

Thursday, 24 March 2022

(9.59 am)

**SIR BRIAN LANGSTAFF:** Good morning, Dr Foster.

Now, you are talking not just to the audience that you see in front of you. The size is limited for obvious reasons of the current -- although -- infection. Although precautions generally may be easing, we take a fairly careful line here. But, in particular, there will be a lot of people who are watching what you have to say online. The proceedings are being live streamed, so bear that in mind when you give your evidence.

Thank you for being with us. In a moment, Katrina will ask you to take the affirmation.

Katrina.

**DR PETER FOSTER (affirmed)**

**Questioned by MS RICHARDS**

**SIR BRIAN LANGSTAFF:** Ms Richards?

**MS RICHARDS:** Dr Foster, I'm just going to start with a very quick overview of your career. Now, you're a doctor but not a clinician. Your degree, as I understand it, is in chemical engineering with a PhD in biochemical engineering; is that right?

**A.** That's correct.

**Q.** In January 1973, you took up a post at the PFC as

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**Q.** Now, you've given evidence on a number of different occasions in a number of different forums, and I'm just going to go through those briefly. You gave evidence in multi-district litigation in the States. Perhaps we can take this from your witness statement. Sully, could we have on screen WITN6914001. And if we go to page 15, we can see bottom half of the page. You explain there your involvement at the request of lawyers from the United States in the MDL (multi-district litigation) 986 in the States.

You say over the page, if we go to page 16, and it's the fifth paragraph, so (viii) -- you refer to your trial testimony being filmed in Edinburgh on 8 December 1997, and you say you believed it was shown at a number of court hearings, all of which found in favour of the defendants.

What's the source of your understanding, Dr Foster, that the litigation to which you refer was found in favour of the defendants?

**A.** That is what I was told by the lead attorney for the defendants when I asked him what had happened to my evidence.

**MS RICHARDS:** I mention it and, sir, I make an observation for wider purposes because it's been drawn to my attention that there is evidence of a number of claims

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a senior biochemist, a post which you remained in until April 1974, before becoming the head of research and development at the PFC; is that right?

**A.** That's correct.

**Q.** And I think your job title changed from time to time, but is it right to understand that that's essentially the role you continued to occupy throughout the lifetime of the PFC?

**A.** That's correct.

**Q.** And was that until, then, 2008?

**A.** Yes.

**Q.** Was that the point at which the PFC ceased to operate?

**A.** That's right.

**Q.** For anyone's note, there's a CV for Dr Foster. I'm not going to go to it, but it's at WITN6914002.

So you were not yourself involved with the treatment of patients; is that correct?

**A.** That's correct. I had no role in that at all because I'm not medically qualified.

**Q.** And there's a part of your evidence, oral evidence to the Penrose Inquiry -- we can look at it if necessary, but I don't think we need to -- in which you explained that you'd never worked in a blood bank and you didn't have practical experience of using cryoprecipitate.

**A.** That's correct.

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within MDL-986, multi-district litigation, being subject to settlement and subject to the payment of sums to the plaintiff, sir. I was asked to clarify that with you.

**SIR BRIAN LANGSTAFF:** Yes, my understanding was that the case -- the claims, at least those that were permitted to proceed in the United States, were settled --

**MS RICHARDS:** Yes.

**SIR BRIAN LANGSTAFF:** -- for what were considered substantial sums, I think.

**MS RICHARDS:** Yes, that's certainly the evidence we've seen.

**A.** Can I just comment?

**Q.** Yes, of course.

**A.** What I was told was that settlement was an out-of-court settlement.

**Q.** Yes.

**A.** But a number of the claimants declined that because they wanted their day in court, and so there were some further cases that were heard, and that's where my evidence was presented.

**Q.** You explain in the next paragraph on the screen, so it's paragraph (ix), that you were asked to comment on an expert report from Dr Nicholas Jewell concerning HIV infections in the UK. Now, I'm not going to go to

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1 the content of it. I just really want to ask about  
2 how you came to be asked to do that.  
3 Dr Jewell, now Professor Jewell, is  
4 a professor of biostatistics and epidemiology. In  
5 fact, I should say he's on the Inquiry's expert group  
6 in relation to statistics. You're obviously -- as  
7 we've discussed, you're a clinical scientist, you're  
8 a chemist by background. You're not a statistician or  
9 epidemiologist. How was it that you came to be asked  
10 to provide that report?

11 A. I can't really answer that, other than Mr Barr  
12 contacted me, gave me a copy of this, and asked for  
13 some comments on it.

14 Q. We can take that down. Thank you.

15 You were also involved in providing evidence for  
16 the purposes of an investigation by the Scottish  
17 Executive and the Health and Community Care Committee  
18 of the Scottish Parliament, and that was in around  
19 2000; is that right?

20 A. That's correct.

21 Q. I'm just going to read the references for those  
22 reports. I'm not going to take you to them, but just  
23 so that others can find them readily. PRSE0000131,  
24 PRSE0001249, WITN6914012, and WITN6914013.

25 Now, you also gave evidence to the Lindsay

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1 that we should do our best to assist the Archer  
2 Inquiry. Even though it wasn't a statutory Inquiry,  
3 it was the only investigation underway. And we both  
4 felt that -- felt so strongly that he approached the  
5 Scottish Executive and was given permission for us to  
6 apply to the Archer Inquiry to give evidence. I think  
7 we were the first health professionals to do so.

8 Q. Again, I'm not going to go to it now. I probably will  
9 ask you to look at a couple of passages in your oral  
10 evidence to Archer in due course. The references for  
11 the transcript are ARCH0002320 which was the written  
12 statement, and then ARCH0000009 which is the  
13 transcript of the oral testimony.

14 We then come to the Penrose Inquiry. Is it  
15 right to understand that you were effectively retained  
16 on a full-time basis by SNBTS to assist them with the  
17 preparation of material for the Penrose Inquiry?

18 A. I had a contract. I suppose you could call it full  
19 time. It was based on an hourly rate. It depended on  
20 how much work I did for SNBTS.

21 Q. Now, you provided or contributed to by way of  
22 co-authorship a number of different statements and  
23 reports to the Penrose Inquiry. For present purposes,  
24 I'm just going to read the references out, but we'll  
25 come back to some of them in the course of the

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1 Tribunal in Ireland. How did that come about?

2 A. I have a vague memory that a solicitor from the  
3 Lindsay Tribunal came to Scotland to have preliminary  
4 discussions. And in advance of that, I had gone  
5 through the file that we had on Ireland, and I'd come  
6 across some correspondence between the director from  
7 the Republic of Ireland to Mr Watt -- sorry, it's the  
8 other way around. From Mr Watt to the director of --  
9 it was Dr O'Riordan in Ireland, where Mr Watt was  
10 suggesting that Irish plasma could be processed at  
11 PFC. And I thought that might be of interest to the  
12 Lindsay Tribunal. So that basically is what started  
13 them asking me to give evidence. And I can't really  
14 remember much about it, other than what is now in the  
15 transcript of their proceedings.

16 Q. It may be I ask you in the course of your evidence to  
17 look at a passage or two from that, but just for  
18 present purposes -- again, we don't need to put it on  
19 screen; it's so that others know where to find it --  
20 the reference is LIND0000320.

21 You then provided evidence for the Archer  
22 Inquiry. Again, how did that come about?

23 A. That was my own initiative. Professor Franklin and  
24 I both believed very strongly that patients deserved  
25 to know the truth of what had happened, and we felt

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1 evidence.

2 There's quite a long list. PRSE0000545,  
3 PRSE0001083, PRSE0003147. That's material relating to  
4 self-sufficiency. PRSE0003349 and PRSE0002291 which  
5 are related to heat treatment. PRSE0000256 which is  
6 a statement in relation to the Penrose Inquiry's topic  
7 C3, heat treatment '85 to '87. PRSE0003480. That's  
8 a background report. I probably will ask you a little  
9 more about that in due course, Dr Foster. PRSE0001478  
10 which was Penrose Inquiry's topic B3. And PRSE0000814  
11 which I can't, for present purposes, remember what  
12 topic that was. And then you gave evidence on  
13 a number of occasions orally to the Penrose Inquiry.  
14 We may look at bits and pieces of that, but  
15 10 May 2011, PRSE0006022. 11 May, PRSE0006023.  
16 6 September 2011, PRSE0006041, 7 September 2011,  
17 PRSE0006042. And 26 October 2011, PRSE0006056.

18 Now, would it be right to understand, Dr Foster,  
19 that in terms of your evidence to the Penrose Inquiry,  
20 or the material which you helped gather together into  
21 reports and documents for the Penrose Inquiry, that  
22 quite a lot of it involved you looking at documents,  
23 looking at material, exploring issues that you  
24 wouldn't necessarily have been directly involved in at  
25 the time?

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1 So, for example, self-sufficiency in England and  
 2 Wales was one of the topics that was covered in some  
 3 of the material that you helped to put together for  
 4 the Penrose Inquiry.  
 5 A. Yes, I think that's probably correct. I was trying to  
 6 pull together as much as I could that was readily  
 7 available to me.  
 8 Q. And then, by contrast, there were some areas where you  
 9 provided evidence to the Penrose Inquiry that fell  
 10 squarely within the events with which you were most  
 11 directly concerned, such as the development of -- the  
 12 research and development work on pasteurisation, heat  
 13 treatment, production of factor concentrates.  
 14 A. Yes, that's correct.  
 15 Q. And just so you know, my focus is going to be on  
 16 issues and areas of which you had some form of direct  
 17 knowledge at the time. It won't be limited to  
 18 research and development, but it'll be focusing  
 19 predominantly on contemporaneous -- your own  
 20 contemporaneous knowledge.  
 21 A. Okay.  
 22 Q. Before we start with that, I'm hoping you can assist  
 23 with some general terms that I think will come up in  
 24 the documents that we look at, and it may be helpful  
 25 for everybody, certainly myself, to understand what's

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1 the 20th Century, proteins were characterised by their  
 2 solubility. Every protein has a different solubility  
 3 behaviour; it's like a fingerprint. And so because  
 4 that was the way proteins were characterised, Cohn was  
 5 very, very familiar with how proteins behaved: how  
 6 they dissolved, how they came out of solution, and  
 7 stuff like that. And he had worked on that for about  
 8 20 or 30 years with a team of people at Harvard.  
 9 So when he was given this task of coming up with  
 10 a blood substitute, he was aware that half of blood  
 11 plasma is comprised -- it's albumin. Albumin forms  
 12 half of the plasma. So it was his concept that if you  
 13 could recover albumin from plasma, that could be made  
 14 into a blood substitute. And he went about designing  
 15 a series of extraction steps which were called  
 16 fractions in order to arrive at albumin.  
 17 Now, albumin is one of the more soluble  
 18 proteins, probably the most soluble, and he would  
 19 remove the least soluble proteins first and eventually  
 20 get to albumin. So there were basically five steps,  
 21 five precipitate fractions, with fraction one being  
 22 the least soluble, and fraction five being the most  
 23 soluble. And fraction five is albumin, so that is how  
 24 he arrived at that sort of sequence of fractionation  
 25 steps.

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1 meant by those terms. So can I ask you to help us  
 2 with a guide, a glossary, as it were, to a number of  
 3 different concepts and terms.  
 4 In very -- in brief terms, what is fractionation  
 5 from the perspective of those involved with the  
 6 production of plasma products?  
 7 A. Fractionation is an industry which is concerned with  
 8 the provision of pharmaceutical products derived from  
 9 human plasma. Simple as that. I can go more into how  
 10 the terminology came about if that would help you?  
 11 Q. No, don't worry. I'm going to ask you to talk us  
 12 through some of the processes in a few minutes, but  
 13 I think that's a helpful short introduction.  
 14 Now, we'll see reference -- we've seen reference  
 15 before in the documents -- to Cohn fractionation.  
 16 What's that referring to?  
 17 A. Edwin Cohn was the person who invented plasma  
 18 fractionation which is the technique for extracting  
 19 different proteins from human plasma. And Cohn became  
 20 involved in 1940 when he was given the task of  
 21 preparing a blood substitute to aid the American  
 22 forces, should they become involved in the war that  
 23 had broken out in Europe.  
 24 He was, at that time, probably the world's  
 25 foremost protein chemist. And in the first half of

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1 And he used a technique called cold-ethanol  
 2 fractionation where ethanol dehydrates proteins, which  
 3 everybody knows if you have a night out and get too  
 4 drunk, you get a headache. Alcohol is a dehydrating  
 5 agent. It dehydrates the proteins and brings them out  
 6 of solution. So he used that technique, and he chose  
 7 ethanol because it had antibacterial properties, so it  
 8 would prevent growth of bacteria while the processing  
 9 took place.  
 10 Q. Now, the main products that were produced by  
 11 a fractionation centre such as the PFC at the time  
 12 with which we're concerned would have been -- and  
 13 we'll come obviously to some of the specific products  
 14 in due course -- would have been albumin, as you've  
 15 just described, immunoglobulins, and then the clotting  
 16 factors, predominantly VIII and IX. Is that right?  
 17 A. That's correct.  
 18 Q. If we go to WITN6914003, please.  
 19 This is an article co-authored by you in,  
 20 I think, 2008, "Fractionated products". And we can  
 21 just see if we read the first few lines. So if we go  
 22 to -- thank you:  
 23 "Fractionated products are plasma proteins that  
 24 have been extracted from pooled human plasma and  
 25 manufactured into stable pharmaceuticals in dose forms

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1 suitable for clinical administration. The major  
2 categories of fractionated products are  
3 immunoglobulins for the treatment of disorders of  
4 immunity, the prevention of specific infections and  
5 the prevention of RhD immunisation, albumin for volume  
6 and protein replacement, and coagulation factors for  
7 haemostasis."

8 So that, I think, is a summary of what I've just  
9 asked you.

10 Top of the next column -- don't think in light  
11 of the explanation you've given us I need to go  
12 through it, but there we have a reference to the work  
13 of Edwin Cohn.

14 Can we go over the page. I just want to look at  
15 the table, the first table. So we've got there  
16 principal plasma products, medical applications -- we  
17 don't need to worry about an estimate of the  
18 quantities used worldwide -- in 2005.

19 If we just look at the plasma products listed on  
20 the left-hand side, and if I ask you to cast your mind  
21 back to the '70s and '80s, so we can ignore  
22 recombinant, were those all produced at the PFC?

23 A. No. We didn't -- if you start at the bottom, we  
24 didn't produce antithrombin III, we didn't produce  
25 alpha 1 antitrypsin, and we didn't obviously, as you

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1 an absorption step and then it would be filtered to  
2 remove any bacterial contaminants, and then it would  
3 be dispensed into either final container and  
4 freeze-dried.

5 Q. I might ask you to break that down a little more in  
6 due course when we ask about the processes and  
7 facilities at the PFC itself. But, again, at a very  
8 general stage at this point, was the process for  
9 Factor IX essentially the same?

10 A. The process for Factor IX, no, it was slightly  
11 different. Following the removal of the  
12 cryoprecipitate, the supernatant would be subjected to  
13 an ion exchange process where the Factor IX binds to  
14 the ion exchanger and you can remove contaminants and  
15 then remove the Factor IX specifically -- not quite  
16 specifically but in a higher concentration and  
17 a higher purity. Then that would be formulated.

18 There would be number of what we call eluents,  
19 sort of fractions removed from the ion exchange  
20 column, and they would be subjected to quality control  
21 tests and, from those tests, specific eluents would be  
22 selected to make up the final product. Then that  
23 would be -- they would be pooled and they would be  
24 filtered to remove bacteria, dispensed, and then  
25 freeze dried.

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1 say, produce recombinant products. Other than that,  
2 they all applied to PFC.

3 Q. Then if we go to the next page, there's a diagram at  
4 the top of the page. Now, I just wondered if you can  
5 talk us through that, not by reference to the  
6 production of albumin or immunoglobulins, but really  
7 just by reference to the production of Factor VIII and  
8 Factor IX, but having regard to the process in the  
9 1970s and 1980s.

10 What would -- if we start with the receipt of  
11 fresh frozen plasma at the PFC or any other  
12 fractionation centre, what are the basic steps that  
13 would be undertaken to produce Factor VIII, first of  
14 all?

15 A. Firstly, this diagram relates to how we manufactured  
16 products much later than the period you're talking  
17 about.

18 Q. Yes.

19 A. So the Factor VIII here would be very high purity  
20 Factor VIII. And it includes steps that would develop  
21 later than the period you're talking about. So in the  
22 '70s, if we start at the top left, in the mainstream  
23 process, the frozen plasma would be thawed, that would  
24 result in the production of a cryoprecipitate. That  
25 would undergo some further purification with

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

2 Can you then just help with a handful of further  
3 other terms and concepts.

4 Fresh frozen plasma versus time-expired plasma.  
5 What were the differences and the different uses of  
6 those?

7 A. Fresh frozen plasma can be used to produce all  
8 products. Time-expired plasma can only be used to  
9 produce albumin and immunoglobulin.

10 Q. Why is that?

11 A. That is because the coagulation factors are what they  
12 call labile, they're very sensitive, and by the time  
13 time-expired plasma has been prepared, there is not  
14 enough of the factor left to make it worthwhile. And  
15 you couldn't make a concentrate that would meet  
16 specifications.

17 Q. Now, some of the terms that we may see as we look at  
18 the documents include a reference to the use of  
19 centrifuges and to filtration. Again, can you just,  
20 in a nutshell, tell us what those processes involved?

21 A. Centrifuges are machines that rotate at very high  
22 speed, and if you feed a mixture into the centrifuge,  
23 any solid material, any particles or precipitates will  
24 sediment and be retained at the wall and the  
25 supernatant, the solution without the particles, will

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1 flow thorough and continue to be processed, and  
 2 following the -- you will reach a point where you've  
 3 retained all the solids that the centrifuge will hold  
 4 or all you've got on your solution to recover. You  
 5 then have to remove the solid from the centrifuge and  
 6 that can be resuspended and redissolved and further  
 7 processed.

8 **Q.** I think you've probably already answered the next term  
 9 I was going to ask you about, which was  
 10 cryoprecipitate supernatant.

11 **A.** Yes, that is the solution that is left after the  
 12 cryoprecipitate has been removed.

13 **Q.** Potency and purity. Those are concepts we see  
 14 referred to in a wide range of the documents. Can you  
 15 give us, again, a nutshell guide to those?

16 **A.** Purity is expressed as the activity of the substance,  
 17 international units in terms of Factor VIII, as  
 18 a ratio compared to the protein. But to make it more  
 19 meaningful, it's perhaps important to appreciate that  
 20 in plasma, Factor VIII is a trace substance. It is  
 21 there present in a ratio of about one part in 160,000.  
 22 In cryoprecipitate and early concentrates it was  
 23 present as one part in about 16,000.

24 So when we talk about Factor VIII, this is not  
 25 Factor VIII. Factor VIII is a trace substance. What

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1 **A.** Heparin is an anti-coagulant which is used clinically  
 2 and it's sometimes used in plasma fractionation, as  
 3 an anti-coagulant, but not commonly.

4 **Q.** Then we're going to explore, it'll probably be  
 5 tomorrow, in terms of the stage of your evidence,  
 6 issues relating to heat treatment, in rather more  
 7 detail, but just by way of introduction, can you help  
 8 us understand in broad terms what's meant by  
 9 pasteurisation and what's meant by dry heating.

10 **A.** Okay. Pasteurisation involves the heating of  
 11 a solution where all of the substances that you're  
 12 concerned with are dissolved. Dry heat treatment, it  
 13 was applied to the heating of the freeze-dried powder  
 14 and, although in one instance it was heating of the  
 15 freeze-dried powder suspended in a solvent, but  
 16 generally it was heating of the freeze-dried powder in  
 17 its final container.

18 **Q.** Now, just again for the benefit of those listening,  
 19 one of Dr Foster's statements to the Penrose Inquiry  
 20 produced a glossary. I'm not going to go to it  
 21 because we've had a helpful overview from Dr Foster,  
 22 but it's page 29 of PRSE0000814.

23 Then can you next, again, really by way of  
 24 introduction, but just talk us through, by reference  
 25 to the PFC itself, the process of -- we'll take

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1 we're talking about is a concentrate of Factor VIII  
 2 where it is ten times more concentrated than it would  
 3 have been in plasma, where that is expressed, for your  
 4 purposes, as international units of Factor VIII, which  
 5 is the activity measured by a clotting assay to the  
 6 ratio of the total protein. Is that clear enough?

7 **Q.** Yes, I think so. So I think you were talking about  
 8 purity. Potency?

9 **A.** Potency is basically the strength.

10 **Q.** I think solubility probably speaks for itself and  
 11 you've told us about labile, and we'll come back again  
 12 to some of these when we come to look at the  
 13 exploration of viral inactivation methods.

14 Fibrinogen: what's that within the context with  
 15 which we're concerned?

16 **A.** Fibrinogen is a protein which tends to co-purify with  
 17 Factor VIII because it has a similar solubility  
 18 profile, and, in fact, in the early days, in the '70s,  
 19 there was a very strong view that fibrinogen was  
 20 necessary for Factor VIII to retain its activity, so  
 21 there was some reluctance to try to separate the two.  
 22 But, of course, that turned out not to be correct.

23 But fibrinogen made up the greater part of  
 24 Factor VIII concentrate in the early days.

25 **Q.** Heparin?

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1 Factor VIII, for present purposes, being produced.

2 So from the point in time at which the fresh  
 3 frozen plasma is delivered to the PFC from the  
 4 regional transfusion services, through to the  
 5 production in bottles or vials of the freeze-dried  
 6 Factor VIII concentrate, broadly speaking, what are  
 7 the different areas within the PFC and the different  
 8 stages of the process?

9 **A.** Well, that would all be handled, really, within the  
 10 production department. And the plasma would be bought  
 11 into the PFC, it would be weighed, and then it would  
 12 be stored in a deep freeze. When the process  
 13 schedules were drawn up, plasma would be brought out  
 14 of the deep freeze. Actually, the night before, so it  
 15 would actually begin to warm very slowly.

16 Because if you tried -- it was stored at  
 17 minus 40 and if you take the plasma at minus 40 you  
 18 can't take the plastic off it because the plastic is  
 19 stuck to the plasma too firmly, so it has to warm up  
 20 a little bit, typically to about minus 10 or minus 15  
 21 and then you can remove the plastic.

22 So the first thing in the morning the operators  
 23 would come in, they would have to remove the plastic  
 24 from the plasma and then the plasma which was still in  
 25 lumps of donations would be fed to a machine where it

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would be broken down into fine particles, still frozen. Then they would, in the early days, be fed into a batch tank for thawing. But, eventually, I know there was a process for thawing, which was also a sort of a tank, but which operated continuously, where the frozen particles would be melted. And during that melting procedure, the cryoprecipitate would form and the suspension would be pumped to the centrifuge to collect the cryoprecipitate.

Once that process was complete, once the volume of plasma that had been scheduled to be processed had all been thawed, the centrifuge would stop, and the cryoprecipitate would be removed. Then that would be resuspended and the various adjustments made to it to further process it before it would then go to the final filtration step.

Now, of the -- we've started first thing in the morning, we would get to final filtration late in the afternoon. Once the solution had been filtered there would be a pool of the final product, which -- in a container in the sterile filling suite, and that would be dispensed into the vial -- final vial in a manner where the contents of every vial would be the same.

And then the vials would all be placed in the

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**A.** It would follow a similar sort of process but Factor IX was prepared much less frequently because the demand for that was much less than Factor VIII. So for Factor VIII, we would run that process twice a week. With Factor IX, I'm not really sure. I was never involved with Factor IX very much because there were never many problems. Dr Smith's process worked so well, it didn't need my involvement.

**Q.** I want to come next to your specific role and responsibilities at the PFC. We'll do that by reference to your witness statement.

So could we have, Sully, WITN6914001, please. If we go to page 20, we just pick up at paragraph 16.1, under the heading "Role and Responsibilities", the first period was the period when you were the senior biochemist engaged in research and development, '73 to '74, and then you've said there see 16.2(i). So if we go to the top of the next page we can see what, broadly speaking, that entailed:

"Evaluating and re-designing equipment for the cold-ethanol ... fractionation of human plasma using computer controlled, continuous-flow ... technology."

I'll come and ask you a little more about that.

"... development ... of a new centrifuge ...

23

freeze dryer and it would be frozen inside the freeze dryer. And the freeze dryer was part of the aseptic system so it was a sterile system. It would be frozen inside the freeze dryer, the freeze drying process would take place and there would be stoppers placed on top of each vial, so when the freeze drying process was completed, a hydraulic system would bring the shelves down and push the stoppers home and seal the vials.

And then the vials would be removed from the freeze dryer. The freeze drying process would take about five days. So, at that time, the vials would be removed and then a proportion of vials would be subjected to quality control testing, including sterility testing, and a whole lot of tests were carried out before the batch could be subject to a release. But it would be labelled and packaged and then put ready for issue.

**Q.** Thank you.

Then, in relation to -- obviously this is pre-heat treatment, I've been asking you about. As I say, we'll come on to heat treatment and the difference that made later. Then, in relation to Factor IX and the production of Factor IX concentrate at PFC, was that in broad terms as you've described?

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subsequently used at the PFC [and] commissioning of the CSVM process at the new PFC centre in Liberton."

So that was for the first year, year and a half, of your work; is that right?

**A.** I would say it was the focus from '73 until almost into '76. That was my major function at that time.

**Q.** When you first joined, Dr Smith was in post. Was he effectively your line manager at that point?

**A.** No, I reported to Mr Watt.

**Q.** Then if we go back to the previous page, if we pick matters up when you became head of R&D, so this is the bottom half of the page, you've given us an overall description, first of all, here:

"Planning, managing, undertaking and reviewing of PFC process and product developments and contract R&D activities ...

"Line management and financial management of the ... R&D department ...

"Planning and direction of the PFC Library and scientific information services ...

"Maintaining a continual awareness of scientific and medical literature ...

"Contributing to the preparation of PFC's regulatory submissions.

"Protection of intellectual property ... by the

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publication or patenting of relevant findings.  
 "Assisting SNBTS in responding to requests under  
 the Freedom of Information Act ..."

That's in the latter period.

Can I just ask you, first of all, a little more  
 about the third and fourth bullet points there, so the  
 planning and direction of the library and scientific  
 information services and maintaining a continual  
 awareness of scientific and medical literature.  
 Again, with the focus on the '70s and 1980s, can you  
 just elaborate upon that and what involved?

**A.** When we moved to the new PFC at Liberton, which was  
 on, I think, 1 April 1974, the administration block  
 became available, it contained a small library, and  
 a lady had been hired to be librarian, and I wasn't  
 involved in her selection. Mr Watt asked me if  
 I would chair the library committee to run the  
 library, which I think is how some academic  
 organisations work. So I did that.

I had a meeting with the library committee and  
 I really learnt that that wouldn't work, it was just  
 everybody had a different idea. We wouldn't get  
 anywhere, so I just carried on, on my own, basically.

