome implemented, which would have
 3 ranged from no action to a complete recall of the
 4 batch.
 5 **Q.** Then can you recall, and if you can't obviously please
 6 say so, whether information on pool sizes was part of
 7 the information that PFC would submit to the licensing
 8 authority when applying for a licence?
 9 **A.** I think it was actually, yes. I think there would
 10 have been a requirement to state -- it was a measure
 11 of the scale of activity which was an important
 12 parameter I think. I don't know whether it is
 13 expressed in kilos, litres or individual donations but
 14 one or all of those would have been used to measure
 15 it. I think that's the case, yes.
 16 **Q.** Then during the lifetime of the licence, you have got
 17 your licence granted for five years, you don't have to
 18 renew for five years. During that period of time, if
 19 there are changes that might have a bearing on risk,
 20 for example, increase in pool sizes or the development
 21 of knowledge that non-A, non-B hepatitis is a more
 22 serious condition than hitherto believed, or the
 23 development of knowledge that non-A, non-B hepatitis
 24 is -- the belief that it is an inevitable consequence
 25 of a first dose with NHS concentrates. If that the

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

3 So I think we had a fairly good idea. I would
 4 not call it a fully developed pharmacovigilance system
 5 as one witnesses nowadays, but it was certainly a link
 6 between individual patients. I think interestingly
 7 though it may have been the case that Factor VIII
 8 infusions to patients so frequently caused elevations
 9 of ALTs and perhaps even jaundice, I don't know the
 10 clinical details, but that was prescribed as
 11 an expected adverse effect. So that wouldn't
 12 necessarily have to be recorded, so we didn't get
 13 routine reports. This is before introduction of heat
 14 treatment, of patients seroconverting for non-A,
 15 non-B, for example. But we would have got reports of
 16 a hepatitis B transmission.
 17 **Q.** This may be a hypothetical question because I don't
 18 know if it happened, but if you got reports of
 19 a hepatitis B transmission reported to you at PFC, do
 20 you know whether in the period really leading up to
 21 the mid-80s or indeed beyond that, the period when
 22 there was Crown immunity, did that get reported by PFC
 23 or by SNBTS more generally to the licensing authority?
 24 **A.** I can't be sure of that. I can't be sure of that. It
 25 would certainly have been reported to the PFC. PFC

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1 kind of information that might have a bearing on risk
 2 comes to light in the course of the duration of
 3 a product licence, do you know whether there was any
 4 obligation on the licence holders to notify the
 5 licensing authority? Or was that just something that
 6 would be picked up at the next renewal?
 7 **A.** I think the licensing authority were interested in
 8 adverse events which fell outside the recognised
 9 adverse events which -- like slight haemolysis or even
 10 transmission of hepatitis viruses. The licensing
 11 authority would have regarded those as fairly frequent
 12 and not remarkable.

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

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

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1 But that was reported to the licensing authority
 2 because it was unusual and I think we hadn't seen it
 3 before so we felt it was appropriate to report it.
 4 But, as I say, the pharmacovigilance systems that we
 5 have now are much more significant and robust.
 6 **Q.** Just so that you understand, Dr Perry, the purpose of
 7 these questions is to really try and get a sense of
 8 how in practice the product licensing system operated.
 9 We have looked in earlier hearings at some of the
 10 legal requirements. We have looked at some of the
 11 applications from commercial companies, but it is
 12 really the extent to which the -- once the licence was
 13 granted, the extent it was an ongoing dialogue with
 14 the licensing authority at this period, late '70s,
 15 first half of the '80s, that prompts the questions.
 16 **A.** I think it wasn't fully developed either because the
 17 licensing authority -- I talked in my Penrose --
 18 I think you showed it in the Penrose, and it was
 19 a confused area. I think it was confused not only for
 20 PFC and the SNBTS but it was confused for the
 21 licensing authority as well. They weren't quite sure
 22 how to deal with an organisation submitting product
 23 licence applications when actually they operated under
 24 Crown immunity, so the status of that relationship was
 25 a little bit confused.

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1 understand from your earlier answers, and please
 2 correct me if this is not right, that a growing
 3 awareness of the seriousness of non-A, non-B hepatitis
 4 would not be something PFC would necessarily report to
 5 the licensing authority because post-transfusion
 6 hepatitis was already a known risk?
 7 **A.** No, I think we would have assumed or I would have
 8 assumed that this was a well known phenomena by the
 9 licensing authority and they didn't need reminding
 10 from one manufacturer that that was the case.
 11 **Q.** Can I then just ask you a little about PFC's
 12 involvement or I think more accurately lack of
 13 involvement in issues relating to donor selection. If
 14 we pick it up again in one of your Penrose statements.
 15 PRSE0001823, please, Sully. If we go I think to
 16 page 3. Second paragraph. Top of the page, please.
 17 Thank you Sully.
 18 You say in the second paragraph:
 19 "Latterly during this period PFC and Regional
 20 Centres worked more closely on the development of
 21 quality systems and standard operating procedures for
 22 the processing and testing of plasma but this did not
 23 extend to issues of donor selection which, at that
 24 time, would have been accepted as the exclusive
 25 responsibility of Regional Directors and their medical

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1 **Q.** If we take the example of increased pool sizes. Do
 2 you think it is more likely than not that that -- that
 3 that wouldn't have been reported by PFC to the
 4 licensing authority during the lifetime of the
 5 licence? Or are you just --
 6 **A.** I think it would have been an unusual event. It is
 7 difficult to define what a small change and a large
 8 change might be. But a small change in pool size
 9 would have been considered not of consequence, of
 10 sufficient consequence, to notify the licensing
 11 authority because they would simply note the position
 12 bearing in mind that most of the products that they
 13 were licensing, which was sensitive to pool size were
 14 commercial concentrates with pool sizes orders of
 15 magnitude larger than the PFC. So if the PFC had
 16 submitted a licence application or an amendment to the
 17 a licence application saying we have changed the -- we
 18 have modified the pool size from 500 litres to
 19 1,000 litres, I don't think they would have taken much
 20 notice of that. I think they would have said, well,
 21 that's still orders of magnitude less than the size
 22 of -- or substantially less than the size of, for
 23 example, commercial pools.
 24 **Q.** Then the example of developing knowledge in relation
 25 to non-A, non-B hepatitis. Would it be right to

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1 staff. This situation remained largely unchanged
 2 until reorganisations of the service in the 1990s. In
 3 its original Licence Applications to DHSS Medicines
 4 Division for Factor VIII information on donor
 5 selection practice or policy was neither supplied by
 6 PFC/SNBTS or requested by the UK Licensing Authority."
 7 So, as I understand it, two points essentially
 8 emerging from that part of your statement. First of
 9 all, in submitting your licence applications, you were
 10 neither asked to provide nor volunteered information
 11 about donor selection practices in SNBTS?
 12 **A.** I think that -- my understanding is that that's the
 13 case yes.
 14 **Q.** Then, secondly, your broader point is that the
 15 approach to donor selection was not something that PFC
 16 got involved with. It regarded that as -- the term
 17 used here -- the "exclusive responsibility" of the
 18 Regional Transfusion Service?
 19 **A.** I think that is correct as well. That subsequently
 20 changed as the quality systems developed -- and PFC
 21 was also -- I was personally instrumental in trying to
 22 expand the concept of quality systems throughout the
 23 Regional Transfusion Centres, driven by the need for
 24 PFC to have a modern and mature quality system in
 25 place. But I think it was still the case that the

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

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

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

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

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

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

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

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1 **Q.** Then:

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

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

8 **A.** On behalf of the management committee.

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

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

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

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

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

14 **SIR BRIAN LANGSTAFF:** Yes. Thank you.

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

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

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

25 **A.** Right.

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

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

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

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

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

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

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1 aim was to make Scotland self sufficient in plasma
 2 products and in particular coagulation factors.
 3 Does that remain, first of all, your
 4 recollection of the position?
 5 **A.** Yes, a very, very clear recollection. And that became
 6 very clear to me very soon after I started in 1981.
 7 It didn't take long for me to understand why the PFC
 8 was there.
 9 **Q.** Do you recall -- if we keep this up on screen in
 10 a moment because we are going to go to a different
 11 page in a moment. Do you recall gleaning or gaining
 12 an understanding of why self-sufficiency was this
 13 dominant goal for the PFC?
 14 **A.** Yes. I think the complexity of the answer to that
 15 developed over time, but initially it was very clear
 16 to me that there was a view that plasma derived from
 17 voluntary non-remunerated donors and used as a raw
 18 material for plasma products was a lower risk material
 19 than plasma or products obtained by the commercial
 20 sector.
 21 So the object of self-sufficiency was to
 22 effectively eliminate the need for commercial products
 23 to be used in Scotland. That was the stated aim. It
 24 was quite clear, it was unambiguous. And clearly --
 25 and I believe everyone that I came into contact with

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1 community but also a target which sought to reduce
 2 the risk to haemophilia patients of transmission of
 3 disease from other countries."
 4 So that remains your evidence, does it, that one
 5 of the prime motivating factors or was it the prime
 6 motivating factor was the issue in relation to safety?
 7 **A.** I think was the prime motivating factor. I don't
 8 believe there was ever a comparison of what the cost
 9 saving is. It certainly wasn't driven by a perceived
 10 lower cost. I'm not sure it was lower cost to produce
 11 one's own products rather than buy commercial
 12 products. So I think that was the clear
 13 justification.
 14 And it was a goal set well before my arrival in
 15 SNBTS by SHHD, who -- I don't think there's any formal
 16 grand statement by SHHD that, "We will become self
 17 sufficient", but it was a concept that they clearly
 18 supported, and funded, because collecting --
 19 collecting increased levels of plasma required
 20 significant injection of revenue funding for blood
 21 bags and the consumables and so on associated with
 22 this.
 23 **Q.** Then in terms of your understanding of what
 24 self-sufficiency meant, I think it is probably in the
 25 same document at page 57, please, Sully. No, it's

