Friday, 18th March 2022

(10.00 am)

Presentation to the Inquiry about the work and evidence of Dr James Smith (responsible for product development at the Plasma Fractionation Laboratory 1975-1992 and Blood Products Laboratory 1979-1982 and formerly of the Protein Fractionation Centre, Edinburgh) by MS RICHARDS (continued)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Sir, when we left off yesterday afternoon we'd looked at some passages in Dr Smith's various statements relating to knowledge and understanding of hepatitis, both in terms of his own -- his understanding of the perception of fractionators, and then his understanding of the perception of clinicians and more generally.

There were then just a handful of contemporaneous documents I wanted to look at. They derive from 1981, and in relation to the first two documents they were described by Dr Smith in his statement as some "first outline proposals to tackle virus transmission". Generated in 1981.

Paul, could we have CBLA0001291.

This is 27 February 1981, and is, as I understand the statements of Dr Smith, a document

of hepatitis risk cannot be ignored, and it is essential that BPL/PFL be well placed to take advantage of such developments. Since this particular development work involves the handling of large quantities of plasma known to be infective, the choice of a location for the work is important. Clearly the work would have to be sited outside the regular production area."

So that's what Dr Smith described as first outline raising of this matter.

Then a second document referenced in, I think, the statement from the HIV Litigation is at BPLL0011141.

This a little later in 1981, 27 July 1981, a memo from Dr Smith to Dr Lane, "Reduction of HBV infectivity of therapeutic concentrates", and Dr Smith says this:

"For historical reasons over and above the line of duty I am very interested in this topic but have not had facilities to pursue it since coming to England. Now that we know a lot more and Brian Combridge has relatively safe preoperative facilities, a bit of cross-fertilisation would seem to be in order. I summarise some pursuits which would involve spiking products with infective virus,

authored by him, although it doesn't bear any particular name. But it says: "Proposal for support of research project". "Project title: The development of methods for the production of coagulation factor concentrates with reduced risk of hepatitis transmission".

The first paragraph starts by talking about improvements in methods for the detection of hepatitis B surface antigen and says that's drastically reduced the incidence of hepatitis B in patients receiving Factor VIII and Factor IX concentrates and then adds this:

"This change has also highlighted the importance of non-A, non-B hepatitis as an undesirable side effect of transfusion of blood and blood products. Although there is some evidence that the risk of transmitting non-A, non-B hepatitis is greater for imported blood products [then again a reference to Dr Craske's 1980 paper], the incidence of non-A, non-B hepatitis following infusion of NHS concentrates is still a cause for concern."

Then there's a reference to two further papers in the next paragraph. Then the third paragraph picks it up by saying:

"The significance of a product demonstrably free

inactivation or removal of virus by simple manipulations, and testing for possible infectivity by controlled tests in chimpanzees -- possibly the only evidence currently deserving credibility."

Now this is, as we see from the heading, concerned with the reduction of hepatitis B infectivity, but I draw attention to it not least because of what is said in paragraph 1, and I think Mr Hill may have referred to this in the course of the week, but there is a reference to the work being undertaken by Behringwerke in relation to heating and the claim of producing a non-effective Factor VIII concentrate. Dr Smith says there's no reputable evidence for the claim:

"I would have a few ideas on how to start, but this might probably be an R&D project."

Then he goes on in the following paragraphs to talk about Factor IX and suggests a discussion that might take place with Mr Watt at PFC in that regard, and then discusses -- if we go just further down the page, please, Paul -- ideas in relation to other products, and then says at the very end:

"I am out of date on the virology side and would welcome further discussions with you and Brian."

So those are two documents from 1981 raising

thoughts about work that might be undertaken but not really going any further than that.

There's then, if we go to CBLA0001446, as we see here a meeting in September 1981, 14 September 1981, between Dr Lane, Dr Harvey and Dr Smith. This is in fact Dr Lane's note of the meeting. His name and the date of 21 September appears on page 2.

We can see the subject:

"1. Hepatitis antigens in plasma and final products.

"2. Submissions for research and development products.

"The object of the meeting was to set out important areas of research and development ..."

Then if we look at the first paragraph, headed "Hepatitis antigens in plasma and final products", we see -- and again, Mr Hill made reference to this issue earlier in the week -- we see there attention being drawn to what was going on commercially, in terms of commercial products:

"The point was made that various commercial manufacturers have now produced both factor VIII and factor IX products claiming that in-process modifications have now substantially reduced the risk of transmission of hepatitis. The basis for these

claims may lack scientific integrity but the ethical pressure brought on clinicians to use such products is clearly established. It is known that certain companies are actively seeking product licences on the UK market. BPL therefore cannot rest its case in this area using a purist argument that the term 'essentially free of hepatitis risk' is meaningless or because precise definition of complete exclusion of hepatitis viruses falls outside our existing methods of detection excepting transmission in primates."

Then there's, it would appear, a discussion of a range of approaches for reducing hepatitis antigen. I'm not proposing to go through them all; the second is heat inactivation but there's a number of others there set out. (9) is "general forms of chemical virus inactivation".

Some of these alternative potential ways of reducing hepatitis transmission are discussed in more detail in Dr Smith's 1990 statement.

The note continues:

"The advantages and/or disadvantages of each of these systems was briefly considered with respect both to factor VIII and to factors II, VII, IX and X."

There's some general conclusions there set out.

If we go over the page, we see then "Submissions

for research and development projects", reference to a meeting of the Scientific and Technical Committee. I think, again, Mr Hill made reference to that.

Then we see in the second paragraph:

"The director [so Dr Lane] invited MJH [Dr Harvey] and JKS [Dr Smith] to proceed with the submissions in areas of ..."

And then there's a range of areas set out, including hepatitis transmission.

I'm not going to go through the remaining documents in this reference but if we just go to the next page you'll see there that this is an extract from a meeting of the Scientific and Technical Committee, where reference is made to research projects.

If we go to CBLA0001506 then next.

This is the later meeting of the Scientific and Technical Committee for the Central Blood Laboratories at 24 November 1981. And we can see if we look at the list of attendees that Dr Smith attended for item 1. Then if we look at item 1, it says:

"Dr Smith gave a short address on the inactivation of hepatitis in BPL products, a summary is attached at annex A."

And if we go to page 5, we've got the summary,

it is very much only a summary so we don't have any more detail, but what this document, which we can see was authored by Dr Smith, says is:

"The review covered the consequences of transmitting both B and non-A, non-B hepatitis viruses, the incidence of infection among multi-transfused haemophiliacs and the special problem of infrequently transfused patients who had no immunological defence. The risk of transmitting hepatitis might be diminished by more specific and sensitive screening of blood donations intended for fractionation; limiting the size of plasma pools for recovery of certain products; neutralisation or adsorption of virus with an excess of hepatitis antibody; vaccination of recipients; selective removal of viruses during fractionation, eg by precipitation with PEG; and by inactivation of virus eg with B-propiolactone or by heating in the presence of reagents preserving the biological activities of plasma proteins. A policy was suggested for the selective application of these approaches to individual coagulation factor concentrates."

We can see there in the course of 1981 thought being given, in particular by Dr Smith, to possible methods of reducing or addressing the risks of

transmission of hepatitis. But at this point in time, it's still very much a subject for discussion with a range of different options or potential options being identified.

If we then just turn to Dr Smith's 1990 draft proof of evidence.

CBLA0000016_034, please, Paul. And we go to page 34.

If we look at the opening words of paragraph 87, bottom half of the page, this is in a section of Dr Smith's statement which deals with restricted pool trials, which I'll come on to, but we can just see from the first sentence what may be a shift in position as between 1981 and 1983. What Dr Smith there says in:

"In 1983, BPL was very concerned about the incidence of NANBH after first use of Factor VIII and Factor IX concentrates in previously untreated patients, even though the source plasma was from unpaid UK donors."

He goes on then to talk about AIDS, which I'll come on to in a moment, but explains a few lines down:

"We were interested in NANBH, first and foremost."

So the work that was being undertaken by 1983

had been triggered, as we see from the 1981 documents, by concerns about hepatitis transmission, albeit, as Dr Smith's evidence as a whole makes clear, it was then the advent of AIDS that really galvanised and introduced a sense of greater urgency and indeed which led, in due course, to the focus upon heat treatment.

And I won't go to it, but it's paragraph 103 of Dr Smith's statement to this Inquiry in which again he says in terms: AIDS bought about a greater degree of urgency to the work.

So if I turn then just to a handful of references in Dr Smith's evidence about the developing awareness of AIDS. If we go to his first Penrose statement which is PRSE0004045, and if we turn to page 8, what we'll see in a moment is a couple of passages in Dr Smith's evidence which again draws a degree of distinction between what he says fractionators thought about AIDS and the possible connection with blood and what his perception was of the position of clinicians on that same issue. So if we pick it up towards the bottom of that page, the penultimate paragraph in bold italics, he says this:

"There was some resistance among haemophilia clinicians to the idea that AIDS was caused by a blood-borne virus."

Then he adds he didn't think that affected the urgency felt by the Scottish National Blood Transfusion Service.

Then if we go to the top of the next page, he then says, in relation to the position of fractionators:

"I believe that most fractionators thought it likely that AIDS was caused by a blood-borne virus even before the seminal publication by Montagnier's group."

Then he refers to his recollection of both when it was published, but it was taken by transfusionists as strong support for a working hypothesis. That was his evidence to the Penrose Inquiry in writing.

If we then go to Dr Smith's statement to this Inquiry, WITN3433001, and go first of all to page 14, please. If I pick it up bottom of page 13, Paul.

You'll see the very bottom of the page reference was made to what he'd said in his Penrose statement, and he was asked essentially to expand upon that. If we go over the page -- I won't read all of it, but he says in paragraph 42:

"In 1982, AIDS seemed to be confined to homosexuals, Haitians and haemophiliacs ... it was hard for many to accept that transmission by body

fluids could be a common factor. As more and more 'categories' and individuals acquired symptoms of AIDS and the subversion of the immune system began to dominate many investigations, it became easier to see that as the key".

Then he refers to a counter-hypothesis.

Paragraph 43, he provides some further observations about what was essentially the counter-view, the counter-hypothesis. So we see, for example, he talks in the fourth line about some US companies encouraging the belief that "junk protein" was causing immunological damage and describes resistance to a viral cause alone, continuing after the Montagnier publication.

If we pick it up in paragraph 44, he says this:

"I imagine that by 1983 most blood transfusion professionals had concluded that the patterns of AIDS transmission strongly suggested involvement of a blood-borne virus."

And then he refers to the Barré-Sinoussi publication probably putting it beyond reasonable doubt. But it's really, I think, the first part of that sentence that's most important.

Then if we go to page 38, paragraph 105, he says this -- perhaps we should just look at the question,

sorry. If we just look at the bold question beforehand, Paul. There's a reference again there to Dr Smith's Penrose statement, reference to the Groningen Conference in November 1984, and he says there -- he's referring to fractionators:

"... not to those clinicians whose long resistance to the viral hypothesis was well established."

So, again, there appears to be a distinction being drawn in Dr Smith's mind between the approach of fractionators and the approach of clinicians.

And then, finally, in terms of references to understanding of AIDS, if we go to PRSE0006059. This is just a short reference in Dr Smith's oral testimony to the Penrose Inquiry. If we go to page 71, we can see from line 6, we've got there the publication date for the article that Dr Smith had been referring to, 20 May 1983. And then lines 12 to 14, Dr Smith was asked about when he first heard about AIDS:

"When you first heard about AIDS and more particularly heard about people with haemophilia having AIDS, can you remember what your reaction was?"

And his response was:

"I first heard about it from my American colleague who brought back a cutting from the Boston

Globe. I did not hear about AIDS through the scientific literature first."

He was asked if he could remember when that was roughly, and answered:

"Perhaps even 1982."

And then if we just go over the page, he goes back at lines 10 to 14, or he is asked again about the publication in May 1983. He says -- he's asked:

"You recollect ... the publication ... was taken by transfusionists as strong support for a working hypothesis, that is a working hypothesis for a blood-borne virus being involved?"

His answer is:

"Exactly."

So that's a flavour of what Dr Smith had to say in his various statements and oral testimonies about his understanding in relation to AIDS. What was done in response to that in terms of the viral inactivation programme, I'll come on to shortly.

The third theme I want to explore through Dr Smith's evidence is the question of the facilities and resources available at PFL and BPL. We'll no doubt be able to hear more evidence about that from Dr Snape in due course, but we can get some of what Dr Smith had to say from various sources.

If we start with PRSE0006059. I think it's the document we just had up. Yes, if we go to page 42, we can see there that Dr Smith was asked in the course of his testimony to the Penrose Inquiry about the Lister Institute and the facilities he described there; the site moving to Elstree.

Then if we go to the next page, we pick it up at line 9. He says, "It", and he's talking there about BPL:

"It had its share of tin huts, but the fractionation was slightly more salubrious than that. At the time I went to Oxford [that was 1975 when he joined Oxford], research had been confined to the tin huts, and we were operating in reasonable circumstances, although all was tightly circumscribed by the breadth of our ambitions and the space we had to work in."

Then the Chair posed the observation:

"And the narrowness of your pockets."

Answer: "Indeed."

Then Dr Smith continued:

"I should perhaps say that blood transfusion in Oxford at that time was operating in twin Nissen huts on precisely the same site, and there was an infamous Oxford triangle [so that picks up on the virtuous

triangle which we looked at yesterday in his witness statement to this Inquiry] which served later for self-sufficiency in England."

If we just carry on, he talks about the plasma being:

"... collected in great amounts by the very willing and helpful Transfusion Service. It was fractionated in the fractionation lab 50 yards away in a brick building and infused into patients 20 yards away. It was a lovely model of what can be done if everyone gets behind it."

That may cast some further light upon what we were discussing yesterday, sir.

Then if we go towards the bottom of this page, he was asked again some questions about facilities at Elstree building works being undertaken, and at line 17 said this:

"I'll try and be brief and non-committal about this, but in 1978 or early 1979 for the first time the medicines inspectors were allowed into BPL which had hitherto, under the previous director operated -- insisted on operating under Crown immunity. It was plain to progressive people that this was not going to last forever. Crown immunity was going to be removed from little pharmacies and equally from fractionation

laboratories eventually. Reluctantly, the medicines inspectors were allowed in, did not like what they saw, perhaps especially in the coagulation factor side. The Medicines Inspectorate were very helpful in explaining to us what was required in 1979."

Then he goes on to talk about the need, essentially, for further work to be undertaken, and a reference to "Mark 1" programme.

And then if we just go a little further down the page, please, Paul. Perhaps I can pick it up at -- yes, if we pick it up at line 13, and he refers to the -- what he described as the:

"... crash programme of renovating, improving the existing premises ..."

Then he refers to being seconded from Oxford to start both these exercises as they concern -- insofar as they concerned coagulation factors:

"We had at the same time as continuing to reduce Factor VIII and Factor IX [I think that should be 'produce' rather than 'reduce'] in less than perfect circumstances to rebuild step by step or at least improve the facilities in each area in turn. This was a very difficult programme."

Then he explains that:

"... the old building had to continue to process

plasma much later than ... hoped because the building programme for the new BPL took rather longer than planned."

So those were some observations in the oral evidence to the Penrose Inquiry.

If we then turn to -- back to Dr Smith's statement to this Inquiry, WITN3433001 and we go to page 28, please. There are then some further observations that Dr Smith made in response to a question about the resources available for research and development at BPL and PFL. And he said this, paragraph 83:

"When I came to PFL in 1975, there was no recognisable R&D department at BPL. Any coagulation factor development being done was in the margins of production. Dr MJ Harvey was appointed head of R&D at BPL around 1980 and set up labs and staff for this purpose."