The librarian was meant to report to the  
 administrator but, for practical purposes, she

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we took, we had this extra resource for searching for  
 literature, and I set up a system whereby we could  
 handle these with a computer. There was a system  
 called Reference Manager, which could organise  
 research reports, and I create a way of -- that  
 couldn't scan words and things like that, that we can  
 do today. It could only pick out numbers.

So I set up a system which had 1,000 numbers in  
 it and I allocated topics to various numbers. So, for  
 example, hepatitis was number 100, Factor VIII was  
 number 230, and so on. So when we got a paper we  
 could identify the topics in the paper, give them the  
 numbers, the librarian could put that into the system,  
 and we could store the paper and then we could  
 retrieve papers just by searching on topics. So that  
 gave -- created an information system that everybody  
 could use.

**Q.** Was the information that you've described that was  
 available at the PFC, was that a bigger resource that  
 was available to the Blood Transfusion Services?

**A.** It was, but they also had their own systems. They had  
 their own libraries. But they had access to the PFC's  
 library as well.

**Q.** Then if we go to the next page, we can see you've  
 broken down into different time periods some of the

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reported to me all the time. The first lady who we'd  
 hired turned out not to be really very good and she  
 realised that the job wasn't -- she wasn't up to the  
 job and she left. I was given the task of hiring  
 a new librarian, which I did, and I was fortunate  
 enough to get a lady who was excellent and she  
 actually stayed until PFC closed. She became our  
 permanent librarian and she was really very good.

So I worked closely with her to create this --  
 the library, which covered a whole host of things from  
 textbooks to pharmacopoeia, to reports, to journals,  
 and one of the key publications that we received was  
 a document called Current Contents, which you might  
 have heard of, where it came out every two or three  
 weeks and it had the contents pages of all  
 publications in the world, basically. And you could  
 get these for different disciplines. You probably  
 could get it in law, I don't know. But we were  
 subscribed to the volume for life sciences, which  
 covered medicine as well, and also for engineering.

So I would review all of those materials and  
 when we came across a paper that looked of interest,  
 the librarian could obtain it from the British lending  
 library.

So, in addition to a whole lot of journals that

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areas of focus for the R&D Department. So if we just  
 go briefly through each of those:

"1974-1977: Leading an SNBTS team to increase  
 the factor VIII activity of plasma ... which resulted  
 in the factor VIII activity of plasma ... being  
 increased significantly."

Again, in broad terms, what did that entail?

**A.** Well, I remember I was still at the Royal Infirmary in  
 the basement when I -- Mr Watt and Dr Smith came to  
 see me. And they explained that they'd been --  
 Dr Smith had been looking at the Factor VIII content  
 of the plasma that was being received at PFC, and we  
 tend to assume, in fact, that in normal plasma  
 Factor VIII content should be one, or if you add the  
 anti-coagulant it's 0.9. They were seeing values of  
 around about 0.6, 0.5, 0.4 and they were concerned  
 that at that point a lot of Factor VIII was being lost  
 before it got to PFC.

And it was suggested that I could lead a team of  
 people from the regional centres to look at this  
 issue, and so I agreed to do that. But it took quite  
 a long time to get off the ground because it had to be  
 agreed with all the transfusion directors and they had  
 to nominate staff to get involved.

But, eventually, I led a group with the

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1 leading -- or the senior technical people from all of  
2 the regional centres to review how the plasma was  
3 handled from the point of donation to the point it was  
4 frozen, to come to PFC. And I gathered together a lot  
5 of information from the literature, and we also --  
6 what I came across in the library were a couple of  
7 volumes of reports that weren't published but they had  
8 come from the United States. And they were reports of  
9 studies -- of research studies in the States where the  
10 National Institute of Health had awarded grants to  
11 people in the States aimed at increasing the yield of  
12 Factor VIII in cryo.

13 And we had copies of the grant applications, the  
14 interim reports and the final reports from all these  
15 investigations and that had a wealth of information in  
16 it, which I summarised for my colleagues.

17 At the time, I didn't stop to think where this  
18 had come from but I now realise it must have come from  
19 Dr Johnson, who was a leading figure in the world of  
20 Factor VIII, from the United States, who was a very  
21 close friend of Mr Watt and he must have given us  
22 these documents. So we had access to a lot of  
23 unpublished material, most of which went on to be  
24 published but, at that time, it wasn't published.

25 But it was able to assist our colleagues in the

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1 precipitation, using a procedure which was known to  
2 discriminate very much on size, and because viruses  
3 have larger sizes or are larger than proteins, the  
4 idea was you could precipitate the virus without  
5 precipitating the protein. That didn't work with  
6 Factor VIII because the Factor VIII complex, as it was  
7 known at the time, was too large to separate from the  
8 hepatitis B virus using this technique.

9 But Dr Johnson thought it was possible to  
10 separate Factor IX from the virus using this  
11 technique. But, in the first method that he used,  
12 that didn't work, and he revised the procedure to what  
13 he called a Mark II method, and that was being  
14 explored with PFC. And Dr Johnson was doing all the  
15 work with virus, PFC's contribution was to scale that  
16 up and to look at the quality of the product.

17 And there were concerns from Professor Cash that  
18 the product might be thrombogenic and, as you've come  
19 across, this concept or this problem with Factor IX  
20 concentrates, that they can cause a thrombosis, which  
21 in some cases could be life-threatening or even did  
22 result in some deaths, and in some animal studies that  
23 Dr Cash was involved in, this product, which was  
24 called Supernine, seemed to cause a greater degree of  
25 thrombosis in the animals than standard product DEFIX,

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1 regional centres to work on how to get -- to have  
2 higher levels of Factor VIII activity in the plasma,  
3 and the end result was that the activity came up, and  
4 it was -- we began to get plasma closer to 0.8 and  
5 0.7, rather than 0.5 or 0.4.

6 Q. Do you know whether a similar problem was being  
7 experienced by BPL in relation to the plasma -- the  
8 Factor VIII activity of the plasma it received at that  
9 time?

10 A. I can't answer at the very beginning but, of course,  
11 Dr Smith went to PFL and he was aware of all of this  
12 work and he began to carry out similar investigations  
13 at PFL.

14 Q. The next area of work you've identified taking place  
15 over a period from '76 to '81 was contributing to  
16 studies aimed at removing hepatitis viruses from  
17 Factor IX concentrates by precipitation, in  
18 collaboration with Dr Johnson, who you've just  
19 mentioned.

20 Now, we'll be coming on to looking at a range of  
21 viral inactivation methods in more detail in due  
22 course. Can you just tell us, again, in a few  
23 sentences, what the focus of this work was?

24 A. The purpose of this was to try to remove hepatitis B  
25 virus from the Factor IX concentrate by a method of

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1 and so more work was required to investigate that.

2 This work was being done by Dr Smith and  
3 Sarah Middleton, who was working with him, but after  
4 Dr Smith left, I began to work with Sarah on this, and  
5 then when she left, I was kind of left holding the  
6 baby, if you like, and took that project to  
7 completion, as far as the research was concerned, and  
8 we were able to demonstrate that there wasn't a risk  
9 of thrombosis in the analytical studies we were  
10 carrying out. And that allowed the project to go  
11 forward to -- for consideration to be a product.

12 And, really at that point, that was out of my  
13 hands. That was led by Mr Watt and Dr Cash but,  
14 ultimately, it never did come to fruition because it  
15 was overtaken by heat treatment.

16 Q. Then the next item, same time frame, '76 to '81:

17 "Leading studies to identify the causes of loss  
18 of factor VIII during the manufacture of Factor VIII  
19 concentrate. Implementing procedures to increase the  
20 yield of factor VIII, including the design of  
21 equipment for thawing plasma continuously which  
22 increased the yield of factor VIII at PFC by about 50%  
23 by 1981."

24 Now, I want to come back to that issue of  
25 increasing yield when we explore the topic of

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1 self-sufficiency in Scotland, but can you just assist  
 2 us in understanding a little more what was going on  
 3 over that period in terms of your own work?  
 4 **A.** This is very complicated. I'll try to keep it as  
 5 simple as I can.  
 6 **Q.** Please.  
 7 **A.** But, obviously, yield of Factor VIII is critical if  
 8 you're going to provide the amounts that were  
 9 required. And how yield was measured changed in this  
 10 period, because there were changes to the way the  
 11 measurements were made or the assays were carried out,  
 12 which apparently caused a reduction in the yield, and  
 13 so the early predictions of yield weren't -- didn't  
 14 stand up and by the mid-1970s when I was involved, the  
 15 yield was a lot less than people had believed in the  
 16 early days.  
 17 And so it became increasingly important to try  
 18 to increase the yield. It was something that Dr Smith  
 19 had been working on, Sarah Middleton was working on,  
 20 in conjunction with Alan Johnson, and I was beginning  
 21 to get involved, particularly as after Dr Smith left.  
 22 And I began to look at it from the process point of  
 23 view which was trying to understand what was happening  
 24 in the manufacturing process, whilst Sarah Middleton  
 25 was doing work in the research laboratory.

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1 And, certainly, I mean, we were talking as well, so  
 2 I suspect he would have known about it. BPL did  
 3 introduce a similar kind of process at some point in  
 4 the early '80s, so I think they were aware of it.  
 5 **Q.** The next item which spans a timeframe from 1980 to  
 6 1986 is described as:  
 7 "Discovering ... the addition of the  
 8 anticoagulant sodium citrate ... and developing the  
 9 addition of calcium to prevent progressive loss of  
 10 factor VIII activity during processing ..."  
 11 You say there "assisted in the introduction of  
 12 virus inactivation technologies", so I'm going to come  
 13 back to that when I come to ask you a little more  
 14 about the heat treatment and viral inactivation work,  
 15 if I may.  
 16 1982 related to discovering a new method for  
 17 reducing fibrinogen content of Factor VIII concentrate  
 18 without loss of Factor VIII; I don't think I need to  
 19 ask you any more about that.  
 20 Then, if we go to the bottom of the page, we can  
 21 see there '81 to '86 is research and development of  
 22 methods of heat treatment. Again, we'll come back to  
 23 that.  
 24 Then over the page, I'm not going to go through  
 25 the detail of any of the rest, but we can see you've

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1 And when she left, I focused more and more on  
 2 the manufacturing process to try to better understand  
 3 what was happening and, at that time, it was obvious  
 4 that the greatest point of loss occurred at the point  
 5 of cryoprecipitation, because by the time we'd  
 6 recovered cryoprecipitate, most of the Factor VIII had  
 7 disappeared. And so the question was, how can we  
 8 increase the yield in cryoprecipitate? So that was  
 9 one of the major focuses that I worked on.  
 10 But I also looked at the manufacturing process  
 11 and I basically fine tuned every detail of the process  
 12 to try to optimise every step, and that had some --  
 13 made some improvements. But, ultimately, it was this  
 14 technique of thawing plasma continuously that made the  
 15 major improvement.  
 16 **Q.** Was that a technique which was shared by the PFC with  
 17 BPL, do you know, say Dr Smith had been involved in  
 18 working on it before he left?  
 19 **A.** Dr Smith had left by the time I began to work on  
 20 continuous thawing but I did present preliminary  
 21 results at a conference in London and he would have  
 22 known about that because the scientific committee that  
 23 was running that conference, he would have been  
 24 a member of that committee. So that was kind of in  
 25 the public domain and he would have known about it.

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1 set out again, in blocks of years, a number of the  
 2 other research and development activities that you  
 3 were involved with.  
 4 In terms of the R&D unit team at PFC, what did  
 5 it comprise, both in terms of numbers of staff in the  
 6 second half of the '70s and first half of the '80s,  
 7 and in terms of the physical facilities that were  
 8 available to you for research?  
 9 **A.** When I first took responsibility, when we moved from  
 10 the Royal Infirmary to the Liberton site, there was  
 11 a relatively small R&D laboratory, and I had, I think,  
 12 probably eight staff including myself. In terms of  
 13 scientific staff there was one person that was  
 14 assigned to working on coagulation factors, one  
 15 biochemist working on immunoglobulins, and one  
 16 biochemist working on albumin and one physicist who  
 17 was working on process control. So those were the  
 18 scientific staff that I had, some technical support  
 19 and lab assistants. That was all.  
 20 **Q.** Did that increase over the course of the '70s and  
 21 first half of the '80s or did it remain roughly --  
 22 **A.** It remained the same for a number of years. There was  
 23 actually a change, or quite a change in staff because,  
 24 as you've heard, Mrs Middleton left because her  
 25 husband had got a job elsewhere in Scotland. And she

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was replaced by Dr Macleod.

The scientist who was dealing with immunoglobulins took Dr Smith's role as head of quality, and she was replaced by Dr Welch. The physicist who was handling process control eventually left, and he was replaced by Dr McIntosh. So I had kind of the same number of professional staff for quite a while.

Then in the '80s, we were able to take on more staff and really, in the second half of the '80s into the '90s, we had some additional scientific staff.

**Q.** Then in terms of the physical facilities available for research and development, so as distinct from production facilities and the like, what were they?

**A.** In terms of the research and development, as I said, we had a really very small laboratory from 1974 through to the early 1980s. And then there was a new extension built to PFC which was called the microbiology extension and that followed the Medicines Inspector report, where they wanted bacteriology to be carried on site, and this microbiology extension included facilities for virology and bacteriology, but it also included an R&D pilot plant.

So we got access to that, probably around about '82/83, I can't give you a precise date but that gave

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this product development group or Factor VIII Study Group of all of the ongoing research work.

**Q.** Then, in terms of Mr Watt's role, until he left in, I think, 1983, what did you understand his role and responsibilities to be, essentially, as the scientific director of the PFC?

**A.** My understanding was that he was responsible for everything within PFC. He saw himself as the sort of the captain of the ship, if you like.

**Q.** If we go back to your witness statement, WITN6941001, page 23, we've got, in the bottom half of the page, just above the heading "PFC (Liberton) 1974-2008", so this is a description of a new organisational structure proposed by Mr Watt in anticipation of the move to the new premises, as I understand it. You've got the various heads of department there set out, including at that time Dr Smith. You as head of the research and development department, and so Dr Watt, would effectively sit over all those departments; is that right?

**A.** That is correct.

**Q.** So you've listed for us over the page, if we just briefly go over the page -- I'm not going to go through the detail -- but you've listed for us there the range of different personnel at different times

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us a much larger laboratory for scaling up processes and, in particular, for the first time we actually got a large freeze dryer so we could do research on freeze drying.

**Q.** You reported to Mr Watt, is that right?

**A.** That's correct.

**Q.** Was there any oversight of your work by Professor Cash or by his predecessor, who I think was Major General Jeffrey?

**A.** Up until 1982, I think Mr Watt reported through the meetings of directors and he reported to General Jeffrey and to Professor Cash directly. So there was that kind of line management, if you like, from me through to them. And I would get information fed back that way. But in 1982, Professor Cash set up a group called the Factor VIII Study Group, under his chairmanship, where he wanted all of the work at SNBTS to be brought under one umbrella reporting to him directly, rather than through the meetings of the directors.

And that system really functioned thereafter.

It was broadened out later on to cover all the products and became the product development group.

So, at that point, although my line manager was always the PFC director, there was also oversight for

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who -- if we just go further down the page a bit, thanks -- who occupied the various roles.

Can I just then ask you to tell us a little more about the facilities. The old centre, so before the new PFC at Liberton became operational, the old Blood Products Unit, I think, as it had initially been called, what did it comprise, in terms of its physical premises?

**A.** It was a basement in the Royal Infirmary of Edinburgh. It was directly below the Regional Blood Transfusion Centre and it had originally been constructed as part of the Transfusion Centre, but it had managerially become separated, about 1970. But it was the same premises, and you actually went in the same front entrance and then after maybe 10 or 20 yards went down the stairs into the basement, where there was one long corridor and a number of rooms going off it.

There was one large fractionation room, cold room for ethanol fractionation, there was couple of laboratories, and another small cold room where coagulation factors were prepared, and there was an area for sterile dispensing, that was really very small, and some offices. And really that's about all there was. There was one big room with a big freeze dryer, that was it.

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1 **Q.** Now, in terms of the new centre then at Liberton,  
 2 you've told us that the administrative facilities  
 3 within that Centre became available from a point in  
 4 1974. At what point did it become operational as  
 5 a centre producing factor concentrates and the other  
 6 products, albumin and immunoglobulin.

7 **A.** I would say that there wasn't a fixed point, it was  
 8 kind of gradual, because we were given access to the  
 9 production building at the end of December 1974, and  
 10 I think a lot of equipment was moved across and began  
 11 to be installed over the Christmas holidays. And  
 12 then, at the start of '75, there was really a lot of  
 13 validation and commissioning to be done, and much of  
 14 1975 was spent just getting up and running, some  
 15 things got running earlier than others. So I can't  
 16 really give you specific answers about what -- when  
 17 various products came on stream.

18 There were various stocks that had been retained  
 19 from production from the previous unit, continued to  
 20 be supplied. And so it was a kind of a gradual  
 21 process that we got off. But by 1976, I think  
 22 everything was functioning.

23 **SIR BRIAN LANGSTAFF:** Was there a stepping stone, as it  
 24 were, between the basement and the premises at  
 25 Liberton? I think there was a time, perhaps, when it

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1 commissioning the plant, and PFC, it may not be  
 2 appreciated, was actually designed to provide albumin  
 3 and when it was built, Factor VIII really wasn't on  
 4 the agenda because the Biggs MRC working party hadn't  
 5 decided what was required.

6 "The real drive to begin with was to provide  
 7 albumin because there was a shortage of albumin in  
 8 Scotland ..."

9 Then you reference to the position in relation  
 10 to the Glasgow BTS, the need to:  
 11 "... provide them with albumin so they could  
 12 stop providing freeze-dried plasma."

13 Then at line 21:  
 14 "So there was this knock-on effect, that we  
 15 first had to provide the albumin then they could stop  
 16 making the freeze-dried plasma and then we could get  
 17 more plasma to make Factor VIII. That's why this,  
 18 what might appear to be a prolonged start-up phase of  
 19 PFC, took place ..."

20 Then there's a reference over the page to the  
 21 keenness of the Glasgow Royal Infirmary to start  
 22 patients on home therapy.

23 So if we just go back to the previous page can  
 24 you assist us in understanding what you were referring  
 25 to when you talked about the PFC being designed to

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1 might have been down in the Cowgate?

2 **A.** No, no, the Cowgate was really -- the Edinburgh  
 3 Regional Centre --

4 **SIR BRIAN LANGSTAFF:** I see.

5 **A.** -- moved into those premises and that was not to do  
 6 with PFC.

7 **SIR BRIAN LANGSTAFF:** It was straight from the RIE, to  
 8 Liberton?

9 **A.** That's correct, yes.

10 **SIR BRIAN LANGSTAFF:** Thank you.

11 **MS RICHARDS:** I just want to ask you to look at a small  
 12 part of your oral evidence to the Penrose Inquiry,  
 13 Dr Foster.

14 PRSE0006022, please, Sully.

15 So this was evidence on 10 May 2011, this was  
 16 the first day of your oral evidence. And if we go to  
 17 page 41, I want to pick it up at line 7, where you say  
 18 this:

19 "This situation is really" --

20 You were being asked here, I think, about issues  
 21 relating to getting plasma and achieving  
 22 self-sufficiency, just to put it in context. Then you  
 23 said this:

24 "This situation is really just after the  
 25 start-up of PFC, which began in 1975 and we were

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1 provide albumin and that being the initial focus?

2 **A.** My understanding is for planning purposes, in the  
 3 documents that I had seen, although we produced, as  
 4 you've already identified, a range of products, the  
 5 greatest demand was for albumin, and that was to  
 6 replace the freeze-dried plasma, which was known to  
 7 carry risk of hepatitis, whereas albumin was viewed as  
 8 being safe because it was pasteurised.

9 And the -- as far as I've been able to  
 10 establish, the planning was primarily all arranged to  
 11 meet this need for albumin. And if we could meet  
 12 albumin, then there'd be more than enough plasma  
 13 available to provide all the Factor VIII requirements,  
 14 was the view that was expressed at the time.

15 I remember Mr Watt said "If we can make all the  
 16 albumin, Factor VIII will take care of itself". That  
 17 was their understanding.

18 **Q.** Then if we turn to WITN3530032. This is an article  
 19 you wrote entitled "The manufacture of blood plasma  
 20 products in Scotland: a brief history". I'm not sure  
 21 whether we've got the date of it or not, but  
 22 I think --

23 **SIR BRIAN LANGSTAFF:** 2016.

24 **MS RICHARDS:** 2016, thank you. If we go over the page,  
 25 I just want to pick it up under the heading

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"1975-1983" then ask you about that. You said this:  
 "Design of the new PFC was centred on a computer-controlled, continuous flow, small-volume mixing (CSVM) cold-ethanol fractionation process for mainstream fractionation of plasma; a technical innovation which offered online monitoring and control, shorter processing times and a high capacity. Multi-stage fractionation was performed using a series of mobile processing modules [we'll see those in a moment] located in a +4 degrees process hall with newly designed refrigerated centrifuges ...

"The new centre was designed to accommodate plasma from the north of England as well as from Scotland [I'll come back to that] ... equipped initially for Scotland's needs only. Meeting demand for albumin was the first challenge. The high capacity of the CSVM process quickly enabled a stockpile of 30,000 litres of plasma to be processed to satisfy Scotland's requirements for albumin. Despite this achievement, processing of plasma from England did not come to fruition, leaving the PFC's CSVM process operating well below its potential capacities."

I'll come back to questions of capacity.

And then if we just go to the next page, we've

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which had feedback control loops, so it was all controlled by a computer.

We, at this time -- to get from plasma, having removed, say, the cryoprecipitate, you want to then go on through the ethanol fractionation process. There were really three stages, three precipitation stages, and so each -- all of the equipment for each precipitation stage was on one module. And there were what I called upstands in this process cold room where -- which had provision of services where you could plug in the module, plug it into the computer, into power supplies, into supplies of ethanol and so on, and each module would obtain these supplies from the basement where there was a plant room where you would provide all of these services.

And each upstand could accommodate two modules. And in this room that you see here, there were 15.5 upstands, so in theory, there was room for -- sorry. There were 7.5 upstands, so there was room for 15 modules. But to meet Scotland's needs, we actually needed to run three modules on a nine-to-five working day. One of the reasons for that was that when I redesigned Mr Watt's process, I was able to increase the throughput by a factor of three. So, in fact, it became even more productive than he had designed it.

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got a couple of photos. We've got a picture there in figure 3 of the module -- you described the mobile processing modules -- and then the picture below that, the main process cold room at PFC.

Can you just again help us understand a little more about the CSVM process and its significance, in particular for issues relating to production of factor concentrates.

A. The standard procedure for preparing -- carrying out these various precipitation steps that we've talked about was to do this in large vessels, where you would fill the vessel with the plasma, change the -- add all the ingredients, mix it up, then it would stand overnight for the precipitate to ripen, and then you'd collect the precipitate in the centrifuge.

What Mr Watt had designed was a way of doing this in a continuous manner, where you brought all of the materials together simultaneously, precipitate would form quickly and then be removed -- I wouldn't say immediately but quite shortly after, and then the supernatant could go on to the next step. And you could go through each of the process steps that way without having to take time filling up tanks and leaving things overnight. And so you could just have this continuous flow of processing going on, all of

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And because we'd been initially supplied with enough modules to handle Scotland, we'd been given six modules, but we only needed three on a nine-to-five basis until 1984, and then we brought the other three into use, and we ran six modules on a nine-to-five basis. But we never used the full capability of the system on a 24-hour basis, other than for a short shift experiment.

Q. And I'll obviously be coming on to some of those issues in due course.

Is it then right to understand that the essential advantage or benefit of the CSVM process was that it would enable the centre to process a significantly greater volume of plasma?

A. It was a number of things. It was that, and it was in a centre that had a relatively small footprint for the amount of plasma it was processing, but it also was intended to give a much greater degree of quality control -- process control that it was believed would give you a higher quality product or a more secure process. Because if you were dealing with proteins that were easily damaged, the faster you process them, the better it is for the protein.

Q. Now, we'll come on in due course to the relationship with BPL, your own relationship and dealings with

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1 Dr Smith and others.  
 2 We have seen evidence to suggest that there was  
 3 a less than harmonious relationship between Mr Watt  
 4 and Dr Lane, if I can put it that way. But was -- do  
 5 you know whether consideration was ever given to  
 6 sharing the technology involved in the CSVM with BPL?  
 7 A. Oh, yes. I think the -- for example, Dr Maycock, who  
 8 was the predecessor of Dr Lane, was involved in visits  
 9 to PFC. They discussed the technologies that were  
 10 taking place in some detail.  
 11 I remember in -- as soon as the new centre  
 12 opened, we had a delegation of staff from BPL coming  
 13 to PFC to view the systems, and so the BPL staff were  
 14 well aware of the processes.  
 15 In 1980, when there were plans to rebuild new  
 16 BPL, there were a number -- a series of meetings to  
 17 examine different technologies, and this was one of  
 18 the technologies that was examined, but ultimately it  
 19 wasn't accepted by BPL.  
 20 Q. If we just go back to your witness statement next,  
 21 then, WITN6914001, page 24. At the bottom of the  
 22 page, you refer to the PFC virology section,  
 23 established in January '74 with the appointment of  
 24 Dr Bruce Cuthbertson. But PFC not having the  
 25 necessary facilities for work with viruses, they were

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1 structure, it physically took place off site?  
 2 A. That's correct.  
 3 Q. In terms of the principal products then -- we can take  
 4 that down, thank you -- produced by PFC, again in the  
 5 period with which we're concerned, the Factor VIII  
 6 concentrate in the late '70s, first half of the '80s,  
 7 is the concentrate referred to as NY; is that right?  
 8 And then in terms of the Factor IX concentrate, it's  
 9 DEFIX.  
 10 A. Yes.  
 11 Q. We may come back to the Supernine project, but as  
 12 you've explained, that work never actually resulted in  
 13 the PFC producing Supernine for use; is that right?  
 14 A. I think they went through some clinical evaluation,  
 15 but it didn't go beyond that.  
 16 Q. In terms of the collection of -- sorry, let me put it  
 17 a different way.  
 18 A specific question I've been asked to ask you  
 19 arising out of some of the evidence the Inquiry has  
 20 heard at an earlier stage, do you know whether plasma  
 21 specifically collected from patients with bleeding  
 22 disorders was ever used at the PFC, for example for  
 23 research into viruses, or the development of assays,  
 24 or for any other purpose?  
 25 A. Plasma from people with haemophilia was essential for

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1 seconded to -- physically to work elsewhere.  
 2 What was the role and function, then, of the  
 3 PFC's virology section? Why did the PFC have one?  
 4 A. At that time, it was to identify donors who might be  
 5 suitable -- whose plasma might be suitable to prepare  
 6 specific immunoglobulins. For example,  
 7 anti-hepatitis B immunoglobulin, and so on. And we  
 8 began to have an anti-CMV immunoglobulin, so there was  
 9 a whole range of immunoglobulins that were  
 10 manufactured. And it was about developing assays so  
 11 that we could detect which donors might have suitable  
 12 antibodies that could be used. So that was the  
 13 primary purpose of this, but obviously, that expanded  
 14 as knowledge of viruses and the risks of viruses  
 15 developed.  
 16 And I should also say that Dr Sommerville, who  
 17 was Scotland's leading clinical virologist, had  
 18 a contract to advise PFC directly on matters of  
 19 virology, and he reported directly to Mr Watt, as far  
 20 as I'm aware. But I never saw any reports that he  
 21 produced, but he certainly came to PFC and had  
 22 meetings with Mr Watt on a regular basis.  
 23 Q. But at this point in time, '70s through to '80s, is it  
 24 right to understand that the virology work you've  
 25 described there, although it was part of the PFC

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1 the assay for Factor VIII. It formed the substrate to  
 2 the Factor VIII assay. And, I mean, I'm not an expert  
 3 on Factor VIII assays, but it was an essential  
 4 component of the Factor VIII assay. We couldn't  
 5 measure Factor VIII without that substrate, and it was  
 6 the very generous, kind donations that we got, that  
 7 were given by people with haemophilia, that allowed us  
 8 to do that.  
 9 Q. Then there's a reference, if we go to DHSC0103209\_172,  
 10 please. Yes, DHSC0103209\_172, I hope. This is  
 11 a letter a number of years before you arrived at the  
 12 PFC, Dr Foster, 1968, but it's about the Blood  
 13 Transfusion Service in Edinburgh. There's one  
 14 specific matter I've been asked to ask you about. If  
 15 we go to page 3, paragraph 8. There's a description  
 16 here of the development of the continuous flow  
 17 process. It says:  
 18 "... a pilot plant is now in operation ... We  
 19 therefore propose that the new Blood Products Unit  
 20 should operate on the continuous flow principle ...  
 21 should be designed to a workload of 1,500 litres of  
 22 plasma per week; but it will be capable of adaptation  
 23 without substantial structural alterations to operate  
 24 at levels of up to 3,000 litres per week should this  
 25 become necessary."