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1 understood that.
 2 **Q.** The reason for asking, Dr Perry, is there might be
 3 a number of reasons why it is said self-sufficiency is
 4 a good goal. It might be, for example, the
 5 elimination of commercial concentrates because
 6 ultimately that would be cheaper for the State.
 7 That's why I wanted to pick up on your understanding
 8 for the reasons for it.
 9 If we could go on in this transcript to
 10 page 118. Picking it up at line 5, you come back to
 11 your understanding about this being a goal:
 12 "My understanding at the time when I joined the
 13 service, as a new person to the blood service, was
 14 that this was a goal or a policy that had been set by
 15 the Scottish executive at the time, that we wanted to
 16 meet the WHO recommendations for self-sufficiency.
 17 But I think also it became very clear that one of the
 18 prime justifications for self-sufficiency was
 19 a belief, which was based on fairly good evidence,
 20 that imported products from the USA, which were the
 21 alternative source of products, were much higher risk
 22 products than those that would be produced from
 23 voluntary non-remunerated blood donors from one's
 24 community. So it was a target which was aimed at
 25 creating a sufficiency of supply from our own

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1 not. Sorry, wrong reference.
 2 Can we go to PRSE0006025. Then page 57 of that
 3 document.
 4 So this is your evidence to the Penrose Inquiry
 5 on 13 May 2011. We don't need to go to it but the
 6 bottom of the previous page you had been asked what
 7 was the goal that you took yourself to be working
 8 towards in terms of self-sufficiency.
 9 Then this is your answer:
 10 "**Answer:** Meeting most, if not all the needs for
 11 plasma products in Scotland, with the exception of
 12 occasional rare products, individual patients who had
 13 idiosyncratic reactions to the product that we had on
 14 offer. We would fully accept that it would certainly be
 15 justified to use a non-NHS product."
 16 Do I understand that last sentence to
 17 mean: justified to use a non-NHS product in the
 18 exceptional circumstance that you described in the
 19 previous sentence?
 20 **A.** If an individual patient had an acute reaction or
 21 a severe reaction to our product, if it was
 22 a haemophilia product and the haemophilia director
 23 judged that his or her patient needed an alternative
 24 product, then I'm not sure that the PFC or the SNBTS
 25 would have had any involvement in that. If that's

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

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

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

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

25 **A.** For all the estimated needs and I think part of the
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1 (2.00 pm)

2 **MS RICHARDS:** Dr Perry, I'm going to ask you to look,
3 still on the topic of self-sufficiency, at a short
4 passage from one of your Penrose statements.
5 PRSE0003755.
6 If we go to the very bottom of the page we can
7 see it says:
8 "At this time [so this is the last two lines]
9 self-sufficiency was an accepted goal for Scotland
10 which dominated its planning throughout the 1980s. It
11 was also accepted that prescribing doctors were free
12 to exercise their own judgment in the choice of either
13 SNBTS or commercial products preserving the important
14 principle of clinical freedom. Therefore whilst SNBTS
15 and Haemophilia Directors collectively embraced the
16 goal of self sufficiency the use of NHS products was
17 not and could not be enforced by SNBTS."

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

24 When you say here it was "accepted that doctors
25 were free to exercise their own judgment ...
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1 SNBTS self-sufficiency planning or work up to it was
2 work that was carried out by Professor Cash and other
3 senior haematologists in Scotland in the '70s and '80s
4 and they sat down and they identified in some
5 considerable detail how much Factor VIII would be
6 needed for the haemophilia population of Scotland.

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

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

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

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

24 (1.01 pm)

25 (The short adjournment)
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1 preserving the important principle of clinical
2 freedom", accepted by whom?

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

16 So, yes, it was a -- I think, from my
17 perspective -- I didn't deal with patients directly,
18 for reasons that are perhaps self-evident, but he
19 certainly took the view that he would try to do
20 everything he could to enable prescribing doctors to
21 avoid the use of commercial products. And to do that,
22 the products that SNBTS provided had to be of
23 a quality and specification that would be considered
24 the product of choice by SNBTS doctors, including the
25 fact that they were derived from voluntary
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1 non-remunerated donors, which at this time was still
 2 an important safety parameter.
 3 **Q.** Do you know what, if any, particular steps were taken,
 4 whether by Dr Cash or by SNBTS or specifically by the
 5 PFC, to try to persuade, influence clinicians to use
 6 SNBTS products rather than commercial products?
 7 **A.** I think there was a regular process, at least once
 8 a year, where the prescribing doctors, the Haemophilia
 9 Directors and the SNBTS directors, including the
 10 PFC directors and SHHD officials, which was the annual
 11 meeting of directors, I think Professor Cash and
 12 myself always sought to influence or just illuminate
 13 the availability of SNBTS products and -- just to make
 14 sure that they absolutely understood what was
 15 available from SNBTS and that, in the absence of any
 16 good clinical reason, took the view that these
 17 products should be preferred over commercial products.
 18 But it wasn't a position that was forced on
 19 Haemophilia Directors. They would have taken part in
 20 those discussions, there might have been discussions
 21 about their need for commercial purchase, but that was
 22 the regular forum in which I think the whole idea and
 23 concept of self-sufficiency was born.
 24 But collectively, I think, and going back even
 25 to the 1970s, haemophilia doctors and SNBTS directors

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1 Do you recall it being drawn to your attention
 2 or coming to your attention that at Yorkhill Hospital
 3 there was significant use of commercial concentrates?
 4 **A.** Yes, I did know that. I don't know when I knew it or
 5 where the information came from but I was aware that
 6 there was a significant use of commercial factor
 7 concentrates in Yorkhill. I don't know the reasons
 8 for that, and certainly that changed quite abruptly
 9 when, I think it was, Dr Gibson became the paediatric
 10 haemophilia director for Yorkhill and the paediatric
 11 service in general for haemophilia.
 12 **Q.** Do you know, and I appreciate you probably can't speak
 13 to the time before you joined PFC, but do you know
 14 whether there was any contact made by the PFC or, more
 15 broadly, by SNBTS or Dr Cash with Dr Willoughby at
 16 Yorkhill to explore why there was this very
 17 significant use for children of commercial
 18 concentrates?
 19 **A.** I don't know, is the honest answer. I think one of
 20 the problems SNBTS had, certainly during the 1980s and
 21 perhaps through the 1980s, we didn't have a clear
 22 understanding of the pattern of usage throughout
 23 Scotland. We knew what was being used of SNBTS
 24 products but we didn't have any regular data from
 25 either individual hospitals or Haemophilia Centres on

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1 and the SHHD had collectively signed up to the concept
 2 of self-sufficiency, I think even as early as the
 3 1970s. They understood the benefits of that in terms
 4 of product safety and I think largely were supportive
 5 of the actions and the efforts that SNBTS was making.
 6 **Q.** Did you ever get reported back to you -- I'm really
 7 thinking of the first half of the 1980s, any
 8 particular concerns being expressed by haemophilia
 9 clinicians about the nature or quality of PFC
 10 products, any reasons why they were using commercial
 11 products in place of SNBTS products?
 12 **A.** Yes, there was. We occasionally got reports. I think
 13 there were issues certainly in the early '80s about
 14 product solubility and convenience. I think it was
 15 a larger dose volume than commercial products. And
 16 I think there may have even been a preference
 17 expressed by some patients that this was a more
 18 convenient product: it dissolved more quickly, there
 19 was a lower infusion volume and they could do their
 20 home therapy much more conveniently with commercial
 21 products. But set against that was the -- it was more
 22 than a perceived risk, it was a known risk, as far as
 23 the SNBTS was concerned, that these products were less
 24 safe than SNBTS products.
 25 **Q.** We can take that down now, thank you, Sully.

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1 their use of non-SNBTS products.
 2 **Q.** Would you have expected someone to be gathering that
 3 data, not necessarily PFC, because PFC essentially is
 4 a producer of its own products --
 5 **A.** Sure yes.
 6 **Q.** -- but someone, again SNBTS or SHHD, to be -- in order
 7 to achieve self-sufficiency, to overcome the obstacle
 8 created by the sacred principle of clinical freedom,
 9 to find out what commercial concentrates were being
 10 used and why, so that there could be a systematic
 11 approach to reducing that usage?
 12 **A.** I think Professor Cash made efforts to understand the
 13 pattern of usage in Scotland and to understand the
 14 reasons why non-SNBTS products were being used in
 15 certain circumstances. I'm not sure that SHHD took
 16 any specific action. I suppose, in a sense, from my
 17 perspective, they could have done, and indeed the
 18 annual meeting of SNBTS directors and haemophilia
 19 directors could have collectively agreed to undertake
 20 that analysis. And I think these data did slowly
 21 begin to emerge and maybe the overriding organisation,
 22 the umbrella organisation, the UKHCDO organisation was
 23 in a position and, I believe, did collect certain data
 24 on the use of NHS products and commercial products but
 25 it didn't break it down into individual hospitals or

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1 individual prescribing doctors.

2 **Q.** Yes. It might be said in relation to the latter

3 organisation, you are right, they might be well placed

4 to know what was being used, but they are the very

5 clinicians who might be jealously guarding the

6 principle of clinical freedom?

7 **A.** Yes, but they wouldn't necessarily jealously guard the

8 information. I think they were collectively signed up

9 to openness and transparency, and I have no reason to

10 believe that individual Haemophilia Directors withheld

11 or certainly falsified information for that reason.