Skipping over a sentence:

"Effectively, however, all work on coagulation factors was delegated to PFL."

And then if we look at the bottom of the page, he talks about taking de facto charge of R&D resources at PFL when Dr Bidwell retired.

If we go over the page, we then get a further

sense of the fairly limited numbers of staff involved. Picking it up fourth line down -- fifth line down:

"The only full-time member of staff in R&D at the beginning of 1983 was Mrs Lowell Winkelman who had considerable experience as an R&D scientist, though possibly not initially employed under that title. She had to work on both Factor VIII and Factor IX until in early 1983 we had permission to recruit Dr Peter Feldman ... both scientists quickly absorbed our policy of seeing a candidate product from the lab bench through to large-scale production at BPL by way of PFL's pilot-scale production. PFL followed a principle of using industrial equipment which could be easily scaled up at BPL. This integrated approach was reinforced by constant interaction between R&D, pilot plant and the QC analytical lab on site -- one of the few benefits of having limited staff and space -- and was happily assisted by the generous personalities of the main players."

Then the next paragraph explains that there was an absence of permanent technical staff, so he says:

"Another unusual feature of PFL in that period was that the R&D scientists had no permanent technical staff. Instead, the production staff, many of whom were of an enquiring mind, were given a chance to

collaborate on lab-scale work with the scientists, being released for about a day a week as production schedules permitted and as an R&D project matured. I would estimate today that on average the scientists had technical assistance one or two days a week."

He then in the next paragraph sets out the advantage of having close interaction with the Oxford Haemophilia Centre.

If we then go over the page, there's a description in paragraph 87 -- I'm not going to read it, but I draw attention to it -- of the infrastructure at PFL.

At paragraph 88, explains there were no:

"... facilities or staff for virus work at PFL, and none at BPL capable of handling highly pathogenic viruses until completion of the new R&D department in the late 1980s."

There's then a description of the QC lab under Dr Snape, but I'll leave that because we're going to be hearing directly from Dr Snape.

Then if we go to the next page, paragraph 90, he talks here about facilities at BPL. Picking it up in the third line:

"The citation from my evidence to the Oral Hearings in Penrose emphasises the defining limitation

on our pasteurising work -- we knew that it could not be exploited at BPL until the new plant had been completed and qualified."

Then he explains why pasteurisation required facilities that BPL did not have.

If we skip down a few lines he explains it was impossible to install such a facility in the existing buildings at BPL, and then goes on to explain, by contrast with pasteurisation, in relation to the dry heating what was required was the large scale ovens in order to scale up the work on 8Y and 9A.

If we then go to page 33, paragraph 93, I'm not going to read this out but just to note there is Dr Smith's observations comparing the facilities at PFL and BPL with the facilities at PFC, where he said space had been allowed for R&D and private operations.

Then if we go to page 34, paragraph 95, he says this:

"Obviously, if the new BPL had already been built by, say, 1980, people like me would have had a more orderly life and might have been able to create more options for virus reduction. As it was, we spent a lot of time working around builders renovating the old premises and in introducing training in modern pharmaceutical practices in preparation for the

new BPL."

So there was some of the physical constraints.

However it is only fair to point out that Dr Smith then continued:

"I believe I kept abreast of the virus-inactivation field throughout and would like to think that, if there had appeared any chink of light about how we might tackle NANBH, I would have noticed it and acted accordingly. In the very early 80s, more time would not necessarily have meant more inspiration. I would like to have had the kind of physical facilities necessary to exploit pasteurisation, and it is conceivable that had PFL been able to combine efforts with PFC we might both have arrived at a common goal sooner, but even in retrospect that seems unlikely. As it happened, it was fortunate that we pursued complementary approaches."

And then finally in this document, page 36. He was asked the question of whether there'd been more resources available to those working on heat treatment and would effective heat-treated products have been produced at an earlier date? To which his answer is essentially he doesn't think so. Obviously, sir, these are all matters for you to assess looking at all

the available evidence, but this is what Dr Smith had to say:

"A number of things would have been 'nice to have' and might have made us more confident of success, but would not have accelerated the programme significantly. More coagulation assays might have allowed us to optimise parts of the process more thoroughly, but with 8Y our path to successful purification and formulation, which usually call for much laborious trial and error, was remarkably smooth. The hitches which always appeared during scale-up were few and relatively easily solved. Having our own facilities on the BPL site for virus spiking, etc, might have allowed us to cover more variables and to measure the additional inactivation achieved at higher temperatures, but would not have led to earlier availability of our severely-heated 8Y and 9A."

So there is Dr Smith's response to the question posed. You'll obviously hear and be able to hear directly from Dr Snape his own recollection, from a slightly different perspective because obviously his involvement was essentially in relation to quality control, but he will be able to tell his recollections of the facilities available at both PFL and BPL prior to the redevelopment.

Sir, the next theme arising out of Dr Smith's evidence relates to the relationship between PFL and BPL on the one hand and the PFC in Edinburgh on the other.

You will hear, both when we look at Dr Lane's evidence later today, and when we look at self-sufficiency and domestic production in Scotland and Northern Ireland next week, some evidence of a degree of tensions between PFC and BPL, at least in relation to the relationship between Dr Lane and Mr Watt. It's right, however, to note that Dr Smith's evidence, both to the Penrose Inquiry and in his statement to this Inquiry, painted a more harmonious picture in terms of his own dealings, in particular with Dr Foster. And of course we'll be hearing from Dr Foster next week and we'll be able to see what Dr Foster has to say about that.

And so if I can just pick up a couple of references in Dr Smith's statement to this Inquiry.

So if we can have back WITN3433001, please, Paul. If we go to the bottom of page 21, please.

What Dr Smith said in paragraph 66 at the bottom of the page was this:

"I was the main PFL/BPL link to our friends in PFC and their work, sharing with them anything which

I thought might help their endeavours on the pasteurisation option. As time went on, our respective scientists were encouraged to form their own links with each other, but factual communication was normally between me and Dr Peter Foster ... or with our blessing. Such exchanges were not scheduled on a regular basis, and never sought to change the other's policies or strategies. However, we could be confident that the lines PFC were following were in the most competent hands, so that we did not have to duplicate their efforts ... It always seemed that our confidence was reciprocated. Those at BPL and PFC who were formally in senior positions to ourselves appeared to understand the nature of our co-operation."

As I say, we'll look at what the perception of Dr Lane and Mr Watt might have been in relation to those issues but Dr Smith paints a picture of there being certainly a degree of dialogue and sharing of information between him and his scientific colleagues with Dr Foster at PFC.

SIR BRIAN LANGSTAFF: And mutual respect.

MS RICHARDS: And mutual respect.

Then if we go to page 32 in the same document, we can see that Dr Smith listed what he said were

"some of the most important and tangible debts we owed to PFC". Don't need to go through all of those, but I think I'll perhaps just pick up a couple of them so the third bullet point:

"- Providing details, as PFC work developed, of promising pasteurisation processes for F.VIII and F.IX.

"- Sharing early Reports from some conferences which we could not attend, most significantly concerning Behringwerke's progress on pasteurising F.VIII, and Rubinstein's on dry-heating.

"- Sharing access to the dog DIC trials which confirmed that 9A was not thrombogenic."

That reference will become clearer when we look at the heat treatment work in relation to Factor IX.

"- Sharing the results of PFC's attempts to explain the resistance of 8Y and other formulations to high temperatures."

So those are some practical examples which Dr Smith listed of information sharing, et cetera, between the scientists at PFL and the scientists at PFC.

Then if we go to page 35, please, Paul.

Paragraph 98, Dr Smith said this in relation to the relationship between BPL, PFL and PFC:

"... it should be clear that this relationship was extremely rewarding, at first in PFL's favour, and perhaps more equally when NANBH was eclipsed by AIDS and we both had to accelerate exploitation of our dry-heating experiences."

A contemporaneous example of discussions between Oxford and Scotland appears in a note from Dr Smith at CBLA0002481.

Sir, you'll see if we look at the head of the page, this is a memo from Dr Smith, 15 February 1983, to Dr Harvey, Dr Lane, Dr Snape and others at BPL, headed "Visit to SNBTS Protein Fractionation Centre and Headquarters Seminar ... February, 1983", and he says there:

"The first day was spent with Dr Foster and Dr McLeod of R&D Department mainly on heat inactivation of hepatitis viruses in coagulation factor concentrates, under the protection of glycine and sorbitol."

Then I don't think we need to go through it any particular detail, but we can see from the headings there was a discussion about the work being undertaken in relation to Factor VIII.

We can see from the next heading there's a discussion about the work being undertaken in

relation to Factor IX and we will see, in the second paragraph under the heading "Factor IX", it says:

"We agreed to continue sharing information on this."

And then the heading "Other information on virus inactivation" suggests there was a discussion about what else was going on outside of Edinburgh, outside of Oxford and Elstree, so there's a discussion of what it's thought is being undertaken by the commercial pharmaceutical companies.

I just draw attention, I don't think one can necessarily make much of it, but the very last few lines on that page you'll see the reference to Immuno, and then it says:

"... (unconfirmed speculation from Dr Boulton's notes of Immuno's recent seminar -- is the Chairman, Professor Bloom, reporting to us?)"

I don't know whether that's a reference to the January 1983 meeting at London Airport. It may well be.

SIR BRIAN LANGSTAFF: It sounds like it.

MS RICHARDS: It does sound like it.

Then if we go over the page, under the heading "Miscellaneous", if we just look at the last paragraph -- again this is relevant to the question of

sharing of information between the different organisations -- Dr Smith says:

"I was given a copy of PFC's 1982 R&D reports without strings. I propose to acknowledge receipt formally, keep custody of the collection, but obviously interested parties will wish to consult them. I will circulate copies of contents."

So, again, we can no doubt explore that further with Dr Foster next week, but that was Dr Smith's recollection of that particular visit.

Then, finally, Dr Smith's evidence to the Penrose Inquiry looked at the question of the relationship between England and Scotland in this regard. It was obviously a matter of greater concern to the Penrose Inquiry, so there were a number of questions that Dr Smith was asked about the extent to which there was any degree of working together between the different fractionation centres. And you'll recall that Dr Smith produced a supplemental note which addressed this issue specifically.

So if we go to that, please. It's PRSE0004368.

Page 8. So this was Dr Smith's supplemental note 6 on "Collaboration between PFC and PFL/BPL in the period 1981-87".

You'll see the headings in Dr Smith's terms,

I think, rather than terms which the Penrose Inquiry had used. So the first is "The Huff". I'm not going to go through the various documents which are referenced here, but we can, I think, get a sense of what Dr Smith was referring to. He refers to a note from Dr Cash and says:

"Dr Cash puts at least the Scottish case for a history of cross-border negativity. The same Note also unwittingly reveals prejudices of the kind which may explain why some Scottish 'bridges' might end in mid-air, having neglected or hindered the construction of a pier on the opposite bank. One might speculate that 'senior levels' may felt able to maintain uncompromising positions, secure in the knowledge that they would not be identified with interrupting scientific and technical progress."

Then he refers to an apparent impasse between PFC and BPL.

So without wanting to anticipate evidence that we may hear in due course, there is a sense of some degree of difficulty, some degree of hostility in relationships between PFC and BPL or PFL.

What Dr Smith then goes on to say in this note is that certainly didn't translate -- if it existed, it didn't translate into any impediment to the working

relationship and sharing of information between him and his colleagues and Dr Foster and his colleagues.

And I'm not going to go through the note in any detail. It would take too long to read out. But we can see, for example, if we just go to the bottom paragraph on this page, he refers to Dr Foster generally keeping information on pasteurisation flowing, he talks about PFC keeping him informed of various approaches that they were undertaking, and so on.

Then, finally on this topic, again as part of the Penrose evidence, if we go to PRSE0002057.

These are, as we saw yesterday, Dr Smith's comments on a chronology put together by the Penrose Inquiry.

We just go to page 3. If we look towards the bottom of the page, you will see there a reference, and I'll pick it up, I hope, when we get to the statement of Dr Lane, but there was a reference to there being "furtive arrangements" between Dr Smith and Dr Foster, and you can see, this is from Dr Cash, just above the italicised passage, it says:

"It is my intention to see what I can do to build these bridges. I do not regard the existing furtive arrangements, as regards factor VIII between

Jim Smith and Peter Foster, however good they may be, as a sound basis upon which the NHS fractionators can combat the commercial people."

Dr Smith's observation is this:

"I continued to be puzzled by Dr Cash's term 'furtive'."

Then he refers to the establishment of a group of which Dr Foster was an active member, and he says that he, Dr Smith:

"... was in touch with other members of the Group throughout the period of interest, and that was never characterised as furtive."

And it's right to note that Dr Lane also said there was nothing furtive. We knew that Dr Smith and Dr Foster were in contact.

Then if we go over the page, if we just pick up the second box, this refers to a letter from Dr Foster to Dr Smith. We don't need to look at the underlying letter but the general observation that Dr Smith made, and this is the third line of the italicised section:

"PRF [Dr Foster] is offering encouraging results very freely, and it would seem that I was responding in kind, since he raises topics obviously of continuing interest to both of us. The final paragraph confirms that we respected confidentiality

and we knew there would sometimes be limitations on sharing."

And then -- yes, sorry, if we just go towards the bottom of the page, it's the third box from the bottom. There's reference to another letter from Dr Foster to Dr Smith, this is in May of 1983, and Dr Smith's italicised comment is:

"Illustrates continuing expectations of shared interests and free contact at a scientific level with BPL as well as with JKS [Dr Smith] at PFL."

That's Dr Smith's account or a potted summary of Dr Smith's account of the relationship from his perspective, at least with his scientific colleagues in Edinburgh.

Sir, the next topic to touch on relates to some observations Dr Smith made in his statement to this Inquiry about pool sizes and some of the specific work that was then undertaken at PFL in relation to what was described as "limited-donor" or "restricted-donor pools".

There will be a broader look in the course of one of next week's presentations for widely at pool sizes, so I'm not going to seek to anticipate that, but I am just going to draw your attention to what it is Dr Smith said in his witness statement on the

topic.

We can pick it up in his statement to this Inquiry at WITN3433001, page 41.

You'll see he identifies three different kinds of starting pool: normal pools, that's paragraph 114; small pools, 115; and then, if we just briefly go to page 43, at paragraph 120, limited-donor pools.

So those are three types of pools which Dr Smith then described further in his statement.

If we go back to page 41, I'm going to start by looking at what he said about normal pools. So he said this in paragraph 114:

"Unless noted below, the default pool size was 200 L (containing about 800 single donation) at PFL, and up to 1500 L (about 6,000 donations) at BPL."

So that was the normal size: 800 at PFL and 6,000 at BPL. It does change from time to time but I'm not going to try to pick up that level of detail today.

The standard product produced at PFL and at BPL was made from these normal pools. So HL was produced by BPL from these normal pools, 8CRV was produced at PFL from these normal pools.

Then if we go to page 44, we can see -- I don't need to read it, but at paragraph 121 Dr Smith set out

the products that were made from the normal pools, the standard vial of intermediate purity concentrate.

And then if we go to ... I'm sorry, I've missed the reference. I can give you the reference in the presentation in any event.

Although the PFL pools were smaller than the BPL pools, Dr Smith said they were never less than 300 donations, and at no time fitted within a definition of what would be described as a small pool.

So that's the position in relation to the bulk of the factor concentrates produced by PFL and BPL.

If we then look at Dr Smith's observations about small pools.

If we have the statement back onscreen, Paul, and go to page 41.

So there's a description in paragraph 115 and over the page about small pools. I don't propose to look at that in any detail this morning because what Dr Smith there sets out, as his statement makes clear, was not actually something that was in use at either PFL or BPL.