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1 Then there's reference to the production of  
 2 plasma protein solution, antihæmophilic globulin,  
 3 gamma globulin and other fractions. Then it says  
 4 this:  
 5 "It will also be possible to produce special  
 6 fractions for research purposes."  
 7 Do you know what that refers to, the special  
 8 fractions for research purposes?  
 9 A. I'm not certain what that refers to, but there were --  
 10 I mean, obviously, plasma contains many, many  
 11 substances, and some of the materials that we  
 12 recovered from plasma were destroyed. They were  
 13 thrown away. So if you could find a use for that,  
 14 whether it was academic or whatever, then that was  
 15 worthwhile. And we did supply materials for research  
 16 that otherwise would have been destroyed. They were  
 17 what are called waste fractions.  
 18 Q. Then just a couple of general questions, perhaps,  
 19 before we break about the PFC product, the NY and  
 20 DEFIX product. First of all, do you recall whether  
 21 the PFC took any steps to try to make its product  
 22 particularly attractive or usable for home treatment.  
 23 For example, we've heard evidence to suggest that some  
 24 of the commercial products would come with a kit of  
 25 everything that was required, might come with things

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1 provided. If someone had come to us and said, 'Look,  
 2 we really need this, can you give it to us', we would  
 3 have addressed that but I'm not aware that happened."  
 4 Is this right: what the PFC supplied for use by  
 5 the Haemophilia Centres was essentially the bottle  
 6 with the concentrate in it?  
 7 A. It was the concentrate and it was the reconstitution  
 8 solution, that was all, yes.  
 9 Q. Then do you recall any feedback being passed on to you  
 10 from haemophilia clinicians about the PFC products,  
 11 issues about solubility, for example, or other -- what  
 12 might be said to be disadvantages of the product?  
 13 A. Yes, I -- the reconstitution time was often an issue,  
 14 and it was -- we were in a difficult position because  
 15 our aim was to meet -- to achieve self-sufficiency,  
 16 whereas the commercial companies didn't have that  
 17 objective so they could do additional processing and  
 18 have removed some of the substances that might be  
 19 making it longer to dissolve, and have a lower yield,  
 20 and that wouldn't have any implication for them  
 21 because they could just put up the price. It had  
 22 an implication for us because we were trying to be  
 23 self-sufficient, so we had different objectives.  
 24 We tried to find -- I suppose it was the best  
 25 compromise we could, but also, I was also working to

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1 like Mr Men stickers to make it particularly  
 2 attractive for use by children.  
 3 A. Yes.  
 4 Q. Did the PFC ever do anything along those lines, as far  
 5 as you know?  
 6 A. We didn't, we didn't. I do remember actually making  
 7 a bid for monies to do something like that and it was  
 8 turned down on the grounds that this was all provided  
 9 by Haemophilia Centres.  
 10 Q. If we just look at what, I think, you told the Penrose  
 11 Inquiry on that particular issue, if we go to  
 12 PRSE0006022, page 36. I think you were asked at  
 13 line 4 about issues such as packaging and having  
 14 commercial manufacturers producing everything the  
 15 patient might need. Your response was:  
 16 "... commercial companies were [operating] in  
 17 a marketplace and they were doing their best to  
 18 provide attractive products."  
 19 Then at line 14:  
 20 "For us in the health service we would just have  
 21 to be quite clear about it. We didn't have budgets  
 22 that would cover that kind of thing and we were hoping  
 23 or expecting that haemophilia centres would provide  
 24 appropriate bits and pieces that were required for the  
 25 treatment of the patient over and above what we

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1 try to improve the reconstitution time and we did  
 2 achieve that. Maybe we never achieved it as much as  
 3 some of the commercial companies but they used  
 4 techniques that we didn't use. And there was one in  
 5 particular that I think I wasn't aware of at the time,  
 6 but was maybe quite important, and that was sealing  
 7 the vial under vacuum.  
 8 Q. That was?  
 9 A. Closing the container in a vacuum, so that when you  
 10 added the needle with the water it would be pulled  
 11 into the solution and it would dissolve more quickly.  
 12 And I think that has implications for dry heat  
 13 treatment in one organisation.  
 14 Q. Okay, we will come back to that then, perhaps, when we  
 15 look at the issue of heat treatment.  
 16 Sir, I've slightly trespassed into our normal  
 17 break time. Perhaps now is a good time to take the  
 18 morning break.  
 19 SIR BRIAN LANGSTAFF: We'll take a break until 11.50, in  
 20 that case. This is the first break, Dr Foster, in  
 21 your evidence. At this break, and in any other that  
 22 follows, you must remember you're giving evidence.  
 23 You must not discuss with anyone, whoever that anyone  
 24 is, what you have been asked already in evidence and  
 25 what you think you might be asked about as the

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1 evidence goes on. You can talk about anything else  
 2 you like.  
 3 **A.** Thank you.  
 4 **MS RICHARDS:** May I just, in the interests of  
 5 transparency, qualify that in one respect. I've asked  
 6 for an additional document to be provided to Dr Foster  
 7 for him to read over the break, because I will want to  
 8 ask him about it in the course of today. I don't  
 9 think it's very likely he will want to discuss it with  
 10 his legal representatives, but the practice we've  
 11 adopted for witnesses who are asked to look at  
 12 material for the first time in the course of their  
 13 evidence is, if there is an issue about that document  
 14 that they need to discuss with their legal  
 15 representative, they can do so but limited to that  
 16 document only.

17 **SIR BRIAN LANGSTAFF:** You have that permission on  
 18 a standing basis.

19 **MS RICHARDS:** Thank you, sir.

20 (11.19 am)

(A short break)

22 (11.49 am)

23 **MS RICHARDS:** Dr Foster, can I just pick up on one further  
 24 issue in relation to the CSVM process.

25 You've told us about the modules. If you'd had,

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1 extension, and that did happen, but only in the 1990s,  
 2 and only for Scotland's needs.  
 3 **MS RICHARDS:** Sir, I won't take time going to it, but  
 4 there is an article by Dr Foster and Mr Watt about the  
 5 CSVM process, exhibited to Dr Foster's statement at  
 6 WITN6914039, which has got diagrams and photographs  
 7 that certainly I personally found useful in  
 8 understanding how the process worked.

9 Can I then move to the Medicines Inspectorate  
 10 and the inspection processes. Now, I think you told  
 11 the Penrose Inquiry you weren't directly involved in  
 12 licensing issues, but you had knowledge, I think, of  
 13 what was going on, partly based on conversations with  
 14 Mr Watt, and also, as a matter of fact, you  
 15 accompanied the inspectors on their first inspection.

16 **A.** That's right. It was the policy of the inspector that  
 17 someone from the organisation should accompany them to  
 18 take notes so they would not be bothered writing  
 19 things down; they could just push on, and somebody  
 20 else would do all the writing down of the issues that  
 21 they found. And I was nominated to do that, so  
 22 I spent two weeks with the inspectors going over --  
 23 the inspection process lasted a week in December and  
 24 a week in January 1980, and I was kind of cheeky by  
 25 jowl with them throughout the inspection, writing down

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1 say, a larger number operating because you had more  
 2 plasma to process, what were the implications for  
 3 that, as it were, for the -- downstream, in terms of  
 4 the production process? Was the rest of PFC equipped  
 5 to keep up?

6 **A.** To a large extent, yes, because once -- when you get  
 7 to the end of that process, the main product is  
 8 albumin, and that is dispensed into bottles. You then  
 9 get into batch size. You can make the batch size as  
 10 big as you like, virtually. Then it has to be  
 11 pasteurised. We had very large pasteurising cabinets,  
 12 so that wouldn't have been an issue; we could have  
 13 dealt with that relatively easily. The main issue  
 14 then becomes storage. And I think we had -- at one  
 15 point, we used quite a lot of off-site storage because  
 16 we didn't have enough. And the medicines inspectors  
 17 weren't comfortable with that; they preferred to have  
 18 it more secure on site, and eventually we did actually  
 19 have an extension. And I ought to say that Mr Watt  
 20 always imagined there would be an extension to PFC for  
 21 these purposes. And he'd even built in -- in fact,  
 22 the end wall of PFC, he called it a false wall. It  
 23 was always his intention that that was a wall that  
 24 could be easily taken down once the extension had been  
 25 built, just to join the existing PFC with the new

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1 everything that they said. And, essentially, my notes  
 2 formed the basis of their report.

3 **Q.** If we go to, please, ARCH0000009. This is part of  
 4 your oral evidence to the Archer Inquiry. It's  
 5 a convenient point to pick up some information about  
 6 the process. If we go to page 25, please. If we pick  
 7 the picture up at line 12, you say:

8 "Plasma products are prescription-only medicines  
 9 ... for legal purposes, they come under the ...  
 10 Medicines Act ... Government body responsible for  
 11 enforcing this Act is the ... MHRA ... formerly the  
 12 MCA."

13 Then you talk about two different types of  
 14 licence:

15 "... two principal types of licence which were  
 16 awarded ... a manufacturer's licence which  
 17 demonstrates that a premises and their operation are  
 18 suitable for the manufacture of pharmaceutical  
 19 products, and a product licence ... sometimes known as  
 20 [a] marketing authorisation, which demonstrates that  
 21 a product has been judged to be suitable for the  
 22 clinical use specified."

23 Now, I'm going to be asking you about the  
 24 manufacturer's licence because that was what the  
 25 inspection, as I understand it, was concerned with.

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1 A. That's correct.  
 2 Q. Now, is this right -- we can keep -- if we keep this  
 3 up on screen, please, for a moment, Sully. But is  
 4 this right that when the PFC opened in its new  
 5 premises, not long after that, your statement suggests  
 6 that Mr Watt was advised -- sorry, Mr Watt wanted  
 7 there to be an inspection; is that correct?  
 8 A. That's correct.  
 9 Q. But his request for an inspection was declined. Do  
 10 you know why that was?  
 11 A. I think the inspectors had higher priorities. They  
 12 were relatively newly formed, and their priorities  
 13 were hospital pharmacies because lots of hospitals  
 14 were making their own solutions, and I think,  
 15 ultimately, they were virtually all closed down, and  
 16 that was what they were focusing on at that time. So  
 17 we actually -- and BPL -- were seen as a lower  
 18 priority.  
 19 Q. And instead, your statement tells us Mr Watt was  
 20 advised just to apply for the manufacturer's licence  
 21 which was granted in 1976 --  
 22 A. That's correct.  
 23 Q. -- for a five-year period. So when we look here at  
 24 what you describe the purpose of a manufacturer's  
 25 licence as being, which is to demonstrate that the

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1 of DHSS representatives at the bottom.  
 2 And then if we go over the page, we've got  
 3 a summary:  
 4 "The inspection of the PFC ... completed in  
 5 January 1980."  
 6 And then there's reference to Mr Watt having  
 7 presented the DHSS with a considerable amount of data.  
 8 And then this:  
 9 "Deficiencies noted in the PFC operations have  
 10 been extracted from sections 1 to 4 and presented in  
 11 section 5 of the report. These shortcomings may be  
 12 grouped into those relating to premises, personnel,  
 13 procedures, documentation, and records and equipment.  
 14 Although many of the points raised in section 5 may be  
 15 considered minor as individual points, when they are  
 16 grouped, they reflect a lack of total Quality  
 17 Assurance in an otherwise well-run, scientific  
 18 operation."  
 19 Then if we go to page, I think it's going to be  
 20 page 5, first of all. Before we look at section 5 of  
 21 the report -- no?  
 22 Go to the next page, please. That's it.  
 23 So just under the heading "General  
 24 Introduction", I wanted to pick it up in the third  
 25 paragraph, where the report records this:

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1 premises and their operation is suitable for the  
 2 manufacture of pharmaceutical products, in fact the  
 3 licence granted to PFC in 1976 was granted without any  
 4 firsthand knowledge by the inspectorate or the  
 5 Medicines Control Agency?  
 6 A. Yes, but the --  
 7 Q. -- (overspeaking) --  
 8 A. -- manufacturing licence is a very complete account of  
 9 everything in the centre, down to every detail that  
 10 you -- Mr Watt could imagine. It was a very, very  
 11 thorough document, and so it was assessed on that  
 12 basis rather than, as you say, a direct visual  
 13 inspection.  
 14 Q. We can take that down now, then.  
 15 Now, in relation to that first inspection, the  
 16 end of '79 and the beginning of 1980, if we go to  
 17 PRSE0002985, please. I'll just find the right  
 18 document.  
 19 Sir, we've got here the report of the  
 20 inspection. We've got the dates, December '79,  
 21 January 1980:  
 22 "Objective: to assess the manufacturing  
 23 operations from a pharmaceutical viewpoint."  
 24 We've got the list of senior personnel who were  
 25 met, including yourself, and then we've got the names

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1 "Owing to the period of financial stringency in  
 2 the early seventies, the industrial complex was not  
 3 completed as originally planned. This, Mr Watt  
 4 indicated, has been detrimental to the blood  
 5 fractionation operations in Edinburgh."  
 6 Do you know what that is referring to?  
 7 A. No, I really don't -- I don't know. I do know that  
 8 Mr Watt was always unhappy with some of the building  
 9 construction, and he would get into a lot of arguments  
 10 about it, because it was being run by the Lothian  
 11 Health Board Building Division, and their experience  
 12 was with building hospitals, not pharmaceutical  
 13 facilities. So I think there was some tension at that  
 14 point and some of that could have been financial --  
 15 related to finance.  
 16 Q. If we then go to section 5 of the report, I'm going to  
 17 try the paragraph numbers but mine's not numbered --  
 18 sorry, the page numbers.  
 19 Can we try page 51, please, Sully.  
 20 Next page.  
 21 So if we go to the bottom of that page, there's  
 22 a heading, "Summary of Deficiencies Noted During  
 23 Inspection", and then there are a range of  
 24 deficiencies identified, I'm not proposing to read  
 25 them out but we see an example at the bottom of the

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page, which was premises where -- in relation to the initial handling of blood; open laboratory; thoroughfare without adequate control.

Then, over the page, there's a range, then, of what might be viewed in isolation, as the inspector said, small points but, taken together, raised concerns, is this right, in particular about the risks of microbiological contamination?

A. Yes, that's correct, that was the inspector's overriding concern throughout the inspection.

Q. Can we then just go on to page -- sorry, what page electronically are we on now, Sully? 53? If we go on a further four pages and see if that takes us to the right one. One page before that, please.

I just wanted to pick up the section 5.1.6 and, in particular, 5.1.6.4. It refers to plasma being hepatitis B surface antigen tested at regional centres:

"However a positive statement as to plasma HBsAG status is not presented."

Do you know what that referred to in particular?

A. I'm not sure what that means, except it possibly is just a confirmation that there came with the plasma to confirm that it had been tested, rather than just assuming that, having left the Centre and sent to PFC

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"7.5 It would be unwise, taking account of 7.1, to increase the scale of manufacture at this point. However, when the deficiencies have been rectified this imposition on product range and volume of production could be reconsidered."

Now, is it right to understand from your statement and other evidence you've given, that neither Mr Watt nor you were particularly surprised by the identification of the range of criticisms that the report set out?

A. No, that would be correct because, as you've established earlier this week, the design of PFC was largely finalised around about 1970, and that was before any of these guidelines had become available. And, by this point in time, 10 years later, we're now in the second edition of the GMP guidelines, and so, clearly, the building wasn't built with that knowledge available, and I think Mr Watt was keen to develop it in conjunction with the inspectors, rather than try and get ahead of that and then find out he'd done it wrongly.

He wanted to do it jointly with the inspectors and that was why he was so keen to have inspections so early on.

I think the fact that that was delayed was

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it had been tested, but you'd be better asking Bob Perry about that.

Q. Then, if we go on to the conclusions which should be another 14 pages, I think, further on, Sully. Nearly but no, not quite. Can you go another 10 pages, sorry. That's it, "Conclusions".

So the conclusions of this first inspection:

"Plasma Fractionation and associated operations are not carried out under the conditions of Good Manufacturing Practice. They do not comply because of the deficiencies in Premises, Personnel, Procedures -- production, quality control and maintenance -- Documentation and thus total Quality Assurance.

"7.2 However, a basis upon which a good Manufacturing Unit could be established does exist.

"7.3 Staff are extremely conscientious and competent in fractionation procedures, but it is apparent there is a lack of knowledge, experience and awareness of the requirements of GMP in the pharmaceutical aspects of sterile products.

"7.4 If an undertaking given is to rectify the deficiencies cited within a reasonable period of time then the manufacturing operations presently undertaken should be permitted to continue. We would define a reasonable period of time as being two years.

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unfortunate.

Q. Paragraph 7.5 on this page indicates that the inspectors were discouraging increasing the scale of manufacture at that point in time until the deficiencies had been rectified. Did that have an impact, at that point in time, upon the PFC's ability to take more plasma for fractionation?

A. I don't think it did. And it might help -- I do remember very clearly what the issue was, because, as you know, I was with the inspectors, and they were most concerned about the fact that the bottle that we used for albumin had a screwtop and they thought that might be an opportunity for bacteria to crawl up the screwtop into the bottle, and they ordered that replaced with a more modern type of container.

Now, the container we were using, which was the same as the one the BPL was using, was called an MRC bottle, which had been approved by the Medicine Research Council but by now was out of date in terms of pharmaceutical practice. So we had to change over to an alternative bottle, and that was the critical issue that they were concerned about, from my memory.

Q. Now, there was a second inspection in October 1981, do you recall how that came about? Was that the inspectors coming back to see what had been done since

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1 their first inspection?

2 **A.** I'm sure it was a follow-up. Obviously, it was

3 a follow-up to the previous inspection. I wasn't

4 involved with this one, so I am not in a position to

5 talk about it in any detail.

6 **Q.** Just, however, for the benefit of those listening, if

7 we can look at that second inspection report, albeit,

8 obviously, in the knowledge that you weren't

9 performing the same function that you had previously,

10 we've got a document at BNOR0000572. If we go to the

11 second page, we can see at the top of the page some of

12 the document is a little indistinct, but it says,

13 I think:

14 "Following the response of the Protein

15 Fractionation Centre to the inspection ... a series of

16 visits for discussions [possibly the word at or

17 something like that] PFC has taken place to progress

18 matters. These were held on the following dates ..."

19 Then we've got dates in June 1981 and then

20 September and 1 October 1981. If we just go down to

21 the bottom half of the page under the heading "General

22 Comments", there's reference to the appointment of

23 Dr Perry as quality control, obviously we can ask

24 Dr Perry about that, and then the last paragraph on

25 that page refers to:

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1 **Q.** But it was the Scottish Home and Health Department

2 that put a stop to that?

3 **A.** Yes. Mr Watt wanted PFC to be judged on the same

4 standards as the commercial sector.

5 **Q.** Now, I'm not going to go through the specific findings

6 on the premises and facilities set out in this report

7 but if we can go to page 7.

8 **A.** May I add, before we leave this point, that when the

9 inspections began in 1984 that was, of course, before

10 Mr Watt had left.

11 **Q.** Yes.

12 **A.** And I think the Department was concerned that Mr Watt

13 was using the inspections and the inspectors to get

14 more money than was justified.

15 **Q.** No doubt Dr Perry may be able to assist us then in

16 relation to events post-Mr Watt's departure.

17 If we then go to page 7, we've got the

18 conclusions. Again, it's not entirely easy to read

19 all of it but 4.1 says:

20 "Progress towards implementing necessary

21 standards of GMP in general Quality Assurance matters

22 including provision of standard process documents and

23 standard operation procedures is generally acceptable.

24 "A major effort regarding these aspects is now

25 coming to fruition."

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1 "Routine visits in the future will review

2 progress of these aspects and an in-depth inspection

3 in approximately three months will be scheduled to

4 cover these aspects and of any necessary advice and

5 recommendations ..."

6 Did that happen, as far as you know, either

7 a further inspection, in-depth inspection, or ongoing

8 visits?

9 **A.** It didn't. Visits did begin again in 1984 on a less

10 formal basis because, shortly after this, we were

11 instructed by the Scottish Home and Health Department

12 that we would not -- we should not meet with the

13 inspectors, and that any relations with them should be

14 done by the Scottish Home and Health Department.

15 **Q.** Do you know why the Scottish Home and Health

16 Department gave that advice to the PFC?

17 **A.** The reason that was given was that we were under Crown

18 immunity, therefore we're not required to do this.

19 And Mr Watt took great exception to that and he was on

20 the point of refusing to issue products until he got

21 legal indemnity by the Scottish Health Department.

22 **Q.** So is it right to understand from your recollection,

23 Mr Watt himself was happy for there to be further

24 inspections?

25 **A.** Oh, yes, he welcomed them.

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1 Then two particular exceptions to that are

2 noted.

3 4.2 says:

4 "Firm proposals to remedy those deficiencies

5 regarding buildings and facilities as reported in the

6 first inspection are still awaited, with dates of

7 implementation.

8 "These deficiencies are as defined in section 3

9 of the report."

10 Now, as you weren't particularly closely

11 involved in it, I'm not proposing to take you through

12 the detail but do you have any understanding as to why

13 proposals to remedy certain deficiencies regarding

14 buildings and facilities was still awaited at that

15 point in time? Was that a question of funding?

16 **A.** It was entirely a question of funding and funding from

17 the Scottish Health Department had to be made

18 available to do this.

19 **Q.** Then we can see 4.3, the passage that's underlined,

20 says:

21 "The present buildings and facilities continue

22 to fail to reach minimum standards of GMP, and

23 a licence would not be recommended for an industrial

24 equivalent unless agreed upgradings were instituted as

25 a matter of urgency."

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1 Do you have any recollection of Mr Watt's view  
 2 on that conclusion or his response to this report?  
 3 A. I think he would -- he was -- welcomed the inspection,  
 4 this statement, and the strength of it, because that  
 5 gave him more ability to try to get the funding that  
 6 was needed.  
 7 Q. Because, essentially, the inspectors were saying, were  
 8 they not, if we left aside Crown immunity and you were  
 9 an ordinary manufacturing facility, you wouldn't be  
 10 getting a licence unless you did something urgently to  
 11 improve the position?  
 12 A. My understanding is the inspectors are stating their  
 13 authority here and, of course, the problem for them  
 14 was that they didn't have as much authority because of  
 15 Crown immunity. So this is my understanding of why  
 16 it's worded that way. But it's essentially  
 17 a statement of authority, and to try to put pressure  
 18 on the Scottish Health Department to provide the  
 19 funding, and Mr Watt would have welcomed that.  
 20 Q. Now, you've described in your statement what you said  
 21 were two positive impacts from the inspections, so if  
 22 we go to WITN6914001, page 31, please. It's the  
 23 bottom half of the page, under the heading "Impact on  
 24 Virus Inactivation". You say:  
 25 "I believe that the impact of the remedial

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1 eventually had, in part at least, the outcome that  
 2 Mr Watt had hoped for, which was that it effectively  
 3 put pressure on SHHD to provide funding for certain  
 4 upgrades of the facilities to take place?  
 5 A. That's right.  
 6 Q. In terms of the impact, longer term, on work relating  
 7 to virus inactivation, was the principal benefit in  
 8 that regard the R&D pilot plant?  
 9 A. That was one of the benefits, yes.  
 10 Q. What other benefits were there that might have  
 11 impacted in terms of the development of viral  
 12 inactivation methods?  
 13 A. Actually, I would just leave it there. It was the  
 14 pilot plant allowed us to do more work on  
 15 pasteurisation that we couldn't have done otherwise.  
 16 And, also, the virology work which we did not only for  
 17 ourselves but for BPL because they didn't have that  
 18 facility.  
 19 Q. You refer to both of those over the top of the next  
 20 page, in fact, at -- on the first two paragraphs on  
 21 that page.  
 22 If the authorisation for the upgrading had been  
 23 made earlier by the Scottish Home and Health  
 24 Department, would it be right to understand that you  
 25 might have -- you, the team, the R&D team -- might

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1 actions agreed with the Medicines Inspectorate on the  
 2 timescale for achieving virus inactivation were  
 3 positive in two respects.  
 4 "The first of these is that permission was  
 5 granted for the construction of a Microbiology  
 6 Extension to PFC, for which plans had been drawn up in  
 7 the mid-1970s, but which had not been previously  
 8 authorised by the SHHD.  
 9 "The main reason for approval being given for  
 10 this extension was the provision of bacteriology  
 11 laboratories, which had been included in its design,  
 12 which the Medicines Inspectorate had requested to  
 13 enable PFC to be able to carry out its own  
 14 bacteriological testing on-site.  
 15 "Also included in the design of the Microbiology  
 16 Extension were a category 3 containment facility for  
 17 work with dangerous pathogens (ie viruses) and an R&D  
 18 pilot plant", which you referred to, Dr Foster, before  
 19 the break.  
 20 Do you know why these facilities had not  
 21 previously been authorised by the Scottish Home and  
 22 Health Department?  
 23 A. Well, the short answer is no, but I assume it was the  
 24 finance.  
 25 Q. So your understanding is that the inspection report

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1 have been able to make use of those facilities  
 2 earlier?  
 3 A. We would have used the facilities, but I don't think  
 4 it would have advanced our work on achieving safe  
 5 products in terms of viruses because that was  
 6 dependent on scientific breakthroughs, not just  
 7 scale-up, which is what this was concerned with.  
 8 Q. Well, we can pick that up when we look at  
 9 pasteurisation and heat treatment tomorrow.  
 10 Just, then, on issues relating to regulation and  
 11 external agencies, if we go back to your evidence to  
 12 the Archer Inquiry, ARCH0000009, and we go to page 30,  
 13 I think, lines 11 and 12. Sorry, just -- in fact,  
 14 I should, I think, probably pick it up at the top of  
 15 the page.  
 16 You refer to there being no further licence  
 17 applications made by SNBTS until Crown immunity was  
 18 removed. Then you say:  
 19 "... PFC continued to interact with the MCA,  
 20 encouraging informal inspections ... acting on the  
 21 advice given."  
 22 And then there's a question from Lord Archer.  
 23 And then you say this at lines 11 and 12:  
 24 "Yes, we were in continuing dialogue with the  
 25 agencies, even though that was not a formal

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1 arrangement."