12 I have no reason to believe that was the case. So

13 there were efforts.

14 It took some time to better understand the use

15 of commercial -- the reason for commercial products,

16 but it all -- the use of commercial product, other

17 than in very few and perhaps rare circumstances --

18 I was never aware of what particular circumstances it

19 would be appropriate to use a commercial product, but

20 by 1983/84 the use of commercial product had all but

21 disappeared, I think as a result of the collective

22 efforts of both haemophilia doctors and SNBTS staff to

23 address that particular issue.

24 **Q.** Did Scotland achieve self-sufficiency, in your view,

25 in the 1980s, and if so, approximately when do you say

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1 introduction of his fairly unique technology for the

2 continuous thawing of plasma. And that yielded very

3 substantial increases in product yield at that time.

4 **Q.** Did the pro rata system as operated in Scotland have

5 any particular role to play?

6 **A.** I think it was originally designed -- if my

7 understanding is correct, the pro rata system was

8 based on the pro rata supply of products in proportion

9 to the amount of plasma that a particular region

10 supplied. There might have been a population bias in

11 that as well but I think it was primarily introduced

12 to incentivise regions to increase their plasma

13 output, because that meant that the regions in which

14 they operated and their respective health authorities

15 would have had reduced costs associated with

16 commercial purchase. So it was -- I think it was done

17 to incentivise plasma collection and to provide some

18 basis for an equitable supply of product.

19 **Q.** Now, in terms of the PFC's ability to fractionate

20 plasma collected other than in Scotland or Northern

21 Ireland, so plasma from England and Wales, what's your

22 understanding of why that did not happen?

23 **A.** In England and Wales?

24 **Q.** So why the PFC was not used to fractionate plasma

25 collected in England and Wales.

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1 that was achieved?

2 **A.** I think it was probably achieved in 1983, early 1984.

3 And I think it was -- it depends how you define

4 self-sufficiency, of course, and I think that was

5 sustained until perhaps 1987/1988, when I think

6 the organisation faced the sort of collective

7 headwinds of increased demand, loss of yield, as

8 a result of introduction of heat treatment and virus

9 inactivation procedures, and I think in 1988 there was

10 a requirement for some commercial purchase. That was

11 a big disappointment.

12 **Q.** To what do you attribute Scotland achieving

13 self-sufficiency by late '83, early '84?

14 **A.** I think I alluded this morning to the fact that it set

15 out fairly early on, on the road to eliminating the

16 use of whole blood transfusions, and therefore being

17 able to collect the plasma which could be used for

18 fractionation. And that process began in the 1970s

19 and certainly progressed in the 1980s, and by 1983/84

20 I think whole blood was very seldom used in

21 transfusion in Scotland, which inevitably meant that

22 there was more plasma available for fractionation,

23 which could increase the output from PFC.

24 The other factor was the work undertaken by

25 Dr Foster to improve process yields at PFC, with the

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1 **A.** In all honesty, I do not think I know the answer to

2 that question. We certainly took the view that we

3 could and perhaps should have done. I'm not familiar

4 with the timeline in England and Wales in terms of the

5 availability of plasma or the capacity of BPL or their

6 building programmes. It may well have been that

7 the plasma simply wasn't available. It could have

8 been a plasma shortage, in which case the fact that

9 PFC had capacity to process more wouldn't have

10 actually improved matters in England.

11 But I think, from my perspective, certainly when

12 I took over as director, it was always my view that

13 had we been approached to process plasma then we would

14 have done our utmost to adjust our activities and our

15 processes and procedures to accommodate that.

16 **Q.** Had you had any involvement or any direct knowledge of

17 the shift working trial in late 1981?

18 **A.** Yes, I was in post then and I was involved in it, from

19 a quality perspective, because at that stage I was

20 responsible for all issues associated with quality, so

21 I had an overview from a quality perspective on the

22 process. So, yes, it was undertaken, as I recall,

23 from basically outdated plasma. It wasn't fresh

24 plasma. And I think its primary purpose was to

25 establish the capacity of its -- of the PFC's central

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

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

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

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

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

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

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

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

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

17 And I think it would have been more secure as
18 well. As it was, BPL were processing at least 90% of
19 the plasma for the UK and the PFC was only producing
20 10%. Now, in any sensible organisation you wouldn't
21 have that imbalance. You would say: in order to
22 secure the long-term security of supply, or at least
23 a minimum level, something closer to a 50/50 split
24 would be appropriate.

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

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1 needed alternative arrangements for paying its staff
2 in ways which we could put in place a shift working
3 process. So it -- and that was necessary not only for
4 coagulation factors but for the -- all the other
5 products as well, that we were constrained by the
6 8-hour day.

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

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

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

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

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

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

22 **A.** Yes.

23 **Q.** In broad terms, what did that entail?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 **A.** There was, yes.

5 **Q.** I think the figure Dr Foster gave the Penrose
 6 Inquiry -- which was -- I think somewhere in your
 7 evidence also you endorsed -- was around
 8 4,000 donations?

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

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

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

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

25 But the requirement to increase pool sizes, as

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

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

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

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

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

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

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

22 **A.** Yes.

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

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

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

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

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

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

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

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

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1 dedication", and I will come later to the question of
 2 batch dedication, but I just wondered if you could
 3 help us with the second paragraph:
 4 "Any moves directed towards restricting donor
 5 pool size (designated plasma pool for each donor) must
 6 be discussed by all directors before implementation.
 7 It is an exciting option but I suspect will have
 8 colossal cost and operational implications. There's
 9 much to be done before we need to consider this
 10 option."
 11 Do you know what Dr Cash was referring to there?
 12 **A.** Yes, I do. I didn't remember this letter until it was
 13 provided to me by the Inquiry and it was a response to
 14 a suggestion by Dr Crawford for a system of
 15 restricting or creating individual donor pools, and
 16 I have to say that I never really understood at the
 17 time what he was actually proposing. But it did seem
 18 to me, and it certainly seemed to Professor Cash at
 19 the time, that it might have been horrendously
 20 expensive and operationally extremely complex. So he
 21 was simply saying, "We have arrangements in place to
 22 control donor pool size". What was the date of this?
 23 **Q.** December '84.
 24 **A.** December '84. By then we had agreed to introduce
 25 a system of batch dedication to control patient

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1 decision-making relating to the use of freeze dried
 2 cryo seen here?
 3 **A.** I don't recall having any detailed discussions about
 4 it. I think it is by 1982 I would have been aware of
 5 this but perhaps primarily from a historical
 6 perspective. I think by the time I arrived at PFC,
 7 I think, as far as I was concerned, the discussion and
 8 debate about this was all but over. There was still
 9 the option, and it hadn't been formally abandoned as
 10 an option, but for all the reasons that have been
 11 provided, freeze dried cryoprecipitate was, I think,
 12 formally put to bed, as it were, in early 1983.
 13 In addition, I think my view at the time was
 14 that such an activity would have required a complete
 15 redesign of the manufacturing facilities. It was
 16 a completely different process. It was small-pool,
 17 multiple small-pool manufacture. We didn't have the
 18 environments in which to do that, the sterile handling
 19 environments and so on, and at that time I was in the
 20 middle of a process of redesigning facility for
 21 large-scale manufacture. So my view would have been
 22 this can't be done.
 23 **Q.** At the PFC?
 24 **A.** At the PFC from a quality perspective.
 25 **Q.** But you didn't have any involvement in the question of

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1 exposure to donors and this, however exciting, was
 2 extremely complicated and should not -- and
 3 Professor Cash's view, and I think probably mine as
 4 well, was that it was not really a viable option.
 5 **Q.** Is it right to understand it received no further
 6 consideration?
 7 **A.** Oh absolutely none, no. Well, that's not fair. There
 8 was no further discussion on this as an option.
 9 **Q.** Freeze dried cryoprecipitate; we know from
 10 documentation that the Inquiry has already looked at
 11 and indeed evidence, oral evidence that the Inquiry
 12 has heard, a little of what happened in relation to
 13 the freeze dried cryoprecipitate production at the Law
 14 Hospital?
 15 **A.** Yes.
 16 **Q.** I think you have seen in the materials provided to you
 17 documents that suggest it is something that Mr Watt
 18 certainly was not keen on, describing it as a step
 19 back in history and a "suitable product perhaps for
 20 Turkey but not Scotland" I think were his words?
 21 **A.** Yes, they were.
 22 **Q.** And I think you'll also have seen some exchanges
 23 between Mr Watt and Dr Cash on it. As I understand
 24 the chronology, it was essentially abandoned in
 25 January 1983. Did you have any involvement in the

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1 whether it could or should be done elsewhere?
 2 **A.** No. No.
 3 **Q.** Can I then come to it the stockpile or surplus that
 4 was built up. I want to look at a handful of
 5 contemporaneous documents with you in a moment.
 6 But what was -- how was it that by the end of
 7 1983 and into 1984 that PFC had built up this
 8 significant quantity of product?
 9 **A.** I think it was a consequence of increased throughput,
 10 plus, and probably more importantly, the rewards from
 11 the work that Dr Foster did in terms of increasing
 12 process yield for Factor VIII at that time.
 13 And I can remember discovering that we had this
 14 large quantity of Factor VIII and doing some simple
 15 calculations and concluding that unless we took some
 16 action, then this product would outdate, and
 17 I communicated that to Mr Watt, and Mr Watt
 18 subsequently communicated it to Professor Cash. Is my
 19 understanding of the events.
 20 **Q.** What I wanted to do is look at a couple of those
 21 communications from '83 and then look at a couple of
 22 communications in '84 with BPL and then explore it
 23 a little more generally with you.
 24 So if we start by looking at PRSE0001576.
 25 This is a memo from you to Mr Watt and others,