There are two contemporaneous documents which contain some discussion about issues relating to pool sizes, however.

So if we start with CBLA0001342_001.

No? Ah. Do you have BPLL0007526, Paul?

Before we look at the document that we do have, I'll just tell you what the other document is and if necessary we can produce it for display after the break.

The first document I referred to, and the reference for the transcript is CBLA0001342_001, is a document authored by Dr Smith, 27 April 1981. And it's called "A comparison of freeze-dried concentrate and intermediate purity concentrates as major products for national self-sufficiency in Factor VIII".

I think I can probably just tell you what's in it without the need to show it to you. It contains a discussion by Dr Smith of frozen cryoprecipitate. It then sets out his knowledge of production of small pool freeze-dried cryoprecipitate in other countries; in particular Netherlands, Finland and Switzerland are referenced.

He then talks about some use of large pool freeze-dried cryoprecipitate and different approaches being taken in Belgium and in France, and then talks about intermediate purity concentrate made from larger pools, which obviously was the product that was the product being produced at PFC and BPL.

He undertakes a comparison of the relative Factor VIII yields of the two different types of product, the freeze-dried cryo on the one hand and the intermediate purity concentrate on the other and then I'll just read his conclusion, which is short, before we then look at the document on screen. He said:

"Small pool frozen or freeze-dried cryoprecipitate has unique advantages for patients needing only infrequent treatment. The best means of meeting these requirements will receive more detailed consideration so that the conflicting aims of Factor VIII yield pool size, manufacturing, hygiene and quality control can be reconciled. However, a close examination of yields taken with a consensus of opinion on the relative safety and convenience of the two kinds of product supports the conclusion that the major component in our national strategy for Factor VIII production should be intermediate purity concentrate."

So I draw attention to that because it's a 1981 comparison by Dr Smith of concentrate versus small pool cryoprecipitate, with a knowledge of what was being undertaken in some other European nations. But with Dr Smith suggesting that the major component of the strategy for England and Wales should be the

production of Factor VIII concentrates.

And I should say that document was a draft produced for a working party on plasma supply.

We can then, if we look at the document onscreen, see a further memorandum from Dr Smith to Dr Lane dated 29 April 1981 on essentially the same topic:

"Small-pool freeze-dried cryoprecipitate and other small-pool products."

You'll see he refers in the first paragraph to a meeting that took place on 23 April 1981, with representatives of the National Blood Transfusion Service and the DHSS. Reference to Haemophilia Centre Director representatives stating their preference for intermediate purity concentrate as the major component in the national supply of Factor VIII. But there's then a discussion about the availability of a degree of cryoprecipitate.

And so there's then a discussion under the heading "Product specification":

"How should we 'design' this product in response to the stated needs?"

There's a number of references there set out. You'll see the reference to pool size, and a reference there again to the pools in France and Belgium.

Then if we go over the page, there's a discussion under the heading "Plasma sources" about plasmapheresis as a major source of plasma for Factor VIII. He refers to a practice in Belgium of a small panel bled at 10 litres per annum, and then sets out a number of other considerations in that regard.

Then we have the heading "Fractionation technology", and there's a discussion of small-volume pools, eg 2kg or ten donations.

Then if we go to the next page, a discussion of larger pools. And then he says:

"This approach is dependent on the kind of intensive plasmapheresis programme operated in Belgium, and some dilution of the current concept of 'accredited' pools, but would approximate more closely to a defensible process for central fractionation."

So it was a discussion document looking at the possibility, as I read it, of the use of substantially smaller pools. Dr Smith's statements, however, explained that this was not something that was ever put into operation at PFL or BPL.

I think I don't have the reference -- or maybe I do. Sorry. If we go back to his witness statement to this Inquiry ... yes, perhaps I can just pick it up at page 43, paragraph 119.

He described this, in paragraph 119, as:

"... one aspect of [his] contingency thinking in the very early 1980s, unable to see on the horizon a quick solution through validated screening of donations or some yet-unspecified means of inactivating NANBH, which at that time posed the most immediate threat."

So this was a thought process consideration, but not actually put into practice, even as a contingency measure.

What was done on a limited basis at PFC is what Dr Smith described as the use of limited-donor pools.

So Paul, if we have the witness statement back on page -- thank you.

So paragraph 120 refers to the limited-donor pools.

And if we go over the page, we can see at paragraph 123 he says -- in contrast to the small pools at paragraph 122, where he says that was never developed, at paragraph 123 he describes how a small number of batches of 8CRV were produced from limited-donor pools.

You'll see there the reference to "Green 4 plasma". What this was, was an arrangement for the collection of plasma organised through Dr Angela

Robinson, whereby, at her Transfusion Centre, in Leeds, plasma was collected by plasmapheresis from experienced blood donors whose last four blood donations had elicited no case of symptomatic hepatitis in their recipients. And they were dubbed "Green 4 donors". The donations would be quarantined for a period of six months in case there was the intrusion of a late infection of hepatitis.

So it's somewhere referred -- elsewhere referred to as "restricted-donor" or "restricted-panel", so there isn't an entirely consistent use of terminology, but the terminology adopted in Dr Smith's statement to this Inquiry is to refer to them as limited-donor pools. Only the Leeds Regional Transfusion Centre was involved in collecting the Green 4 plasmapheresis donations.

Dr Smith's recollection in his statement was that the plan was for these products to be used by Dr Rizza in the Oxford Haemophilia Centre, mainly to provide an insight into whether that method of recruiting or obtaining plasma from repeat donors who were thought to have a reduced risk of hepatitis might make a difference to non-A, non-B infection rates for at least the most susceptible patients.

Dr Smith's recollection was that Dr Rizza

reported verbally to him some apparent transmissions from this product which would be consisted with one or two of even these highly selected donors being infective. What Dr Smith then said in his statement was that this project, this Green 4 restricted pool project, then essentially became caught up in the demand for heated products and essentially was overtaken by heat treatment.

If we then, just on the question of whether this is a trial that could have been scaled up to a larger scale in the 1980s, Dr Smith said this ... I'll just find the reference. Page 54. He suggested in paragraphs 154 and 155 of his statement that it wouldn't have been feasible to produce Green 4 products on a larger scale. He said in paragraph 154:

"It would have taken almost as much equipment and trained staff to process each of the [smaller] pools as to process a single [larger] pool. The QC burden rises ..."

So he says it wouldn't have been feasible at BPL's scale. At paragraph 155:

"BPL could not have accommodated the staff and equipment to run multiple 100-litre pools of accredited plasma."

And he suggests another major issue would have

been the recruitment and training of the teams of appropriate staff.

And then paragraph 156, he confirms the proposal or the consideration of the project overtaken by the virus inactivation measures, by which he is referring to heat treatment.

That then leads neatly to the question of heat treatment, in which Dr Smith was very closely involved in terms of the work undertaken at PFL.

As you will have heard from Mr Hill in the course of this week, there were essentially three different ways in which heat-treated product was made available through PFL or BPL. There was a very limited trial of heating 8CRV, and I'll pick up upon a number of references in late 1983, which led to that product being given heated to three patients but only three patients in March of 1984. So that was the first time heated BPL, or PFC products I should say -- sorry, PFL products -- were used in patients.

There was then, in the later part of 1984 into 1985, as Mr Hill explained, the products of 8CRV and HL that were held in stock, or were in the pipeline, were heated as an interim measure whilst the production of 8Y was being scaled up. And then, finally, there was the production of 8Y rolled out in

the course of 1985.

I'm going to ask you to look now at Dr Smith's 1990 draft proof of evidence at CBLA0000016_034. This contains, of all his various statements and oral testimonies, the most detailed account of the work undertaken in relation to heat treatment.

We pick it up at page 12. He explained in paragraph 30 -- and, again, one must obviously understand this was a draft statement never finalised, and so on, but Dr Smith said no reason to think it was inaccurate. He said in paragraph 30:

"My involvement with the idea of heat treatment can be traced back to 1981, during the course of which I reviewed potential research and development work."

And he refers to, in the documentation at the time, passing reference to heat treatment. That may be a reference to the documents that both Mr Hill and I have shown you from 1981.

He then said in paragraph 30:

"... it was not until November/December 1982 that heat treatment began to emerge as a topic for further study. At about the same time, we thought of the possibility of using small pools of donations from donors with a long history of trouble-free donations to provide plasma."

And that's the reference to the Green 4 plasma that I spoke about a few minutes ago.

He then in paragraph 31 said this:

"At the time, we had no research and development virology capability at PFL or BPL. The initial catalyst for starting experimental work on heat treatment was informal contact between the Plasma Fractionation Centre in Scotland and PFL in about November 1982. During the summer of 1982, we'd begun to get word of some success in the field of heat treatment through the usual gossip at scientific meetings, and in November 1982, Dr Peter Foster at PFC telephoned me to discuss some work which they were doing on the heat treatment of Factor IX."

Dr Smith then said in paragraph 32:

"... worth putting the commencement of this activity in the context of some commonly held beliefs in 1982."

If we go over the page. I'm not proposing to read these aloud, but it's important to note what he set out in paragraph 33 was a concern or view or attitude at the time that Factor VIII could be modified by processing in a way that could potentially be harmful. So that was one of the underlying concerns.

And then paragraph 34, just go further down the page, raises the question of yield, and if we go over the page, whether heating might result in a significant loss of yield of Factor VIII in the heated product.

If we then go to page 15, please, Paul, paragraph 37. We looked at the introduction to this paragraph yesterday when considering hepatitis. And then, as I mentioned yesterday, what Dr Smith set out in his draft proof is a range of different potential options in relation to ameliorating the risk of hepatitis.

If we go over the page, we can pick up towards the bottom of the page, "Pasteurisation", and then we'll see shortly "Dry heating" on the next page.

So Dr Smith described here pasteurisation:

"... thought to be highly effective against viruses ... also familiar and acceptable ... clinicians through its use in relation to albumin. However, there was still no convincing clinical trial at the time that showed hepatitis inactivation by pasteurisation of Factor VIII."

There's reference then to what was understood to be the position in relation to the work undertaken by Behringwerke.

And then if we go to the top of the next page, we can see Dr Smith said in relation to pasteurisation and BPL this. He said:

"This [that's a reference to potential problems of re-contamination] was compounded by the fact that, at the time, the BPL production facility had been criticised by the Medicines Inspectorate. The basic problem with pasteurisation, as perceived at the time, was that Factor VIII would not survive the process without the addition of non-physiological concentrations of preservatives which might also have the effect of preserving the very viruses the process was being used to destroy."

And he sets out a number of other issues relating to pasteurisation.

And then if we go to the next paragraph, Dr Smith introduced the idea of dry heating, which we know obviously was a solution that was ultimately adopted:

"It was thought that the low water content of freeze-dried Factor VIII would mean much lower virus inactivation efficiency by dry heating than by pasteurisation in solution."

Then if we pick it up a few lines from the bottom of the page:

"By the summer of 1982, it had been briefly reported by scientists working for Hyland that dry heating (rumoured to be 60ºC for 72 hours) prevented the transmission of hepatitis in Factor VIII concentrates when the product was used in chimpanzees."

Then he refers to:

"... unconfirmed abstracts presented by Rubinstein at a meeting ... in Budapest in August of 1982 ..."

Dr Smith then sets out a number of other possible methods of tackling transmission of viruses. I don't propose to go through those, but it's right to point out that neither pasteurisation nor dry heating were the only options under consideration.

Then we go to the next page. Indeed, this is where Dr Smith made that point:

"It was therefore against this background in 1982 that thoughts were moving towards heat inactivation, but as will be seen from the description above, this was only one of a number of potential routes to the goal of virus inactivation. It must be remembered that the work was undertaken against the background of hepatitis B ceasing to be of much practical concern and hepatitis non-A, non-B not yet

being recognised for the serious condition it later emerged to be. In the circumstances, viral inactivation, whilst desirable, was not an imperative."

So it might be thought a sense there from Dr Smith that whilst these were matters that were being considered, discussed, no -- the practical work in relation to pasteurisation, and in particular dry heating, was still in the future at this point in time, potentially for the reason he described there, that virus inactivation was seen as a desirable goal, but it was the emergence of AIDS which effectively translated it into an imperative.

Now, what we then have in Dr Smith's statement, and I'll just introduce this perhaps before we take the break, is a very detailed account drawn, if we look at the bottom of this page, paragraph 41, from what he talked about loose-leaf books describing the 8H and 8Y experiments. 8H was essentially a product that was developed in the course of the experiments but never actually went into production, never actually used. And then he describes those loose-leaf books being based in turn on the primary notebooks used at PFL. And what he describes over the page and in the pages that follow is essentially an almost

month-by-month account of the work that was undertaken at PFL.

What I'll do after the break, sir, is I'm not going to read it all out because that would take a very considerable period of time, but I'll just headline the various passages and the various different stages of the work that Dr Smith then describes. But perhaps I'll do that, given the time, after the morning break.

SIR BRIAN LANGSTAFF: Yes. Well, we'll take a break now, shall we, until 11.45. 11.45.

(11.17 am)

(A short break)

(11.45 am)

MS RICHARDS: Sir, before I go back to Dr Smith's 1990 proof of evidence, just to pick up the picture as at the end of 1982 from a couple of further comments he made on the Penrose chronology.

Paul could we go back to PRSE0002057, please.

Page 2, the penultimate row, we can see the entry there is 3 November '82, and the reference is a letter from Dr Smith to Dr Foster. The quote from the letter is:

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

fibrinogen removal."

And then this was Dr Smith's comment:

"ie, not with a view to inactivating viruses."

So that was as at November '82.

Then if we go over the page, and look at the entry, third entry down, 15 December 1982, there's reference to a BPL meeting. And then the observation in italics from Dr Smith, as at December '82 is:

"E&W [England and Wales] were still far from starting serious work on virus inactivation."

So if we then go back to the 1990 proof of evidence, CBLA0000016_034, and we pick it up at page 20, as I indicated before the break, what we get is a detailed description by Dr Smith of the work that was being undertaken.

So we can see it really starting in 1983, paragraph 45 refers to the start of the 8H project work taking the form of a proposal prepared by him in around February of 1983.

Sorry, we need the paragraph above that, Paul.

That's at paragraph 43.

And there, the suggestion was to concentrate on "heating in solution", and he refers to that work being assigned to Mrs Winkelman in June 1983.

There's a description in some preliminary work

being done up to May 1983 in relation to removal of fibrinogen and fibronectin.

Paragraph 45 talks about experimentation in June and July 1983.

Then if we go over the page -- as I say, I'm just really going to skate over this so you can see where it is, it really requires to be read at leisure -- Dr Smith then describes between August and December 1983 the work that was being undertaken in relation to -- and this is still pasteurisation which is being explored here, and we can then see, paragraph 47, he refers to the period January to July 1984, focused on the problems presented by fibrinogen before and after pasteurisation.

If we go over the page, paragraph 49 refers to the period July to October 1984, making batches of product on a sub-pilot scale.

And he describes this as -- and this is the fifth line of paragraph 49 -- "the very credible highest point in PFL's development in heating in solution". And then he explains in the last part of that paragraph that:

"... yield considerations and the difficulty of protected in bulky solutions of pasteurised Factor VIII through several stages of downstream

processing in an elderly facility at BPL told against this approach; no such product ever reached the GMP pilot-scale for chemical trials."