2 Which agencies were you referring to there? Is

3 that simply the MCA?

4 A. Yes.

5 Q. And do you know what, if any, dialogue there was with

6 the MCA or with the inspectors from 1981, when that

7 second visit took place and the report was produced,

8 through to 1984 when they returned?

9 A. No, I have no knowledge of that.

10 Q. And who would have been most closely involved, then?

11 Would that have been Mr Watt and Dr Perry?

12 A. That's correct.

13 Q. Can I ask you next a little about pool sizes. I want

14 to start, if I may, by taking you to a passage in your

15 evidence to the Penrose Inquiry, so that's

16 PRSE0006041, please. And if we go to -- I think it

17 should be page 38. So there's an exchange here. If

18 we pick it up at line 8 and 9, you were asked about

19 the use of the word "batch" and the use -- and your

20 statement that at the end of 1983, you'd been working

21 with about 4,000 donations per batch.

22 And then if we go to the next page, if we pick

23 it up at line 14, you were asked this:

24 "So when we see references to a batch, we should

25 understand by that the total of, say, 4,000 donations

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1 the pool size, the batch size, increased to this

2 number. It was thought that we could maximise our

3 output of Factor VIII. Because the challenge for us

4 was to produce more Factor VIII to minimise the amount

5 of commercial Factor VIII being used, and there was no

6 other way we could do it, other than by increasing

7 pool size.

8 Q. So it would be right to understand that, then, by the

9 end of 1983 or thereabouts, you would have -- if we

10 use the terminology here, first of all, of

11 "donations" -- around 4,000 donations, so that would

12 be probably 4,000 different donors?

13 A. That would be -- that's correct. It would be --

14 typically, between 800 and 1,000 litres of plasma

15 would go in to processing, and as an estimate, that

16 could be up to 4,000 donations.

17 Q. I think sometimes we see reference to litres;

18 sometimes we see reference to kilograms in the

19 material. Are you able to assist us with why the

20 different measurements are used?

21 A. When plasma is received into PFC, it's weighed so that

22 there's a record of how much has been received from

23 each centre. But it was provided -- the plasma was

24 contained in a plastic bag. The plastic bag is in

25 a carton, and it's weighed like that, so some account

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1 that is, as it were, processed together; is that

2 right?"

3 And your answer was:

4 "That's correct. Yes."

5 Can you just help us understand the reference

6 there to batch and 4,000 donations, and then I just

7 want to ask you a little more, more generally, about

8 pool sizes.

9 A. Are we talking just about Factor VIII?

10 Q. Yes. For present purposes, yes.

11 A. Okay.

12 As we talked about earlier, the process begins

13 with thawing the plasma, and the -- that is done in --

14 the amount of plasma that is taken out of the cold

15 storage was a matter of production scheduling. And in

16 the mid-'70s until the -- near the end of the '70s,

17 that was done by the batch process. And they would --

18 that batch tank was sized, I think probably by

19 Dr Smith, to take about 150 litres at a time. By the

20 late '90s -- sorry, the late -- '79, I was introducing

21 this continuous process, and that allowed us to

22 increase the volumes that we could manufacture. And

23 we needed to increase the volume in order to increase

24 the output of Factor VIII. That was the only

25 mechanism we had available to do that. And that is why

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1 was taken to remove the weight -- to remove the weight

2 of the carton in what was called a tear system, so

3 that was deducted from the weight. But the weight

4 still included the weight of the plastic, so when you

5 see kilograms of plasma, it's actually kilograms of

6 plasma plus plastic. And we made some measurements to

7 the amount of plastic -- the weight of the plastic.

8 I don't know if that was adjusted from any of the

9 figures that were used in annual returns or how much

10 plasma was received.

11 So my assumption would be that those figures of

12 kilograms are plasma plus plastic. Of course, I think

13 you discussed earlier in these proceedings that the

14 density of plasma is not the same as the density of

15 water, and therefore you can't say that 1 kilogram

16 equals 1 litre. And so the only measurement of volume

17 that we had was after the cryoprecipitate had been

18 removed and the plasma had been thawed, and we would

19 make that measurement as a volume. And the amount of

20 cryoprecipitate was about 1 per cent of that, so there

21 was a slight decrease in volume. I hope this makes

22 sense, but those are what those figures refer to. So

23 you could either work with kilograms -- bearing in

24 mind that includes plastic, and the density is

25 different to litres -- or you could work with litres.

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1 So it is obviously confusing for people who are not  
2 familiar with what was taking place.  
3 **Q.** Then I just want to ask you to look at a written note  
4 produced by the Inquiry which the Inquiry heard about  
5 yesterday afternoon. It's INQY0000346. Now, you,  
6 I think, were travelling to London and weren't able to  
7 listen to the Inquiry hearings yesterday. I just want  
8 to ask you to look at a couple of the charts and then  
9 really invite you to comment in the most general  
10 terms, because you won't have had any opportunity to  
11 look at any underlying material.

12 If we go to page 9, there's a table at the top  
13 of the page which shows the period from 1978, '79,  
14 through to 1983 to '84. And this is the Inquiry's  
15 estimate, based upon various sources of data which  
16 have been identified in the note, of the changes in  
17 pool size in terms of -- expressed in litres and then  
18 estimated donations. And we see in broad terms an  
19 upward trajectory.

20 Now, without expecting you to be able to say  
21 specific figures are or are not accurate, is that  
22 overall a picture that seems right to you from your  
23 own experience?

24 **A.** I would say the first line is incorrect. The 114 is  
25 far too small. It was more like 160.

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1 output, and the pressure on all of us was to provide  
2 more Factor VIII concentrate.  
3 **Q.** What, if anything, was the impact of the capacity of  
4 the freeze dryers at the PFC to handle the plasma  
5 pools?  
6 **A.** Well, that was the principal bottleneck in the  
7 process, and so you had to anticipate when you might  
8 need greater freeze drying capacity. And it took  
9 about 18 months to 2 years to obtain a new freeze  
10 dryer because these were made to order, specified and  
11 made to order, and took a long time. So you really  
12 had to have that foresight to be able to plan ahead  
13 and to get the finance to bring in new freeze dryers.  
14 And we largely managed to do that. We never ran out  
15 of freeze drying capacity, except at one point where  
16 we were close to doing that, but we managed to insert  
17 an extra shelf in the freeze dryer by getting smaller  
18 vials from BPL that allowed us to do that. So that  
19 carried us through that difficult period.  
20 **Q.** So is it right to understand, then, your evidence in  
21 this way: that the increase in pool sizes reflected  
22 the aim of achieving self-sufficiency domestically for  
23 Scotland, and thus not having to be reliant upon  
24 commercial concentrates?

25 **A.** Yes.

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1 And I actually did prepare a report for  
2 Professor Cash where I documented every batch that was  
3 processed from 1975 right through until the early  
4 '80s, and every volume for every batch, and that  
5 report should be available in our system. And I don't  
6 remember it being as small as 114. It was typically  
7 160.

8 In 1979, there was a mixture because the batch  
9 process was 160 -- 167 here -- but the -- what was  
10 a pilot continuous thawing process ran at 300 litres,  
11 and then I had -- the full-scale continuous process  
12 came into play, came into use in 1981, and that went  
13 up to 1,000 -- up to 800 to 1,000 litres. So these  
14 figures are not really correct.

15 **Q.** Okay. Well, it may be that you'll be able to provide  
16 us with any observations you have on the specific  
17 figures in writing.

18 But is it right -- if we just go, perhaps, to  
19 page 11, which provides at the bottom of the page  
20 a graphical overview. It's right, is it, to  
21 understand that there was an increase in pool sizes in  
22 this period from '78 --

23 **A.** Yes, that's correct.

24 **Q.** -- into the '80s --

25 **A.** As I said, that was the only way we could increase

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1 **Q.** Then can you tell us how and by whom decisions as to  
2 pool sizes or increases in pool sizes would be made at  
3 the PFC over this period?

4 **A.** That would be the director in conjunction with the  
5 production manager and it was about -- I mean, about  
6 really product scheduling in order to maximise output.  
7 But I should say that when we get into the early '80s,  
8 we did have the group that we talked about earlier,  
9 which Professor Cash was chairing, which was  
10 Factor VIII Study Group. Under that, there was  
11 a group called the Safety Action Group, and they were  
12 really brainstorming on everything or anything that  
13 could be done to try to minimise or reduce risk, and  
14 from the notes that they prepared, I never saw any  
15 suggestion about pool sizes.

16 But, of course, we did have the small pool  
17 product that was cryoprecipitate, that was, to the  
18 best of my knowledge, always available from SNBTS.

19 **Q.** Yes, and I will come back to both cryoprecipitate and  
20 the issue of freeze-dried cryoprecipitate at a later  
21 stage.

22 Then, still in relation to pools but a different  
23 question now, to what extent was plasma that was being  
24 used for the production of specific immunoglobulins,  
25 was that processed separately from plasma fractionated

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1 to produce factor concentrates?

2 **A.** Yes, the high premium pools always processed

3 completely separately. No other product was

4 manufactured from them, other than the immunoglobulin.

5 **Q.** So there should be no cross contamination?

6 **A.** No.

7 **Q.** I want to ask you next about the relationship between

8 the PFC and a number of other organisations, and

9 bodies. So, first of all, PFC's relationship with the

10 wider SNBTS; how did that work in principle?

11 **A.** In principle, PFC was part of SNBTS. It began as part

12 of SNBTS and remained as part of SNBTS.

13 **Q.** So what kind of dealings or interactions took place

14 between PFC and the regional transfusion services that

15 made up the remainder of SNBTS?

16 **A.** As we touched on, PFC originated as part of a Regional

17 Transfusion Centre and, when I arrived, quite a lot of

18 the analytical work was being done by the staff in the

19 Regional Transfusion Centre including Factor VIII

20 assays, and that relationship continued when we moved

21 to PFC, in that we would still get Factor VIII assays

22 done by a Regional Transfusion Centre in Edinburgh.

23 And, even when we were entirely running our own

24 factory assays, we would get a duplicate done with the

25 Edinburgh Centre just for security.

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1 centre of being part of a National Blood Transfusion

2 Service as opposed to being separate from it?

3 **A.** It was a huge advantage because that's where our raw

4 material came from, and we were closely connected to

5 them. So there were systems in place to ensure that

6 we could get the raw material we needed, and have

7 a dialogue. I'm not sure that existed in England to

8 the same extent.

9 **Q.** Did you have any dealings on any regular basis with

10 Regional Transfusion Directors in England and Wales?

11 **A.** No.

12 **Q.** Do you recall whether you or colleagues at the PFC had

13 any sight of the minutes of the regular meetings that

14 took place between Regional Transfusion Directors in

15 England and Wales?

16 **A.** I didn't. I don't know about -- I can't speak for the

17 director.

18 **Q.** Did you have any dealings yourself with the CSA, the

19 Common Services Agency, in the '70s or '80s?

20 **A.** No, I can't remember having any.

21 **Q.** Then the Scottish Home and Health Department, did you

22 have direct dealings with SHHD or was that left to

23 Mr Watt or Professor Cash?

24 **A.** I was invited by Mr Watt to take part in the annual

25 meetings that were held with the Department and

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1 So there was always a continuing relationship.

2 The relationship with Glasgow was less strong because

3 it was further away, and obviously the other centres.

4 But there was always a good relationship, and that was

5 through the directors whom met regularly, and we

6 met -- I talked about, earlier this morning, I was

7 leading a project team which involved senior technical

8 staff from all of the Transfusion Centres throughout

9 Scotland.

10 And the -- so the staff knew each other well.

11 There was lots of interactions. I mean, just as

12 an aside, the scientific staff independently began to

13 meet under their own volition to share findings. From

14 about 1974, we would have regular scientific meetings

15 that were just kind of *ad hoc*. And that led,

16 ultimately, to the formation of an annual conference,

17 called the Scotblood Conference but that began with

18 the scientific staff taking their own initiative to

19 meet independently.

20 **Q.** Now, the role you've described of the PFC, as part of

21 SNBTS, in the way in which you've just referred to, is

22 obviously different from the relationship between BPL

23 and the Regional Transfusion Centres in England and

24 Wales. Do you have any thoughts or observations about

25 any advantages or disadvantages for a fractionation

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1 Haemophilia Centres and SNBTS from 1981. I attended

2 those meetings, and through until 2008, I think. So

3 I did attend those meetings. Much later I attended

4 various meetings at the Department but not in the '70s

5 and '80s.

6 **Q.** What then of the relationship with the Haemophilia

7 Centres in Scotland? How did contact between the PFC

8 and the Haemophilia Centres take place, if at all?

9 **A.** It was -- to the best of my knowledge it was via the

10 medical staff of the transfusion service, it would be

11 Professor Cash, Dr Boulton, people like that, and

12 also, by attending the annual meeting with the

13 Haemophilia Directors. Whether Mr Watt had other

14 arrangements, I don't know. I do know that he was

15 a personal member of the Haemophilia Society and he

16 received the minutes of their minutes and bulletins,

17 but that was very much on a personal basis because he

18 wanted to be kept informed.

19 **Q.** You said in your statement that it was SNBTS policy

20 that it was the SNBTS medical staff that would

21 interact with clinicians, rather than PFC staff. Do

22 you know why that was the policy?

23 **A.** PFC had no medically qualified staff on its books.

24 **Q.** Then, in terms of supplying PFC concentrates to

25 Haemophilia Centres, did you have any dealings

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1 directly with the Haemophilia Centre Directors in  
 2 terms of their requirements?  
 3 A. No, that was never dealt with through me. It would  
 4 always go to the director of PFC.  
 5 Q. I'll just ask you about one document at HSOC0002690.  
 6 This is a memo from you to Dr Perry, it's  
 7 18 November 1986. You say:  
 8 "I have noticed that there is a meeting of SNBTS  
 9 and Haemophilia Directors due in February. In the  
 10 past, information has not been particularly  
 11 forthcoming from this group, and I wonder if we should  
 12 perhaps table some formal questions in advance of the  
 13 meeting."  
 14 Then you set out a number of questions in  
 15 particular in relation to HIV positivity and treatment  
 16 history.  
 17 Are you able to elaborate upon that second  
 18 sentence, "information in the past having not been  
 19 particularly forthcoming from this group"? What kind  
 20 of information had PFC not -- had wanted but not  
 21 obtained?  
 22 A. Well, I think number 1 in this list is how many  
 23 patients there were in Scotland. And I think, not so  
 24 much myself, but Professor Cash, was always trying to  
 25 find out more about how much commercial product was

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1 Q. What was that?  
 2 A. That was the technique that Baxter used to enable them  
 3 to dry heat treat their product.  
 4 Q. I may come back to that, then, tomorrow and ask you  
 5 about that a little more.  
 6 Did you -- you've referred to Mr Watt being  
 7 a member of the Haemophilia Society. Did you have any  
 8 particular relationship or connection with the  
 9 Haemophilia Society.  
 10 A. No, I didn't.  
 11 Q. Then, in terms of the relationship with BPL, your  
 12 statement suggests that you and your colleagues, your  
 13 scientific colleagues at PFC, had a good relationship  
 14 with Dr Smith and others at BPL; is that correct?  
 15 A. Yes.  
 16 Q. The Inquiry has seen evidence that might suggest the  
 17 relationship between Mr Watt and Dr Lane was not  
 18 a harmonious or positive one. Did you have any  
 19 knowledge of that at the time?  
 20 A. No, I can't say I did. I only met Dr Lane a small  
 21 number of times. I only remember him coming to PFC  
 22 once and being shown around, and everything was quite  
 23 cordial.  
 24 Q. Do you think there was room for improvement in terms  
 25 of the joint working arrangements between BPL and PFL,

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1 used and didn't always get satisfactory information.  
 2 And those were the issues, I think, that we had  
 3 difficulty with because it would have helped us to  
 4 know, or Professor Cash, for planning purposes, to  
 5 know about these things.  
 6 And I think the other points here are just kind  
 7 of my brainstorming at that point in time, what would  
 8 have been useful to know about. But I don't know if  
 9 any of this ever happened.  
 10 Q. You have observed in your statement that you had less  
 11 contact with haemophilia clinicians than Dr Smith did  
 12 in, from his perspective at PFL -- BPL. I think it's  
 13 right you didn't attend meetings of UKHCDO or have  
 14 access to their minutes; is that right?  
 15 A. That's correct, yes.  
 16 Q. Would it have been useful, do you think, for you to be  
 17 able to either attend the meetings or have at least  
 18 access to copies of what was being discussed?  
 19 A. From the minutes that I've seen, I would say yes. Not  
 20 so much attended the meetings, because they were very,  
 21 very large attendance but having access to the minutes  
 22 would have been very helpful to me and, in particular,  
 23 there was one piece of technical information in one  
 24 minute that would have been very important for me to  
 25 know, but I didn't know it at the time.

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1 on the one hand, and PFC, on the other?  
 2 A. I don't. I think we got on extremely well. All of  
 3 the staff knew their counterparts and could phone you  
 4 any time. It was a two-way process. We saw them as  
 5 being part of the same organisation, just a different  
 6 branch, and being a highly specialised area of work,  
 7 if you're working on something and there's only one  
 8 person in the country doing the same thing, then  
 9 they're the person you want to talk to, and so that  
 10 happened, we did have this dialogue.  
 11 Q. Can I ask you to look at one document, PRSE0003692 --  
 12 PRSE0003962, sorry, Sully.  
 13 This is a minute dated 30 August, or a memo  
 14 dated 30 August 1988, from Dr Forrester to the Chief  
 15 Medical Officer, so it's an internal SHHD document, as  
 16 I understand it. I just wanted to read the first  
 17 two paragraphs and then ask you whether you have any  
 18 observation. It says:  
 19 "Mr Hamill questions the lack of proper R&D  
 20 links between Scotland and England. Formal attempts  
 21 to forge them have been made and collapsed into  
 22 acrimony. I attach a DHSS minute of 10 June 1987  
 23 saddling Scotland with the blame. However that may  
 24 be, the indications are (and I think Dr Scott would  
 25 agree) that only coercion from above and some resolute

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1 decisions about R&D funding would get SNBTS and CBLA  
2 to make common cause.

3 "It should be remembered, as I pointed out to  
4 Mr Donald some time ago, that the picture of Punch,  
5 (England?) and Judy (Scotland?) at blows is only what  
6 is presented to DH and to SHHD. If you go behind the  
7 scenes after the show, the two are in bed together --  
8 for instance, PFC are conducting virus elimination  
9 research for BPL now, by mutual arrangement."

10 Now, this is someone else's opinion, obviously,  
11 that's being referred to here but, from your own  
12 perspective, do you have any either knowledge of or  
13 reflections on what is set out there, both in terms of  
14 the reference to acrimony and absence of common cause,  
15 but also the reference to behind the scenes mutual  
16 co-operation?

17 A. I'm very familiar with the behind the scenes mutual  
18 co-operation because, shortly after I joined PFC in  
19 1973, Mr Watt asked me to lead a delegation from PFC  
20 to BPL so the staff could meet their counterparts, and  
21 neither he nor Dr Smith nor Mr Grant, who were the  
22 senior staff, attended because they wanted the middle  
23 grading staff to meet their counterparts without any  
24 involvement of themselves.

25 And I think there were about a dozen of us went

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1 we were just chasing this ever-increasing demand as  
2 hard as we could and Dr Cash was banging the drum to  
3 get more and more plasma, and we were doing everything  
4 we could to produce more and more, but of course the  
5 aspirations of the doctors and the patients, which one  
6 can understand, is that this was so successful that  
7 they were running ahead of us all the time."

8 Now, first of all, does that remain your  
9 recollection of the picture as at, perhaps, '75, '76,  
10 '77?

11 A. And beyond.

12 Q. So how did it change, as far as you can recall, or to  
13 what extent did it change?

14 A. Sorry, I don't quite understand the question.

15 Q. Forgive me, let me make the question clearer.

16 Here you're talking about demand going up, so  
17 demand for concentrates, as I understand it, is what  
18 you're referring to, increasing, so the targets that  
19 you needed to meet changing, Dr Cash wanting to get  
20 more and more plasma. Did there come a point at which  
21 that picture changed, and if so, roughly when?

22 A. Firstly, the difficulty was that information on how  
23 much was being used was always available  
24 retrospectively because it was collected by HCDO and,  
25 by the time it was processed, it was maybe 18 months

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1 down to BPL for the day and everybody met their  
2 counterpart, got to know who they were. They were  
3 encouraged to dialogue. And BPL made a reciprocal  
4 visit to PFC. So at my level and even the level below  
5 me, there was a lot of what is called being "in bed  
6 together" was going on, really, from the mid-1970s.

7 If there was any problems at a senior level, we  
8 didn't know about it.

9 Q. I'm going to move to a different topic now, which is  
10 that of self-sufficiency, with a focus on Scotland.  
11 I'm then going to ask you about the ability of PFC to  
12 fractionate plasma from elsewhere.

13 I'll just start with part of your oral evidence  
14 to the Penrose Inquiry at PRSE0006022. If we go to  
15 page 43, I just wanted to pick up the picture at the  
16 bottom ten lines or so, from line 18 down. You said  
17 this:

18 "PFC had only just opened ..."

19 So we're in, probably, around 1976 at this  
20 point:

21 "... and it was opened with some kind of  
22 expectation that this was going to solve everyone's  
23 problems, and of course that didn't happen because the  
24 target that had been set turned out to be not what  
25 happened. The demand went up and up and up and really

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1 or even two years out of date, so we were really  
2 driving in the dark and we were trying to hit a moving  
3 target in the dark. And so you were dependent to some  
4 extent, and this really amounts to the plasma side, in  
5 trying to predict how much plasma was required.

6 And I think this is where Professor Cash  
7 probably made a big difference. Before  
8 Professor Cash, the national medical director was  
9 Major General Jeffrey, and he died at the end of 1976,  
10 and there was a hiatus, really, until Dr Cash took  
11 over in 1979, and I think his first task was to begin  
12 to reconsider this area and instead of looking in the  
13 rearview mirror, he started trying to plan  
14 prospectively what might be required in terms of  
15 clinical needs of patients in the future and he came  
16 up with quite -- figures that were quite different to  
17 those that had been seen before.

18 I remember meeting him. I was going to  
19 a conference where I was giving a presentation on  
20 self-sufficiency, and he said, "What's the target for  
21 Factor VIII?" And I gave him the target that General  
22 Jeffrey had produced, and he just laughed in my face,  
23 and he said, "Oh that's ridiculous", then he got up on  
24 the train and got in the First Class compartment and  
25 I didn't see him again. But he was working in figures

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1 that were completely different to those that General  
 2 Jeffrey had.  
 3 Q. Different in what way? Much smaller or much larger?  
 4 A. Sorry, much larger.  
 5 Q. So once -- well, I don't want to put words into your  
 6 mouth. So you paint a picture, then, of Dr Cash,  
 7 Professor Cash, coming along, producing targets or  
 8 figures that were more realistic, as far as PFC  
 9 understood the position; is that right?  
 10 A. Yes.  
 11 Q. Then how did PFC respond, in terms of trying to meet  
 12 that increased demand?  
 13 A. It wasn't so much PFC; it was getting more plasma.  
 14 That was the limitation, and that was where Cash  
 15 played a very strong part. He took that -- took it on  
 16 very aggressively indeed.  
 17 Q. If we just go back to your evidence to the Archer  
 18 Inquiry, ARCH0000009, page 37, I believe. You  
 19 identify here, I think, two measures in terms of  
 20 trying to meet the demand. If we pick it up --  
 21 actually, we'll read, I think, probably the whole  
 22 page:  
 23 "When it was realised this would not be the case  
 24 [that refers to an assumption that you'd obtained  
 25 sufficient Factor VIII as a byproduct of albumin],

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1 Q. Then the second element that you describe in your  
 2 evidence to the Archer Inquiry was the increase of  
 3 Factor VIII yield. And you say that you managed to  
 4 increase that by about 60 per cent. Over what period  
 5 of time was that done, roughly?  
 6 A. I probably began that in the '76/'77 period, but that  
 7 major increase occurred when I started to introduce  
 8 the continuous thawing process in 1979, 1981. That  
 9 was when that had the biggest impact.  
 10 Q. And in short and simple terms, how was that done? How  
 11 did you increase Factor VIII yield significantly?  
 12 A. In the first steps that I took, I fine-tuned each of  
 13 the steps in the manufacturing process. For example,  
 14 there were different -- you had to mix the  
 15 cryoprecipitate to dissolve it, and there were  
 16 different mixes that were available, and I examined  
 17 which one was best in terms of not damaging the  
 18 Factor VIII. And there were various adjustments like  
 19 changing pH or adding various chemicals. And  
 20 I examined every step, just to optimise it absolutely.  
 21 And at the end of that process, there were some  
 22 increases. When you eventually got to the end of the  
 23 process, it came out as -- with a higher yield.  
 24 But, eventually, it was when we moved on to the  
 25 continuous thawing which was able to -- the problem

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1 considerable effort was made to increase the  
 2 production of Factor VIII concentrate. The amount of  
 3 plasma required could not be met by recruiting more  
 4 donors. Instead, plasma had to separate from blood  
 5 soon after donation, leaving hospitals to use red  
 6 cells instead of whole blood for transfusion, a  
 7 concept known as component therapy."  
 8 You were asked then what period of time that was  
 9 referring to. Late '70s, early 1980s.  
 10 And you say:  
 11 "This was a major change to establish medical  
 12 practice, and to encourage hospital doctors to make  
 13 this change SNBTS medical staff embarked on a process  
 14 of education and persuasion. SNBTS eventually stopped  
 15 issuing whole blood altogether, unless it was first  
 16 approved by an SNBTS doctor."  
 17 Then you go on to talk about a second element  
 18 which I'll come on to in a moment because that's one  
 19 you were directly involved in.  
 20 But, presumably, what's set out here is not  
 21 something you would have had direct knowledge of.  
 22 This is your understanding of what was happening more  
 23 widely within SNBTS; essentially the use of red cell  
 24 concentrates.  
 25 A. That's my understanding, yes.