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1 18 November 1983. It says:
 2 "A recent survey ... of the stock levels of
 3 FVIII concentrate both at RTCs and within the PFC
 4 'sausage machine' indicates the development of some
 5 important and interesting trends which I feel should
 6 be examined as a matter of urgency by the SNBTS so
 7 that appropriate action (if any) can be taken".
 8 Then you refer to the stock levels here.
 9 I don't, I think, need to read out that second
 10 paragraph.
 11 Then looking at the third paragraph you say:
 12 "Looking back at the SNBTS annual statistical
 13 sticks for 1982/83 the SNBTS issued [approximately]
 14 25,000 vials of Factor VIII. Assuming this rate of
 15 usage is maintained present stocks represent 1.4 years
 16 supply. If this stockpile continues to grow at the
 17 present rate (ie 10,000 vials/year) then we will soon
 18 be in a position of manufacturing Factor VIII which
 19 will inevitably outdate."
 20 Then you conclude:
 21 "However, I have a feeling that we may already
 22 be in a position where other existing material or
 23 future batches will outdate."
 24 Then you suggest trying to "gain a more accurate
 25 picture of where we are holding". We can see there
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1 was the waste of product in terms of haemophilia care
 2 that was shocking and, in a sense, having a surplus
 3 product in itself is not a problem, you can destroy
 4 it, but that would have been a criminal act I think.
 5 Q. Then if we go to PRSE0001537.
 6 This is Dr Cash to Mr Watt, 29 November 1983,
 7 copied to you or referred to you as well, as we see
 8 from the stamp. If we just look at the first
 9 paragraph to start with:
 10 "Recent correspondence with colleagues at PFC
 11 and odd comments gleaned from others has indicated
 12 that we may be genuinely moving near to a national
 13 (SHS) surplus of factor VIII."
 14 SHS, is that Scottish health service?
 15 A. Scottish health service, yes.
 16 Q. "It would be imprudent to make any rash moves at the
 17 moment -- we will take the opportunity of examining
 18 the position together in the near future.
 19 "There are two points I would wish to make at
 20 this time."
 21 Then the first:
 22 "Outdating
 23 "It would be a very serious matter if product
 24 outdated when patients South of the border continue to
 25 be exposed to commercial material."
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1 you and Mr Grant have done some form of stock
 2 exercise?
 3 A. Yes. I can't remember whether it was initiated by
 4 Mr Grant or maybe just in terms of my routine sort of
 5 surveillance of the centre, I noticed we had very,
 6 very large quantities of Factor VIII and perhaps asked
 7 Mr Grant, who was the manufacturing manager, to do
 8 a stock take and find out some details of what product
 9 existed, what its expiry dates were and so on.
 10 And I remember being quite shocked at the
 11 outcome that we had accumulated that amount of
 12 material whilst still operating a pro rata
 13 distribution system. But we may come on to that.
 14 Q. Your concern was that you were going to have more than
 15 you needed to issue and you were essentially going to
 16 be left with outdated concentrate that couldn't be
 17 used?
 18 A. It's not so much --
 19 Q. It would be wasted or --
 20 A. Well, yes, in a sense, but the concern that I and
 21 certainly Professor Cash had, and others, was that
 22 this was valuable material, the UK was short of
 23 Factor VIII, certainly NHS Factor VIII, and it would
 24 have been a shocking waste of material if this was not
 25 usefully used for haemophilia care in the UK. So it
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1 So that is the point I think you were just
 2 making?
 3 A. Yes.
 4 Q. "I have a gut reaction (but we need this corroborated
 5 by PFC) that supplies may be sufficient for us to pull
 6 out RTC deposited product that has 6 months shelf life
 7 left and offer it to the NBTS."
 8 Then he asks Mr Watt to provide him with certain
 9 information.
 10 Then we go over the page, just so we don't need
 11 to come back to this document, we can see there the
 12 second point is:
 13 "Batch issue to individual patients
 14 "I have long dreamt that this might eventually
 15 be introduced (even gradually) -- to reduce the number
 16 of donor exposures. I would be most grateful for your
 17 thoughts on how this would be introduced in your
 18 region."
 19 Then the PS:
 20 "An answer to (a) is more urge lit required than
 21 (b)."
 22 So we will come back to the issue of batch issue
 23 or batch dedication --
 24 A. This letter was, I think, almost certainly sent to
 25 regional directors as well, because he is asking them
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1 for data on the amount of product that they had in
 2 their centres.
 3 **Q.** So that is end of November 1983, the existence of this
 4 surplus or stockpile appears to have been clearly
 5 identified, a little work being done to ascertain
 6 exactly what was held and to consider options and to
 7 deal with it:
 8 **A.** Yes.
 9 **Q.** We then move, I think -- in terms of the documents I'm
 10 going to ask you to look at, and then I'm going to see
 11 if you can help fill the gap -- to June 1984.
 12 CBLA0001850.
 13 Now, of course, that was -- the document we just
 14 looked at was 29 November 1983. Mr Watt left soon
 15 after in December 1983. You took over in the
 16 beginning of '84 as acting director, and this is sent
 17 by you in your capacity as acting director to
 18 Mr Pettet at BPL, 8 June. If we go to the text of the
 19 letter:
 20 "I understand that agreement has been reached
 21 between Dr Cash and Dr Lane that excess stocks of PFC
 22 Factor VIII are to be decanted to CBLA for subsequent
 23 distribution to Regional Transfusion Centres in
 24 England and Wales. Dr Lane has also indicated that
 25 you are the most appropriate person to liaise with
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1 from you, 7 September 1984, to Mr Pettet. It says:
 2 "Following our telephone conversation I can now
 3 confirm that 2,123,500 a IU of ..."
 4 **A.** The "a" is a typographical error.
 5 **Q.** "... of Factor VIII Concentrate will be delivered to
 6 your centre on Friday, 14 September."
 7 You explain it is equivalent to 8,320 vials.
 8 Then the next paragraph:
 9 "It is difficult at this stage to assess how
 10 much will be available in the next quarter
 11 (December '84) ..."
 12 Then you give an estimate of what the surplus
 13 may be but say that:
 14 "... you shouldn't plan on this being
 15 available!"
 16 Now, having looked at that correspondence, can
 17 you help us understand, first of all, why, on the
 18 basis of this correspondence, it looks like it took
 19 until the middle of 1984 for the arrangement to be
 20 made to supply surplus to BPL?
 21 **A.** Yes.
 22 **Q.** Do you know why that couldn't have taken place more
 23 quickly?
 24 **A.** No, I think there was one parallel activity that was
 25 going on at the time, at the beginning of 1984, when
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1 PFC ..."
 2 Next paragraph:
 3 "You will appreciate that a regular supply
 4 commitment cannot be made but our best estimate is
 5 that the a total of 7-9 x 10 [to the power of] 6 IU
 6 [I think that says] could be decanted to England and
 7 Wales within the current financial year."
 8 **SIR BRIAN LANGSTAFF:** It is 7 to 9 million, isn't it?
 9 **A.** It is 7 to 9 million units, yes.
 10 **MS RICHARDS:** "I am now most anxious to establish the
 11 necessary arrangements for product supply.
 12 "We will supply the product in our standard
 13 package ... and I would suggest that a quarterly
 14 collection would be the most practicable arrangement.
 15 "Perhaps you could let me know when you will be
 16 in a position to receive and distribute this material
 17 and no doubt you will contact me if you require any
 18 further information from this end. Our interest in
 19 the material once it has been sent to CBLA will be
 20 restricted to arrangements for product recall in the
 21 event of a product defect/adverse reaction. In such
 22 an event, I believe it would be most sensible if you
 23 acted on our behalf."
 24 So that's you writing to BPL, 8 June '84. Then
 25 if we go to CBLA0001882. This is a further letter
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1 I took over as acting director from Mr Watt, and that
 2 was the dismantling of the pro rata system and putting
 3 in its place a supply arrangement based on clinical
 4 need, on a truly national distribution system,
 5 irrespective of the amount of plasma that was coming
 6 on. And that decision was proposed and agreed by
 7 directors on the basis of the stocks that had been
 8 built up.
 9 So I think -- I'm trying to reconstruct what
 10 might have happened and -- which will have caused
 11 this -- I wouldn't call it a delay -- why we didn't
 12 actually formalise the arrangement until June, and
 13 that was we were waiting to see what impact that
 14 arrangement would have on stock levels and so on. Or
 15 maybe it was no more complex than wanting to
 16 reconfigure our supply arrangement in Scotland and
 17 then move on to this as a separate topic.
 18 I don't think we perceived it as an urgent
 19 activity.
 20 **Q.** And then --
 21 **SIR BRIAN LANGSTAFF:** Just on that last point, the letter
 22 from John Cash of 29 November 1983, where he spoke
 23 about the need to reduce it and asked for an answer to
 24 two points, point (a) and point (b). He said, in
 25 effect, point (b) can wait but point (a) can't and
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1 point (a) was this. So if it wasn't urgency, it must
 2 have been the next best thing.
 3 **A.** I think Professor Cash was making the point it was
 4 urgent from a SNBTS perspective to establish exactly
 5 what the stock level was at the Regional Transfusion
 6 Centres as well as the PFC. I do not think he was
 7 implying that there was an urgent requirement to
 8 decant the product, other than its imminent outdating.
 9 So he was simply saying we need to fix this problem
 10 first because we cannot be seen to be allowing
 11 Factor VIII to outdate on our shelves. That would be
 12 a shocking dereliction of duty, I think his view was
 13 and I think I shared that view.
 14 **MS RICHARDS:** Do you know what else was done with the
 15 surplus? Was this supply to BPL essentially the
 16 answer to the issue identified by you, by Dr Cash?
 17 **A.** Well, it was envisaged at that stage to be an initial
 18 step. I think I made -- I was quite surprised when
 19 I reviewed this correspondence to see that I had
 20 estimated 7 to 9 million units. That would have
 21 clearly been over a long period of time and I think,
 22 with hindsight, it probably didn't take account
 23 properly of losses on heat treatment which were coming
 24 in and increased demand and so on. So it was probably
 25 a slightly exaggerated, or at least over-optimistic,