Then he explained between May and October 1984 the 8Y series of experiments started. Dr Smith put it this way:

"They started as a sub-plot in the pasteurisation story focusing on an unpasteurised product which would be an improvement on the intermediate purity concentration at equivalent yield, provide an untreated control for clinical trial and virus transmission by pasteurised concentrates, and offer the basis for alternative virus inactivation strategies to compare with pasteurisation compared with virucidal efficiency, yield, quality and safety in clinical use. The basic strategy was confirmed by August 1984. Dry-heating and solvent detergent options for virus inactivation had been subject to cursory examination by October 1984, and the first clean pilot batch ... was run on 16th October 1984."

Then he described in paragraph 51:

"The first ... pilot batch with a defined product in mind was run in PFL's GMP area on the 9th November 1984. This batch gave material for standardised freeze-drying and a wide range of

dry-heating temperature/time combinations, from which 80ºC for 72 hours was chosen as the most severe combination giving acceptably small losses in yield and quality. There were still no viruses inactivation data to support the effectiveness of this dry-heating. This batch became finished batch 8Y2201, dry-heated at 80ºC for 72 hours, and the first batch to be released for clinical trial in April 1985."

He then, paragraph 53, made this observation:

"It should be borne in mind that a development programme for a product such as 8Y normally takes three years, and in the event, because of course HIV was very firmly on the scene by 1984, the typical development programme was compressed into a few months. One consequence was that huge extrapolations were made about the product on the basis of very limited virus data. Clinical trials were organised with some haste but, of course in retrospect, the end product proved to be everything we hoped for."

Then if we go over the page he notes in paragraph 55 that "at least 50 independent and inter-dependent variables were studied during the overall development of 8Y", but adds "their significance would need lengthy explanation".

So that's an overview, but giving an account of

the different stages of the work, of how PFL got to, ultimately, the production of 8Y.

What Dr Smith then turned to in this statement, at paragraph 56, was the dry heating of Factor VIII concentrate in its intermediate purity form. We can pick that up in paragraph 57. He referred to the Groningen conference, which again we've already heard about from Mr Hill and indeed elsewhere in the course of the evidence, which was October 1984, but he explained in his statement, halfway thorough this paragraph, that:

"We had in fact already decided, as a consequence of discussions in September 1984 between myself, Mrs Winkelman and Dr Lane, to go all out for the production of a severely dry-heat treated product which was designated 8Y."

Explains that they were already engaged in heating 8CRV/HL in case they were asked for a heat-treated product.

He referred in paragraph 58 to there having been a universal prejudice against what he described as:

"... insulting Factor VIII, especially by protracted holding at an above-ambient temperature ..."

If we then go over the page, what we can see is

a further description, again by reference either to months or to -- individual months or a group of months of work being undertaken dry heating 8CRV.

So:

"In June-August 1983 ... it was found that dry-heating one batch of standard 8CRV at 60ºC for ten hours did not affect either recovery or solubility of Factor VIII:C, but that noticeable deterioration started at 80ºC for ten hours or 75ºC for 24 hours."

Then there's a further description of the experimental work that was undertaken.

If we go to the bottom of the page, Dr Smith referred to these experiments being extended to include the intermediate-purity concentrate from BPL, so to now include the HL product. That was October 1983.

Then if we go over the page, having undertaken those experiments, paragraph 61, Dr Smith said this:

"Dry-heating was then virtually shelved, as a promising option we could return to, while we went on with pasteurisation which we thought would inactivate hepatitis NANB more securely."

And then we pick up I think the picture for -- in the second part of paragraph 62, Dr Smith said -- oh no, sorry, that's a reference to PFC.

We pick up the picture in paragraph 63.

Sir, you will have heard already, both from Mr Hill and from what I've already said, that there were three patients who received a heated 8CRV before the events of late 1984 and then the ultimates roll-out of 8Y, and we have a description of that here from Dr Smith in paragraph 63. He says:

"... in March 1984, we were asked by Professor Stewart (based at the Middlesex Hospital), for a heated concentrate for a patient who was especially anxious not to get hepatitis. We prepared three batches for this and two further patients of Dr Colvin (from the London Hospital) from restricted plasma pools [presumably that's Green 4 plasma], and successfully heated the products at 60ºC for 72 hours. These were the conditions judged to be most likely to do at least some damage to hepatitis NANB in the light of rumours of competitors methods, whilst doing the least damage to protein. These three patients suffered no ill effects, but despite knowledge amongst some influential clinicians that dry-heated 8CRV could be provided if requested, there were no further takers until, on 12th December 1984 [I think that's probably a reference to the 10 December 1984 meeting at BPL which Dr Smith attended], the Haemophilia Centre

Directors told us that HIV was a greater evil that possible hypothetical immunological consequences. I am almost certain that Dr Rizza, Prof Bloom, Dr Preston and other Reference Centre Directors knew that dry-heated 8CRV was available on request in 1984. Although no one was formally told the product was available I believe this was spread by word of mouth, etc."

I'll come back to the rest of the statement in a moment, but if we can just go to the statement to this Inquiry at WITN3433001, and go to page 47.

Dr Smith was asked about why he thought there were no further takers of this product until December 1984, and he said:

"I would have thought that by mid-1984, with convincing evidence of a viral aetiology for AIDS and its prevention in patients undergoing trial of heated, 'hepatitis-safe' commercial concentrates, without any marked incidence in inhibitor formation or other detrimental effects, the benefits of heating must be outweighing speculations about inhibitors ... and the even more speculative issue of neoantigens."

And then if we go -- that is his answer, so it's not necessarily a direct answer to the question, but he does set out his view that he would have thought

that by mid-1984 -- as I read it, he's saying that the benefits of heating ought to have been, or might well have been thought to be apparent to clinicians.

It doesn't obviously help in understanding why there was no further take-up of the facility which had been made available to Professor Stewart for one patient and to Dr Colvin for two patients.

We'll look this afternoon at what Dr Lane had to say about that as well.

If we then go back to the 1990 HIV proof -- sorry, HIV litigation proof, CBLA0000016_034, and go to page 27. Paragraph 64 then explains the position really towards the end of 1984. Dr Smith said:

"... BPL was committed to the 8Y product but had only got as far as two pilot-scale runs at PFL. Time is needed for BPL to learn the method, tool up for processing, specify order, build, deliver and commission the large heating ovens necessary."

Then he sets out the position therefore that was decided until the launch of 8Y, which was to heat the existing batches of 8CRV and 8L using what Dr Snape described as method two, HT2.

If we then go over the page to page 28, you'll see that Dr Smith also set out a detailed narrative of the work undertaken in relation to Factor IX.

He said in paragraph 67 that:

"... the work in this regard began somewhat earlier than the similar work in relation to Factor VIII, [and] the period during which the work took place spans 1982 to 1985."

He explained in paragraph 68 that:

"... dry heating [as with Factor VIII] grew out of work on heating Factor IX in solution."

Explained that the:

"... Factor IX yield of pasteurisation never looked as promising as for Factor VIII."

But then set out in paragraph 69 the additional complicating factor in relation to Factor IX, which was the issue of potentially causing thrombosis.

I'm not going to go through the detail of it, but if we go over the page, you will see that in relation to Factor IX, again, Dr Smith set out by reference to particular periods of time from 1983 onwards, or indeed I think from November 1982 onwards in relation to Factor IX, the work that was there being undertaken.

And that part of his statement continues. If we go to page 32, we can see at paragraph 80, picking the picture up in the second half of 1984, he says:

"Between July and December '84, work on dry

heating was resumed [and] the most severe conditions giving good Factor IX recovery were fixed at 80ºC for 72 hours. The last problem, thrombin generation, was confirmed in further batches in about December 1984."

Then there's further work described in the following paragraphs in relation to addressing the difficulty in relation to the presence of thrombin.

And that description of the work in relation to Factor IX continues to paragraph 86, page 34 in his statement. I am not going to go through the detail of it, but it's there.

What I want to do next, sir, in relation to heat treating is now look at some of the contemporaneous documents, some of which are referred to in Dr Smith's various statements, some of which are referred to in Dr Lane's draft proof of evidence. But it's convenient, I think, to pick them up whilst we're looking at Dr Smith's evidence.

So if we start with CBLA0001691. Some of these documents but not I think most of them -- but some you will have seen with Mr Hill in the course of the week.

This is a memo from Dr Lane to Mr Mallory, but it's copied to a number of other recipients, including Dr Smith. It's dated 24 March 1983. You can see it's headed "AIDS". It refers to Professor Bloom having

drawn:

"... to the attention of the CBLA at their meeting on ... 23 March problems that are becoming associated with blood transfusion and blood product administration with the increasing incidence of reported AIDS cases ..."

The second paragraph describes that Professor Bloom will continue to keep the CBLA informed. Dr Gunson will be attending a Council of Europe meeting.

Third paragraph says this:

"Meanwhile, patients potentially at risk in the UK, notably haemophiliacs, are evidently concerned, and resistance against the use of imported American coagulation factor concentrates is becoming apparent. Equally, there's a likelihood that a return to cryoprecipitate is a desirable form of treatment may become irresistible whether logical or not.

"It is necessary for this laboratory to develop a policy which may only be implemented on a short-term basis, which will allow for the presentation of a large proportion of NHS Factor VIII as cryoprecipitate. Staff will be aware that many Regional Transfusion Centres have not made wet cryoprecipitate for some time and would now be both

out of practice and, in some cases, without the facilities to recommence large scale production."

Pausing there. That's not particularly reflected in the oral evidence that this Inquiry has heard from a number of Regional Transfusion Directors.

SIR BRIAN LANGSTAFF: No, it isn't.

MS RICHARDS: Then this, and it may be an important sentence because it may help understand Dr Lane's perspective on this. He said this:

"The implications for BPL source material are very real."

SIR BRIAN LANGSTAFF: Just unpicking that paragraph. Does he mean, when he speaks about the policy which will allow for the presentation of a large proportion of NHS Factor VIII as cryoprecipitate, is he really saying: we should not ask for as much plasma from the regions because they will be expected to use that plasma themselves -- hence our policy will allow for this -- to make cryo? We, for our part, will go on doing what we get, but we must expect less. That may the implications for the source material. That's how it might fit together.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: I wondered earlier what the rather strange description "which will allow for the

presentation of large proportion as cryoprecipitate" was intended to say. And it has occurred to me, actually just recently, that it might mean what I've just suggested to you.

MS RICHARDS: It might do. We know, of course, that isn't what happened --

SIR BRIAN LANGSTAFF: No.

MS RICHARDS: -- but it might do.

SIR BRIAN LANGSTAFF: But that would mean that what he is really saying is, "We may have to do this, but it's got implications for us."

MS RICHARDS: Yes.

And then just to continue with the next paragraph, because this is what then leads to a meeting in which Dr Smith was involved, Dr Lane said this:

"A meeting involving those circulated with this memorandum should be set up at the earliest convenient opportunity to discuss the strategic alternatives at BPL for manufacturing small pool freeze-dried cryoprecipitate to offset the requirement for manufacturing at BTS level. Considerable adjustments to resources should be envisaged and taken account of. Equally, a (temporary) fractionation programme commencing with cryoprecipitate supernatant from the

BTCs should also be taken into consideration. The implications concerning Factor IX production will need to be examined and the potential benefits of pasteurisation of Factor IX given some priority."

And so he then asks for a meeting date to be set up.

SIR BRIAN LANGSTAFF: I suppose that fits with the suggestion I've made as to one way at least in which the third paragraph up from the bottom might be interpreted.

MS RICHARDS: Yes. And it appears that Dr Lane was throwing out ideas, I suppose. One of which is whether BPL could turn to the manufacture of small pool freeze-dried cryoprecipitate, it would appear. Although, again, we know that didn't happen, but it's an idea that he is there identifying for discussion.

The meeting that took place, pursuant to the memo on the 18 April, is at BPLL0008758. We can see that the first item of the meeting is "AIDS", the Chair of the meeting is Dr Lane, and the first paragraph tells us that Dr Lane:

"... advised the meeting that Professor Bloom had raised the subject of AIDS ... and at the next CBLA meeting, he [that's Dr Lane] wished to respond to any questions raised on AIDS."

Next paragraph refers to:

"Letters on AIDS have been circulated to Haemophilia Directors by the supra-regional directors. BPL has to decide now whether to change course if a move away from concentrates (Factor VIII and Factor IX) is requested."

There's then a discussion. Mr Vallet refers to recommendations from the US about donor screening and other matters. You may wish to note the paragraph beginning:

"No directive has been issued with regard to Factor VIII. Discussions with Dr Aronstam indicated that the relationship of AIDS to haemophiliacs had not been established, nor the extent of the risk."

Now, it's not clear from this who had held those discussions, whether it was Dr Lane -- perhaps most likely Dr Lane -- or whether it was one of the other attendees, but that is what is being reported back.

Reference to the producers of concentrates being concerned. An expectation that there will be a statement. And then --

SIR BRIAN LANGSTAFF: That's from the Bureau of Biologics?

MS RICHARDS: Yes.

Then if we look at the last paragraph on that page:

"Dr Snape stated that the BOB [Bureau of Biologics] reaction was predictable and that an association was now being formed between heat treated concentrates in reducing the risk from AIDS."

And obviously Dr Snape can be asked further about that when he gives evidence.

But if we go over the page, we then have:

"Dr Lane commented on the price increase now being seen for commercial concentrates, and the emphasis on marketing hepatitis-reduced risk material."

And then this from Dr Smith:

"Dr Smith remarked that at the present time there was little firm knowledge on how effective heat treatment is on non-A/non-B or AIDS, nor what the effect on yields would be."

Then various comments recorded:

"1) Do the UK haemophiliacs perceive the threat as serious as do the USA?

"2) Is large pool material worse than small pool?"

The answer that's given, apparently, is there's "very little evidence in this area".

"3) What would be the effect if BPL only able to produce one half of the UK requirement of F.VIII,

if heat treated yields were much lower than those seen currently for normal material.

"4) The arguments for non-A/non-B and AIDS were separate and different with respect to risk, eg the risk of non-A/non-B were seen in low and medium users, whereas AIDS would be of greater risk to heavy users.

"The Director asked the meeting to consider a situation where AIDS was established in the UK and that some haemophiliacs had evidence on an altered immune state (AIDS related or not) -- what is the ability of BPL to respond to a request to make small pool material, or that only heat-treated product was required by the Haemophilia Centres?

"The general feeling was that a response to these requests would be difficult."

There's then a reference to US plasma sources. And then it said:

"The UK is different in that only large donor pools are used, ie there is still no major use of small panel plasmapheresis plasma, and that plans are in progress to increase plasma collection primarily by the use of SAG(M) with secondary use of plasmapheresis."

It's said:

"It would be difficult to change the philosophy,

once major progress had been achieved in the SAG(M) programme. In addition, the use of small panel accredited donors would be very expensive."

Over the page picking it up in the second paragraph:

"The answer to the AIDS question was therefore to consider what was feasible and what was not. Thus, if BPL was to be involved in the preparation of small pool concentrates, free of AIDS, there would have to be an extensive pool of accredited donors (or at least a high follow-up procedure for donors)."

There's then a further discussion in relation to that. Then if we just go a little further down, we see a paragraph beginning:

"The Director asked Dr Smith whether BPL should promote the collection of small pool material into a working programme, eg by the use of increased Leeds Haemonetics material (currently 100kg/week)."

That's the Green 4 plasma programme that I was referring to before the break.

"Dr Smith felt that Dr Robinson ... would be unwilling (for reasons associated with the present programme) or unable to provide significant increases in Haemonetics plasma."

So there appears to be a consideration of the

question could they ask Dr Robinson for more, and this is the response from Dr Smith.

Dr Smith is then recorded as suggesting:

"... that the meeting differentiate between small pool (ie small volume pools) and small panel (ie large volume pools with few donors) and asked whether BPL should not be making small panel F.VIII and F.IX in addition to the normal concentrate. If the answer was yes, a careful costing exercise would need to be carried out. The general feeling of the meeting was that BPL should go for both small panel and heat treated products.