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1 with batch thawing is that in order to melt the  
 2 plasma, you have to add heat. But the Factor VIII  
 3 which was in the cryoprecipitate would redissolve once  
 4 the temperature got to about 3 or 4 degrees  
 5 centigrade. And in the batch tank, the temperature of  
 6 the water to heat it was about maybe 20 or 30 degrees  
 7 at the wall. And so any cryoprecipitate at the wall  
 8 would start to redissolve, and the Factor VIII would  
 9 go back into the solution.  
 10 The continuous process that allowed us to take  
 11 the melted plasma with the Factor VIII -- with the  
 12 cryoprecipitate in suspension away from the source of  
 13 heat as soon as it melted so it didn't have a chance  
 14 to redissolve, and that was the major achievement in  
 15 being able to prevent that Factor VIII redissolving,  
 16 so it was retained in the cryoprecipitate and could  
 17 then be processed into the final product.  
 18 At the same time, because we had more  
 19 Factor VIII, that gave us an increased potency, it  
 20 gave us an increased purity, and it dissolved more  
 21 quickly.  
 22 Q. When we're talking about increasing Factor VIII  
 23 yield -- this is maybe a massive oversimplification,  
 24 but you're talking about getting, essentially, more  
 25 Factor VIII at the end out of the same amount of

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1 plasma?

2 **A.** That's correct.

3 **Q.** Leaving aside the CSVM process, which PFC had but BPL

4 didn't have, were any of the other methods you used

5 being used at BPL, as far as you know?

6 **A.** Method of preparation of Factor IX was identical at

7 that time.

8 I think in the early days, the method of

9 Factor VIII was virtually identical as well. The

10 chemistry for producing the products was similar, but,

11 technically, they used the batch process, and we had

12 the continuous process. But the chemical changes, the

13 additives that you introduced to cause the changes in

14 solubility, were pretty much the same principles.

15 **Q.** So does it go back to then the major advantage that

16 you had at PFC over BPL on this point was the

17 availability of the CSVM method?

18 **A.** Yes.

19 **Q.** Then just in terms of the first way or the first

20 method we discussed, which was the use of red cell

21 concentrates instead of whole blood, you referred in

22 your evidence to Archer, and, indeed, in your evidence

23 to the Penrose Inquiry, to there being programmes in

24 relation to trying to educate clinicians, and so on, in

25 relation to that. Is that something of which you have

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1 resources, and I've documented those in my documents

2 for the Penrose Inquiry, and I think it's around about

3 1983.

4 **Q.** You said, I think, in your evidence to the Archer

5 Inquiry and I think probably also to the Penrose

6 Inquiry that Scotland was the first in the world to

7 achieve self-sufficiency from voluntary donations.

8 What was the -- what's the basis for your

9 understanding for that claim?

10 **A.** I wasn't aware of any other country that had achieved

11 that, from all of the -- any documents or literature

12 I'd read or any people I'd spoken to.

13 **Q.** Did you yourself undertake any particular

14 investigations or inquiries into what had happened in

15 other countries?

16 **A.** My general knowledge was that virtually all countries

17 were importing commercial Factor VIII from the

18 United States. The US was supplying 70 per cent of

19 the world's needs for concentrates at that time. And

20 the only countries that maybe didn't were reliant on

21 cryoprecipitate or no treatment at all.

22 **SIR BRIAN LANGSTAFF:** Does it follow from that that the

23 United States itself was self-sufficient?

24 **A.** Yes, when I say "self-sufficient", I mean

25 self-sufficient from unpaid donors.

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1 any direct knowledge?

2 **A.** No.

3 **Q.** So you picked that up from the documents, essentially?

4 **A.** I was -- remember being present at a meeting where

5 Dr Cash was encouraging the medical staff to be even

6 stronger with their clinical colleagues in the

7 hospitals. He wasn't happy with the progress that was

8 being made, and I had direct -- I was present when

9 that was taking place. But other than that, I have no

10 knowledge.

11 **Q.** What is the point in time at which you would say -- if

12 there was a point in time -- Scotland became

13 self-sufficient in factor concentrates?

14 **A.** I think when we look back, we can see -- I mean, in

15 the '70s, I always thought there'd be a plateau, and

16 we'd meet the demand, and then it would settle out,

17 but in reality, that never happened. The amount of

18 Factor VIII being used has increased year on year on

19 year on year until almost to the present day.

20 So the issue then was, going back year by year,

21 was could you meet the demand at any particular point

22 in time, given that it was actually going to be an

23 increasing demand? Could you meet at any point in

24 time? I think there were a number of points in time

25 where we didn't meet the demand from our own

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1 **SIR BRIAN LANGSTAFF:** Right. So that's the definition

2 we're using?

3 **A.** Yes.

4 **MS RICHARDS:** Yes, and I should have -- I think the way in

5 which I put it was -- well, the way in which you put

6 it to the Archer and Penrose Inquiry was the

7 achievement of self-sufficiency from voluntary

8 donations, was the point that you advanced to those

9 inquiries.

10 Did you have, back in the late '70s, early '80s,

11 any knowledge about the extent to which particular

12 centres in Scotland might be using commercial

13 concentrates?

14 **A.** I didn't have any direct knowledge but I am aware now

15 that Mr Watt was involved in dialogue and

16 correspondence with some of the centres about that,

17 and there was concern about that.

18 **Q.** By way of example, the Inquiry has heard evidence, in

19 particular, relating to the use of commercial

20 concentrates at York Hill. Leave aside any documents

21 that you might have seen years later, do you recall

22 that ever being discussed within PFC in the '70s or

23 early '80s?

24 **A.** No, no.

25 **Q.** I want to turn, then, to England and Wales. I'm going

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to look, largely, at the extent to which plasma from England and Wales might have been fractionated at the PFC. But, before I do that, there's just one short point that perhaps we can pick up before the lunch break?

If we go to PRSE000545, please. This is one of your written statements to the Penrose Inquiry, and if we go to page 3, there's a heading "The Policy of the United Kingdom Government on Self-Sufficiency". Now, I'm not, for the most part, going to be asking you about that because, as I understand it, for the most part, it is not something you had direct knowledge of at the time. But you -- there was a point in time at which you had some interactions through the union, of which you were part, the ASTMS, and you refer in this section of your statement to your understanding that Mrs Thatcher's Government announced support for self-sufficiency only after a trades union, the ASTMS campaigned against a proposal by the Government to privatise BPL and an investigation was undertaken by journalists from Granada TV. And you describe you having a direct involvement in both of those activities.

Can you just, again, assist us in understanding how you came to be involved in that issue, and briefly

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detail of those, the way in which you put it in your statement was that your understanding is that that led to Parliamentary questions being put on this issue; is that right?

A. That's correct, yes.

Q. Then, in relation to the second point that you made in your statement, the World in Action investigation into the potential privatisation of BPL, what was your involvement in that issue?

A. Well, I had been at another meeting at BPL, I think it must have been late September, and Dr Lane was very distressed, and he basically said Beecham were about to sign on the dotted line, and he was clearly unsympathetic to that approach but felt that that was going to be what was going to happen. And I happened to be -- before I came back to Edinburgh, I dropped off to visit an old friend in London and had just happened to mention this in conversation.

Then two days later, I got a phone call from a journalist from World in Action, who was interested in this issue, and he had been involved in the earlier World in Action programme that had been shown in the mid-1970s, and his name was Laurie Flynn.

So I told him all I knew about it, and he then began to carry out his own investigations, and then

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what steps you yourself took on that point?

A. During 1980, as you know, it was appreciated that BPL needed to be rebuilt and, in beginning to plan for that, advice was being sought from experts across the UK as to what sort of technology the new BPL might use. And there was a working party set up under Dr Dunhill from University College and number of us from PFC went to BPL to take part in these discussions and have these wide ranging technical discussions about what new technology was available and what should or shouldn't be used.

And it was in attending one of those meetings that I learned from Dr Lane that there was a plan to sell -- the Government were planning to sell BPL to Beecham, and I brought that to the notice of my trade union because I thought they should know about that and, personally, I was uncomfortable with that because thought that might undermine the concept of the unpaid volunteer donor in the UK.

Q. I don't think we need to go to it but we've got, I think, a handful of documents which are memorandums between union officials, or communications with you and then communications between union officials and Members of Parliament, which are at PRSE0003588.

The way in which -- again, without going to the

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one day I got a phonecall and he said could he come to my flat to see me, and I said of course. And about ten minutes later he turned up with a colleague and they had a copy of the BPL inspection report, which I had never seen, and I knew it existed, and they wanted me to explain what it meant.

So we spent two or three hours going through it and I did my best to point out what it meant, and then he -- some time later, he phoned and he said that his colleague, who was called Michael Gillard, had made a discovery, and they had prepared a programme that was going to be broadcast the following Monday. But before they could broadcast that programme they were required by Granada Television to inform the Minister, and he was going to do that the next day.

The next day, which was the Friday, he phoned me back to say he had informed the Minister and that afternoon there had been a Parliamentary question tabled asking what was going to happen to BPL and the Minister had replied that it would stay in the NHS.

Q. Now, you won't know, presumably, what internal discussions were going on within the Department of Health and what advice may or may not have been given about that option but, in terms of your own interactions with BPL, was it your impression or

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1 understanding that Dr Lane, at least, understood this  
 2 to be a serious proposal?  
 3 **A.** Well, it was very -- as I said, he believed -- they  
 4 were about to sign on the dotted line, was how he  
 5 actually expressed it. So it was very advanced.  
 6 **Q.** The Parliamentary answer from the Minister, I think,  
 7 was 26 November and the reference for that -- we don't  
 8 need to put it on screen but just for the benefit of  
 9 those following -- is PRSE0000063.  
 10 Sir, I'm going to move to the question of --  
 11 **A.** Can I just say that the programme that was intended to  
 12 go out the following Monday did not go out.  
 13 **Q.** It went out a little later?  
 14 **A.** It was changed because the Minister had changed his  
 15 position and so the programme was changed.  
 16 **MS RICHARDS:** Sir, I'm going to move to now the next  
 17 topic, which is the potential for plasma from  
 18 elsewhere to be fractionated at PFC, which will take  
 19 a little while. So, bearing in mind it's nearly 1.05,  
 20 perhaps we could take lunch now.  
 21 **SIR BRIAN LANGSTAFF:** Yes. Well, let's take a break then  
 22 until 2.05. 2.05.  
 23 (1.05 pm)  
 24 (The Luncheon Adjournment)  
 25 (2.05 pm)

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1 documents in that regard, and I want to just have  
 2 a look at them with you and then invite your  
 3 observations on some of the broader issues. If we  
 4 start with WITN6914041, please.  
 5 This was the job ad that you responded to, if we  
 6 go over to the second page, "The Scottish National  
 7 Blood Transfusion Association Protein Fractionation  
 8 Centre":  
 9 "Application ... invited for the post of senior  
 10 biochemist ..."  
 11 So that's the application you responded to in  
 12 the early '70s which resulted in you taking up the  
 13 post in 1973.  
 14 **A.** That's correct.  
 15 **Q.** And if we just go to the next page, we've got a job  
 16 description there, and if we just look at the top half  
 17 of the page, please, Sully. Thank you.  
 18 So the second sentence in the first paragraph  
 19 refers to new premises being under construction. Then  
 20 it says:  
 21 "The Centre has the prime function of processing  
 22 human plasma collected in Regional Transfusion Centres  
 23 in Scotland, and later in north England, to provide  
 24 materials for clinical use."  
 25 So is it right to understand your perspective

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1 **MS RICHARDS:** Dr Foster, if I can just go back briefly to  
 2 the discussion we were having before lunch, was there  
 3 anything else you can recall that you learnt, whether  
 4 from your interactions with the union or with the  
 5 journalists that you described which cast any light on  
 6 the issue of the Department of Health decision-making  
 7 in relation to the sale to Beecham, as far as you can  
 8 recall?  
 9 **A.** Yes. When Mr Flynn phoned me to say that they had  
 10 prepared a programme that was going to be broadcast  
 11 the following Monday, he said this was based on  
 12 a discovery that his colleague, Michael Gillard, had  
 13 made, and in his research, he had discovered that the  
 14 minister had a personal interest in Beecham. That was  
 15 the matter that was put to the minister, and it was  
 16 following that that a decision was taken by the  
 17 Department of Health not to privatise Beecham.  
 18 **Q.** Obviously the Department of Health might have  
 19 a different perspective on that, but thank you for  
 20 making that clear, and we can obtain such other  
 21 evidence as may be appropriate in due course.  
 22 Can I then move to the question of PFC's  
 23 capacity to fractionate not just plasma collected in  
 24 Scotland but plasma collected from elsewhere. You've  
 25 referred in your witness statement to a number of

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1 when you took on the job, your understanding was that  
 2 the PFC would be fractionating plasma supplied from  
 3 the north of England?  
 4 **A.** Yes, that's correct.  
 5 **Q.** And then if we pick up another document exhibited to  
 6 your statement, WITN6914007. This is the letter you  
 7 referred to, I think, earlier when I was asking you  
 8 about evidence that you gave to the Lindsay Tribunal.  
 9 It's a letter from Mr Watt to Dr O'Riordan, Blood  
 10 Transfusion Service Board in Dublin, 11 November 1975.  
 11 And we can just, I think, get a sense of Mr Watt's  
 12 thinking if we look at the paragraph in the bottom  
 13 half of the page, so if we could zoom in on that,  
 14 please, Sully.  
 15 This is Mr Watt, November 1975:  
 16 "The PFC was designed to handle a minimum of  
 17 1,500 litres of plasma per week, working on a 46-week  
 18 year, but with capacity to increase to at least [is  
 19 that] 3,000 litres per week. Of this plasma, it was  
 20 expected, at the 1,500-litre level, to process  
 21 200 litres of fresh plasma with the remainder as  
 22 outdated or partly aged plasma. At the level of 3,000  
 23 litres per week, it was expected that 1,000 litres  
 24 would be provided as fresh plasma. The plasma was  
 25 expected to come from Scotland and from the English

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Blood Transfusion Service on a contract basis. At the minimum level of working, it was expected that 1,000 litres of plasma would come from Scotland each week, and the remaining 500 litres would come from England. How this will work in practice is difficult to define at the present time since there is no plasma available in England to send to Scotland. Elstree is, for the present, able to absorb all available plasma from the English Blood Transfusion Service. This is a matter for some concern since it affects the economic viability of this Centre."

Then if we go over the page, Mr Watt describes the way in which the Centre was designed. And then the bottom half of the page, he sets out the position as at the end of 1975. He refers to there being a current stockpile and the like.

So two points potentially emerging from Mr Watt's letter. The first is that, is this right, or rather was this your understanding: that the way in which the Centre had been designed by Mr Watt from the outset was in the expectation that it would accommodate plasma not just from Scotland but from elsewhere?

A. That's right, yes.

Q. And then his concern at the end of '75 is that that

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meeting or what the response was of the union officials?

A. I have a vague memory that Mr Watt was wanting to find out how he could take this forward, and he was advised by the trade union officials the terms and conditions of employment were negotiated through the Whitley system that was in place, and that is how he should proceed. And I really heard nothing more after that from the trade union side. And all I heard from Mr Watt was reports of these meetings that are mentioned here later, where he gave briefings to the PFC management team, but they were rather vague descriptions of problems emerging and he wasn't sure if they could be sorted out. We didn't hear anything in any detail at all. I'll have to say the staff, in general, knew nothing of this. They were completely in the dark.

Q. Well, if we just pick up these two meetings. Although you weren't present at them, there are couple of matters where I'm hoping you may be able to help us understand a little more about what was being said.

So the first meeting that you've referred to is WITN6914042. And we can see it's a meeting of 11 March 1977, and it's a joint DHSS/SHHD meeting. If we go -- well, at the bottom of the page, of this

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isn't happening and that may impact upon the economic viability of the Centre.

A. Yes.

Q. Do you recall any discussions or conversations with him on that issue?

A. Yes. Mr Watt was a consultant for a number of countries. He consulted for Canada, he consulted for New Zealand, he consulted for Iran, and in the process of that work, he reached a view that to be economically viable, a fractionation centre should support a population of at least 15 million. So the population of Scotland was too small, in his opinion, for this to be economically viable, and that is why he saw England as being essential to the future survival of PFC, as well as obviously to the benefit of England.

Q. If we then pick matters up in your witness statement. Sully, could we have WITN6914001. If we go to page 152. If we pick matters up in (v), just a little further down, you say:

"I was present at a meeting in 1976 that Mr Watt held with full-time trades union officials to discuss how changes to conditions of employment should be negotiated to enable shift working to be introduced."

Do you have any greater recollection of that

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page, is a discussion about fractionation needs, and then it says:

"The effective fractionation capacities for the above products for the UK central laboratories were ..."

Then the figure for:

"Elstree and Oxford, 1,400 litres per week

"Edinburgh, 1,500 litres plasma per week

(supplies sufficient ... ) [I think that probably means for Scotland's needs]."

Then reference to a shortfall in capacity.

If we go over the page, I just wanted to pick up the next two paragraphs:

"PFC Edinburgh's effective capacity was, however, much lower than its potential capacity due to the problem in the present phase of incomes policy of entering into an agreement with the trade unions on shift working."

Now, if we just leave aside a moment the issue about incomes policy and shift working, do you have an understanding of what's meant by "effective" versus "potential" capacity here?

A. Yes. It means operating a continuous flow process for a longer period of time, and that required staff working longer periods of time.

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1 Q. So that's the potential capacity?  
 2 A. Yes.  
 3 Q. And then there's reference there to what could be  
 4 achieved if a shift system were introduced:  
 5 "... capacity could rise to 6,000 litres plasma  
 6 per week (three shifts) or 3,000 litres per week two  
 7 shifts. The extra cost was not expected to be more  
 8 than about £30,000 a year. As the Scottish National  
 9 Blood Transfusion Service could produce no more than  
 10 1,500 litres of plasma per week, the additional  
 11 quantities of plasma required to keep Liberton  
 12 functioning economically would have to come from  
 13 England. A two-shift system could just be viable on  
 14 a turnover of 2,000 litres per week, which suggested  
 15 that initially England would have to supply an  
 16 additional 500 to 600 litres per week. English/Welsh  
 17 RTDs would be consulted about the possibility of  
 18 this."  
 19 Then there's reference to the planning for the  
 20 Liberton plant, having been on the assumption that it  
 21 would receive 500 litres of time-expired plasma a week  
 22 from England and Wales. And then paragraph 2.3 --  
 23 **SIR BRIAN LANGSTAFF:** Just -- if I may, just one question  
 24 arising out of what's in that text.  
 25 The suggestion is that the capacity could rise

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1 pay policy. The Chairman agreed that it was essential  
 2 to try to break the existing deadlock and to raise the  
 3 matter again within DHSS, if SHHD would supply full  
 4 details; the new round of pay policy being drawn up  
 5 might provide opportunities which the present policy  
 6 did not provide. It would of course be necessary to  
 7 ensure that the additional plasma would be available  
 8 in the event of the dispute being settled."  
 9 The discussion continues. I don't think I need  
 10 to ask you to look at the rest of it.  
 11 I'll come back to some observations you make in  
 12 your statement about the incomes policy point in a few  
 13 minutes, but this appears to suggest that there had --  
 14 there was a dispute at the PFC, and that there was  
 15 an inability on the part of Whitley Council to make  
 16 an acceptable offer. Were you involved with the  
 17 union, with the ASTMS at that time?  
 18 A. Yes, I was chair of the union group at that time.  
 19 Q. And do you have any knowledge of what might be being  
 20 referred to here when it talks about the dispute at  
 21 PFC?  
 22 A. No, I'm afraid I don't, no. I think, in general, the  
 23 staff were receptive to a shift system, if it was  
 24 properly negotiated, and it would have made their job  
 25 a lot easier.

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1 to 3,000 litres per week, two shifts, but 6,000,  
 2 three shifts. Why is it double for the three-shift  
 3 system over two-shift? What further -- what's missing  
 4 in the two-shift system? What makes it able to do  
 5 that?  
 6 A. I'm not really sure I can answer your question. I'd  
 7 have to think about it.  
 8 **SIR BRIAN LANGSTAFF:** Because, mathematically, the 1,500,  
 9 one shift, 3,000, two shifts, that figures. But on  
 10 that basis, it would be 4,500 for a three-shift  
 11 system.  
 12 A. It could be that there's time taken to shut down and  
 13 clean things out that has to be taken into account.  
 14 **SIR BRIAN LANGSTAFF:** Why wouldn't that apply to the  
 15 two-shift system?  
 16 A. Well, it would. So, yes, I can't answer your  
 17 question, actually. It's a good point.  
 18 **SIR BRIAN LANGSTAFF:** Thank you.  
 19 **MS RICHARDS:** It may potentially just remain a mystery.  
 20 **SIR BRIAN LANGSTAFF:** A mystery.  
 21 **MS RICHARDS:** Then paragraph 2.3:  
 22 "SHHD said that they had explored all possible  
 23 approaches to settling the dispute at PFC Edinburgh  
 24 but the PTB Whitley Council Management Side were  
 25 unable to make an acceptable offer because of current

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1 Q. We'll come back to some of the other matters more  
 2 thematically, as I say, in a few moments. The second  
 3 meeting that you referred to in your statement is at  
 4 WITN6914043. So this is now August 1977, and it's  
 5 described as a joint DHSS-SHHD meeting on mutual  
 6 problems. It's held at the PFC and we can see that  
 7 Mr Watt was present for this meeting.  
 8 If we look -- well, we've got the heading  
 9 "Plasma from BPL to PFC". Paragraph 3.1 refers to  
 10 Dr Maycock having:  
 11 "... written to the DHSS to the effect that  
 12 25,000 litres of plasma per year (500 litres per week)  
 13 would be available for fractionation by the PFC and it  
 14 was thought that this could begin in the Autumn; the  
 15 product required would be PPF."  
 16 So that's a protein plasma fraction, PPF,  
 17 talking about there; is that right, Dr Foster?  
 18 A. That's correct.  
 19 Q. Then if we go to the next paragraph, we see Dr Lane,  
 20 who was due to take over from Dr Maycock, saying:  
 21 "... it was his intention to concentrate on the  
 22 production of Factor VIII at BPL. The latter and the  
 23 laboratory at Oxford were both funded by DHSS and it  
 24 would be wrong, in his view, to send plasma from  
 25 [RTCs] in England to the PFC, if this had the effect

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of leaving spare capacity to Elstree and meant services charges having to be paid. In his view this would have the effect of duplicating costs. He envisaged that only time expired plasma would be sent to the PFC and was unwilling to enter into any long term agreement to have regular quantities of plasma fractionated in Edinburgh."

Then paragraph 3.3:

"It was, however, pointed out that in a fundamental departure at this stage from what had already been agreed about the fractionation by the PFC of plasma from England (the original intention had been that the plasma should be from the North of England Transfusion Centres) could seriously jeopardise the working arrangements in the PFC and in particular could raise questions about the need to introduce shift working. While the PFC could function with or without plasma from England a sustained commitment to processing English plasma required agreement on regular quantities of plasma providing continuity of production over a period of some years. It was therefore necessary for the English BTS to state the quantity and nature of processing to be carried out and the period over which such a service would be required so the PFC could plan accordingly.

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depend on the rate of progress in resolving the problems of shift working arrangements on which the future progress on co-operation depended."

**SIR BRIAN LANGSTAFF:** May I just ask, do we know who, that is either DHSS or SHHD, took the minutes of this meeting?

**MS RICHARDS:** No. I have to say, in appearance, in terms of both typeset and the way it's set out and what's at the top of the page, it looks very similar to documents we've seen produced by the Department of Health but that's a rather casual comment on my part.

**SIR BRIAN LANGSTAFF:** Yes.

**MS RICHARDS:** I'm sure we can find the answer to that, because this version of the document has been produced by Dr Foster as an exhibit to his witness statement.

**SIR BRIAN LANGSTAFF:** Yes.

**MS RICHARDS:** The Inquiry will -- if it's a DHSS document, the Inquiry will probably have it as a DHSC -- from DHSC files and I can find out the answer to that.

**SIR BRIAN LANGSTAFF:** The reason I ask is that it's not unknown for documents prepared by a person who is, as it were, on one side of an argument, to reflect that side more favourably than the other.

**MS RICHARDS:** Yes. It was chaired by someone from the SHHD, and it took place at the PFC but I don't know

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The PFC had been planned to cater for plasma from England and, therefore, both SHHD and DHSS, were answerable to Ministers for the maximum and most economic use of the facility."

Then the discussion continues over the page. I won't, I think -- because there is obviously quite a lot we need to get through -- go through all of it.

There is a discussion, we can see, under the heading "Shift Working at PFC", paragraph 5.1, that suggests there had been a "failure to reach agreement on the introduction of shift working through the Whitley machinery", and the suggestion that's therefore made is that a case should be prepared for the PFC to be accepted as a "pharmaceutical factory type development with a staffing structure outwith Whitley arrangements", and that was going to be sent to the Civil Service Department for comments.

Then if we go -- well, actually, I don't think the meeting actually leads to any particular conclusion. If we just go over to page 4, paragraph 15 says:

"There was general agreement that the meetings were a valuable means of exchanging views between administration and directors and should continue. The next meeting would be in London but the date would

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whether that casts any further light on it. I'll do my best to find out the answer to that overnight, sir.

**SIR BRIAN LANGSTAFF:** Thank you.

**MS RICHARDS:** Dr Foster, obviously, you weren't present at this meeting but do you have any recollection of Mr Watt reporting back to you or your colleagues at the PFC about what was being discussed here?

**A.** Yes, he reported back to the PFC heads of department both of these meetings, the previous one and this one. But, as I said, that was in more general terms. He wasn't very specific about what the problem was but he did go on to say they were now looking into the possibility of PFC being considered as part of the Civil Service and having our terms and conditions changed to Civil Service arrangements, and we would -- we then waited to see what would happen and nothing happened. It just all went dead.

**Q.** In your capacity with the union, the ASTMS, if that matter had been taken further forward, do you think you would have known of it?