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1 units and where there was, as we've said before, high
 2 degrees of co-operation, there was never large-scale
 3 transfer of product.
 4 **MS RICHARDS:** Was consideration given by you or by Dr Cash
 5 or anyone else, to your knowledge, to providing some
 6 of the stockpile to Northern Ireland given the
 7 relationship that already existed with Northern
 8 Ireland and the difficulties that Northern Ireland
 9 faced in terms of the effect of the pro rata system?
 10 **A.** I don't know that I've got a clear memory or
 11 recollection of that. I don't recall there being
 12 discussions but I think, as I mentioned before lunch,
 13 that would have been an appropriate thing to do.
 14 **Q.** Then this letter envisaged that there may be a further
 15 supply in December 1984.
 16 **A.** Yes.
 17 **Q.** Did that ever happen or did that get overtaken by
 18 events --
 19 **A.** That was overtaken by events.
 20 **Q.** Is it right to understand -- and obviously we will
 21 come on to this -- the surplus that was held by PFC
 22 was then effectively heat treated --
 23 **A.** Yes.
 24 **Q.** -- to enable supply of the heat-treated product to
 25 patients in Scotland?

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1 view of how much could be supplied to England and
 2 Wales.
 3 **SIR BRIAN LANGSTAFF:** Just on that point, in this letter
 4 that's currently on the screen, the quarter in which
 5 14 September falls, 2 million. The quarter in which
 6 December falls, 2 million. That's a rate of 8 million
 7 a year.
 8 **A.** Yes, I don't think the intention was to do it on
 9 a continuous basis at 8 million a year. I think the
 10 surplus that had been built up had been built up over
 11 a number of -- well, not a large number of years but
 12 maybe '83 and '84 we had built this stockpile and
 13 I think it was simply -- I think in some ways it was
 14 demonstrating proof of principle, that it was possible
 15 and appropriate to transfer products from one part of
 16 the NHS in Scotland to another part of the NHS in
 17 England and Wales. I don't think it was ever
 18 envisaged as an on-going arrangement. It was
 19 a mutually agreed and satisfactory and, I think,
 20 appropriate thing to do in the circumstances, because
 21 product -- I think this was quite unprecedented.
 22 I know that sounds quite surprising in today's world.
 23 But it was unprecedented at the time that product from
 24 Scotland should be transferred to England or vice
 25 versa. They were administratively quite separate

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1 **A.** Correct, yes.
 2 **Q.** Can we just look before we leave this topic at
 3 a discussion in your oral evidence to the Penrose
 4 Inquiry.
 5 Sully, it should be PRSE0006025, please.
 6 If we go to -- sorry, page 28 I think it might
 7 be. This is in the course of a series of questions
 8 and answers about the surplus and what was done with
 9 it, but I just wanted to ask you about the exchange
 10 here. So you refer towards the top of the page of
 11 importance of finding out -- this is lines 4 to 5 --
 12 what the Regional Transfusion Centre stock was, which
 13 is what I think you referred to a few minutes ago.
 14 Then there is a reference to the Glasgow figure.
 15 If we just go further down the page -- I'm
 16 sorry, there is a passage that I'm -- yes, sorry, top
 17 of page 30. My apologies. Yes, you pick up in your
 18 answer in relation to the Glasgow figure and you talk
 19 about -- this is lines 4 to 5:
 20 "Certainly the stock level in Glasgow was much
 21 higher than I thought it would have been."
 22 Can you recall anything about that now, the
 23 particular detail in relation to the level of stock
 24 held in presumably the Glasgow Regional Transfusion
 25 Centre?

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1 A. We're really talking about 1984 -- mid-84 now, aren't
 2 we --
 3 Q. Yes.
 4 A. -- or certainly late '83 when you were carrying out
 5 this exercise.
 6 Q. Yes.
 7 A. Yes, I think all of these observations and narratives
 8 actually contributed to my -- one of the first things
 9 I did when I became acting director which was to
 10 dismantle the pro rata system and build in a system
 11 which was based on supplying Regional Transfusion
 12 Centres with product based on their stock levels and
 13 their estimated clinical need and, built into that
 14 system from early 1984, was a requirement for Regional
 15 Transfusion Centres to feed back on a monthly basis
 16 what their stock levels were and then PFC could, as
 17 the central unit responsible for supplying products,
 18 would have a much better overview of the overall stock
 19 position in what I described earlier as a sausage
 20 machine.
 21 Q. You can take that down, thank you, Sully.
 22 I want to move next then to the topic of
 23 hepatitis and specifically your knowledge of hepatitis
 24 and what was understood about hepatitis at the PFC.
 25 At the time you took up your role in 1981, what, if

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1 deepening with time through discussion with PFC
 2 colleagues and wider SNBTS colleagues.
 3 So, going back to, I think, a question I asked
 4 you earlier, would it be right to understand that
 5 there was no formal training that you received about
 6 risks of viruses or hepatitis in particular?
 7 A. No. I had no formal training. I think, without
 8 wishing to be too immodest, I think I learnt very
 9 quickly from the regular and detailed discussions and
 10 correspondence and meeting with doctors and visiting
 11 Regional Transfusion Centres and so on, but it was not
 12 a formal structured programme to educate me in issues
 13 associated with hepatitis.
 14 Q. Do you recall learning relatively quickly or otherwise
 15 about non-A, non-B hepatitis?
 16 A. Yes, it was the first time I'd heard of such a thing
 17 when I joined the SNBTS but, as I say, again, within
 18 weeks I was educated in what this actually meant at
 19 a very superficial level. You know, there is
 20 hepatitis B which I was familiar with -- well, I was
 21 aware of but I had never heard of non-A, non-B
 22 hepatitis before I joined the Blood Service in
 23 Scotland.
 24 But, as I say from discussions with colleagues
 25 and basically the work of PFC and from Mr Watt as

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1 any, knowledge did you have of hepatitis?
 2 A. Of hepatitis? Very little indeed. I think in my
 3 witness statement I described I spent a very
 4 informative and interesting year working as
 5 a biochemist in the Royal Postgraduate Medical School
 6 in Hammersmith in the chemical pathology unit, and
 7 I guess that's where I first came across hepatitis
 8 because samples were supplied for analysis in yellow
 9 tubes and, when I asked what the yellow tubes meant,
 10 they said that's coming from a patient that is
 11 suspected of having hepatitis, and we were told to be
 12 very careful with it. That was probably the extent of
 13 the intervention that occurred.
 14 But beyond that, and from discussions with
 15 colleagues and doctors that worked in the unit in
 16 Hammersmith, I had some understanding of what sort of
 17 patients that material would come from. But beyond
 18 that, I had no knowledge of its pathology and its
 19 clinical sequelae to becoming infected with hepatitis.
 20 So it was very rudimentary understanding.
 21 Q. Then you've said in your witness statement to this
 22 Inquiry that you became aware of the association
 23 between hepatitis viruses and blood and blood products
 24 within weeks of joining SNBTS. You describe it as
 25 a knowledge that was superficial initially but

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1 well, I think my learning curve was quite steep in
 2 respect of non-A, non-B hepatitis.
 3 Q. And in terms of the nature of non-A, non-B hepatitis,
 4 do you recall what the prevailing view was in PFC that
 5 was being shared with you about the nature of it or
 6 the seriousness of it or its potential for long-term
 7 sequelae?
 8 A. At the beginning of the 1980s?
 9 Q. Yes.
 10 A. I think it probably reflected the wider perspective on
 11 non-A, non-B hepatitis, which was it wasn't properly
 12 understood. I think, to be honest, the view that was
 13 conveyed to me or the view that I took away from
 14 discussions and conversations with colleagues was that
 15 it was a mild, self-limiting disease -- undesirable;
 16 you wouldn't want to catch it -- but it's not a major
 17 issue. That was at the beginning of the 1980s. Now,
 18 as we know, I think that particular view that
 19 I'd picked up developed quite quickly into a better
 20 recognition of what this disease caused and what its
 21 long-term sequelae was.
 22 But I only -- I learnt these -- I got my
 23 perspective from discussing with colleagues in the
 24 SNBTS and attendance at -- and particularly when
 25 I became acting director and I attended regional

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

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

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

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

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

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

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

15 **Q.** Then just still sticking with the end of 1981, if we
16 look at CBLA0001464. These are the minutes of
17 a meeting of the UK Haemophilia Centre Directors,
18 9th October 1981. If we go to the third page, we can
19 see you're in attendance. You are the sixth name down
20 or thereabouts, Dr Perry.

21 **A.** Yes.

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

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

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1 would not be sustainable in the longer term."