"The overriding concern was that in trying to provide full UK demand with a secure product, BPL may end up not being able to say supply the demand.

"The Director also asked whether the current problems posed by AIDS could be used to obtain financial support for more work in this area.

"Several views were expressed -- notably the lack of space and staff, and the doubts on which programme of direction to follow. The overriding view was one of wait and see."

And then there's a reference to Dr Harvey discussing some findings of Dr Kernoff in relation to non-A, non-B hepatitis.

So the meeting then goes on to discuss other matters which I don't think I need to take your time with.

There is a further discussion about Haemonetics, plasmapheresis plasma, bottom of the fifth page and top of the sixth page of the meeting minutes. But that's the discussion, with the end result appearing to be a "wait and see" approach, and I'll pick up some of that again when we look at Dr Lane's draft proof of evidence.

So that's April 1983. The next contemporaneous document which I think helps illuminate what was happening is CBLA0001786.

This a memo from Dr Smith to Dr Lane and others, 3 January 1984, "Proposal for Special Preparation - 8CRV pasteurised dry".

Then under the heading "Introduction and Motivation", Dr Smith referred to work being undertaken by commercial companies, and he sets that out.

Third paragraph he says:

"Faced with the publicity over AIDS, it is understood that Hyland took the decision in May to issue only dry-heated Factor VIII in future, although heating was almost certainly introduced to combat

NANBH ... and there is only an unsupported hope that the transmissible agents of AIDS, if any, is heat sensitive."

Then Dr Smith explained that:

"We elected to try dry heating of our existing product 8CRV with the following reasons and reservations."

And we saw from the narrative account in his 1990 draft proof of evidence the work that was being undertaken at this point in time in relation to the 8CRV.

So he explains there a number of reasons and reservations:

"1.1. Faced with the understandable anxieties of patients over AIDS and the insinuations of commercial producers, the Haemophilia Centres feel the need to offer at least some hope that NHS products will carry a reduced risk of transmitting AIDS."

"1.2. Although the evidence from Hyland's study of (presumably) dry-heated factor VIII in chimpanzees is unsatisfactory, there was a suggestion that the infectivity of NANBH had been reduced or attenuated by heat treatment.

"1.3. It is now common to meet the assumption that virtually all patients receiving either

commercial or NHS factor VIII or factor IX for the first time will contract frank or sub-clinical infection with NANBH. Incubation period and severity may differ, but the long-term sequelae are equally feared."

Now that appears to be, by January 1984, a recognition of the potential seriousness of the longer-term consequences of non-A, non-B hepatitis in contrast with what we saw earlier.

The fourth point is this:

"1.4. We recognised the lack of evidence for dry-heat inactivation of either HB or NANBH in factor VIII; the work from PFC suggests that some hardy model viruses are inactivated only very slowly at 60ºC, even in solution, and one might predict that heating in the dry state should be less effective (and possibly more variable) than heating and solution."

Then, 1.5, he says this:

"Our late start in more rigorous inactivation studies might leave us without a product to offer for a year or more, by which time many of the small group of suitable patients would have been committed to testing other products."

Over the page, 1.6, he says:

"There need be no intention to convert all

BPL/PFL product to dry-heating, at least on the grounds of NANBH reduction; given the clear-cut pattern of infectivity of current concentrates, a few batches for clinical trial in a modest number of suitable patients might suffice, and a decision to widen this application might be taken on the success of this and commercial dry-heated factor VIII."

And pausing there, this is January '84 and it was March '84 when, indeed, dry-heated 8CRV was supplied to the three patients that Dr Smith described in his 1990 proof.

And then at 1.7 he says:

"We might expect that, even if dry-heating would not completely inactivate 'high concentrations' of NANBH in commercial factor VIII, heating factor VIII from a potentially cleaner source plasma might tip the balance toward non-infectivity in at least a proportion of patients."

He then sets out a strategy, methods, records results.

If we go to page 5, I'm not, in the interests of time, going to go through all of this, but we can see there's a heading just over halfway down the page "Selection of batches for heating and clinical trial", and at 6.3 he says, picking it up in the second line:

"... it seems reasonable to apply dry heat first to those batches already carrying the minimum risk, ie, Haemonetics batches."

Reference in 6.4 to his understanding that Dr Rizza was seeking permission to use an Armour heat-treated concentrate.

Then over the page he sets out a number of practical considerations. Again, in the interests of time I won't go through that, but they're, I think, not unimportant.

So that was 3 January '84. There's a further memo from Dr Smith, just -- about two weeks later, at CBLA0002487. This is in relation to hepatitis safer Factor IX concentrates, and he said this in his memo to Dr Lane and Dr Snape:

"While we are considering how best to proceed with 'hepatitis-safer' factor VIII concentrates, we should reflect on a parallel procedure for factor IX concentrate. The main differences from factor VIII are ..."

Then he sets out four differences:

"(a) the safety of heat-treated concentrates may deserve more rigorous study, eg with respect to thrombogenicity.

"(b) there is no overt competition from imported

concentrates ...

"(c) there are far fewer congenitally deficient patients, and most have been treated generously or even prophylactically.

"(d) there are semi-legitimate applications in acquired deficiencies, currently discouraged for fear of transmitting hepatitis."

Then he sets out some figures about the numbers of Factor IX patients in the United Kingdom.

If we pick it up in -- it's the penultimate paragraph beginning "The average annual use", third line down in that paragraph:

"Even if we cannot get the level of information which seems to be forthcoming for factor VIII concentrate, I believe we should be doing our best to get the safest concentrates to the most important patients -- those seldom or never treated before and the younger patients who might benefit most from less frequent insult with infective material."

Then he sets out a potential strategy over the page. He says:

"I do not think that small-panel factor IX will be sufficiently reliable to open up to the other category of high-risk patients. However, that possibility may be more real for dry-heated

concentrates and we should be prepared to acknowledge this difference between the factor VIII and factor IX trials at the next stage."

Then this:

"Swift application of the few measures at our disposal will help to persuade our customers that we are taking the problem seriously and may even help to keep one or two patients out of trouble."

That's then, the beginning of 1984, the experimental work and research and development work, as I say, we've seen described in the 1990 proof of evidence.

Sir, I'm going to pick up the contemporaneous documents, then, up next in November of 1984, at CBLA0001920.

This is a memo from Dr Smith and others to Dr Harvey, 12 November 1984. It's headed "Options for heat treatment of coagulation factor concentrates", and he said this:

"This memo is intended to survey what products have been developed to meet the [need] for safe concentrates, what stage they are at, what they are expected to achieve and when they might provide clinical products first from PFL and then from BPL."

Then we can see Dr Smith and the co-authors of

this document set out under the heading "Factor VIII concentrates" a number of categories: "Restricted-pool 'intermediate' specific activity concentrate, 8CRV", which we've already discussed.

And that's the reference, in terms of the restricted pool, to the Green 4 plasmapheresis donors, courtesy of donations collected at the Leeds Regional Transfusion Centre.

Then 1.2 "Dry-heated 8CRV or HL".

There's then a further description of the work in that regard.

If we look at the sentence that's been underlined in the penultimate paragraph, that refers to the three patients who had been given the heated 8CRV earlier in 1984, and Dr Smith says those:

"Three patients have received large doses of dry-heated 8CRV, none has contracted hepatitis or AIDS to date."

Then over the page there's a lot more detail about the heating of 8CRV, which I won't go into, but then at the bottom of the page we can see there then the new product, a new concentrate of higher specific activity, 8Y:

"This product has been under intensive development only since July. It was designed not

primarily as a clinical product in its own right, but as an intermediate more suitable than 8CRV for heating in solution ... It is now evident that, besides meeting that requirement, it is suitable for

"(a) finishing as a product with advantages over 8CRV or HL

"(b) dry-heating with highest ability than 8CRV or HL

"(c) inactivation of lipid-enveloped virus eg NANBH by detergent treatment."

Then, over the following page, Dr Smith gives further information about the work being undertaken effectively to scale up production of 8Y.

Then if we go to page 5, there's a similar description in relation to Factor IX concentrates. So paragraph 2.1 deals with dry-heated 9D, explains -- and 9D was the existing Factor IX concentrate that was produced. Dr Smith said:

"As for factor VIII, dry-heating was approached somewhat sceptically, as a first stopgap pending heating in solution. However, there is now a lot of evidence that 9D will withstand much more severe dry heat than 8CRV without loss of quality ..."

But he then goes on to talk about the problem in relation to thrombogenic activity and the need for

dog trials.

Then we get a description, at 2.2, production of "9D and 7D heated in protected solutions", a number of obstacles to that as a course of action. And then there's a discussion towards the bottom of the page of other treatments.

We know, of course, that dry heat was the solution adopted both in relation to 8Y and what became 9A, but it's worth noting that, even as at November 1984, this still seems to be, as it were, a relatively recent development and understanding that's being described.

There's then a meeting at CBLA0001923 which discussed the implications of the memorandum that we've just looked at. So we can see it's an internal meeting on 13 November to consider options for heat treatment of Factor VIII. Dr Smith was one of those present, and the first sentence refers to Dr Smith's memo.

I don't need to go through the details of the discussion, but if we go over the page to the paragraph just over halfway down the page headed "Target date for implementation of heat treatment", we can see the decision that's then taken:

"Following Dr Lane's remark prior to the

meeting, it was recognised that every effort must be made to start heat treatment as soon as possible. It was realised that undue delay may be caused because of the formal tendering requirements. Once the specification for the ovens was available, it was agreed that Dr Lane would be consulted in an attempt to bypass some of the requirements.

"A very provisional date of 1 April 1985 was set, although it was recognised that at this stage it is impossible to judge its feasibility."

So that was the planning ahead as at November 1984.

There's a further memo from Dr Smith, 20 November '84, at CBLA0001926. So this is headed "Clinical use of dry heated restricted pool 8CRV". And if we look at the first couple of paragraphs, Dr Smith said this:

"In our haste to commit national Factor VIII supplies to emergency measures, there's a danger of losing information which can never be retrieved again. Although non-A, non-B hepatitis is not seen as the main problem for the moment, and it looks as if restricted pool trials (including the control element in the northern centres trial) are dead, we still have a unique opportunity to learn more about non-A, non-B

hepatitis transmission if we are selective about the first use of dry heated 8CRV intended to prevent transmission of AIDS."

And there is then a discussion of the arrangements for the heating of the stockpile of 8CRV and an identification of the categories of patients for whom that could be made available.

I'm not going to go through the detail of that because, to some extent, it was overtaken by then the meeting on 10 December 1984 at BPL at which a strategy in relation to use of concentrates was agreed.

We've got the minute of the meeting at CBLA0001948. We've obviously looked at this document on a number of previous occasions, but what we haven't I think necessarily looked at in any detail is what was said by Dr Smith at the meeting.

And so if we turn to page 7, we can see under the heading "Progress with heat treatment of NHS Factor VIII", Dr Lane is recorded as stating:

"... that BPL had begun 1984 with two objectives:-

"1) A product with an inactivation of non-A, non-B, [hepatitis]

2) A product acceptable for general use ...

"R&D had been making good progress on these

points which now coincided well with the current AIDS problem."

Then there's a description from Dr Smith, a review of the current work programme:

"He added that there had been difficulties with the effectiveness of dry heat for the inactivation of non-A, non-B ... therefore this had not been progressed as the first option. The current product had been dry heated at 60°C in conditions suitable for recovery of Factor VIII activity. This material had been available since March 1984 on a limited basis in solution."

If we go over the next page, pick it up in the second paragraph. He refers to priority having been given to Factor VIII:

"... although Factor IX was capable of being heat treated."

And then identifies the further problem with Factor IX:

"... present stock of Factor VIII is being considered for heat treatment. Not all batches were suitable, and these would remain available as non-heat-treated product.

"Current work is directed to making available limited supplies of a heat-treated product

to April 1985 when, it is expected that all batches will be heat-treated. A new product of higher specific activity is already being prepared [this is 8Y] which will withstand more severe heat treatments and other treatments designed to inactivate hepatitis viruses as well as HTLV-III."

Then we know that, following this meeting, the AIDS advisory document was put together. There is some comment on that in Dr Lane's statement that we may look at later today.

After this meeting, Dr Smith sent a memo to Drs Lane, Snape and Harvey at CBLA0001952. I'm not proposing to go through it in detail, but he set out essentially the work that needed to be done, effectively in order to give effect to what had been discussed at the meeting. He said this in the first paragraph:

"Since days are precious, if BPL/PFL are to be seen to be doing their utmost to help the Haemophilia Centre Directors, I summarise decisions which I believe we took on Monday 10 December, action taken since at PFL, some procedures tentatively agreed with HQC and further decisions which are needed by the review meeting on 19 December."

And then he set out a description of what he

thought needed to be done.

We can see over the page he set out a range of actions that needed to be taken effectively immediately, the week of 10 December, in relation to the current stocks of 8CRV and HL, in terms of heating them.

And then the next page describes action to be taken the following week. If we look, for example, at paragraph 2, we can see a real sense of urgency appearing here. Dr Smith explains the steps that need to be taken if they're not to lose oven time and so on.

The, I think, final document on 1984 that I wanted to show you was just a memo from Dr Smith, 3 December 1984, describing a visit he'd made to Edinburgh. It's CBLA0001942. You will see it refers to a visit to the PFC, 29 to 30 November 1984. Under the heading "SNBTS policy on Factor VIII", he said this:

"The press have inflated dry heating to a revolutionary process. They [that's obviously SNBTS] have seen seroconversion not only from US concentrates but from cryoprecipitate and in 16 patients receiving only Scottish NY concentrate. Most of the latter had been recipients of one or two

suspect batches now almost exhausted. Under clinical pressure to 'supply something or they will buy US heated concentrate', they are recalling large batches and subjecting these and their current stock (approximately one year) to dry heat. Their concentrate will not stand 24 hours at 70 degrees, and the exposure is much briefer, shorter than they or I could be happy about."

Obviously that's a matter that we can pick up with Dr Foster, but that was Dr Smith's perspective.

And then he set out a joint policy in relation to Factor IX and the dog trials that were regarded as essential.

There are some further documents referred to in Dr Smith's various statements from early 1985 in relation to the arrangements for the supply of heated concentrates to Haemophilia Centres. But I think we can probably more usefully pick those up with Dr Snape in due course.

The final topic in relation to heat treatment that I wanted to explore was the topic of what was being said about the efficacy of 8Y in terms of non-A, non-B hepatitis.

So we know from all that we've seen that 8Y was being introduced. Whatever the origins of the work on

it, it was being introduced as a response to AIDS, by the time we get to the meeting in December '84 and the roll-out in the course of 1985.

We know from other material and evidence that the Inquiry has examined that whilst 8Y was effective in relation to preventing the transmission of non-A, non-B hepatitis, the equivalent product in Scotland was not. And so one issue that we will no doubt be wishing to pick up with the witnesses that we hear, in particular Dr Perry, will be to what extent efforts could or should have been made to obtain any quantity of 8Y from England to enable the treatment, for example, of previously untreated haemophiliacs in Scotland.

What I just wanted to look at then are just a handful of documents that give an indication of some of the information that was being made available about the 8Y product.

We can ... if I just check a reference. Yes, if we go to CBLA0002263, these are notes of a meeting on 8 October 1985, and it's Regional Transfusion Directors meeting, BPL.

If we go to the third page, we can see there Dr Smith gave an update on 8Y and 9A.

He said:

"Historically, NHS products gave 90% NANBH in new haemophiliacs -- looked at how to make products safer during 1983 and 1984. The AIDS panic in December 1984 and 1985 has accelerated the programme, but the main objective has always been to combat NANBH."