**A.** Certainly, yes.

**Q.** As far as you're aware, did any further meetings take place involving Mr Watt on this issue?

**A.** I'm not aware of any.

**Q.** Is it right to understand then, that from your

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1 perspective at the PFC, this issue of fractionating  
 2 plasma from England then, essentially, went into  
 3 abeyance for a period of time until around 1981?  
 4 **A.** Yes.  
 5 **Q.** When there was --  
 6 **A.** That's correct.  
 7 **Q.** -- there was the shift working trial?  
 8 Do you recall any expression of frustrations or  
 9 concerns or, indeed, any other sensation from Mr Watt  
 10 during that time?  
 11 **A.** Yeah, he was enormously frustrated the whole time. He  
 12 felt that PFC needed more plasma to be economically  
 13 viable and he saw it as his role to achieve that and  
 14 he was still sort of nagging away to try and get that  
 15 done.  
 16 **Q.** I think we then next pick matters up in the autumn of  
 17 1981, in terms of your own knowledge and perspective.  
 18 So if we go to SBTS0001455\_012, this is an article,  
 19 September/October 1981. It records a visit by  
 20 representatives of the ASTMS, the union to which you  
 21 belonged, to the Edinburgh Centre.  
 22 If we just scroll down slightly, please, Sully,  
 23 in fact if we pick it up, bottom of the page,  
 24 left-hand side.  
 25 So it's not entirely clear, in terms of what's

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1 the viability of private drug companies investing in  
 2 the Centre".  
 3 **MS RICHARDS:** Right.  
 4 **SIR BRIAN LANGSTAFF:** It's "given" or "even", I don't  
 5 know, "the Scottish Home and Health Department had not  
 6 been [consulted or involved] to the same extent of the  
 7 DHSS", et cetera. I can't quite work out the last  
 8 line.  
 9 **MS RICHARDS:** Yes, in any event --  
 10 **A.** Can I just comment? This really follows on from the  
 11 earlier discussion about the plans to possibly  
 12 privatise BPL and I think the trade unions were also  
 13 concerned that that might be applied in Scotland and  
 14 that was, I think, that's what they were concerned  
 15 with.  
 16 **MS RICHARDS:** Then, in any event, we can see, if we pick  
 17 it up in that second column:  
 18 "... it was pointed out by the Centre's Director  
 19 that there was capacity in the Plant to increase  
 20 production considerably without high scale new  
 21 investment.  
 22 "Some 90 per cent of the blood products used in  
 23 Scotland are manufactured in the Edinburgh Centre,  
 24 making Scotland virtually self-sufficient. It was  
 25 stressed however that the Plant was considerably under

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1 printed there but I'm going to try to read the last  
 2 two paragraphs on the left-hand side:  
 3 "The delegation had the opportunity to meet the  
 4 ASTMS Representative [or it might be Representatives],  
 5 and had lengthy discussions with the Director of the  
 6 Centre ..."  
 7 **SIR BRIAN LANGSTAFF:** It will be "Representatives" again,  
 8 I think.  
 9 **MS RICHARDS:** Yes:  
 10 "... from the Scottish National Blood  
 11 Transfusion Service, the Common Services Agency, [and  
 12 then looks like something around] the Plant.  
 13 "... became clear during these [might be  
 14 discussions] that some tentative [and I'm not sure the  
 15 next word] have been made about [something] private  
 16 drug company [something] in the Centre ..."  
 17 Well, in any event, I'll pick it up, it talks  
 18 about "some investment is", and then we go to the  
 19 column, top of the next column, which happily is  
 20 entirely clear:  
 21 "... progressing in the Edinburgh Centre with  
 22 the building of a new Bacteriology Laboratory, it was  
 23 pointed out" --  
 24 **SIR BRIAN LANGSTAFF:** I think now that it's reduced, it's  
 25 easier to read. And it may be "had been made about

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1 utilised and could process blood to serve a population  
 2 of around 25 million.  
 3 "The capital investment needed to increase  
 4 production would be mainly in the area of new  
 5 warehouse and storage facilities. Of course such an  
 6 increase would require running the plant for longer  
 7 periods and would inevitably lead to the introduction  
 8 of a shift system."  
 9 Then there is a reference to talks:  
 10 "... being held between the DHSS and the  
 11 Scottish Home and Health Department with the view to  
 12 looking at the possibility of the plant serving some  
 13 of the blood product needs south of the border."  
 14 I don't think I need to read the rest of that.  
 15 But that is an article from the perspective of one of  
 16 the officials within the ASTMS, as I understand it,  
 17 Gordon Craig; is that right, Dr Foster?  
 18 **A.** That's correct, sorry.  
 19 **Q.** We'll see later on in a different context, some of  
 20 your communications with him.  
 21 Now, that then led to -- or the next event,  
 22 I should say that you refer to in your statement,  
 23 is -- the trial that was carried out at PFC towards  
 24 the end, I think, of 1981. You weren't present during  
 25 the actual trial because your statement tells us you

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1 were absent with illness but what was your  
 2 understanding of what was going to be happening?  
 3 A. My understanding was that this was a -- if physical  
 4 proof that the system could do what Mr Watt was  
 5 claiming it could do, so that he wasn't just  
 6 extrapolating on the basis of calculations but was  
 7 demonstrating in practice that the system could  
 8 actually do what he claimed it could do.  
 9 Q. Were you involved in any of the discussions about, you  
 10 know, how that would be done and how many shifts it  
 11 would be or how long it would go on for?  
 12 A. No, I wasn't.  
 13 Q. If we then go to --  
 14 A. I might say, when I returned from illness, I did hear  
 15 from -- kind of indirectly from the staff involved  
 16 that it was meant to last for three weeks but it only  
 17 ran for two weeks because they ran out of plasma.  
 18 Q. I think we can get a sense of Mr Watt's perspective  
 19 from a document at SBTS0000612\_026. So we can see  
 20 this document is entitled, "Notes on 'An Interim  
 21 Report on a Study of the Continuous Fractionation of  
 22 Plasma' by JG Watt, November 1981", and if we go over  
 23 the page --  
 24 A. Could I just comment there?  
 25 Q. Yes.

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1 back to the full page please, next, to the "CSVM SPPS  
 2 Production in Shift Mode", I don't think I need to  
 3 read that but, if we just look at Dr Cash's notes,  
 4 this, then, is Dr Cash's assessment:  
 5 "The shift mode experiment has demonstrated  
 6 beyond doubt that PFC has a maximum fractionation  
 7 capacity in a 46 working week year, using all 15  
 8 stations in the CSVM system of approximately 500,000  
 9 [kilograms of plasma per year]", et cetera.  
 10 The second paragraph suggests that:  
 11 "... the existing ... accommodation would be  
 12 adequate to cope with this 350,000 [kilograms per  
 13 year] as fresh plasma [but there is] insufficient  
 14 finishing capacities ..."  
 15 Then the third paragraph suggests that:  
 16 "On an interim basis, in the existing  
 17 accommodation, and subject to agreement by the  
 18 Medicines Inspectorate, PFC could, given a 3 shift  
 19 working day and appropriate staffing structure take on  
 20 a commitment from the [National Blood Transfusion  
 21 Service] of 2,000-2,500 [kilograms per week per 46  
 22 working week]. There is little doubt that this would  
 23 have to be outdated plasma or supernatant I until such  
 24 times as a new freeze dryer was installed ..."  
 25 Then there's a reference to the need to obtain

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1 A. This is a note by Professor Cash on John Watt's  
 2 report.  
 3 Q. Thank you. So we can see the introduction -- sorry,  
 4 can you go to the next page.  
 5 Can you help us with this. The underlying  
 6 passage, are those Professor Cash's notes on what --  
 7 A. Yes, that's my understanding, yes.  
 8 Q. Mr Watt said? Thank you. So if we go back to the  
 9 previous page, we can see under the heading,  
 10 "Introduction", it says:  
 11 "During the run up period to what became known  
 12 as the PFC Shift Experiment it became evident that the  
 13 DHSS was particularly interested in the production of  
 14 plasma protein fractionation rather than Stabilised  
 15 Purification Protein Solution."  
 16 There's a further description in relation to  
 17 that.  
 18 Further detail is then set out. If we go to the  
 19 next page, there's a discussion or there's a note from  
 20 Dr Cash, top of the page, saying:  
 21 "It would appear that the CSVM fractionation  
 22 system can be used to produce an albuminoid product  
 23 similar, with respect to albumin content, to the PPF  
 24 produced at BPL", et cetera.  
 25 Then we can see there's a reference, if we go

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1 clearance from the Inspectorate.  
 2 Bottom of the page:  
 3 "The proposal above is seen as an interim one  
 4 only for in the opinion of the author it would be in  
 5 the best interests of the UK as a whole to plan the  
 6 future of PFC towards an operating capacity of around  
 7 350,000kg plasma [per] year."  
 8 I just wanted to unpick a couple of points with  
 9 you, Dr Foster, if I may. The reference in  
 10 paragraph 3 of Dr Cash's notes to the new freeze dryer  
 11 being required, that was necessary, was it, if the --  
 12 anything other than time-expired plasma was going to  
 13 be used?  
 14 A. That was required for obviously for freeze-dried  
 15 products, which -- really Factor VIII. I think what  
 16 I would comment on here is that, even if only PFC  
 17 could take time-expired plasma, that would release  
 18 more capacity at BPL to process fresh plasma, because  
 19 the plant capacity of all of these facilities has to  
 20 cope not only with the fresh plasma but with the  
 21 resultant supernatant to process that to albumin. And  
 22 if we could relieve BPL of pressure on that route,  
 23 that would allow them to take in more fresh plasma and  
 24 produce more Factor VIII.  
 25 Q. So would it be right to understand, from this, and

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from your perspective, that, subject to sorting out financing, shift-working arrangements, and so on, in terms of what the Centre could physically accommodate, it could take the time-expired plasma pretty much straightaway, and have the indirect consequence for BPL of being able to fractionate more fresh frozen plasma itself.

Then in the longer term, with a new freeze dryer installed, PFC would be able to receive fresh frozen plasma from England and Wales and fractionate that to produce factor concentrates; is that right?

A. That's correct.

Q. Leaving aside Dr Cash's own particular comments here, do you recall Mr Watt's views, following the PFC shift experiment, what he thought it showed?

A. Actually, I don't, because, as you mentioned, I'd been absent with ill health and I was away for a long time, and when I got back I was suffering from very severe brain fog that you've heard about in these sessions, and I think Mr Watt was trying to keep stuff off my desk, so he didn't discuss this with me.

Q. We then, I think, in terms of the handful of documents you refer to in your witness statement, pick matters up at WITN6914044. Now, this is not a document you'd have seen at the time. It's an internal DHSS

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DHSC0002333\_018. This is a letter, which I think we've looked at in the course of the current tranche of Inquiry hearings. 15th September 1982, from the Scottish Home and Health Department to the Department of Health and Social Security, second paragraph refers to noting not without some sense of relief that PFC has been ruled out. There's then reference to the PFC being:

"... designed to work on the continuous flow system ... capable of a high throughput when operated in this mode."

Then there's a suggestion of an amendment to the document that's been provided by the DHSS. It says:

"The impression is given in lines 5-7 that the capital investment of £6-7 million would be required solely for the processing of English plasma. In fact half of this sum would have to be spent in any case to fractionate plasma for Scotland and Northern Ireland to Medicines Inspectorate standards."

Then the next paragraph then refers to a line on the shift-working issue, and the letter continues:

"... we here take the view in light of the known attitude of the main Scottish union official involved that an acceptable agreement can be negotiated, though not without difficulty. I am a little unhappy about

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document. But if we go to the third page, we can see the heading "PFC, Liberton", halfway down the page. There's reference in paragraph 10 to the PFC's capacity and the SHHD's estimate as to what PFC could handle if a continuous shift system could be negotiated. It says, last sentence in paragraph 10:

"Revenue costs, including transport and processing, would not be markedly higher than at BPL."

Then in the next paragraph refers to consideration by the Policy Steering Group -- I'm not going to go through the details of that -- and then, halfway down that paragraph, it refers to:

"... it would be more expensive to build a smaller BPL ... and invest £4 million in PFC than to build a BPL capable of achieving self-sufficiency ... In any case, in the view of DHSS officials, it remains highly doubtful whether a shift-working agreement can be negotiated with staff at PFC without serious repercussions on pay of other groups in the NHS and the Industrial Civil Service."

Now, we'll just leave that there. I want to refer to two other documents and then I want to ask you to assist in understanding the observations you make in your statement about these materials.

So the two further documents are PRSE --

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the decision on this topic being based to any material extent on the concept of shift working being too difficult for the NHS."

Now, in relation to that paragraph, is that consistent with your own understanding that, from the union's perspective, this ought to be capable of being agreed?

A. Yes, and the trade union official who is being referred to here would be Mr Craig, who had written in the article that you quoted from earlier, who acknowledged that shift working was required.

Q. Then the next document I wanted to ask you to look at is one that I think you had -- well, some involvement with the chain of correspondence that we'll come back to, but it's PRSE0001727.

A. Can I just say one thing before we go on to this?

Q. Yes, absolutely.

A. We did actually achieve a shift working system at PFC in the early 1990s and it was negotiated locally and it was more to do with what was required for high purity Factor VIII rather than running the continuous form modules.

Q. I think your statement tells us that was 1991; is that right?

A. Yes.

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1 Q. So this is a letter we'll come back to because it's  
 2 part of a chain of correspondence between  
 3 Lord Glenarthur and Clive Jenkins of the ASTMS, in  
 4 which you had, I think, a part behind the scenes. If  
 5 we just go over the page, we look at the section  
 6 headed "[Paragraph] 5", which suggests that:  
 7 "... Elstree is capable of fractionating all the  
 8 plasma currently available.  
 9 "Should the situation arise where the plasma  
 10 supply builds up beyond the fractionating capacity of  
 11 the existing laboratory, we should need to examine  
 12 whether any surplus capacity at the [PFC] could be  
 13 used.  
 14 "At present, however, PFC would not have the  
 15 storage, filling and packaging facilities to handle  
 16 a substantial amount of extra plasma, even if it were  
 17 available."  
 18 That's the position being set out by the  
 19 Department as at January 1984. We'll look at this  
 20 correspondence in more detail later in the afternoon,  
 21 but what's your perspective, if any, on the suggestion  
 22 that PFC wouldn't have the facilities there described  
 23 to handle extra plasma?  
 24 A. I think when -- by the time this was written, these  
 25 areas were already being addressed following the

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1 Do you have any observation upon the statement  
 2 that the function of the PFC was to concentrate on the  
 3 needs of Scotland and Northern Ireland?  
 4 A. Well, this is the first time that that had been made  
 5 explicit, as far as I'm aware. Prior to that there'd  
 6 always been understanding within PFC that we would be  
 7 processing plasma from England.  
 8 Q. Now, those are the various documents on this issue  
 9 that you referred to in your witness statement. I now  
 10 want to ask you to look at your statement, and I just  
 11 want to go through a number of comments you make and  
 12 explore some of them with you.  
 13 It's WITN6914001, and we can pick it up at  
 14 page 155. Under the heading "Comments", halfway down  
 15 of the page. So you having set out the various  
 16 documents we have just looked at, you said this:  
 17 "The first impediment to processing plasma from  
 18 England at PFC was a claim in 1977 that the staffing  
 19 arrangements ... were not compatible with the  
 20 Government's Incomes Policy.  
 21 "The Incomes Policy ... (known as the Social  
 22 Contract) concerned annual pay awards, which provided  
 23 an increase in pay for the same job.  
 24 "PFC were seeking to introduce new terms and  
 25 conditions of employment (to encompass shift working)

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1 Medicines Inspection report, and so it had -- there  
 2 had been advances, so the situation wasn't as is  
 3 described here. I think there were extra facilities  
 4 available and, of course, more would be needed. We  
 5 couldn't just wave a magic wand and expect things to  
 6 happen overnight, but I didn't see this as  
 7 an impediment.  
 8 Q. Then the last letter on this issue that you refer to  
 9 in your statement is another letter to the ASTMS. So  
 10 it's at MACK0002271\_012. So this is from John MacKay,  
 11 Minister for Health and Social Work, 14 May '84, to  
 12 Clive Jenkins of the ASTMS. It refers to the  
 13 correspondence with the Lord Glenarthur, and then says  
 14 this:  
 15 "The function of the PFC is to concentrate on  
 16 the needs of Scotland and Northern Ireland. It  
 17 performs this role satisfactorily: we are virtually  
 18 self-sufficient in Factor VIII. As Simon Glenarthur  
 19 explained in his letter of 2 April [that's a follow-up  
 20 letter we don't need to worry about], the needs of  
 21 England and Wales are to be met by a new production  
 22 unit being built at BPL Elstree, and not looking to  
 23 any expansion of production at PFC. There is thus no  
 24 need to consider your interesting suggestions whereby  
 25 this could be achieved."

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1 with a suitable rate of pay. As this new rate of pay  
 2 was for a new job, it should not, in my opinion, have  
 3 contravened the Government's incomes policy."  
 4 Now, is that an observation you're making,  
 5 effectively, wearing your then trade union hat, to  
 6 some extent?  
 7 A. No, it's just a general observation that, in my  
 8 understanding of -- from that time of what the  
 9 Government's incomes policy was intended to achieve,  
 10 that it was annual pay awards, and this wasn't  
 11 an annual pay award.  
 12 Q. Okay. The next point you go on to make is to refer to  
 13 the opposition from Dr Lane, opposing the processing  
 14 of fresh frozen plasma. You suggested:  
 15 "This implies he believed that BPL could  
 16 fractionate all of the available plasma with  
 17 sufficient capacity to meet the needs for England &  
 18 Wales for [Factor VIII] concentrate."  
 19 If we go over the page, you then continue in the  
 20 next two paragraphs by saying:  
 21 "That meant the issue being addressed at this  
 22 meeting was only the processing of outdated plasma  
 23 [which would result in the production of albumin]. As  
 24 albumin was pasteurised to eliminate the risk of  
 25 hepatitis transmission, the consideration facing civil

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1 servants (and government) was the cost of importing  
2 Albumin, rather than the risk of disease  
3 transmission."

4 Then you say that Dr Lane's opposition and his  
5 opinion that PFC would only be dealing with albumin:  
6 "... may have reduced the pressure on civil  
7 servants to resolve the apparent conflict between the  
8 government's incomes policy and the staffing needs of  
9 PFC."

10 Could I ask you to explain a little more what  
11 you mean in those two paragraphs?

12 A. From the minutes that have been -- of those meetings,  
13 Dr Lane, as the Director Designate, made it clear that  
14 he didn't see fresh plasma going to PFC because he  
15 thought BPL could handle all of that, and all PFC  
16 would get would be outdated plasma. Outdated plasma,  
17 or time-expired plasma, was only used to produce  
18 albumin, which was a safe product because it was  
19 pasteurised, whereas if Factor VIII had been part of  
20 the equation and it was known that that had a risk of  
21 disease transmission, which was believed to be much  
22 greater with imported products, then that would have  
23 put more pressure, in my opinion, on the civil  
24 servants to try to resolve this problem.

25 But, having that issue taken away, might have

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1 A. No, I -- what I was -- all I was doing was suggesting  
2 that there were actually numerous reasons being cited,  
3 not just a single reason, and they were all consistent  
4 in their outcome.

5 Q. Then, if we go further down the page, you there then  
6 refer to the issue in relation to cost. Your take is  
7 that it would have been less expensive ultimately to  
8 go down the route of utilising PFC than to go down the  
9 route of the full redevelopment of BPL; is that the  
10 point you're making there?

11 A. It would have been less expensive and quicker.

12 Q. Then if we just go over the page, I just wanted to  
13 pick up the third paragraph on that page, where you  
14 say that Dr Lane's suggestion that Mr Watt was  
15 exaggerating the operational capacity of PFC was  
16 incorrect.

17 Can you just expand upon that, please?

18 A. Well, I actually can't remember Dr Lane's comments,  
19 but I would agree with Mr Watt's opinion about the  
20 capacity of the process.

21 Q. Let me just remind you, sorry, it would be easier if  
22 I showed you what Dr Lane had said. It's set out in  
23 your statement at page 150. It's material we looked  
24 at over the course of the last week.

25 Sorry, page 150. So paragraph (c) on that at

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1 left them under less pressure to try to resolve the  
2 situation.

3 Q. So your take -- and ultimately it will be a matter for  
4 submission and for the Chair to consider in due  
5 course, as necessary, but your take on that material  
6 that we've looked at was that, is this right, that the  
7 civil servants or the decision-makers within the  
8 Departments concerned were not really being confronted  
9 with the significance of the fact that this could help  
10 address the transmission of hepatitis?

11 A. Yes, that's my opinion.

12 Q. You then, if we then just pick it up at the third  
13 paragraph down, you move to the next point, you say --  
14 you refer to the impediment being raised in the 1982  
15 documents, that it could have "serious repercussions  
16 on the pay of other groups in the NHS and the  
17 industrial Civil Service".

18 Then you continue by saying PFC would have to  
19 hire additional staff:

20 "It is difficult to see how people ... would  
21 have applied for positions involving shift-work,  
22 without a shift premium."

23 Are you there taking issue with the suggestion  
24 that it would have repercussions on the pay of other  
25 groups and the NHS and the Industrial Civil Service?

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1 page quotes from Dr Lane's draft proof of evidence,  
2 which refers to "exaggerated claims" made by Mr Watt,  
3 "grandiose claims" made by those responsible for PFC's  
4 administration, and then he refers to the belief that  
5 there was any spare capacity immediately available for  
6 fractionating plasma as a myth. So that was what  
7 Dr Lane was saying. From your own knowledge of PFC,  
8 and the CSVM system --

9 A. My own knowledge is that the claims being made by  
10 Mr Watt were correct.

11 Q. Thank you.

12 A. And, also, I would say that I would agree with Dr Lane  
13 when he says that spare capacity wasn't immediately  
14 available. If he means immediate like tomorrow, then  
15 that obviously would be true. It would take some time  
16 to organise these things.

17 Q. Can I then just ask you some just more general  
18 questions.

19 First of all, is it your view, based upon not  
20 what is said in any of these documents but your own  
21 knowledge of PFC -- its capacity, the CSVM system --  
22 is it your view that PFC could have fractionated  
23 plasma from England and Wales, as it had been  
24 originally designed to do?

25 A. Yes.

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1 Q. And as I think you've already alluded to, it may be  
2 that that would have to have started with the  
3 fractionation of time-expired plasma, but once there  
4 was a new freeze dryer, it could have then  
5 fractionated fresh frozen plasma.

6 A. Yes.

7 Q. Do you know have any sense -- sorry, do you think that  
8 the PFC could have fractionated a third of the plasma  
9 from England and Wales, as had been proposed back,  
10 I think, at the end of 1969 when Mr Watt was first  
11 designing the new plant?

12 A. Yes.

13 Q. And now there are just two further passages I wanted  
14 to invite you to comment on in the documents on the  
15 issue of capacity. The first is at CBLA0000664. This  
16 is a document produced by Dr Maycock. I just wanted  
17 to draw your attention to the -- if we go to the  
18 bottom half of the page. Sorry, it's Dr Maycock's  
19 1977 report on BPL. Third paragraph up from the  
20 bottom says this:

21 "Also creating uncertainty at BPL is the  
22 unfortunate situation in which the problems of BPL, as  
23 they relate to NBTS in England and Wales, seem to have  
24 become entangled with the problems of PFC Liberton,  
25 the design, size and development of which were carried

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1 Could you go on to -- it's page numbered 12, so it'll  
2 be four pages further on. It's the internal  
3 pagination at the top.

4 Thank you. So if we pick it up four lines from  
5 the top, it refers to Dr Macdonald giving a talk about  
6 supplies of Factor VIII concentrate, refers to  
7 cryoprecipitate, and then:

8 "Dr Macdonald referred to the costs of building  
9 the PFC ... showed figures illustrating the amount of  
10 plasma that had been sent to Liberton ... Dr Macdonald  
11 said that the PFC at Liberton had the capacity to make  
12 60 million units of Factor VIII per year. To reach  
13 this target, the Centre would need about £25,000 for  
14 new capital equipment and money for extra running  
15 costs which would include payment for staff to operate  
16 a 24-hour shift system of working."

17 Then it goes on to discuss a number of other  
18 matters, including the plan to send plasma to the PFC  
19 where Mr Watt was ready to receive it. Dr Lane took  
20 issue with what Dr Macdonald there said, and we don't,  
21 of course, know if the minutes were accurate.

22 Do you have any observations either about what's  
23 said about PFC's capacity in terms of making units of  
24 Factor VIII or what it would need by way of equipment?

25 A. My understanding is that the equipment would probably

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1 forward entirely independently apart from an agreement  
2 in principle that it should fractionate 500 litres  
3 time-expired plasma weekly ... Planning the future of  
4 BPL should not wait until the problems of PFC have  
5 been resolved."

6 Were there, to your knowledge, problems at PFC  
7 at this time that were an impediment to the PFC  
8 fractionating English or Welsh plasma?

9 A. No.

10 Q. And then PRSE0002268 --

11 SIR BRIAN LANGSTAFF: Well, it might refer, might it, to  
12 the problems of PFC Liberton as was said, I gather at  
13 the time, being uneconomic or unviable if it didn't  
14 have enough plasma to process.

15 A. I didn't read it that way.

16 SIR BRIAN LANGSTAFF: Very well.

17 MS RICHARDS: PRSE0002268. These are the minutes of  
18 a meeting of Haemophilia Centre Directors,  
19 13 January 1977, obviously not a meeting that you'd  
20 have been involved in. I just wanted to ask you about  
21 something that's said about PFC's capacity that  
22 Dr Lane took issue with, and I think you're probably  
23 the only person from the PFC at the time that I can  
24 ask this question of. You may not be able to cast any  
25 light on it. It's page 12. No, it's not, sorry.

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1 be the cost of a freeze dryer, and I think  
2 Dr Macdonald's figure of the million units of  
3 Factor VIII is probably correct. I did do some  
4 calculations when you sent me this to try and work it  
5 out, and it did seem to me to be correct.

6 Q. And then if the freeze dryer is the new capital  
7 equipment referred to, is £25,000, as at January 1977,  
8 the right kind of ballpark?

9 A. That would be possibly the case. I would have --  
10 I can't be certain.

11 Q. That's fair enough.

12 Can I then just move to the question of Northern  
13 Ireland. Your statement tells us you were not  
14 involved in the decision-making regarding the receipt  
15 of plasma from Northern Ireland for fractionation; is  
16 that right?

17 A. That's correct.

18 Q. Are you able to assist us in understanding whether it  
19 was the Northern Irish plasma was fractionated  
20 separately from Scottish plasma or pooled with  
21 Scottish plasma?

22 A. It was separated to begin with, just to be sure that  
23 it behaved appropriately and it was validated  
24 suitably, and once that had been achieved, it was just  
25 mixed in with the Scottish plasma.

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1 Q. We know that arrangement was entered into in the early  
 2 1980s. From your perspective at PFC, in terms of the  
 3 PFC's own capacity, could it have fractionated plasma  
 4 from Northern Ireland earlier than that?

5 A. Yes.

6 Q. I'm going to move next, then, to a different topic  
 7 which is hepatitis.

8 You've said in your statement that in relation  
 9 to hepatitis B, the risks of hepatitis B were  
 10 something which all fractionators were well aware; is  
 11 that right?

12 A. That's my understanding, yes.

13 Q. In terms of non-A, non-B hepatitis, what's your  
 14 recollection of your own knowledge of non-A, non-B  
 15 hepatitis, both as a concept and in terms of its  
 16 seriousness?

17 A. I was aware of it as a concept from around the  
 18 mid-1970s. I can't be specific about now exactly  
 19 what -- how I learnt about it. But I do remember  
 20 there was a member of staff who worked for me who  
 21 himself had had an episode of hepatitis, and  
 22 fractionation required probably, and he took a great  
 23 interest in hepatitis. And I remember him stopping me  
 24 in the corridor and saying, "I've got some good news  
 25 and some bad news. The bad news is there's a new form

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1 Q. Do you recall whether you saw the World in Action  
 2 documentary that was broadcast end of 1975?

3 A. I did, yes.

4 Q. And do you recall whether there were any discussions  
 5 within PFC about that and --

6 A. There were a lot of discussions because Mr Watt took  
 7 part in it.

8 Q. And was there any -- was there any consideration of  
 9 what the implications were for PFC?

10 A. The implication was that we needed to produce more  
 11 Factor VIII and to minimise the importation of  
 12 commercial Factor VIII.