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

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

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

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

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

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

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

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

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

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

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

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1 confidential or anything like that. And indeed, on
 2 the occasions that I did attend these meetings,
 3 I would often write a report and circulate it to
 4 colleagues. It was part of the collegiate discussions
 5 that the transfusion services had with haemophilia
 6 directors. I don't think they would have served any
 7 purpose if they had been confidential.
 8 **Q.** No, I wasn't suggesting that they were confidential,
 9 Dr Perry. It is really just a question as to whether
 10 you can recall whether -- we know Dr Craske did
 11 produce written reports. I was simply --
 12 **A.** He did indeed.
 13 **Q.** -- wondering whether they were made available beyond
 14 Haemophilia Centre Directors?
 15 **A.** Well, they would have been circulated -- if I had
 16 received such a report from Dr Craske at the meeting,
 17 then as soon as I got back to Edinburgh I would have
 18 circulated that to colleagues. It would have been
 19 photocopied and posted out.
 20 **Q.** Then if we just move forward, perhaps before the
 21 break, to the second UKHCDO meeting you would have
 22 attended.
 23 So PRSE0000185, please, Sully.
 24 So this refers to the Haemophilia Directors'
 25 annual meeting, 13 to 14 September 1982. These are
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1 of the page I just wanted to ask you about.
 2 So there is a reference to a presentation, it
 3 would appear, by Professor Zuckerman on non-A, non-B
 4 hepatitis. Then a presentation by Dr Snape, which is
 5 described as containing no revelations. But then it
 6 says:
 7 "It was the declared policy of BPL in (in the
 8 future) to establish a system whereby all incoming
 9 plasma would be quarantined for 6 months in order to
 10 enable reports of post-transfusion hepatitis from
 11 centres to be traced to plasma donations or pools."
 12 Do you know whether a similar system was -- or
 13 policy operated at PFC?
 14 **A.** No, we did not operate that policy.
 15 **Q.** And do you know whether any consideration was given to
 16 whether -- one that should be adopted on receipt of
 17 this?
 18 **A.** I don't know. This was 1982, wasn't it?
 19 **Q.** Yes, September '82.
 20 **A.** If we had done that, that would have required the
 21 express consent, approval and support of Mr Watt and
 22 Professor Cash to do that. And removing effectively
 23 six months' supply of plasma would have severely
 24 affected our ability to maintain our output and so on.
 25 I'm not absolutely sure whether BPL did actually
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1 not the minutes. This is a note taken by someone in
 2 attendance.
 3 If we go to -- I think it's probably page 3. Is
 4 this your note, do you think?
 5 **A.** I have seen this. And I have tried to work out myself
 6 whether -- in a sense it could be. It sounds like it
 7 might have been written by me, but it might have been
 8 written by somebody like Dr Chris Prowse, who was very
 9 familiar with coagulation factor products.
 10 It seems to have a fair amount of high level
 11 scientific and clinical data in it for me, at that
 12 stage in my career, to have competently written this,
 13 but some of the phraseology does sound familiar to me.
 14 **Q.** In any event, whether it was written by you, it would
 15 appear from the very top of the page, where it says
 16 "Notes (On Matters of Relevance to PFC)", it was
 17 written by someone associated with PFC for the purpose
 18 of sharing with the PFC, is that a fair inference?
 19 **A.** Absolutely, yes, yes. Yes. This would have been
 20 circulated throughout the SNBTS I think.
 21 **Q.** Then I just want to ask you briefly about something at
 22 page 5.
 23 You can see -- you don't need to look at the top
 24 of the page, but there is a discussion about liver
 25 disease in haemophiliacs. Then it is the bottom half
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1 implement this, because the same -- there would have
 2 been the same downside for BPL to -- it's basically
 3 post-transfusion surveillance.
 4 **Q.** Then if we see there is a reference there to a policy
 5 in relation to infrequent uses of Factor VIII and IX.
 6 Then over the page in relation to regular users.
 7 I just wanted to ask you about the first of those. We
 8 can see the second, "Selective Vaccination", the
 9 third, "Heat Inactivation - currently being
 10 investigated". The first:
 11 "Improvements in donor screening and pool
 12 security."
 13 Do you know what's meant by that?
 14 **A.** No. Can we go back a page, please?
 15 **Q.** Yes. It is the bottom of the previous page.
 16 **A.** Is that -- or is that just the heading?
 17 **Q.** Yes.
 18 **A.** "Removal of Viral Contaminants ..."
 19 What is that?
 20 **Q.** It is a note of Dr Snape presenting BPL policy in
 21 relation to infrequent users and then, over the page,
 22 regular users?
 23 **A.** Yes, okay.
 24 **Q.** It is just the reference to -- obviously donor
 25 screening is, I think --
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1 A. "Improvements in donor screening and pool security."
2 I'm not quite sure I can explain what that
3 means.
4 "Selective Vaccination" is fairly obvious.
5 That's perhaps infecting -- injecting susceptible
6 haemophilia patients with hepatitis B vaccine, because
7 that was the only vaccine that was available for
8 hepatitis viruses at the time.

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

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

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

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

25 Then if we just look at paragraphs 94 and 95.

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

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

4 SIR BRIAN LANGSTAFF: Yes. We will take a break now until
5 3.50 pm.

6 (3.23 pm)

(A short break)

8 (3.50 pm)

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

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

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

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

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1 94 you say this:

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

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

9 A. Yes, it is part of that.

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

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

15 What particular research did you have in mind
16 there?

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

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

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

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

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

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

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1 hardening up, I think.
 2 **Q.** Then if we look at your witness statement,
 3 WITN6920001. If we go to page 28 and look at the
 4 bottom of that page, I think you say at paragraph 79:
 5 "I do not recall any specific practical actions
 6 being undertaken by PFC in response to early reports
 7 concerning AIDS other than paying close attention to
 8 emerging UK, international and regulatory
 9 (particularly FDA) opinion."
 10 Then, over the page, you refer in the second
 11 line at the top of the page to:
 12 "SNBTS and PFC staff regularly attended UK and
 13 international meetings and conferences in which AIDS
 14 increasingly featured in the scientific programmes and
 15 discussions."
 16 So I think it is right to understand from your
 17 statement that, at this point in time, late '82 into
 18 1983, there was nothing in particular PFC did as
 19 a response to the emerging and increasing knowledge
 20 about AIDS.
 21 **A.** I'm not sure when -- I think the answer to that is no,
 22 we didn't do anything in particular. I'm not quite
 23 sure when -- I can't remember, although it's been
 24 discussed recently at the Inquiry, when the first
 25 leaflets were proposed to be sent to donors and so on.

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

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1 **Q.** Yes, and that's a little later in 1983 --
 2 **A.** That's a little later, yes.
 3 **Q.** -- so we see discussions emerging or taking place
 4 certainly in Scotland in May of 1983.
 5 **A.** Yes. My recollection -- what we did do (but it wasn't
 6 in response to AIDS, it was in response to non-A,
 7 non-B hepatitis) which was establish the SNBTS
 8 coagulation factor study group under Professor Cash
 9 and, of course, had that been -- had early success,
 10 then it would have been applied to HIV risk as well as
 11 non-A, non-B risk.
 12 **Q.** We heard from Dr Foster about his attendance at the
 13 World Federation of Haemophilia conference in
 14 Stockholm in the middle of 1983. Did you attend
 15 that conference?
 16 **A.** No, I don't remember going to that, no.
 17 **Q.** Now, a meeting you did attend, and which you refer to
 18 in your statement, is the meeting of Haemophilia
 19 Centre Directors in October 1983. If we can look at
 20 the note that I think you made, or someone from PFC
 21 made, about that meeting, it is at PRSE0000040 please,
 22 Sully. We can see it is entitled:
 23 "Notes on the Fourteenth Meeting of UK
 24 Haemophilia Centre Directors at Oxford RHA
 25 17th October 1983."

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

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

11 That's presumably Dr Foster?

12 A. Yes.

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

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

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

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1 Q. Then the note continues:

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

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

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

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1 and it says that Terry seemed to reinforce this view.

2 So I think Terry, representing BPL, reinforced that
 3 view that the output of BPL, if they were to heat
 4 treat their products, would fall by a further 25%.

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

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

14 A. Sorry, what was the date of this?

15 Q. It is 17 October 1983.

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

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

6 A. Yes.

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

9 "Comprehensive written reports were circulated
 10 (attached)."

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

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

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

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

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

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

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

25 "Conclusion -- Serious disease in haemophiliacs

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1 a low possibility??"

2 I don't know whether you can, at this distance

3 of time, say, Dr Perry, but is that your

4 interpretation of what -- the figures that have been

5 delivered or is that you recording a discussion at the

6 meeting about numbers at risk and the extent to which

7 serious disease --

8 **A.** I think this is -- they are certainly not my figures.

9 I don't think I would in -- been in a position to do

10 those calculations. I think these were -- the data

11 that was presented. I have to say it was a -- in many

12 senses, as we know now, they were wildly off the mark,

13 and simply because they were just taking numbers of

14 known patients with AIDS and dividing that by the

15 total population and, in a sense, projecting that as

16 a risk, which clearly completely underestimated the

17 number of patients that seroconverted to HIV but had

18 yet to be detected.

19 **SIR BRIAN LANGSTAFF:** It wasn't dealing with risk at all,

20 was it? It was dealing with perceived incidence.

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

22 **MS RICHARDS:** There's then a summary of the UK situation

23 and reference to details of haemophiliac cases A1 and

24 A4. That, I suspect, is a reference to the

25 individuals that we have referred to as the Cardiff

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1 BPL cannot determine the pool size used to make the

2 batch."

3 Now, that first paragraph under the heading

4 "Hepatitis":

5 "NHS material is no better than commercial

6 product, with suspected disease transmission."

7 Would be a fairly fundamental piece of

8 information, would it not, for PFC, whose

9 raison d'être, as you've described it, has been very

10 much "domestic NHS concentrates are safer than

11 commercial concentrates". Can you recall the

12 discussion about that issue?