And then there's a summary of the work that was undertaken in relation to the various inactivation methods.

Then if we go over the page, under the heading "8Y Clinical trial", it's recorded:

"20 patients/5 batches now passed 10 weeks. More than half have passed 12 weeks. (A few now at 20 weeks) therefore so far 8Y is a super product in terms of its ability not to transmit hepatitis."

So that's October '85, obviously what's said to be notes at a Regional Transfusion Centres meeting.

If we then look at a publication -- we don't, I'm afraid have the precise date, but it's sometime in 1986. It's PRSE0003186.

This is Haemophilia Society Bulletin, number 3 of 1986, and if we go to page 6, there's an article by Dr Smith, and indeed we can see there's a picture of Dr Smith there. There's an article "Factor VIII 8Y -- from lab bench to national product in one year".

I'm not going to read through it, sir, in the interests of time but it is an account that's worth reading, from Dr Smith.

If we pick it up under the heading "Scaling up", the right-hand side, we can see in the third paragraph there it says:

"... the advance batches of PFL's pilot production went to clinical trial to prove that 8Y was safe and effective in haemophiliacs even after its very severe heat treatment. Armed with hard data from Dr Rizza, Dr Kernoff and Dr Jones ... we could extend the clinical trial to answer the crucial question -- does the heat treatment really prevent transmission of AIDS and hepatitis?

"All the laboratory and clinical reports suggest that we have many thousand-fold 'overkill' of the AIDS virus and none of the susceptible first-treatment haemophiliacs in the trial have shown any signs of hepatitis so far.

"But we need the continued enthusiastic co-operation of the Haemophilia Centres and the brave haemophiliacs who agree to the lengthy follow-up, to test many more batches rolling off the production line."

Then -- sorry, if we just look at the next

column of that article, so it's the second column from the left, it concludes:

"This time next year we will know whether AIDS and hepatitis transmission have been defeated in the first determined assault. Even if it turns out that we have only punched a large hole in the problem, we will have tricks in reserve to finish the job and guarantee a brighter future for haemophiliacs than looked remotely possible in 1984."

That's what was being said by Dr Smith in the Haemophilia Society Bulletin.

He was asked by Mr Watters in February 1986 to prepare that article, but, as I say, the precise date of publication I haven't yet been able to ascertain.

There are just a handful of other documents, however, in which the promising early results in relation to 8Y were considered. So if we look at PRSE0004378, this is an article authored by Dr Smith, Mrs Winkelman and PA Feldman, Dr Feldman.

If we look at the top of the page we can see it appears to be in relation to a symposium that took place in Melbourne, Australia, in 1986.

My understanding from other evidence from Dr Smith is that that was probably in May of 1986.

In any event, it's headed "Interim results of

surveillance for NANBH in patients receiving heated concentrates produced in England", and if we go to the third page, if we can just pick up the last two paragraphs under the heading "Discussion", having set out the interim results, Dr Smith said this:

"Let me again concede that this collection of data variable quality does not carry the full authority of a formal perspective clinical trial. However, when all reservations have been made about imperfect follow-up data, the weight of this varied evidence justifies our asking clinicians to put many more previously untreated patients into a more formal trial, using even more batches of product.

"Although these early interim results on a limited number of batches, we think we are justified in thinking that the severe heating has been more effective in preventing transmission of NANBH than the milder heating accorded to Hyland and Armour products in studies published last year. It is too early to know whether NANBH transmission has been eliminated by severe dry heating, or whether we may see transmission by only a few batches, as has occurred with Alpha's factor VIII concentrate heated in heptane."

Then we can just pick the picture up in a letter

from Dr Smith to Dr Kernoff in August 1986.

OXUH0003754_047.

This is Dr Smith writing to Dr Kernoff on 19 August 1986. It's headed "LFT surveillance after 8Y and 9A". I'm just going to read the first paragraph:

"You asked me for a summary of results to date to review for the Haemophilia Centre Directors in September. I am sending this information only part-cooked, since it may give you a chance to formulate further questions. After a further round-up of delayed data, I suppose it should be published more widely, warts and all. For that reason, I am copying this letter to others who may offer guidance on selection of data and arguments for publication. I would be glad if you would acknowledge the list of physicians who have entered patient data ..."

Then there is a list of the physicians.

Then this:

"Much of this data has already been presented to most of the [Haemophilia Centre Directors] at the Blood Club in March, and I gave another interim view at the IABS in Melbourne in early May."

That the document we just looked at in terms of the Melbourne document.

And then the data is set out. As I say, I don't propose to go through the detail of it.

The other two documents on this issue then, finally, BPLL0006186_002.

This is from Dr Smith, Mrs Winkelman and Dr Feldman, 10 March 1986, "Interim report of surveillance for non-A, non-B hepatitis after first infusions of 8Y and 9A into deficient patients". Again, I don't propose to go through the detail of it, but this may be, in broad terms, the kind of information that was being discussed at the Blood Club in March of 1986.

And then, finally, PRSE0003764.

This is, again, March 1986, 17 March 1986. It's the note of a meeting at the PFC on 17 March 1986, with a number of representatives from BPL and SNBTS, including Dr Smith. This is a note compiled by Dr Perry. No doubt we can ask him about it.

But if we go to the third page and look at paragraph 5, towards the bottom of the page, there is there reference to the clinical trial results of 8Y.

"Dr Smith outlined clinical trial results of the 8Y F VIII product so far. While results cannot be considered conclusive at this stage, he indicated that no cases of virus infection have occurred

(attributable to 8Y material) after 12 months experience of 8Y in virgin haemophiliacs."

Set out in the note, the presentation note, sir, a number of other references to discussions about the interim results, in terms of non-A, non-B hepatitis infection. There was a paper put together for presentation in autumn 1986 to a meeting of Haemophilia Centre Directors, and the various references in relation to that are in the written presentation note.

There are then -- if I can just give you some references in Dr Smith's various pieces of evidence about heat treatment. I am not going to take any further time up in going to the core documents.

In his witness statement to the Inquiry, WITN3433001, Dr Smith described the work undertaken in relation to heat treatment in some detail in paragraphs 58-111.

I've taken you, sir, to his 1990 proof of evidence rather than the 2020 statement to this Inquiry because the 1990 proof of evidence is both more detailed and obviously closer in time to the events in question. But there are some important aspects of the overview that Dr Smith gave in his statement to this Inquiry which shouldn't be ignored.

He addresses the question of whether things could or should have been done earlier, and cautions, I think it's fair to say, against the use of hindsight in that regard.

But it will be for you, sir, to read what he says in that regard, reach your own assessment having regard to such submissions as Core Participants may wish to make to you in relation to that.

Then in his evidence to the Lindsay Tribunal -- again, we don't need to put it up on screen, LIND0000318 -- there is a discussion in particular about the issues relating to difficulties in heat treating Factor IX that appears in the transcript from page 10 onwards and particularly pages 15 to 16.

And then there are the notes which Dr Smith produced to the Penrose Inquiry at PRSE0004045. And, again, if I just give you the page reference there. It's pages 20-21 of that document. It may be important, sir, for you and others to read Dr Smith's perspective on why the focus at BPL was on dry heating, and the focus at PFC was on pasteurisation. But I propose to say no more about that, not least because it's an issue for exploration with Dr Foster in terms of the approach taken by the PFC.

Sir, the very final topic in relation to

Dr Smith's evidence, then, that I propose to address orally -- simply his views on reversion to cryoprecipitate. We've looked at some references in contemporaneous documents to that, so I'm going to simply draw your attention now to what he said in his statement to this Inquiry.

Paul, can we have then that statement again, WITN3433001. And if we can go to, first of all, page 52. Sorry, if I can just pick it up on page 51 so we can see the question that he's responding to.

There is some description about the usage of cryoprecipitate generally in paragraph 145. Then on the bottom of the page, he asks whether -- he is asked whether a return to the use of cryoprecipitate was a practical possibility in the period '82 to '85. And at the top of the next page, he answers that question "No," but I think it's probably important to realise --

SIR BRIAN LANGSTAFF: The question is about the product at BPL and PFC.

MS RICHARDS: Yes. And, of course, BPL wouldn't have been producing cryoprecipitate.

SIR BRIAN LANGSTAFF: No.

MS RICHARDS: So perhaps not the most usefully worded question. But the answer is, rightly, I think, in

terms of the evidence we've heard from others:

"Provision of cryo was always considered to be a responsibility of the RTC at the request of haemophilia clinicians in its region."

And then if we go to paragraph 148 further down the page, the question was asked whether --

SIR BRIAN LANGSTAFF: Can we just have a look at (c)?

MS RICHARDS: Of course.

SIR BRIAN LANGSTAFF: Question (c).

MS RICHARDS: The question was:

"What would the effect on overall levels of production of blood products at BPL/PFL have been given the economies of scale involved in producing cryoprecipitate?"

Dr Smith said:

"Envisaging a dedicated factory for small pool Factor VIII and Factor IX, the answer is at Q38(c)."

Which is on ... in fact, I'm not quite sure which passage he's referring to there. Question 38 starts on page 49. Yes, so it'll be the bottom of page 50.

But what he's looking at in his answers, entirely understandably because he's looking at it from the perspective of a fractionator based at BPL/PFL, he's not looking at what could have been done

in Regional Transfusion Centres. He then looks at the question of what fractionators could have done by producing --

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: If their facilities had been given over to cryoprecipitate.

SIR BRIAN LANGSTAFF: Well, it's more or less what the question assumes, I think. It's slightly ambiguous because it either means nothing very much, which I can understand, talking about given the economies of scale involved in producing cryoprecipitate. If one puts a comma after the "involved", so:

"What would the effect on overall levels of production ... have been given the economies of scale involved[,] in producing cryoprecipitate?".

It is really the effect of producing cryoprecipitate on.

So, in other words, what he's asking is: if you produce cryoprecipitate, what's the effect of BPL/PFL, given the economies of scale?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: The implicit suggestion is that you lose some of the economies of scale because you lose scale.

MS RICHARDS: In any event, if we then go back to what's

on the screen at paragraph 148 in the context in which you've just explored, sir. In response to the question, "Was this approach considered in the UK?" he responds with the question:

"Considered by whom? Not by fractionators, for the reasons already stated. Not by RTCs, who did not relish the scale of expansion predicated."

Just pausing there again. Whether there's an evidential factual basis for that, or whether that is -- and I don't mean this pejoratively -- speculation on Dr Smith's part is unclear. The Inquiry has heard now evidence from a number of Regional Transfusion Centre Directors about what would actually practically have been involved about -- in a reversion to cryoprecipitate in the Regional Transfusion Centres.

And then he says this:

"Not the staff of Haemophilia Centres, for whom the dissolution and pooling of frozen gobbets of cryo was a fiddly job requiring air-filtration facilities and training in aseptic technique. Only a new 'factory', probably producing freeze-dried cryo, would have had the capacity to replace all large pool concentrates."

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: That may be an answer to a different question in one sense than the question which may be of more immediate interest to the Inquiry: could reversion to cryoprecipitate or greater use of cryoprecipitate have been an interim measure in 1983 or '84?

SIR BRIAN LANGSTAFF: Well, he's not really answering the question if it were proposed by someone with oversight of the whole scheme. That, for the time being, until it's clarified what the position of those who receive factor concentrate, commercial factor concentrate from the US is, can we go back to having cryo, use cryo, and use very much less factor concentrate? That has implications for BPL. Because you're producing very much less concentrate, you may get very much less plasma. That's really the question, isn't it?

MS RICHARDS: Yes. And of course it is always -- it's also proper to bear in mind that, I think as Mr Hill noted in the course of the week, of course, plasma was not required or not used only for the production of factor concentrates, although that's obviously our focus.

SIR BRIAN LANGSTAFF: No, but the -- I suppose the issue would then be: can you provide the supernatant which you get from producing cryo in the regions in any

sensible and usable form to BPL?
MS RICHARDS: Yes.
And then Dr Smith continued in his statement, paragraph 149, he set out his own view of cryoprecipitate in the third line of paragraph 149:
"... a pharmaceutically inferior medication which should be replaced as soon as possible."
And he sets out what he says a number of disadvantages with cryoprecipitate. He, of course, was not a clinician administering the treatment.
And then over the page, paragraph 150, he says:
"I agree that a patient in the mildly affected group might justifiably have insisted on cryo rather than concentrate between, say, 1983 and 1984."
Then this:
"It's always been the business of the clinician not the fractionator to assess risks and benefits for different patients and categories of patient."
SIR BRIAN LANGSTAFF: And he then returns again to the theme of centrally produced cryoprecipitate.
MS RICHARDS: Yes.
Sir, that is a tour through aspects of Dr Smith's evidence. Obviously, his statement ought to be read in full --
SIR BRIAN LANGSTAFF: Yes.

(The Luncheon Adjournment)
(2.00 pm)
Presentations to the Inquiry about the work and evidence of Dr Richard Lane (Director of the Blood Products Laboratory from 1978) by MS RICHARDS
SIR BRIAN LANGSTAFF: Yes.
MS RICHARDS: Sir, we turn now to the evidence of Dr Richard Lane, who was the director of BPL from the autumn of 1978 to 1990.
If we just bring up onscreen CBLA0000005_002.
You will see there the first of the 484-page draft proof of evidence of Richard Spencer Lane, which I'm going to be referring to.
This is really the only evidence we have from Dr Lane apart from obviously the large volume of contemporaneous documentation to which he contributed or which records his views. There is no statement or evidence from Dr Lane subsequent to 1990, so no evidence to Lindsay or to the Penrose Inquiry or elsewhere, and no statement that we were able to obtain from him for ourselves.
So this is really what we have.
The presentation is going to focus upon what is set out in this document, but before we look in more detail at it -- Paul, could we have INQY0000341.

MS RICHARDS: -- to give it full justice, particularly his statement to this Inquiry. But I hope that looking at some of his earlier evidence, looking at some of the contemporaneous documents helps illuminate aspects of the evidence that he's provided to the Inquiry in his written statement in 2020.
SIR BRIAN LANGSTAFF: It's been very helpful. Thank you.
MS RICHARDS: Sir, what I'll do then after lunch, a little later than anticipated, is pick up with the evidence of Dr Lane. It may be that I don't finish that this afternoon. I'm not proposing we sit later than the normal time this afternoon. But, if necessary, I can take an hour or so on Tuesday before we then turn to looking at self-sufficiency and domestic production with regards to Scotland and Northern Ireland. And that won't do any overall violence to the timetable next week.
SIR BRIAN LANGSTAFF: Yes. Well, that sounds like a sensible proposal. So if we don't have enough time to finish, as I think you're telling me you don't expect to have, then that's what we'll do.
MS RICHARDS: Thank you, sir.
SIR BRIAN LANGSTAFF: So from now, it just remains for me to say 2.00. 2.00.
(1.03 pm)

This is an explanatory note which the Inquiry provided to Core Participants back in April 2020, when various documents provided to the Inquiry were disclosed to Core Participants, including the statement that I've just referred to, the statement of Dr Lane.
The purpose of putting this up on screen is really to provide a bit of background, because there are number of different versions of Dr Lane's statement. We have, I think, something in the region of six or eight versions. The two that we've referred to in the presentation are what's referred to as the draft number 5, and that's the one with the reference that I read out a few moments ago, the CBLA0000005_002 version. That draft is dated 10 December 1990.
There is then a draft 6, dated 11 December 1990. We don't need to put it up on screen, but the reference to that, for the transcript, is CBLA0000034_002. That's a much shorter document. If we go to the second page, please, of this note, we've explained towards the bottom of the page our understanding of the status of the draft proof of evidence.
So the second paragraph under the heading "Dr Lane's [draft] Proof of Evidence" explains that

the proof was prepared, as we understand it, "with the assistance of Clifford Chance for the purpose outlining CBLA/BPL's response to the allegations of negligence and breach of statutory duty contained in the Plaintiff's Re-Amended Main Statement of Claim".