13 Q. Can we look at ARCH0000009, please -- this is back in  
 14 your evidence to the Archer Inquiry -- and go to  
 15 page 45. Sir, if we pick it up at the bottom of the  
 16 page, this is on the topic of non-A, non-B hepatitis.  
 17 You've said at the bottom of the page:

18 "Non-A, non-B hepatitis in haemophiliacs was  
 19 first reported by doctors to a meeting of the World  
 20 Federation of Haemophilia in 1975."

21 Then paragraph 5, you say:

22 "Research was begun around the world, including  
 23 research at SNBTS, to try to discover the cause of  
 24 non-A, non-B hepatitis, which was presumed to be due  
 25 to one or more viruses."

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1 of hepatitis. It's called non-A, non-B. The good  
 2 news is it's no worse than the common cold." And that  
 3 would have been about the mid-1970s. And I already  
 4 knew about non-A, non-B when he told me that. So that  
 5 was the perception that existed at that point in time.

6 Q. And then how did your understanding of the seriousness  
 7 of non-A, non-B hepatitis, which obviously sadly is  
 8 infinitely more serious --

9 A. Firstly, I would say we always took it seriously,  
 10 whether it was even -- as like the common cold, we  
 11 still took it seriously, and we would have wanted to  
 12 deal with it and remove it from the product as a risk.

13 In terms of its clinical seriousness, it was  
 14 probably not until the early 1980s that that began to  
 15 seep through that this may be more serious than had  
 16 been originally believed.

17 Q. Do you recall whether -- well, let me put this  
 18 a different way.

19 We know there was a publication by Dr Preston in  
 20 1978 which some clinicians, at least, have described  
 21 to the Inquiry as being very significant in the  
 22 evolution of their thinking. Do you have any  
 23 recollection of whether that's something that was seen  
 24 or discussed within PFC at the time?

25 A. Um ... probably not within PFC, no.

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1 What's the research at SNBTS that you were  
 2 referring to there?

3 A. There was a scientist at SNBTS called Dr Robert  
 4 Hopkins who was employed full time to do research on  
 5 hepatitis, and this was one of the areas on which he  
 6 specialised, and I think he even published a paper  
 7 about it, the potential cause of non-A, non-B, but it  
 8 turned out to be not correct.

9 Q. Do you recall there ever being any discussions within  
 10 PFC in the second half of the '70s, into the early  
 11 '80s, about the implications of non-A, non-B hepatitis  
 12 on PFC's working, in particular as regards pool sizes?  
 13 Was it recognised that the larger the pool size -- and  
 14 as we discussed this morning, the trajectory was an  
 15 upwards one -- potentially the greater risk of  
 16 transmitting non-A, non-B hepatitis?

17 A. Yes, but the situation was as I described it this  
 18 morning: that the objective was to minimise the use of  
 19 imported concentrates, and the only way to do that was  
 20 to produce more from PFC, so pool size wasn't an  
 21 option -- reduction in pool size wasn't an option.

22 And I also mentioned how by that time we had  
 23 the -- the group that Professor Cash had set up to  
 24 look more closely into all of these things, and at no  
 25 point did they suggest that pool sizes should be

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1 reduced, bearing in mind that, as I said this morning,  
 2 SNBTS provided cryoprecipitate as a small pool  
 3 product.  
 4 **Q.** Can I then just ask you about some research in  
 5 relation to Factor IX. WITN22350010, please. I think  
 6 I've got it wrong. Hold on a second. WITN2235010.  
 7 If we go to the next page, this is a publication in  
 8 the *British Journal of Haematology*, 1981. "Use of  
 9 Factor IX concentrates in man: a 9-year experience of  
 10 Scottish concentrates in the south-east of Scotland".  
 11 It's by Doctors Prowse and Cash.

12 If we just go to page I think it's 13. Next  
 13 page, sorry. We can see under the heading  
 14 "Acknowledgements", there's thanks to you for your  
 15 help in preparing and reviewing the manuscript, so  
 16 something that you would have seen at the time.  
 17 Did you have any involvement in the study itself  
 18 that was described in this paper?

19 **A.** No, I didn't. And I think this paper just describes  
 20 the use of Factor IX concentrates from PFC probably  
 21 over a period of time prior to its publication, which  
 22 would have been the 1970s.

23 Dr Prowse asked me if could provide details of  
 24 the methods of manufacture and the properties,  
 25 characteristics of the products, and that's what

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1 hands.  
 2 **SIR BRIAN LANGSTAFF:** Let's have it all in one chunk,  
 3 shall we, so we'll take a break now and come back at  
 4 3.30. So 3.30, if you please.

5 (3.09 pm)

6 (A short break)

7 (3.34 pm)

8 **MS RICHARDS:** Sir, just before I move to the next topic,  
 9 can I just note a couple of matters.

10 Firstly, you asked whether the minutes of that  
 11 meeting in August 1977 were produced by the Scottish  
 12 Home and Health Department or the DHSS. Thanks to the  
 13 diligent efforts of those sitting behind me, it looks  
 14 as though they were, regardless of who produced the  
 15 first draft, they were agreed minutes, and there is  
 16 some evidence that might make it more likely that they  
 17 were produced by SHHD rather than DHSS, so completely  
 18 contrary to what I said, but I'll confirm the position  
 19 tomorrow.

20 The second point is Dr Foster in one of his  
 21 earlier answers when I was asking him about UKHCDO  
 22 referred to the fact that it might have been useful to  
 23 see UKHCDO minutes because of a reference to Baxter's  
 24 work. We've found a couple of sets of minutes which  
 25 contain some reference to the heat treatment work

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1 I gave him, and that is what I reviewed. And I had no  
 2 involvement in any of the medical work.

3 **Q.** If we just go to the top of the page, then, it may be  
 4 you won't be able to assist with the other question.  
 5 Picking it up at the end of the fifth line:

6 "In addition, other side effects of Factor IX  
 7 concentrate therapy must be considered. Apart from  
 8 the perennial problem of hepatitis B, recent findings  
 9 on the transmission of non-A, non-B hepatitis by  
 10 Factor IX concentrates make it probable that many of  
 11 the patients with milder disorders presented above  
 12 would now be treated more conservatively (either not  
 13 at all with fresh frozen plasma), at least until  
 14 further data is available on individual concentrates.  
 15 The incidence of hepatitis following the use of the  
 16 two concentrates described in this study is currently  
 17 under investigation."

18 Do you have any knowledge of or did you have any  
 19 involvement in the investigations there referred to in  
 20 relation to the incidence of hepatitis?

21 **A.** No, I don't know that.

22 **Q.** I'm going then to move to the issue of AIDS.

23 Sir, I note the time. I'm moving to a  
 24 completely new topic. We could take the break early,  
 25 or I can get started for five minutes. I'm in your

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1 being undertaken. We'll provide those to Dr Foster  
 2 overnight, and no doubt he will be able to confirm  
 3 tomorrow if that's what he had in mind, or whether  
 4 it's some other set of minutes, in which case we'll  
 5 continue looking.

6 **SIR BRIAN LANGSTAFF:** Let me say now and straight away  
 7 that if you wish to consult or chat to anyone about  
 8 those particular documents, by all means, feel free to  
 9 do so.

10 **A.** I can tell you now what it was I was referring to.

11 **MS RICHARDS:** By all means.

12 **A.** It was the formulation of their product. It was an  
 13 additive that they used which allowed them to -- the  
 14 product to tolerate heat treatment, and that  
 15 information was in those minutes. And I made that  
 16 discovery independently, but it would have been nice  
 17 to have had access to that information.

18 **Q.** In any event, we'll supply you with the minutes that  
 19 we found overnight, and you can let me know if that's  
 20 the particular document you had in mind or not.

21 So I'm going to ask you now, Dr Foster, about  
 22 your developing knowledge in relation to AIDS, your  
 23 attendance at two international conferences in  
 24 Stockholm in 1983 and some memos you produced as a  
 25 result, and then some correspondence that you had --

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(39) Pages 153 - 156

1 sorry, some correspondence that took place with the  
2 ASTMS union in which you had a role to play after  
3 the -- behind the scenes. So those are the issues I'm  
4 going to explore with you today.

5 If we go to one of your written statements to  
6 the Penrose Inquiry first, PRSE0000545, please. And  
7 if we can pick it up at page 6. Thank you. The  
8 penultimate paragraph under the heading "1981". You  
9 say you:

10 "... first became aware of AIDS from  
11 a television programme in late 1981 in which a strange  
12 illness amongst homosexual men in the USA was  
13 described ... cause of the illness was not known, use  
14 of recreational drugs by homosexual men was put  
15 forward as the most likely cause."

16 Just showing you that as a reminder. That's  
17 what you've said to the Penrose Inquiry was your first  
18 knowledge. Does that remain your recollection --

19 A. It does, yes.

20 Q. Now, you then -- we're going to have to switch between  
21 various different documents, I'm afraid. If we go to  
22 your statement to this inquiry, WITN6914001, and if we  
23 go to page 46. If we pick it up under the heading  
24 "HIV/AIDS", you say this:

25 "I believe that fractionators would have known

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1 syndrome, I was expecting a discussion, and I was  
2 quite taken aback when everyone stood up and left the  
3 room. And that seemed to me to indicate that there  
4 must have been a belief that these men were gay, and  
5 people didn't want to talk about it because  
6 homosexuality in those days wasn't considered in the  
7 same way as it is today.

8 Q. So there was no discussion at that congress in  
9 Budapest about -- which was a congress of the  
10 International Society of Haematology and the  
11 International Society of Blood Transfusion. There was  
12 no discussion at that congress about the potential  
13 implications of the MMWR information for blood and  
14 blood products?

15 A. No. I think this -- the congress preceded the  
16 publication of MMWR, or it maybe just about coincided  
17 with it, but that was certainly the first point of  
18 contact for me, the first I heard of it.

19 Q. And then if we continue with it chronologically, if we  
20 go back to PRSE0000545 and we go to page 7, you'll see  
21 the third paragraph refers to the MMWR. That was the  
22 source of my suggestion to you that you might not have  
23 read it at the time you attended the congress, because  
24 that's what you say here, but I don't think anything  
25 turns on that.

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1 from 16 July 1982 issue of MMWR that three people with  
2 haemophilia in the USA had been diagnosed with PCP,  
3 two of whom had died."

4 Now, as I understand it, reading this combined  
5 with your Penrose statement, you yourself did not see  
6 this particular edition of the MMWR immediately, but  
7 your observation here is that it would have been  
8 available to fractionators.

9 A. Yes, I think I probably would have seen it as well. I  
10 mean, it took a bit of time to come, but we subscribed  
11 to that, so I would have seen it. But I knew about it  
12 before this because I was at the conference in  
13 Budapest where it was announced.

14 Q. In that case, we can leave aside the question of  
15 whether or not you did read the MMWR and I think  
16 perhaps just go then to the congress in Budapest.

17 So what you said in your statement to the Penrose  
18 Inquiry was that reference was made to those three  
19 cases in the course of the congress. Do you have any  
20 further recollection of how that information was  
21 disseminated or what the response or reaction was?

22 A. Yes. I -- as you've indicated, I was aware of the  
23 condition of AIDS when I attended that conference.  
24 And so when it was announced that there were three  
25 haemophiliacs who had been diagnosed with this

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1 The next paragraph is the one I wanted to ask  
2 you about. You say:

3 "In late 1982, I saw another television  
4 programme on AIDS in which a parallel was drawn with  
5 hepatitis, a comment which led me to believe that  
6 a blood-borne infectious agent was the most probable  
7 cause of the syndrome."

8 I don't know whether you can assist us any  
9 further about what that programme was or --

10 A. It was on ITV, and it was one of these programmes  
11 about the plague in the village sort of thing. And  
12 the presenter just made this comment that all of the  
13 people who seemed to be developing this syndrome are  
14 also at risk of hepatitis, and that was when my -- it  
15 made my hair stand on end, and I thought, "Whoa, this  
16 could be an infectious agent."

17 Q. I think we next, in terms of your own involvement in  
18 matters, pick things up in March 1983. Bottom of this  
19 page, you refer to being invited by Dr Ludlam to give  
20 a talk on progress towards development of  
21 non-infective blood products, and you say:

22 "During my presentation on 8 March, I referred  
23 to the possibility that AIDS might be caused by  
24 a blood-borne infectious agent. I do not remember if  
25 I commented specifically on risks associated with

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commercial products as opposed to UK-derived products."

The presentation itself is at PRSE0001201. So we'll come back to this in more detail tomorrow in terms of viral inactivation, but if we just go, please, to page 5, there's the heading "Some proposed solutions to the hepatitis problem", and then three proposed solutions set out. "Problems", and then the fourth is:

"? Other infectious agents (CMV, AIDS)."

Now, that's a fairly, obviously, brief reference to AIDS.

Can you recall whether there was any greater discussion than is suggested by this about that issue at this presentation in March?

A. No, there wasn't, but I could add one point. I mean, I have here a question mark which suggests there was still an element of uncertainty in my mind. And one of the reasons why there was an element of uncertainty was that Mr Watt had been to the United States in January of that year, and when he came back, he came straight to see me, and he said he'd spent the whole day with David Aronson at the FDA, who was the top official at the FDA who was concerned with coagulation factors. And he said they looked at all of the data

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and said they were convinced that this was not an infectious agent. Now, I wasn't convinced by that, by any means. I thought this was wishful thinking. But maybe that might indicate why I still had that question mark in there.

Q. Now, we know that there was a further MMWR publication in December 1982 which had referred to what has been called the San Francisco baby case. And we know also from other evidence the Inquiry has heard that there were -- was a meeting in January 1983, not a meeting in which you were involved, Dr Foster, at London Airport in which Dr Craske provided an update on that and other matters. There were some other meetings in January 1983 which I don't need to trouble you with. But that was an issue being discussed at least by haemophilia clinicians to some extent.

You told us you didn't have much direct contact with haemophilia clinicians. Obviously, this presentation is an example of some contact, but do you recall there being within PFC in this early part of 1983, January, February, March, anything being raised either about the San Francisco baby case or more generally about AIDS and blood, other than what you've told us about Mr Watt?

A. I don't remember it, no.

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Q. Now, if we then turn to PRSE0001111, we're now in early May 1983 and this is a memo that you wrote to Mr Watt and "HODs", is that heads of department?

A. That's correct.

Q. We can see the subject is "Heat Treatment of [Factor VIII]. A Strategy". I may need to come back to some of this tomorrow in relation to viral inactivation but I just want to pick up here what you say about AIDS.

So if we can go down the page, please, Sully. Thank you.

So it says in the first paragraph:

"Until very recently the objective of our heat treatment proceeded was to cope with the hepatitis problem in haemophiliacs."

Then there's a further discussion in relation to that. Then the memo continues:

"The possibility that another more serious infectious agent (AIDS) is now involved suggests that we may need to review this strategy. In the new scenario:

"The haemophiliacs most at risk are the severe rather than the milds and moderates.

"There is already evidence of a panic recourse to cryoprecipitate."

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Can you recall what the basis was for your understanding that there was a panic recourse to cryo?

A. I'm afraid I can't, no.

Q. Then, if we go a little further down the page, I just want to pick up the last three paragraphs or so:

"Timing may become crucial for a number of reasons:

"The publicised view that [Factor VIII] is infectious and that there may be a long incubation period (ie 3 years). We may argue that this has not been proven but hard data (one way or the other) could take years to achieve. Meanwhile decisions will probably be taken according to a 'worst case' hypothesis."

Then (ii):

"There are some who would find a move back to cryo attractive and if this gathers momentum (it would only need 1 suspected case from NHS [Factor VIII]) we could see our [fresh frozen plasma] disappear overnight."

It continues over the page, I'll just show you before we turn back. You say:

"There may therefore be a case for accelerating our heat treatment programme".

Then you go on to discuss that and, as I say,

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1 I'll come back that.  
 2 If we can go back to the previous page, bottom  
 3 of the page again. Do you know what you were  
 4 referring to when you talked about the publicised view  
 5 that Factor VIII is infectious?  
 6 **A.** Well, I must have been referring to the concern over  
 7 AIDS.  
 8 **Q.** In terms of the timing, this is a memo dated  
 9 3 May 1983. There had been publication in the media,  
 10 in the Sunday papers on the 1 May, I think.  
 11 **SIR BRIAN LANGSTAFF:** It was the 1st, yes. This will be  
 12 a Tuesday, the 3rd, and there'd been -- more than one  
 13 paper had published warnings about the nature of AIDS,  
 14 including a reference to it being a killer transferred  
 15 by blood. I forget the exact phrase. That was on the  
 16 Sunday.  
 17 **MS RICHARDS:** Yes. Do you recall whether you'd read that  
 18 or whether that was what might have triggered the  
 19 thought?  
 20 **A.** It's possible. It depends which newspaper it was, and  
 21 I think there may be articles in The Lancet, but I  
 22 can't remember the dates.  
 23 **Q.** Then when you say, "We may argue that this has not  
 24 been proven but hard data (one way or the other) could  
 25 take years to achieve. Meanwhile decisions will

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1 caught unawareness if it happened, because if we lost  
 2 our fresh frozen plasma, we'd have to work out how to  
 3 continue processing time-expired plasma, cryo  
 4 supernatant, how we would provide Factor IX  
 5 concentrate, which didn't come from cryoprecipitate,  
 6 those sort of details would have to be worked out.  
 7 **Q.** Then can you recall, between this period and then the  
 8 point in time at which you went to Stockholm for the  
 9 conferences there, in around July, do you recall any  
 10 further discussions within PFC, perhaps in light of  
 11 the fact that there had been this media publicity and  
 12 the reference in The Mail on Sunday, or whichever it  
 13 was to "killer blood"?  
 14 **SIR BRIAN LANGSTAFF:** It was The Mail on Sunday. I'm  
 15 trying to remember what the other paper was. It may  
 16 have been The Observer but I may not be right about  
 17 that.  
 18 **MS RICHARDS:** Yes, I feel -- I know I ought to know but  
 19 I can't remember without checking either.  
 20 **A.** I say I would have read The Observer. I would not  
 21 have read The Mail on Sunday.  
 22 **Q.** But somebody else might have drawn it to your  
 23 attention, in any event?  
 24 **A.** Possibly.  
 25 **Q.** In any event, do you recall now any particular

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1 probably be taken according to a 'worst case'  
 2 hypothesis", do you think you were there suggesting  
 3 that that was -- that decisions should be taken on the  
 4 basis of the worst case hypothesis because it might  
 5 take years for proof to arrive or were you just  
 6 recording what you thought others might think?  
 7 **A.** I think both.  
 8 **Q.** Then you say:  
 9 "... some who would find a move back to cryo  
 10 attractive ..."  
 11 Who did you have in mind?  
 12 **A.** I can't quite remember who that would have been but  
 13 I think, perhaps, the move back to cryo would be  
 14 attractive because it would have a lower risk, is what  
 15 I was implying.  
 16 **Q.** It might be said that the expression here about "we  
 17 could see our [fresh frozen plasma] disappear  
 18 overnight", is an expression of concern more for the  
 19 position of PFC than for the position of those who,  
 20 you know, might be at risk of being infected. Would  
 21 that be an unfair way to read this or --  
 22 **A.** Slightly unfair. I was addressing the issues within  
 23 PFC and perhaps contingency planning we would need to  
 24 take in order to cope with that sort of situation, so  
 25 people would start thinking about that and not be

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1 conversations or levels of concern within PFC? Was  
 2 there a sense growing that this was something hugely  
 3 worrying?  
 4 **A.** There was a growing concern and there was concern to  
 5 accelerate our work on pasteurisation.  
 6 **Q.** Now, that brings us then to your attendance at I think  
 7 it was two congresses in Stockholm, the World  
 8 Federation of Haemophilia Congress and then the  
 9 ISTH Congress in Stockholm; is that right?  
 10 **A.** That's correct.  
 11 **Q.** Before we look at three documents that were produced  
 12 by you at or shortly after the conference, can you  
 13 tell us what you can recall about, firstly, the World  
 14 Federation of Haemophilia conference and the  
 15 discussions about AIDS?  
 16 **A.** I remember there was one specific presentation by  
 17 Bruce Evatt from the United States which was very well  
 18 attended. Unfortunately, we were given an abstract  
 19 book with the conference but the page for his abstract  
 20 was blank, so there was no information provided ahead  
 21 of time. But it was very well attended, and there was  
 22 quite -- there was quite a lot of discussion that took  
 23 place at that, which I tried to record the sense of.  
 24 **Q.** I'll come back to what you say in those documents in  
 25 a moment. Do you have any recollection of

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1 a presentation by Dr Shelby Dietrich -- I'm not sure  
 2 I pronounced that --  
 3 A. I don't. That doesn't mean I wasn't there but I don't  
 4 remember it.  
 5 Q. Or a presentation by Dr Christine Lee?  
 6 A. Again, I don't remember but doesn't mean I wasn't  
 7 there.  
 8 Q. Can you recall, after Dr Evatt's presentation, what  
 9 the reaction was amongst the attendees?  
 10 A. The reaction was very mixed. There was some people  
 11 who thought that this was -- he was -- the situation  
 12 was being exaggerated, and there were others who  
 13 thought it was -- it could be really very serious.  
 14 Q. Did you have any discussions or conversations at the  
 15 conference, as far as you can recall, with any  
 16 clinicians from the United Kingdom?  
 17 A. The only clinician I spoke to, and it was really just  
 18 a very casual comment, which was Dr Bloom, and I was  
 19 at a reception standing on my own and he came up to me  
 20 and he talked about our work on pasteurisation and  
 21 said how important it was, and that was all.  
 22 Q. But there was no discussion with Professor Bloom about  
 23 AIDS itself?  
 24 A. No.  
 25 Q. Did you have any discussions or conversations or

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1 sent direct from Stockholm to where he was at  
 2 an international conference on the subject."  
 3 He says he has typed it up because your writing  
 4 was difficult to read.  
 5 If we go top the next page, this is your letter  
 6 typed up, as I understand it. I'm going to read it  
 7 aloud and then ask you about it. We can see it's sent  
 8 from the hotel in Stockholm:  
 9 "Dear Gordon  
 10 "AIDS and Blood Products  
 11 "I have just been sitting through the latest  
 12 update on AIDS and haemophilia. The following points  
 13 may be of interest.  
 14 "(1) Latest monthly returns to CDC (ie June)  
 15 show that AIDS is still increasing exponentially.  
 16 This is consistent with the view that an infectious  
 17 agent is involved.  
 18 "(2) There are now 16 AIDS cases amongst USA  
 19 haemophiliacs (8 have died) and 5 overseas (ie 3 in  
 20 Spain, 1 in Wales and 1 in Canada).  
 21 "(3) There are two distinct diseases groups:  
 22 "(a) Those who develop Kaposi's Sarcoma;  
 23 "(b) Those who develop opportunistic  
 24 infections.  
 25 "(4) Predicted mortality is:

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1 meetings with anyone from The Haemophilia Society, the  
 2 UK-based Haemophilia Society?  
 3 A. No.  
 4 Q. Do you recall whether there was any discussion about  
 5 what, if any, information should be provided to  
 6 patients?  
 7 A. I don't recall anything like that.  
 8 Q. If we then look at the first document that you wrote  
 9 at ASTM0000039\_001, please. Now, if we go to the  
 10 second page, there's a memo from Gordon Craig of the  
 11 ASTMS of the union, it's dated 11 July 1983, and he  
 12 explains that he's enclosing two letters received from  
 13 you. It says:  
 14 "... you will recall that this Centre processes  
 15 blood products in Scotland and unlike Elstree is  
 16 an extremely modern production unit which is presently  
 17 looking at substantial expansion.  
 18 "Peter is very well versed about developments,  
 19 and he consistently keeps me updated with the  
 20 activities of the Centre, and is a very active member  
 21 of ASTMS. You will see from both letters he is very  
 22 much involved in the problems associated with AIDS and  
 23 how these problems could be countered."  
 24 Then the last paragraph says:  
 25 "The most recent letter written by Peter was

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1 "Kaposi -- 100% in 3 to 4 years  
 2 "Infections -- 100% in 25 months  
 3 "(5) Haemophiliacs are in the group who develop  
 4 infections rather than Kaposi's Sarcoma.  
 5 "(6) Epidemiology strongly suggests  
 6 a transmissible agent. Close contacts have developed  
 7 AIDS (eg sexual partners, male and female, siblings).  
 8 "(7) Haemophiliacs with AIDS are located in  
 9 areas where there is no AIDS in the community (it is  
 10 still found mainly in New York, San Francisco and  
 11 [LA]). This strengthens the association with blood  
 12 products.  
 13 "(8) Epidemiology amongst gay males strongly  
 14 suggests an incubation period of 1 to 3 years. Those  
 15 with the disease may be infectious at any time.  
 16 "(9) Preliminary data from Holland and Sweden  
 17 suggests that haemophiliacs in these countries who use  
 18 USA products have an abnormal immunological status  
 19 compared to those who have used only local products.  
 20 "The accuracy and relevance of those studies is  
 21 contentious."  
 22 Over the page at (10):  
 23 "The USA manufacturers and clinicians are doing  
 24 their utmost to play down the situation. It is  
 25 claimed that the risk to USA haemophiliacs is only '1

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1 in a million'; details of this calculation are not  
 2 given.  
 3 "Current causes of mortality amongst USA  
 4 haemophiliacs were listed as:  
 5 "bleeding 36%  
 6 "AIDS 11%  
 7 "cancer 11%  
 8 "heart disease 7%  
 9 "ie bleeding is more serious than AIDS.  
 10 "(11) USA speakers also point to the fact that  
 11 no [I think it should be AIDS] cases have been  
 12 reported in Germany even though the use of American  
 13 products is massive in that country."  
 14 Just before I read the last two paragraphs, is  
 15 it right to understand that what you have set out in  
 16 points 1 to 11 are the points that have emerged from  
 17 the presentation that you have attended?  
 18 A. That's right.  
 19 Q. Then the next two paragraphs are your own  
 20 observations:  
 21 "My own feeling is that with an incubation  
 22 period of 1 to 3 years and the first haemophilia case  
 23 only 12 months ago, we may only be seeing the first  
 24 puffs of smoke from the volcano.  
 25 "In the UK there is the danger that the

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1 In terms of transmissible agents, so  
 2 paragraph 6, "epidemiology strongly suggests a  
 3 transmissible agent", do you recall any more about  
 4 what was being said by, presumably, Dr Evatt about the  
 5 route of transmission?  
 6 A. I'm afraid not no. I mean, I would have taken notes  
 7 at the time, which is how I've managed to produce  
 8 this, and those notes might still be somewhere in  
 9 SNBTS but I don't have access to them.  
 10 Q. Then paragraph 7, which refers to haemophiliacs with  
 11 AIDS being located in areas where there's no AIDS in  
 12 the community, as strengthening the association with  
 13 blood products. Now, as I understand it, you're there  
 14 reporting what had been said rather than that being  
 15 your own assertion?  
 16 A. Correct.  
 17 Q. But do you recall any more about why that was said to  
 18 be strengthening the association with blood products?  
 19 A. Because those cities were known to have communities of  
 20 gay men, whereas elsewhere in the United States, the  
 21 gay population wasn't so concentrated, and that,  
 22 therefore, because the infections with haemophiliacs  
 23 weren't in these centres, then that strengthened the  
 24 idea that these were from blood products, rather than  
 25 from men who were gay.