13 **A.** I think this relates to -- unless my timing is wrong,

14 but to the really quite key and sentinel publication

15 by Dr Kernoff, who did detailed studies in patients on

16 NHS product and on commercial product, and he found

17 that I think -- I think something like 8 out of 9

18 patients on NHS product developed symptoms of non-A,

19 non-B hepatitis, 100 per cent for commercial product,

20 and I think it is referring to that. So in my note

21 this is simply a shorthand referring to an appendix.

22 So maybe there is more detail in the appendix but

23 I can't remember what that appendix actually

24 contained.

25 But if this meeting is from late 1983, I think

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1 case and the Bristol case, or Cardiff patient and

2 Bristol patient. In any event, do you have any

3 recollection of discussions within PFC or within SNBTS

4 about the fact that by October 1983 there were cases

5 in haemophiliacs in the United Kingdom? Do you

6 remember that being a subject of discussion and

7 concern at SNBTS?

8 **A.** There were two cases, weren't there, in haemophilia

9 patients?

10 **Q.** Yes.

11 **A.** That's right. I can't remember whether -- I'm pretty

12 certain it will have been discussed. This was

13 a report that went out to all my colleagues in PFC and

14 certainly colleagues in RTCs. So it would have

15 provoked discussion. I can't remember what that

16 discussion was or what the outcome of that discussion

17 might have been.

18 **Q.** Then if we just look at the bottom of this page, we

19 have got the heading "Hepatitis":

20 "NHS material is no better than commercial

21 product, with respect to disease transmission.

22 "In a small study using an 'accredited donor'

23 pool, manufactured by BPL, one in eight recipients

24 have so far developed signs of NANB hepatitis. So far

25 this study is of two months duration and unfortunately

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1 it was certainly known by then that NHS products were

2 not free from the risk of non-A, non-B hepatitis.

3 They were believed, certainly in the early studies, to

4 have lower severity of disease and the clinical

5 symptoms were shorter lived. Whether that turned out

6 to be a valid observation, I don't know, so there were

7 differences but the idea that NHS products were safe

8 was simply discounted as a result of this.

9 **Q.** Can I then just ask you to look briefly at the formal

10 minutes of the meeting, rather than your note.

11 We will find those at PRSE0004440.

12 We have got the date there again,

13 17 October 1983, and your attendance is recorded on

14 the second page.

15 If we go to, I think it should be page 9, first

16 of all, Sully.

17 I don't have a question for you in relation to

18 this, Dr Perry, but I'm going to flag up that if we

19 look at the penultimate paragraph on the page, it

20 says:

21 "In reply to a query Dr Snape said that BPL

22 hoped that not more than 10-15% of the factor VIII

23 yield would be lost in the making of the virus free

24 products."

25 I just draw attention to that, because I think

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1 your note had recorded a possibility of up to 25%. It
 2 may not be inconsistent but I just wanted to draw that
 3 out.
 4 **A.** Okay.
 5 **Q.** If we go to the next page, there is a discussion under
 6 the heading "Any Other Business", and this is
 7 a passage the Inquiry has looked at on a number of
 8 occasions, but it refers to Dr Chisholm, who was the
 9 Haemophilia Centre Director in Southampton,
 10 identifying a problem of patients not wanting to take
 11 up commercial Factor VIII and a discussion about
 12 reversion to cryoprecipitate. And Professor Bloom's
 13 response:
 14 "... no need for patients to stop using the
 15 commercial concentrates because at present there was
 16 no proof that the commercial concentrates were a cause
 17 of AIDS."
 18 Then Dr Chisholm is recorded as saying she can
 19 get unlimited supplies of cryoprecipitate, other
 20 directors report the same. And then it records
 21 an agreement that:
 22 "... patients should not be encouraged to go
 23 over to cryoprecipitate for home therapy but should
 24 continue to receive the NHS or commercial concentrates
 25 in their usual way.

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1 the moment. You then say:
 2 "BPL (Elstree) were exploring dry heat as
 3 an option on a collaborative basis with PFC."
 4 In terms of 1982, what is the reference there to
 5 collaboration with PFC? What was it that PFC was
 6 contributing to BPL's dry heat work?
 7 **A.** I think we were simply sharing information. I don't
 8 think there was a jointly agreed research programme.
 9 I think it was simply an observation that PFC and BPL,
 10 or PFL, were exchanging information, particularly in
 11 terms of BPL's success or otherwise with their dry
 12 heat treatment programme. And likewise the PFC with
 13 its pasteurisation process.
 14 **Q.** Then the next item that you record, "1983/1984":
 15 "International debate as to causative agent of
 16 AIDS. Consensus view that causative agent was
 17 an infectious agent (virus) emerged in mid-1984."
 18 Now, why were you identifying the consensus view
 19 emerging in mid-1984, as you put it, as the next
 20 significant item here?
 21 **A.** I don't really know. I think what I was reflecting
 22 was that there were other -- at that time, perhaps,
 23 maybe a little earlier than mid-1984, that there were
 24 other putative explanations in terms of T cell
 25 abnormalities and repeated infusion of high quantities

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1 Now, that is a debate perhaps of most direct
 2 interest to haemophilia clinicians, but is it one that
 3 you have any recollection of, that part of that
 4 meeting?
 5 **A.** No, I don't recall the detail of the meeting, I'm
 6 afraid. I think -- I was certainly aware subsequently
 7 that this was beginning to be the case, but, I'm
 8 sorry, I can't elaborate on that at all.
 9 **Q.** Can I then just pick matters up at PRSE0001885.
 10 We looked earlier at this letter from you to
 11 Dr Cash in March of 1988, attaching the summary of
 12 events. I just want to ask you about a couple of
 13 passages now in the summary itself.
 14 So if we go to page 2, please, Sully.
 15 Under the heading "Summary of SNBTS response to
 16 HIV contamination of PFC coagulation factors", which
 17 is the heading, if we can zoom in on the top half of
 18 the page. What we have got identified there under the
 19 heading "[Factor] VIII heat treatment developments" is
 20 as follows:
 21 "Early 1982. In response to known hepatitis
 22 risk of [Factor] VIII concentrates, PFC initiated
 23 development programme for solution heating of
 24 Factor VIII ..."
 25 I'm not going to ask you further about that at

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1 of protein through regular infusions and so on. And
 2 Professor Ludlam, he didn't advocate these. He simply
 3 suggested that these might either contribute or could
 4 conceivably -- or there was evidence that they could
 5 conceivably be the case. I think I'm simply
 6 reflecting there from my own personal knowledge that
 7 by that time it was absolutely clear.
 8 **Q.** The next entry is October '84. That's the "Report
 9 from SEBTS of seroconversion of haemophiliac cohort",
 10 which we will come on to in due course.
 11 Then October '84 still refers to PFC examining
 12 tolerance of the unheated stock to withstand dry heat.
 13 And then we have reference to the Groningen
 14 conference.
 15 Can you just assist in unpicking this. It says:
 16 "Present at conference (Groningen) ..."
 17 Were you present at that conference?
 18 **A.** I was, yes.
 19 **Q.** "... where first virus inactivation results were
 20 announced (US) from CDC/Cutter study within one day of
 21 results being obtained."
 22 Is that saying that the announcement in the
 23 conference was within a day of CDC/Cutter having that
 24 data?
 25 **A.** It was. I think CDC had been invited to the meeting

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

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

12 **A.** Yes, of course. Yes, yes.

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

20 Is that a fair inference?

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

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

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

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

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

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

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

7 You can take that down, please, Sully.

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

14 **A.** Yes.

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

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

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

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

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

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

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

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

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1 size of the respective messages, were authorised as
 2 a result of being granted a marketing authorisation.
 3 So we would have gone through that process and
 4 you're right to say that when I joined in 1981 I'd had
 5 no impact -- or input into that. But I think --
 6 I can't remember exactly when, maybe 1982 -- I did
 7 a review of the packaging, particularly for
 8 coagulation factors, and within that review I would
 9 have certainly reviewed the precise wording and made
 10 any changes that were necessary, and had that approved
 11 by the PFC director and his medical adviser, who was
 12 Professor Cash.
 13 **Q.** We'll look at the language of the pharmacopoeia in the
 14 morning rather than now.
 15 Just in terms of the input or involvement of the
 16 licensing authority, would it be right to understand
 17 that what happened is PFC would submit its application
 18 which would contain, as you say, draft wording,
 19 contain -- and we will look at an example in the
 20 morning -- a leaflet or insert which had certain
 21 information about hepatitis on it?
 22 **A.** Yes.
 23 **Q.** But it would be submitting that as part of the product
 24 application process?
 25 **A.** Yes.