So it arose in the context of the HIV Haemophilia Litigation. The CBLA had been joined as an additional defendant to that litigation. The CBLA retained Clifford Chance solicitors to represent them and Clifford Chance took steps to obtain proof of evidence from Dr Lane.

As we've set out there, there are a number of different drafts. The reason for referencing versions 5 and 6 are as follows: they're the two latest in time, and version 5 is the most complete version. It appears, in fact, to be a complete draft, subject to the fact that there are certain questions, presumably questions from the solicitors, in the text of it. Certain drafts relating to queries for Dr Lane to follow up or documents to be followed up.

So that's why we have identified those two as the two documents that may be most relevant to consider.

If we go back to CBLA0000005_002, and if we just go, purely by way of example, to page 53, if we

look at paragraph 133 you'll see it refers to a document -- the fourth line refers to "document no. 486". And there are documentary reference throughout the Dr Lane proof of evidence. The documents listed are documents in the CBLA's list of documents for disclosure in the HIV Haemophilia Litigation.

In order to find where those documents exist on our database, we provided a schedule at the same time as a note we looked at a moment ago.

So in April 2020 we provided Core Participants with a schedule or spreadsheet which lists the document numbers, but also then provides the relativity reference number. So recognised legal representatives and those Core Participants who have access to relativity using that can find the documents referred to by Dr Lane in this proof of evidence.

The other way of finding any of the documents that Dr Lane refers to on relativity is by going into the reference ID section of relativity and putting in the document number and that will produce it. And that, I hope, will make the life of anyone trying to make sense of Dr Lane's proof of evidence a little easier, being able to find the documents that he comments on.

SIR BRIAN LANGSTAFF: Yes, I would hope that in what you say, that if there are any particularly important documents, that those people who are members of the public but are not Core Participants will need to know what they are otherwise they won't be able to make sense of it.

MS RICHARDS: Yes. In fact, Dr Lane's proof normally either contains quite a decent description of the document so that you can see what it is, or quite often contains an extended quote from it.

In the presentation note, we've referred to some of the documents in more detail. I am not, this afternoon, going to go to very many of the contemporaneous documents. That's really for two reasons. The first is, we've seen the key ones already, either in the course of this week or in the course of earlier hearings. The second reason is we'd be here for longer than an afternoon, or frankly longer than a week, there are so many documents referred to in such detail in the draft proof of evidence. So I'm actually only going to go to a handful of them.

But it's not particularly difficult to make sense of what Dr Lane is saying, because he gives this quite detailed description of most of the documents

that he's referring to.

SIR BRIAN LANGSTAFF: Am I entitled to infer, because this is a draft, plainly prepared by solicitors for him to look at, that the ordinary process by which this draft would have been reached would have been there would have been discussions between him and the solicitors in which he orally or in writing put out what he had to say, they then organised it in a way which suited the purposes of the litigation, and put it back to him to say, "Is this fair and full?" And he would say, "Well ..." And there will be further discussions about various aspects of it.

So that this fifth draft is not necessarily what he would have ended up saying, but it is a pretty good indication of what he would have ended up saying, if that was the process, which I think I'm entitled to infer, but you can confirm that, would be almost certain to have happened.

MS RICHARDS: Certainly such documents as I've seen that emanate from Clifford Chance, correspondence and so on, that -- nothing of any great moment in the contents of them, but they are absolutely consistent with the process which you described.

What, of course, it is important to bear in mind in relation to this proof of evidence, and your

evaluation of its contents in due course, is it was never finalised. It was never signed. It was produced in the context of litigation. And we'll see, as we go through it, it's very much directed at responding to the allegations in the amended statement of claim in the HIV Haemophilia Litigation. And it's very much aimed at putting forward the arguments of the CBLA as to why they should not be found to be negligent or in breach of any statutory duty.

So it is in part a submission, and we'll see that Dr Lane at various stages identifies particular allegations and then sets out the CBLA's response to those allegations, effectively, so it's tailored towards the defence of the CBLA's position in litigation. That's not meant as a criticism, that's merely a statement of fact. That's the purpose for which it was produced.

As a result, although it's vast, it doesn't necessarily reflect the broader evidence that Dr Lane could have given had this Inquiry taken place many years earlier than it is. It doesn't contain some of the analysis observations, some of the more discursive reflection that others who have provided written statements or indeed oral evidence to this Inquiry have been able to bring to bear, because it was

produced for the purposes of defending litigation.

It also essentially stops in 1985, and its content is focused upon the particular allegations that were being levelled against the CBLA and the litigation.

SIR BRIAN LANGSTAFF: Yes. Well, I have to bear in mind, I think, that this is the director of an organisation which was a defendant.

MS RICHARDS: Yes, exactly.

SIR BRIAN LANGSTAFF: And though normally technically a witness statement should contain and contain only statements of material fact, most of the statements that I've seen so far in this Inquiry have gone beyond that in expressed views. I suppose, in one sense, you can say it's a matter of fact as to what the view is of CBLA.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: But I have to take care in looking at it that way.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And concentrate on what the facts are with the assistance that he can give because he was there and knew what other people around him had in mind to do, and why things happen, and give such weight to his comments as I think appropriate.

MS RICHARDS: Precisely so. It's informed commentary, but it's being delivered from a particular standpoint. Exactly.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Which is the standpoint of a defendant to litigation, and obviously was never completed because the litigation settled.

SIR BRIAN LANGSTAFF: And from the very particular standpoint -- we saw an example of this perhaps this morning when there was discussion about what Dr Smith might have meant or might have been meant in documents, which -- the position of BPL is not the position of other parties or -- parties -- other people whose activities we are examining.

MS RICHARDS: Absolutely.

SIR BRIAN LANGSTAFF: It has a very particular role to fill.

MS RICHARDS: Absolutely. And that becomes very clear because it's not simply that we are looking more widely than BPL. Even when we're looking at BPL, we're looking more widely than the CBLA. The CBLA came into existence in December 1982, and so, with some force, Dr Lane points out at various stages in the statement that the CBLA, which is the defendant to the litigation, isn't responsible for decisions taken

by others seven years before it came into existence.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: So that's why -- it's an unfortunate fact that we don't have any evidence from Dr Lane in a broader context beyond this litigation statement, and of course beyond what you'll be able to see from the contemporaneous documents, most of which, as I say, you've already looked at --

SIR BRIAN LANGSTAFF: Yes. Thank you.

MS RICHARDS: -- in terms of the key documents.

So, much of the presentation is actually going to be a guide to the statement because it is a document that really does have to be read in full, but it takes a very long time to read it in full, I can assure you.

I'm going to start then just with a brief overview of Dr Lane's career to put it in context before we dive into the statement.

Prior to taking up his role at BPL, Dr Lane had various medical positions in paediatrics, medicine and surgery. He became a Senior House Officer in pathology at the West Middlesex Hospital in 1961.

Between 1962 and 1966, he was a Research Fellow in haematology in Glasgow, the department of pathology, Royal Maternity and Samaritan Hospitals.

And then from 1966 to 1973, he was employed as a scientific officer at the Medical Research Council's experimental haematology unit at St Mary's Medical School. He also during that period, from '69 to '70, spent some time in the States as a Senior Fellow of Medicine at the University of Washington's department of haematology and medicine and at the King County Central Blood Bank in Seattle.

Then from 1973 to 1975, he held a post as a lecturer in haematology at St George's Hospital.

And then from 1975 until his appointment to BPL, he was a consultant haematologist to the Northeast Thames Regional Blood Transfusion Centre in Brentwood, Essex. So not, I think, a Regional Transfusion Centre Director but a consultant based at the regional Transfusion Centre for a period of time.

In 1977, April '77, he became the Director Designate of BPL in anticipation of Dr Maycock's retirement, and then he took over from Dr Maycock as Director in September of 1978.

There is an introductory section in his statement -- in his proof that's worth looking at, so if we can have the proof back on screen, please, Paul. CBLA0000005_002.

If we go to page 2, you'll see there's a section

on BPL from paragraph 4 onwards. Mr Hill has taken you to some of the central facts in relation to BPL's history, so I don't propose to go through the detail of that, but that continues from paragraph 4 through to paragraph 13.

You will see at paragraph 13 on page 5, Dr Lane references there the medicines inspection of the BPL facility in April 1979, and their report it was seriously substandard as a pharmaceutical manufacturing factory. And he picks up on that later in his statement, and I'll come back to that.

If we go over the page, there's a very brief narrative in relation to PFL, but he mainly refers there to the evidence of Dr Smith which we looked at yesterday in that regard.

Then if we go to page 7, there's a section headed "CBLA", and this is important for the reason I've already given: it's because the CBLA was the defendant or one of the defendants in the litigation, but had only come into existence with effect from 1 December 1982. And you will see there set out an account of the membership of the CBLA which continues over the page. Details of the staffing of BPL. That is, I think, as at 1990, the date of the statement. 380 staff; in the case of PFL, about 30.

And an account of who had been the first chairman of the CBLA, and a brief account of the establishment of the CBLA in November 1982.

You'll see towards the bottom of paragraph 21 there's reference to an appendix. I should have said there are number of appendices to Dr Lane's proof. I'm not, I think, likely to go to any of them, but I will just give details of the reference numbers for them.

So they range from -- and this is just for the transcript, Paul; you don't need to pull anything up -- BPLL0004825 through to BPLL0004844. They cover a range of different issues, so the appendix, as referred to here, is simply a copy of the 1982 order which established the Central Blood Laboratories Authority.

The second appendix which is referred to, if we go to the next page, paragraph 22, is a -- or includes a list of -- a range of committees, which may be useful at some point to consider.

There are then -- there's then appendices regarding supply and demand which Mr Hill referred to in the presentation earlier in this week, and then a whole range of other matters.

Those appendices have been disclosed to Core

Participants, but it's not my intention today to refer to them.

Some of them gather together in information. So, for example, there's some that gather together information about advice given to Haemophilia Centre Directors. I don't know, we don't know, who put the appendices together. There's nothing in, for example, that appendix -- gathering together advice relevant to Haemophilia Centre Directors -- that refers to any material that we haven't otherwise seen. It's not in fact complete. It doesn't include material that we have seen, and so the appendices themselves are not necessarily particularly reliable. They may have been compiled by Clifford Chance, or some of them may have been compiled by Clifford Chance, but that's speculation on my part.

We can then see the next introductory heading in Dr Lane's proof is the "National Blood Transfusion Service". And if we go over the page, we can see in paragraph 25 Dr Lane's description of the National Blood Transfusion Service, and this is a theme which emerges in various points throughout his proof of evidence and, indeed, in a number of the contemporaneous documents.

If I pick it up four lines above subparagraph

(a), Dr Lane said this:

"It [that's the National Blood Transfusion Service] was, in effect, a loose confederation of 14 RTCs, regionally financed, which varied considerably from region to region and were neither controlled nor financed in the same way as BPL/PFL. There were effectively four links with the Department of Health."

Then he sets out those links. The first is the role of the part-time consultant and advisor on blood transfusion to the Department of Health, which, as we know, after Dr Maycock's retirement, was Dr Tovey who thereby provided a link between the Department of Health and the Regional Transfusion Directors but had no particular link with BPL, unlike Dr Maycock, and then became Dr Gunson.

The second link is the periodic meetings of Regional Transfusion Directors, but as Dr Lane there observes:

"This 'body' was not constituted statutorily. The meeting carried no executive function, and although its purpose was in part to advise the consultant advisor, it served as an unofficial informal mechanism for exchange of information between constituent units of the NBTS and the [Department of Health]."

If we go to the next page, the third link between the Transfusion Service and Department of Health described as the "Central Committee for the [National Blood Transfusion Service] was formed by the [Department of Health]".

We see there the terms of reference set out.

Then if we go further down the page, in terms of its membership Dr Lane says:

"The part-time Consultant Adviser and two elected Regional Transfusion Directors were members of this Committee. The Committee included representatives nominated by the Royal College and other members ... The Chairman was the Deputy Chief Medical Officer of the [Department of Health]."

Then the fourth link, the meetings of the regional donor organisers under the chairmanship of a senior administrator of the Department of Health:

"This particular Committee existed largely to review publicity material for blood donor recruitment, since much of this material, which was of a high quality, was produced separately by the DOH in conjunction with the Central Office for Information ('COI')."

So that's Dr Lane's account of the links between the Blood Transfusion Service and the Department of

Health. Obviously we've heard a range of evidence in relation to that.

Then, over the page, this is a statement of opinion on the part of Dr Lane, but nonetheless worth considering. He says at paragraph 26:

"I think it is fair to say ... that the organisation which existed within the Transfusion Service during the period which is relevant to this litigation, limited the development of the national aspects of the service. The RTCs were poorly represented centrally as described above, and the Central Committee itself was only an advisory committee to the DOH and, on national or any other aspects of the Transfusion Service, the DOH was not (for procedural reasons) able to instruct Regions on the allocation of finance to [Regional Transfusion Centres]. The [Regional Health Authorities] were not necessarily involved in national policy-making for the NBTS, although central policies quite require RHAs to commit allocations of extra funds from Regional budgets to finance development at RTCs."

So, in one sense, nothing there that we haven't heard from other sources, but we note there that that was Dr Lane's perception as well.

The next introductory section of his proof is

headed "Haemophilia". I don't propose to go through anything that was set out there by way of a very brief summary in relation to bleeding disorders.

If we go to page 14, there's then a heading "Coagulation factors - preparation and use". There's a reference to cryoprecipitate in paragraph 34. Halfway through paragraph 34 we can see Dr Lane observing that cryoprecipitate was the principal product used to treat haemophiliacs for a long time and confirming that BPL and PFL have never produced cryoprecipitate, that's always been produced by the Blood Transfusion Centres.

Then we'll note on the next page, paragraph 37, Dr Lane provides details of the names of the BPL and PFL products. So 8IP became HL, the BPL intermediate purity product. And then the PFL product, 8CRV, as we've already heard. And then the intermediate concentrate Factor IX was 9D. And then he refers to these being replaced by the heat-treated products 8Y and 9A.

There is then some observations about risks of viral transmission, which I'll come back to.

There's a section in the statement starting on page 19 about HIV.

Then, if we go to page 20, you'll see the

structure, then, of the statement that emerges.

So Dr Lane sets out in the proof the claims advanced against the CBLA in the re-amended main statement of claim.

Then if we go over the page, we will see the first main topic which Dr Lane addressed in the proof of evidence, and that's "Self-sufficiency and the Blood Transfusion Service".

Before we look at any of the detailed content of it, the structure of this part of Dr Lane's proof was as follows. He set out an overview, setting out in broad terms his view on matters relating to self-sufficiency. He then sets out, year by year, a chronological narrative, but it's a narrative by reference to individual documents. And what we don't know is how the documents were selected or by whom. And so you will see as we go through it, but he has a heading for each year. He sets out certain documents relevant to that year. Not necessarily a comprehensive account but nonetheless there is a lot of material that he refers to.

Sometimes he simply describes the document and the event to which it relates, so a paragraph might simply say, "I sent a memorandum", and then there's an accurate summary of what the memorandum said, but

quite often there is additional comment or observation by Dr Lane. And in what I draw your attention to this afternoon, and Tuesday morning, I'm going to be focusing on those paragraphs of relevance to the issues that you're considering, where Dr Lane does something more than just describe the document or the event, where he adds something by way of comment.