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1 Government may use the situation to look at commercial  
 2 manufacturers again. Sources tell me that the DHSS  
 3 have already approached Speywood to see what they can  
 4 do!!"  
 5 If we just go back to the first page, I wanted  
 6 to ask you a handful of questions arising out of this.  
 7 Page 3, of the overall document. Thank you.  
 8 Was this arising out of Dr Bruce Evatt's  
 9 presentation?  
 10 A. I think it must have, yes.  
 11 Q. It sounds as though you wrote this to Mr Craig whilst  
 12 it was fresh in your mind because it refers to having  
 13 just sat through the latest update. Do you know now  
 14 what prompted you to want to write straightaway to the  
 15 union about this?  
 16 A. I had already been in touch with Mr Craig because of  
 17 my concerns that PFC was being under utilised and  
 18 I had believed that commercial products were being  
 19 imported into the UK because BPL didn't have the  
 20 capacity, and I thought PFC could assist with that.  
 21 That was my initial reason for writing to him, and  
 22 this was just a continuation of that.  
 23 Q. We'll look, possibly later this afternoon, possibly  
 24 tomorrow morning, at that, your earlier letter to him,  
 25 which I think is the previous month.

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1 Q. Then if we just go over the page, the reference to USA  
 2 manufacturers and USA clinicians doing their utmost to  
 3 play down the situation, is that you recording your  
 4 impression of what Dr Evatt was saying?  
 5 A. No, that was my impression of what the audience were  
 6 saying in the discussion afterwards.  
 7 Q. Okay. We might pick that up in one of the later memos  
 8 when you go back to the one in a million point,  
 9 I think.  
 10 The turn of phrase you used, "first puffs of  
 11 smoke from the volcano", we'll see another turn of  
 12 phrase used in one of your other memos, is it right to  
 13 understand that, not least because of, as you say  
 14 here, the issue about incubation period and this being  
 15 a relatively recent problem presenting itself, you  
 16 feared that there was a much bigger problem further  
 17 down the road, so that no comfort could be placed upon  
 18 the fact that there were -- in absolute terms, the  
 19 number of reported cases were, at that stage, quite  
 20 small.  
 21 A. Yes.  
 22 Q. Let's then just look at the two further memos which  
 23 you sent over the next few days. The first is at  
 24 PRSE00002014. This is a memo from you to Mr Watt,  
 25 13 July 1983, the subject here is "T Cell

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1 Abnormalities & Haemophilia", and you say this:  
 2 "As a number of reports are appearing from our  
 3 Scottish colleagues on this topic it might be useful  
 4 if I mention some of the key points that came out of  
 5 the [World Federation of Haemophilia] and ICTH  
 6 meetings (prior to a full report).  
 7 "A number of presentations were given at both  
 8 the World Federation of Haemophilia & ICTH  
 9 sub-committee meetings; some of the participants  
 10 attempted to make the following points ..."  
 11 Then you set out two points in relation to  
 12 studies in terms of the T cell ratios.  
 13 Then you say this:  
 14 "It was clear that many European participants  
 15 were implying that USA products and/or plasma were bad  
 16 news."  
 17 Just pausing there, again, are you able to cast  
 18 any further light, do you have any further  
 19 recollection of the discussions or contributions that  
 20 have led you to make that observation?  
 21 A. I'm sorry, I can't remember.  
 22 Q. Actually, before I then go on, can we just look at the  
 23 very top of the screen. Sorry, we can keep the screen  
 24 as it is but the top of the page, the text, you say:  
 25 "As a number of reports are appearing from our

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1 that these sort of measurements that were being made  
 2 by Dr Ludlam are not my area of expertise, so I was  
 3 looking at it really quite naively and just trying to  
 4 give some kind of summary of what was taking place.  
 5 Q. Then I think we get, at the very bottom of this page,  
 6 your own input. You say:  
 7 "My own feeling was that there was something of  
 8 an attempt to suppress AIDS 'hysteria' ..."  
 9 An attempt by whom? Is that a reference again  
 10 to the North American response?  
 11 A. That's correct.  
 12 Q. Then you continue:  
 13 "... but, as an uninformed observer, some of the  
 14 more scientific explanations of the T cell situation  
 15 did appear to make sense."  
 16 Can you recall what aspects of it you thought --  
 17 A. The one thing I can remember is seeing people putting  
 18 up slides with a lot of data points which were very  
 19 scattered and then drawing the line of best fit. And  
 20 I wasn't sure how accurate that really was, in  
 21 statistical terms.  
 22 Q. And then we can pick matters up with the third  
 23 document you produced in July of 1983. This is one we  
 24 looked at before, but not obviously with you,  
 25 Dr Foster. ARCH0002544. 15 July 1983. So this is,

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1 Scottish colleagues on this topic ..."  
 2 Do you know what reports you were there  
 3 referring to?  
 4 A. I think these are reports about T cell ratios that  
 5 have been published from Glasgow and Edinburgh and the  
 6 implication was that people with haemophilia had  
 7 abnormal T cell ratios as a result of the lower purity  
 8 of the products, rather than because of some  
 9 infectious agent. And, therefore, people who were  
 10 saying this didn't necessarily equate to infection  
 11 with AIDS because it was assumed that the patients in  
 12 the UK, who had only had Scottish products, would not  
 13 have been infected.  
 14 Q. Then if we go back, the sentence I just read about  
 15 European participants "implying that USA products  
 16 and/or plasma were bad news" continues:  
 17 "The North American response was initially to  
 18 cite Ludlam et al but later to attack the validity of  
 19 any of this data."  
 20 Then you set out four points that were being  
 21 made.  
 22 Again, do you have any further recollection now  
 23 other than the points that are there set out about  
 24 what was being said regarding Dr Ludlam's publication?  
 25 A. I'm afraid I can't think of any more. I have to say

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1 again, to Mr Watt. And you -- we can see you say:  
 2 "It might be helpful if I summarise the key  
 3 points concerning AIDS from the WFH and ISTH Stockholm  
 4 meetings (prior to a full report). Most of the  
 5 information was presented by Dr Evatt.  
 6 "1. The June ... figures ... show the total  
 7 number of USA confirmed cases is marginally higher  
 8 than would be predicted from an exponential growth,  
 9 ie, this is consistent with the view that AIDS is a  
 10 transmissible agent."  
 11 Then there's a reference to cases in Haiti:  
 12 "2. Epidemiology strongly suggests  
 13 a transmissible agent."  
 14 Then there's reference to suggested stages of  
 15 the disease.  
 16 If we go further down the page, we can see this,  
 17 again, largely overlaps with what you've already set  
 18 out in your letter to Mr Craig at the ASTMS.  
 19 If we pick it up at the bottom of the page,  
 20 please, Sully, we can see in paragraph 7 after you've  
 21 set out the confirmed cases, you've recorded that:  
 22 "Other delegates seemed to think that there were  
 23 more cases than this outside USA, (eg, Canada,  
 24 Germany, Israel, Sweden). It is possible that these  
 25 have not yet been confirmed by CDC."

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1 Is that something that you were picking up from  
 2 the discussions that followed the presentation, do you  
 3 think, or from conversations with other delegates more  
 4 generally?  
 5 A. I'm afraid I can't remember.  
 6 Q. Then you refer to paragraph 8, to a case having been  
 7 reported of a mild haemophilia B case.  
 8 And then if we go over the page, paragraph 9  
 9 refers again to strong evidence for transmission by  
 10 Factor VIII. And, again, we've discussed that in the  
 11 context of your letter to Mr Craig.  
 12 Paragraph 10, you say this, or you report this:  
 13 "Common lots of Factor VIII concentrates seemed  
 14 to be rare or non-existent. There are two known  
 15 Factor VIII lots prepared in plasma containing two  
 16 AIDS donations. Haemophiliacs who received this  
 17 material have been followed for two years with no sign  
 18 of AIDS yet."  
 19 Do you recall any particular discussion about  
 20 the significance of that?  
 21 A. I don't recall, no.  
 22 Q. And then you recorded there a bit more information  
 23 about the AIDS haemophiliac in Cardiff. Do you know  
 24 where that came from? Was that information that had  
 25 been provided by Dr Bloom at the conference or by

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1 down the situation, your letter to Mr Craig I think  
 2 had referred to clinicians and -- I should just check  
 3 the wording. You refer to clinicians and I think USA  
 4 manufacturers.  
 5 Do you have any memory of which USA  
 6 manufacturers had some form of representative who were  
 7 at the conference who was contributing?  
 8 A. I'm sorry, I can't. I mean, they were all  
 9 represented. I mean it was a very busy meeting, and  
 10 all the companies had delegates there. They had  
 11 stalls, commercial stands. But I can't remember  
 12 specifically which ones were saying this.  
 13 Q. Then if we go to the bottom of the page, we had the  
 14 puff from the volcano before here. You've said:  
 15 "... the first haemophiliac case only 12 months  
 16 ago ... possible incubation period from 1 to 3 years.  
 17 A number of delegates (mainly European) were clearly  
 18 uneasy and felt that we may be still only seeing the  
 19 tip of the iceberg."  
 20 So what we saw from your letter to Dr Craig was  
 21 your own concern. Here appears to be a concern that  
 22 was shared by others, by others delegates at the  
 23 conference; is that right?  
 24 A. Yes, that's correct.  
 25 Q. And what was your purpose in writing to Mr Watt and

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1 others?  
 2 A. It must have been presented at the conference, but I  
 3 can't remember who presented it.  
 4 Q. And then point 12 says:  
 5 "For donor screening, it was suggested that the  
 6 presence of circulating immune complexes plus anti-HBc  
 7 would identify 98.4% of AIDS cases. Rejection on this  
 8 basis would remove 10% of all the plasma pool."  
 9 Is it right to understand, then, that that was  
 10 a suggestion of possible surrogate markers for AIDS?  
 11 A. Yes, that's correct.  
 12 Q. Do you recall any further discussion of that issue, of  
 13 that possibility of surrogate testing?  
 14 A. I don't, no.  
 15 Q. And then we get your impression. A concerted attempt  
 16 from USA delegates to play down the situation. You  
 17 refer to the -- it being said on a number of occasions  
 18 that the risk to haemophiliacs was one in a million,  
 19 and we saw that again from your letter to Mr Craig.  
 20 And then you say this:  
 21 "... though simple arithmetic suggests 1 in  
 22 1,000." Can you remember what your thinking was  
 23 about --  
 24 A. Again, I can't remember, no.  
 25 Q. And then in terms of the US delegates who were playing

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1 sending this memo?  
 2 A. I had been planning to write a full report, but it  
 3 struck me that that would -- writing a report takes  
 4 a long time, especially when you've been to two  
 5 conferences, and so I thought I should let Mr Watt  
 6 know as soon as possible of the key points that had  
 7 come out of these meetings, so I wrote these two memos  
 8 to him. As it was, he had already offered his  
 9 resignation and was about to leave PFC. I was really  
 10 very, very busy trying to develop a pasteurised  
 11 product, and I never did write a full report for these  
 12 meetings.  
 13 Q. If we leave aside for a moment the perhaps unfortunate  
 14 timing in terms of Mr Watt's resignation, was it your  
 15 expectation that this seemingly very significant  
 16 information that you'd gleaned from the conference  
 17 would be circulated more widely within SNBTS?  
 18 A. Oh, yes. That was my intention, was to provide it to  
 19 Mr Watt as soon as I could so that he could then  
 20 forward it to whoever he thought was appropriate.  
 21 Q. And do you know what happened in that regard? Was it  
 22 forwarded to --  
 23 A. No, I'm afraid I don't.  
 24 SIR BRIAN LANGSTAFF: Just before we turn away from this,  
 25 I've just been reflecting upon the -- your answer to

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1 the question about the one in a million and simple  
 2 arithmetic suggesting one in a thousand.  
 3 How many haemophiliacs do you suppose there are  
 4 in America, in the USA?  
 5 **A.** Sorry, I can't answer that.  
 6 **SIR BRIAN LANGSTAFF:** Well, I think it may be somewhere  
 7 between 10,000 and 20,000. If so, then there being  
 8 11 cases would fit within that range. I don't know if  
 9 you had something like that in mind. You were noting  
 10 the number of cases there are said to have been in the  
 11 haemophiliac population known to the TVC, albeit that  
 12 their scope was wider than the States.  
 13 **A.** Sorry, I really can't --  
 14 **SIR BRIAN LANGSTAFF:** You can't help. Very well.  
 15 **A.** -- think that far back.  
 16 **MS RICHARDS:** Now, you referred a few moments ago to the  
 17 earlier correspondence that you'd had with Mr Craig of  
 18 the ASTMS, and I want to finish today by picking up  
 19 some of that correspondence. So if we could go,  
 20 please, to WITN6914017. We can see these are a number  
 21 of documents relating to your correspondence with the  
 22 union which you provided to -- as I understand it,  
 23 provided to the Penrose Inquiry.  
 24 Can we go to the next page, please, Sully. This  
 25 is a letter from you to Mr Craig dated 9 June 1983.

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1 Reference then to imported products in  
 2 paragraph 3.  
 3 Then you say this, picking up on what we  
 4 looked at earlier in relation to the PFC:  
 5 "4. While I fully support the need for a new  
 6 and enlarged NHS facility at BPL, Elstree, I am very  
 7 concerned that the equivalent NHS facility in Scotland  
 8 (PFC, Edinburgh) remains seriously underused, despite  
 9 the above situation south of the border. [And the  
 10 above situation south of the border is the importation  
 11 of commercial concentrates.]  
 12 "I would estimate that the capacity of the  
 13 Scottish Centre could be increased threefold almost  
 14 immediately (with the introduction of shift working)  
 15 and about tenfold with the provision of extra  
 16 warehousing, cold storage and services."  
 17 Top of the next page, you then refer to your  
 18 understanding that it had been decided not to utilise  
 19 the Scottish Centre and resignation, you thought, of  
 20 Mr Dunnill -- sorry, Dr Dunnill.  
 21 "The Scottish Centre has been operational since  
 22 1976, and I would estimate that the policy of  
 23 neglecting this facility has probably already cost the  
 24 NHS about £50 million, as well as resulting in the  
 25 importation of disease (hepatitis, AIDS)."

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1 Was this the letter you were referring to earlier?  
 2 **A.** That's correct.  
 3 **Q.** So we can see, if we go down the page, please, you set  
 4 out a number of points:  
 5 "1. ... still very little known about AIDS, but  
 6 there does seem to be increasing evidence that an  
 7 infectious agent is involved and that this can be  
 8 transmitted by blood and at least some blood products.  
 9 "2. In this situation, the use of blood or  
 10 blood products in the USA and/or from paid donors  
 11 probably represents a higher risk than from non-USA  
 12 unpaid donors. However, it should be recognised that  
 13 the risk from UK unpaid donors may still represent  
 14 a problem."  
 15 What you say there I think is probably very  
 16 clear, but at the risk of stating the obvious, is it  
 17 right to understand that you weren't assuming that  
 18 domestic products would be necessarily free from AIDS?  
 19 **A.** That's correct.  
 20 **Q.** And I may want to pick that theme up with you tomorrow  
 21 morning. But you continue:  
 22 "This balance of risks is likely to continue  
 23 until non-infected products can be guaranteed either  
 24 by donor screening or by treatment of the products to  
 25 render them non-infective."

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1 Then you refer in the next paragraph to work on  
 2 viral inactivation and the sharing of information with  
 3 your colleagues at BPL Elstree.  
 4 Then if we just look at the PS below your name,  
 5 you say:  
 6 "The research on item (5) [that's viral  
 7 inactivation] is not yet public, but I will be  
 8 presenting much of this information at an  
 9 International Congress on 5 July."  
 10 That, as I understand it, was one of the key  
 11 reasons for your attendance in Stockholm.  
 12 **A.** The key reason for my attendance was I'd been invited  
 13 to present our work on continuous thawing, but I took  
 14 the opportunity to submit presentations on heat  
 15 treatment as well.  
 16 **Q.** Now, reading that letter as a whole, would it be right  
 17 to understand that you weren't really by this stage in  
 18 any doubt that AIDS could be transmitted by blood and  
 19 blood products?  
 20 **A.** Yes.  
 21 **Q.** That's correct?  
 22 **A.** That's correct.  
 23 **Q.** If we then -- sorry. Actually, before I go to the  
 24 next document, you're recognising as we looked at in  
 25 paragraph 2, if we just go above -- sorry, the

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previous page, Sully. My apologies. Paragraph number 2.

So recognising there the possibility that the UK volunteer donors could be infected with AIDS and transmit that through donation. Do you recall whether any consideration was given around -- whether around this time or over the coming weeks or months, to any particular risks in that regard posed by Edinburgh, in terms of gay population, numbers of overseas visitors.

A. Yes, I knew Dr McClelland was preparing a leaflet to discourage gay men from donating blood, and he was working closely with the gay community to achieve that. I was aware of that.

Q. And then bottom of the page, please. How did you reach the conclusion that the capacity of the PFC could be increased in the way you described, so threefold almost immediately, and then tenfold with the provision of the extra facilities and services you identify?

A. Because I'd been involved in developing the continuous flow system, and I understood its capacities.

Q. If we go then, please, to page 4 of this, we can see that there's then a letter from the ASTMS's health and safety officer to you, 28 July 1983. I don't need to go through that, but if we then go to the next page,

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ask you about.

What -- in terms of the long incubation period, it appears to be fairly clear to you what the significance of that was in terms of not placing comfort upon the relatively small number of cases that had thus far been reported; is that right?

A. That's correct.

Q. Again, do you recall any conversations you were having with colleagues at the time about the significance of the incubation period?

A. No, I don't recall that.

Q. Is there any reason why that, which was apparently obvious to you as a non-clinician, should not have been obvious to clinicians?

A. I think it should have been obvious, yes.

Q. And then if we move on to page 10, we can see here a letter from Lord Glenarthur, who we know was the minister with particular responsibility for blood and blood products, to Clive Jenkins, who was the general secretary of the ASTMS. He is responding to a letter which Mr Jenkins had sent to Lord Trefgarne. We've looked at this letter, Dr Foster, on a number of occasions in Inquiry hearings, so I can take it fairly quickly, but if we just go further down. So we can see the first main paragraph says:

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we can see you wrote to Ms McKechnie of the ASTMS on 5 August 1983. I don't think I need to ask you to look at anything on the first page, but if we go over the page, if we pick it up in the second paragraph, you've referred to the potential equivalence with hepatitis B and the possibility of adopting hepatitis B type precautions.

And then halfway through the paragraph, you say:

"The very long incubation period now being proposed suggests that AIDS victims may be infectious for at least 1 year with no symptoms for another 1 to 2 years with non-specific symptoms."

Then if we ignore the next paragraph, we look at the paragraph beginning:

"For the UK, the critical question is how prevalent is AIDS here or will it become?"

"If it can be restricted to a small number of cases, it may be only a relatively minor problem. Possible that USA publicity ... check the spread of disease in the UK. Equally possible that the incubation period is such that the disease is already with us. We should know the answer in the next 6 to 18 months."

Then you go on to discuss some issues relating to viral inactivation which I don't think I need to

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"I should emphasise, firstly, there is no conclusive evidence that AIDS is transmitted ... Nevertheless we are taking all practicable measures ..."

There is reference in the next paragraph to the leaflet and then in the further paragraph to the position in relation to what was described as regulations initiated by the US Food and Drugs Administration. I'm not going to go through it in any detail, as I say, because we've looked at it in other hearings. What I want to do then is turn to the next page -- sorry, the page after that, page 12. Is it right to understand from this that the letter from Lord Glenarthur was forwarded to you with the invitation to you to comment on it?

A. That's correct.

Q. To pick up those comments -- yes, we need to turn to page 50. I've skipped over a number of the intervening documents, Dr Foster. They include papers that were going to be provided to the Advisory Committee on Dangerous Pathogens?

A. That's correct.

Q. Am I right in understanding that in part was the understanding of your context with Sheila McKechnie because she and the union were concerned about the

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1 implications for employees?

2 **A.** That was partly the case, yes.

3 **Q.** So we can then pick up -- and I think this probably

4 will be the concluding document we look at today --

5 your response to the ASTMS commenting upon

6 Lord Glenarthur's letter. Your letter is dated

7 29 September 1983. If we pick it up in the second

8 paragraph, you say this:

9 "I would like to comment on the letter from

10 Lord Glenarthur Arthur to Clive Jenkins. I found the

11 letter surprisingly complacent about the blood

12 products situation and there are number of points to

13 take up."

14 Then you refer to the line of there being no

15 conclusive evidence, and your comment is this:

16 "The evidence is very strong. There are now

17 about 20 haemophiliacs with AIDS. This figure is

18 likely to underestimate the risk because of the

19 apparently long incubation period. Haemophiliacs in

20 Europe are contracting AIDS in locations where the

21 disease had not previously existed."

22 This Inquiry has examined with a number of

23 witnesses the departmental line to take of "no

24 conclusive evidence". Other than your comment about

25 the letter as a whole being "surprisingly complacent",

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1 providing much by way of reassurance that the products

2 would be safe?

3 **A.** Yes. They are probably better than nothing at all,

4 but they wouldn't take us very much further forward.

5 **Q.** Now, just in terms of attempts to identify donors from

6 high-risk groups, your observation there in the

7 context of paid donors was that donors who really need

8 the money may not be truthful. Would you accept that

9 there might be also be constraints upon volunteer

10 donors within voluntary systems such as Scotland,

11 England, Wales and Northern Ireland in being truthful,

12 not because of the wish to be paid, but because of the

13 social stigma associated with potentially admitting to

14 behaviour that would identify someone as being in

15 a high-risk group?

16 **A.** I think the point about social stigma, maybe in men

17 who hadn't come out, and who didn't want to reveal

18 this in front of their colleagues, was a sort of issue

19 that could have happened.

20 **Q.** I know that donor screening, donor selection, was not

21 your field of responsibility, and you already told us

22 you were aware of initiatives by Dr McClelland in

23 relation to the leaflet. Was that an issue you recall

24 being discussed within the PFC at all, the potential

25 limitations of the leaflet?

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1 do you have any particular observations about that

2 particular line which you had been asked by

3 Ms McKechnie to comment on?

4 **A.** Well, it's probably true that it wasn't conclusive,

5 but I think it was so strong that you had to take

6 notice of it.

7 **Q.** Then your next point relates to Lord Glenarthur's

8 reference to the FDA regulations. Your comment:

9 "These regulations rely on the use of interviews

10 and questionnaires to identify donors from high risk

11 groups. The success of this approach is unlikely to

12 be high because of the fact that all donors are paid

13 and a donor who really needs the money may not be

14 truthful. Paid donors are usually recruited from low

15 income groups ..."

16 Then if we look at the bottom of that page, you

17 say:

18 "If AIDS continues to grow exponentially in the

19 USA then I would not expect the current FDA

20 regulations to help very much. They are simply

21 a stopgap until progress is made in screening donors

22 or in treating products to render them non-infective."

23 Is it right to understand from this, Dr Foster,

24 that for the reasons you've there set out, you didn't

25 regard the new FDA recommendations/requirements as

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1 **A.** I can't really say. It would have been known by

2 Mr Watt and Dr Perry. Whether they had any

3 reservations or comments on that, I don't know.

4 **Q.** Then if we just go to the next page, so we can look at

5 the rest of this letter, your third point commenting

6 upon Lord Glenarthur's letter is:

7 "It seems that despite the introduction of the

8 above regulations we are still to carry on as before.

9 There must be a real danger that the UK could become

10 a dumping ground for USA companies to get rid of their

11 non-regulated products."

12 Was that a concern, as far as you can recall,

13 shared by colleagues or by others within SNBTS: the

14 fear of the UK being a dumping ground?

15 **A.** It wasn't, as far as I was aware, in Scotland, because

16 as far as we were aware, there were no commercial

17 products being used in Scotland.

18 **Q.** Then you, in the next paragraph, or your next point,

19 point 4, you refer to the lack of fractionation

20 capacity, and say this:

21 "The fact that the Scottish fractionation plant

22 is substantially underused seems to be being ignored."

23 You refer again to how the introduction of shift

24 working could increase capacity.

25 I then just ask you about the comment you make

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at point 5 in relation to the Haemophilia Society. So Lord Glenarthur said in his letter that:

"Haemophilia Society is aware of the situation and has in fact made known to me its opposition to any move to ban American [Factor VIII]."

Your comment is:

"I am not sure that the Haemophilia Society are fully aware of the UK situation and particularly the true capacity of the Scottish Fractionation Centre and the reasons for its neglect (in my opinion this is a scandal which deserves an inquiry in its own right)."

"In seeking the views of users of FVIII (eg clinicians & patients) one should be aware that many users are associated with commercial companies (eg clinicians who act as paid consultants to the companies)."

Were there any particular clinicians that you had in mind in making that observation, or was that a general sense that you had?

**A.** I was aware of one clinician who Mr Watt had shown me documents to show me that he was a paid consultant. I'd heard generally from Dr Smith and Dr Boulton that that was more prevalent amongst the haemophilia doctors but I wasn't sure which ones.

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Would that have been a job for Mr Watt or his successor?

**A.** Mr Watt and Dr Cash. And, I mean, it's conceivable that they did, but I can't answer whether they that -- whether they did or not.

**MS RICHARDS:** Sir, I'm going to move to another letter next, so I'm conscious of the time, and there are a few more documents and a few more questions arising out of this issue, so perhaps I could pick that up at 10.00 in the morning.

**SIR BRIAN LANGSTAFF:** Yes, I think that's sensible. We'll take a break now then until the morning. 10.00 tomorrow morning, if you please.

(4.35 pm)

(Adjourned until 10.00 am the following day)

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**Q.** Who was the particular clinician who was identified to you?

**A.** Dr Jones.

**Q.** Dr Peter Jones of Newcastle?

**A.** Yes.

**Q.** Now, you have said that you weren't sure that The Haemophilia Society were truly aware of the UK situation and the position in relation to the PFC's capacity. Was any effort made either by you or, to your knowledge, by your colleagues at the PFC to make contact with The Haemophilia Society directly to explain the availability of the PFC?

**A.** I'm not sure that there was. And it might have contravened the Medicines Act because you weren't allowed to promote our products directly to patients, and that might have been seen as not being appropriate. We didn't deal directly with patients.

**Q.** Now, I'm conscious you were head of the R&D department. If there was somebody within the PFC who might be able to make an approach to The Haemophilia Society, or indeed someone within the SNBTS who might be able to make an approach to The Haemophilia Society, perhaps not to sell particular products but just to say -- flag up the bigger picture of the PFC having capacity, who would that have been?

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(72) products... - recognising

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(73) recollection - risks

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(76) stating... - than



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(81) wouldn't... - zoom