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1 complies with the monograph.
 2 **Q.** Then just in terms of who the audience was for the
 3 inserts or the labels on the vials and so on, can
 4 I just ask you to look at an extract from your
 5 evidence to Penrose. PRSE0006038.
 6 If we start -- so this is your evidence on
 7 24th June 2011. If we start on page 95 -- I just want
 8 to pick it up from the bottom half of the page from
 9 line 14 onwards. You were asked essentially the same
 10 question that I'm asking you: who were those pack
 11 inserts designed for? Was it for the doctors, the
 12 patients or who. And this is your response:
 13 "It's a good question. Certainly nowadays you
 14 have a thing called a 'product information leaflet'
 15 and a 'technical information leaflet' and they have
 16 different target audiences and they are written in
 17 completely different ways."
 18 Just pausing there, Dr Perry, do you know when
 19 that particular change or --
 20 **A.** I think it was the early 1990s.
 21 **Q.** Then you say:
 22 "At that time, I think the answer to your
 23 question is they were targeted in the way they were
 24 written, certainly at prescribing doctors. They gave
 25 some basic characteristic but also some of the

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1 **Q.** It might or might not then be approved. But the
 2 licensing authority didn't itself come up with
 3 a required form of wording; is that right?
 4 **A.** Periodically, they may have -- in response to any
 5 manufacturer submitting a licence application, there
 6 might be some form of words, particularly to do with
 7 the product inserts where different companies take --
 8 use different wording. It's not standardised, it's
 9 not one size fits all and they may well come back and
 10 ask for changes or a different emphasis and so on.
 11 I think our product inserts were fairly simple
 12 and fairly straightforward and -- but it is the case
 13 that the licensing authority could come back and ask
 14 you to change something.
 15 **Q.** Yes, I accept that. I think my question was
 16 a slightly different one. The licensing authority
 17 didn't itself produce a form of wording for use on
 18 Factor VIII concentrates.
 19 **A.** No.
 20 **Q.** It would respond to what was being submitted to it by
 21 PFC or BPL or Amour or whoever it might be?
 22 **A.** That's right. But if we -- and we did, we called our
 23 product "human anti-haemophilic product BP", so that
 24 would automatically trigger the licensing authority to
 25 look at the BP monograph and check whether our wording

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1 information was very accessible to lay people in terms
 2 of how you reconstituted the product, how you used it
 3 and so on."
 4 A question was:
 5 "Was part of the purpose of the package insert
 6 to give information about the possibility of there
 7 being risks of viruses being transmitted through the
 8 product?
 9 "A. The package inserts that we had in common
 10 with the rest of the industry certainly included
 11 warnings that -- I think we were very general in our
 12 warnings saying, 'this product, although the plasma is
 13 tested for hepatitis B it cannot be assumed to be free
 14 of infectious risk', or words to that effect. So,
 15 yes, it was designed to give a warning to both
 16 patients and certainly to doctors, but doctors already
 17 knew this."
 18 And then we continue with your answer at 16
 19 that:
 20 "... these products carried a risk associated
 21 with them. So the document that was included with
 22 each vial was really part of that process but also to
 23 satisfy our essentially legal obligations within the
 24 pharmaceutical industry ... even then the industry was
 25 required for prescription medicines to have some sort

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1 of information leaflet associated with them."
 2 It would appear from that answer you're
 3 suggesting it's, is this right, predominantly aimed at
 4 doctors but also with a view to providing information
 5 to patients?
 6 **A.** I think they were designed and designed primarily for
 7 doctors and, indeed, pharmacists. I think the whole
 8 product insert leaflets at that time were there to
 9 inform not only the prescribing doctor but if there
 10 was a pharmacy -- for our products, that wasn't the
 11 case because they weren't supplied through pharmacies
 12 but, as a general principle, these leaflets were there
 13 to provide important information to both prescribers
 14 and pharmacists who were fulfilling prescriptions.
 15 I think I always took the view, and I think
 16 others did, that these products were supplied with the
 17 product and patients on home therapy would have been
 18 supplied with the whole package, so that they would
 19 have had the leaflet and many of them may well have
 20 read it. But I think the precise wording was
 21 prescribed by the requirement to satisfy the
 22 professional requirements for the product, rather than
 23 the individual patients. Those leaflets came later.
 24 **MS RICHARDS:** Perhaps we can pick that up in the morning
 25 by looking at the actual wording, which will take

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1 a little time so I won't embark upon it now.
 2 **SIR BRIAN LANGSTAFF:** Yes. We will take a break now,
 3 then, until 10 o'clock in the morning, if you please.
 4 So 10 o'clock in the morning.
 5 **(4.31 pm)**
 6 **(Adjourned until 10.00 am on Friday, 1 April 2022)**
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(52) capacity - coagulation

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(53) coagulation... - consumables

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(54) consumables... - deepened

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(60) from... - had

<p>H</p> <p>had... 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I	28/18 28/22 33/12 33/25 35/2 42/21 54/10 56/4 57/6 60/5 61/8 61/14 64/21 71/4 75/17 75/20 82/9 82/17 83/12 86/19 91/18 95/7 95/15 97/12 103/4 103/7 103/19 109/12 112/13 115/6 115/20 123/3 125/9 132/18 134/8 134/17 135/10 135/11 143/3 143/8 145/6 147/18 150/25 152/21 154/16 158/23 161/2 161/9 164/6 164/17 166/5 167/7 167/21 I feel [1] 125/5 I find [1] 73/18 I first [1] 138/7 I got [2] 140/22 145/17 I guess [7] 4/12 16/3 66/14 67/15 76/22 115/12 138/7 I had [21] 2/6 12/7 12/12 13/17 15/11 15/11 17/5 17/16 18/8 52/18 54/22 54/25 77/7 77/9 108/21 133/19 138/16 138/18 139/7 139/21 145/15 I have [20] 11/13 28/11 54/14 58/2 62/2 66/4 68/1 98/19 105/9 105/12 118/5 119/1 121/16 125/21 128/4 128/14 144/24 146/5 146/5 161/11 I honestly [1] 16/5 I imagine [2] 1/8 90/8 I joined [7] 57/23 76/12 92/21 94/12 139/17 139/22 173/4 I just [19] 25/1 41/12 50/5 67/1 68/13 92/17 120/21 120/25 121/2 136/9 141/5 146/21 147/1 148/7 156/18 165/2 166/12 175/4 175/7 I knew [2] 28/20	103/4 I know [3] 45/11 108/1 134/22 I learnt [2] 139/8 140/22 I list [1] 9/15 I made [2] 77/4 133/18 I mean [2] 28/18 160/4 I meant [1] 3/5 I mentioned [2] 117/1 135/12 I met [1] 55/1 I might [1] 23/4 I move [1] 60/6 I moved [1] 2/10 I must [1] 72/18 I need [2] 42/21 115/20 I never [2] 65/11 121/16 I note [2] 72/11 151/2 I noted [1] 172/5 I noticed [1] 126/5 I only [1] 140/22 I pointed [1] 157/4 I pretended [1] 152/18 I probably [2] 63/4 64/21 I readily [1] 15/20 I recall [4] 20/10 48/22 108/22 112/25 I recognise [1] 74/3 I regularly [1] 152/6 I remained [1] 7/7 I remember [1] 126/10 I reported [1] 64/14 I reviewed [1] 133/19 I right [1] 117/20 I said [1] 54/10 I sat [1] 159/22 I saw [1] 15/12 I say [9] 10/16 48/13 53/7 62/11 69/18 85/4 139/17 139/24 160/3 I shared [1] 133/13 I should [1] 64/15 I spent [1] 138/3 I started [1] 93/6	I suggested [1] 20/24 I suppose [1] 104/16 I suspect [2] 121/7 161/24 I then [9] 2/7 29/9 63/7 65/21 87/11 115/17 124/3 164/9 166/9 I think [364] I think, need [1] 125/9 I thought [1] 136/21 I took [6] 20/10 21/24 108/12 109/21 132/1 140/13 I turn [1] 42/23 I understand [11] 4/4 14/20 40/6 46/15 53/14 59/10 64/4 88/7 96/16 122/23 129/20 I undertook [1] 76/15 I want [9] 18/11 76/5 79/5 92/9 92/13 92/15 124/4 137/22 170/2 I wanted [4] 53/21 94/7 141/15 172/10 I was [44] 2/6 2/9 3/20 6/18 9/25 12/9 15/13 16/9 16/11 16/15 16/16 18/6 29/2 31/12 52/16 52/16 52/17 52/21 75/3 75/7 75/12 76/2 79/22 88/21 89/5 103/5 105/18 108/18 108/18 108/19 123/7 123/19 133/18 139/18 139/20 139/20 144/1 144/17 145/11 156/16 166/6 167/21 168/18 172/6 I wasn't [1] 145/8 I will [8] 2/24 10/6 10/16 19/22 21/8 34/1 109/22 121/1 I won't [2] 4/2 178/1 I would [23] 10/3 22/7 23/8 30/2 33/19 58/4 66/14 75/7 79/7 80/16 80/21 82/3 87/7 123/4 128/16 145/3 145/17 149/18 152/1 152/18 157/23 161/9 173/8	I wouldn't [3] 26/15 132/11 143/3 I'd [4] 57/5 139/16 140/19 173/4 I'd heard [1] 139/16 I'd picked [1] 140/19 I'll [1] 170/1 I'm [42] 5/22 7/15 8/23 32/25 35/1 35/7 37/5 59/17 76/6 77/11 79/17 89/16 95/10 96/24 99/2 102/6 104/15 108/3 112/10 129/9 129/10 132/9 136/15 136/16 144/19 147/25 149/2 149/13 149/19 151/2 151/9 152/12 153/21 153/22 162/11 164/18 166/5 166/7 166/25 168/5 171/11 175/10 I'm just [1] 144/19 I've [3] 30/3 35/24 135/10 I've got [1] 135/10 I've said [1] 35/24 i.e [1] 157/2 idea [9] 27/14 33/20 34/24 46/22 64/15 77/20 82/3 101/22 164/7 ideal [1] 40/19 ideas [1] 151/17 identical [1] 57/17 identified [11] 33/3 34/1 35/14 37/14 49/7 98/4 129/5 133/16 156/17 166/18 172/16 identify [4] 18/18 19/3 33/16 91/19 identifying [3] 150/12 165/10 167/18 idiosyncratic [1] 96/13 ie [1] 125/17 if [146] 10/8 10/16 10/20 13/4 13/6 13/15 17/6 18/12 18/15 18/15 21/8 23/16 23/21 26/2 26/21 31/2 31/13 31/19 31/20 32/17 36/22 39/24
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