At the end of his review year by year in relation to self-sufficiency, there is then a section of the proof in which he sets out, or the solicitors have set out for him, the allegations against the CBLA in the re-amended main statement of claim, and then he sets out his response on behalf of the CBLA to those allegations. So that's the structure of the statement. And that pattern is followed for the other subjects in the statement. So when he goes on to consider hepatitis, HIV, heat treatment and so on, it, broadly speaking, follows a similar structure.

So if we then turn to the first topic, which is self-sufficiency, at paragraph 59 Dr Lane sets out the essential argument, or his characterisation of the essential argument in the claim:

"... that had England and Wales been self-sufficient in Factor VIII concentrate, fewer haemophiliacs would have required imported commercial

Factor VIII concentrate which carried a higher risk of contamination with HIV."

And then paragraph 60 refers to the position in relation to Factor IX, the assertion that England and Wales was self-sufficient in relation to Factor IX.

Then paragraph 61 sets out Dr Lane's response in a nutshell:

"My own opinion is that the Plaintiff's contention is probably correct. In a way the data that has emerged it regard to the relative extent of HIV infection amongst haemophilia B sufferers treated exclusively with NHS Factor IX produced by BPL/PFL suggests that pro rata there was a lower incidence of infection when compared with the rate of infection of haemophilia A sufferers who used commercial US Factor VIII concentrate. So far as we are aware, there is little difference between Factor VIII and Factor IX in terms of their inherent potential to transmit HIV when manufactured from infected donations of plasma, and the quantity of Factor IX required to treat severe haemophilia B sufferers is comparable with the quantity of Factor VIII used by haemophilia A sufferers."

Over the page:

"Nevertheless, the pro rata incidence of HIV

infection amongst haemophilia B sufferers is lower ..."

And he sets out the two factors which he thinks reflect that, of which the second is:

"the fact that Factor IX was manufactured inclusively from plasma ... voluntarily donated in the UK ..."

However, having agreed broadly with the plaintiff's contention that had there been self-sufficiency in Factor VIII, fewer haemophiliacs would have required imported concentrates which carried the higher risk of contamination, he then qualifies that in paragraph 62 in the following terms. And again, I'm going to read it out because this is an important part of the position that he was advancing. Picking it up in the third line of paragraph 62 he said this:

"Because of the chronology associated with the emergence of HIV and the length of time that it takes to achieve 'self-sufficiency', it would be necessary to build and plan a manufacturing facility during the mid-1970s for production to have reached anything like the level necessary to satisfy the needs of the haemophilia A sufferers by the late 1970s when HIV, (as it is now known), appeared."

Pausing there, it may not be inaccurate to say that HIV first appeared in the late 1970s, but it's not entirely clear whether what he's saying -- that essentially by 1979, or the late 1970s, the die was cast in terms of HIV infection, because that wouldn't be reflective of the evidence the Inquiry has heard, which is that most of the infections took place during the course of the first half of the 1980s.

In any event, the other point that Dr Lane makes is about the length of time that it would take to plan and build a manufacturing facility.

And he says there:

"The planning and financing of increases in the supply of FFP would have required a similar timetable. In short, any decision to pursue self-sufficiency as a goal, could only have been taken at a time when HIV was unknown and, therefore, on the basis that self-sufficiency was not just desirable but necessary for some other reason. The Plaintiffs suggest that such a reason was the risk presented by hepatitis and contend that, as with HIV, US commercial Factor VIII concentrate manufactured from plasma donated by paid donors was inherently more dangerous than the equivalent NHS product manufactured from voluntarily donated plasma. For the reasons given under the

heading 'Hepatitis' below [that's a stage of his statement I'll come on to later], my view is that this is fallacious. Additionally, hepatitis is very different indeed in terms of risk when compared to HIV."

Those are statements you will be able to assess the validity of for yourself. What I think, in terms of direct evidence, is perhaps more instructive is what Dr Lane said in the next paragraph.

SIR BRIAN LANGSTAFF: Can I just come back to one aspect of it? Just go back to the previous page.

MS RICHARDS: Sorry, the previous page, please. Thank you.

SIR BRIAN LANGSTAFF: Thank you.

It's what he says about halfway down, the sentence beginning "In short". He seems to be saying that the goal of self-sufficiency, if it was desirable that's not enough for Parliament or Government or a proper administration to decide that that's what they should have.

MS RICHARDS: Possibly. Of course the goal of self-sufficiency was neither, ultimately, the policy of CBLA, and he's tailoring his evidence to what might or might not be, as it were, laid at the door of the CBLA.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: He goes on to say a little more at various places in the statement about that, but yes, he's -- in one sense, obviously, the first part of that sentence is correct: the decision to pursue self-sufficiency in order to have the effect of avoiding HIV would need to be taken not on the basis of HIV.

SIR BRIAN LANGSTAFF: No, no, because you don't know --

MS RICHARDS: It's obvious.

SIR BRIAN LANGSTAFF: But that -- leave aside the question of whether one takes into account unknown viruses, but ...

MS RICHARDS: Exactly.

SIR BRIAN LANGSTAFF: But it was -- the idea for -- which seems to be put forward, which I'll have to give further thought to, that what he's looking for is something which is not just desirable, but necessary. And that's a curious word.

MS RICHARDS: It is, and it's a very high test or high threshold, potentially, to surmount.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: If we go to -- and of course, I mean, amongst other matters, as we saw in Dr Smith's -- one of Dr Smith's statements, by 1975 the World Health

Organisation itself was endorsing self-sufficiency for nations.

SIR BRIAN LANGSTAFF: And whatever one may say about what happened, Parliament itself was told, and seemed not to disapprove, of a policy announced by the Minister for Health at the time, that self-sufficiency should be the aim.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: And that plainly wasn't on the basis of HIV as HIV.

MS RICHARDS: No.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Sir, if we go to the next page and look at paragraph 63, this is Dr Lane's take about the goal of self-sufficiency:

"In the 1970s, self-sufficiency was considered desirable but it was not seen as an imperative in that external alternative sources of supply were available."

That too is potentially quite curious, because clearly, the "external sources of supply", he must be referring to commercial concentrates. But in one sense the whole point of self-sufficiency is to avoid the need for the use of commercial concentrates. So it is arguably a slightly odd way of looking at

things. It is, of course, only one sentence, but there is -- there is, as we'll see, a little more later on.

What we then get in the next couple of paragraphs is Dr Lane setting out the position in relation to the CBLA. He makes the point -- which is absolutely correct, as a matter of fact -- that by the point in time, in December 1982, when the CBLA took over responsibility for BPL, approval had already been given for the rebuilding of the new manufacturing facility and upgrading of the existing facility. And so that, as I understand it, leads to his assertion in paragraph 65:

"In these circumstances CBLA cannot be responsible for a failure to achieve self-sufficiency aside from the fact that, in common with their predecessors in managing BPL/PFL, they did not control the Transfusion Service, and, more importantly, the funds necessary to substantially increase production."

It's unfortunate, really, that what we have from Dr Lane is only this statement in the context of the litigation, because what we don't have, perhaps more fully, is a warts and all account of -- more widely of what his fuller views might have been, because he is here focused upon the position of the CBLA.

of severely affected haemophiliacs who were using the largest quantities of commercial Factor VIII throughout the latter part of the 1970s had already become infected with HIV."

And the factual basis for that may be questionable. Again, we will look and see what he says later in the proof. But we have seen evidence of a range of dates of seroconversion --

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: -- carrying on well into '83, '84, indeed '85.

SIR BRIAN LANGSTAFF: Well, yes.

MS RICHARDS: Obviously, in some cases, even '86. That raises slightly different issues.

Then he says in paragraph 68:

"In my opinion, to aim for self-sufficiency with a view to achieving it before the emergence of HIV would have to have involved taking a decision to do so (and starting to implement this) by the mid 1970s and, as I describe below, against the background of inability on the part of all those concerned to make any accurate assessment of what 'self-sufficiency' really equated to and a complete lack of any knowledge of HIV or the risk it was to present some 8 years later."

SIR BRIAN LANGSTAFF: Well, he's saying that self-sufficiency wasn't necessary -- it might have been desirable, wasn't necessary -- but anyway you can't blame CBLA for it.

MS RICHARDS: Yes, that is essentially what he's saying.

SIR BRIAN LANGSTAFF: Or for failing to achieve it, I mean.

MS RICHARDS: If we go over the page he also sets out some views in relation to the position of the earlier period, 1978 to 1982, and this may be, again, maybe something that will need to be looked at with a degree of critical analysis.

He says in paragraph 67:

"Nor do I believe that any decision taken during the period from 1978 to 1982 when [North West Thames] were responsible for BPL would have made any difference to the scope of the problem now faced by the Plaintiffs. If at the time NWT took over from the Lister Institute in 1978 a decision had been taken to rebuild the manufacturing facility, it would not have been ready in less than three to four years (based on our subsequent experience after 1982), and would only have been commissioned in about 1981/82 at the earliest. It is my opinion (see my comments under the heading 'AIDS' below) that by this time, the majority

The proof then refers to self-sufficiency --

SIR BRIAN LANGSTAFF: Just come back for a moment, just let me think about that. Can I just have that highlighted? The paragraph we were on. The previous page.

It's "the risk it was to present some 8 years later". And what he is saying in the paragraph before is that he sees the majority of the severely affected haemophiliacs using the largest quantities of commercial Factor VIII were already infected by 1981/82. And that would have been a -- it must be an L-shaped curve or something of the sort. So eight years back from then is 1973. I don't just quite for the moment see how that fits together.

MS RICHARDS: Yes. Well, the eight years might be a reference possibly, if you take the mid-1970s, in paragraph 68, to 1983, which you could say is the year in which the risk of HIV -- or HTLV-III/AIDS --

SIR BRIAN LANGSTAFF: Became known --

MS RICHARDS: -- became particularly acutely known.

SIR BRIAN LANGSTAFF: Or one might reasonably think it did, yes.

Well, HIV was known in 1982. It wasn't necessarily known as risk to haemophiliacs then. That's something I have to decide.

MS RICHARDS: Yes. And obviously there were the first reports of infections in haemophiliacs, or AIDS in haemophiliacs, halfway through 1982. But absolutely. The volume of evidence mounts up as we get into 1983 and continues to increase.

There are a number of different points that Dr Lane, it would seem, is making here. The issue about the inability to make an accurate assessment of what self-sufficiency really equated to is an issue which Mr Hill has been exploring during the course of the week, and we'll come on to see what Dr Lane says about various aspects of that shortly.

The reference to "complete lack of any knowledge of HIV or the risk it was to present some 8 years later" goes back to this point about that he's saying: well, self-sufficiency might have been desirable but wasn't necessary because we didn't know of the existence of something like HIV. That obviously begs questions in relation to hepatitis, which -- we'll look at what he says about hepatitis in the course of the statement, but it also obviously raises the question that you referred to a few moments ago of unknown viruses and whether there was a proper understanding of the inherent dangers of use of blood and blood products, or whether you simply had to wait

until HTLV-III came along and then respond.

SIR BRIAN LANGSTAFF: It may well be just a very clumsy way of saying a lack of knowledge, or knowledge of the risk, which you only had eight years later, as you've pointed out, but even then that wouldn't put it in the mid-seventies -- yes, you can put it, I suppose, in the mid-70s, at very earliest '75. But it's -- yes, it's curious. A curious number of years to choose, I think.

MS RICHARDS: So we then have a heading "Self-sufficiency in detail". And if we go to the next page, having referred to a couple of the appendices, in paragraph 71 of the proof Dr Lane suggests it might be sensible to distinguish the period '73 to '77 and then '78 to '85, because it's the latter period when he was directly working at BPL.

And so he says that his comments in relation to that first period, '73 to '77, are:

"... derived from an examination of the documents with the benefit of my background knowledge as a consultant haematologist working in the North East Thames Regional Blood Transfusion Centre."

Then in relation to the second period he said he was director of BPL and he had firsthand knowledge of the events relevant to the issue of self-sufficiency,

and then he explains why the end of 1985 has been taken as a cut-off.

So if we turn over the page we'll see the heading "1973 to 1977", and we can see here some of the observations that Dr Lane makes in relation to that.

I'm obviously not going to be reading out vast chunks of the statement or we'll be here forever but there are some paragraphs that I think are really quite important to read and this is one of them. So Dr Lane said this:

"Self-sufficiency was considered a desirable objective [there's that word again] from about the early 1970s for several reasons."

Then he identifies, first of all, the World Health Organisation advocacy. And then he observes -- this is five lines down:

"From the point of view of England and Wales, another reason why self-sufficiency appeared desirable was the economic one. There was a general belief ... that it was more economic to manufacture Factor VIII through the state owned BPL/PFL than to purchase commercial product on the open market."

Although Dr Lane then raises some questions about the economic argument on the basis that there

was never a real assessment of what the cost was to -- globally, as it were, to the state of BPL.

And if we look at the last few lines on that page, he says:

"Since BPL/PFL were, however, fractionating FFP produced by Transfusion Centres funded by Regional Health Authorities, there was a cost involved and it is not correct to characterise the NHS concentrates as truly 'free'."

He also observes there was no system for charging Regional Health Authorities for the product.

Go to the top of the next page. He repeats his view that self-sufficiency was seen as desirable but not immediately essential. This is now -- he's saying at the start of the 1970s. And then he sets out what he says were a number of obstacles in the path of self-sufficiency. The first, and this is paragraph 74, was the lack of "proper financial co-ordination" to implement policies covering Blood Transfusion Centres, which had to produce the plasma, BPL, which had to fractionate it, the Haemophilia Centres which made the decisions in relation to treatment.

So a lack of co-ordination is his first point.

At paragraph 75 he then talks about the

consequences of the system of funding whereby it was Regional Health Authorities who were responsible for the allocation of budgets, and the Department of Health would not intervene. And then he contrasts that, this is about nine lines down in paragraph 75, with the position of BPL and PFL which he says were "funded directly by the [Department of Health] which closely controlled all but very minor expenditure".

He continues by pointing out that:

"Whilst the Regional Health Authorities controlled the Blood Transfusion Centres ... there was no discernible benefit to them ... flowing from their expenditure ... to increase the supply of FFP for fractionation ... Regional Health Authorities had no direct control over the funding of BPL and PFL and with it any expansion in their capacity to fractionate. There was no direct correlation between the [fresh frozen plasma] ... provided to BPL and the amount of Factor VIII which they received back ..."

Until, obviously, we get to the pro rata system later.

And then if we go over the page, paragraph 76, he expands further upon this:

"The practice of the DoH in leaving Regional Health Authorities to determine how they should spend

the funds allocated to them ... and the distinct reluctance of the [Department of Health] to interfere in any way with the Regional Health Authorities autonomy ... created difficulties in striking a balance between increasing the supply of FFP and increasing the capacity of BPL/PFL to fractionate it ..."

So there is a more detailed explanation of what he means by the lack of financial co-ordination.

And then if we -- well, there's an observation in paragraph 78, almost an aside, but perhaps picks up on, I think, an exchange you had with Mr Hill.

There is a description there of Dr Maycock's responsibilities as consultant advisor to the Department of Health, a role:

"... (all of which he did 'with a staff of one, no finance and no vested power or authority') ..."

Is the observation at the end of paragraph 78.

Dr Lane then poses the rhetorical question:

"What was 'self-sufficiency'? Reality proved difficult to forecast."

Then he sets out a range of facts, concerns, views, about the issue of estimating the future requirements for supply of Factor VIII concentrates.

I'm not going to go through it line by line, but

if we go over to the next page, paragraph 8, he makes the point that throughout the '70s, estimates of Factor VIII use were constantly increasing.

Then he sets out a number of points in relation to those estimates. Paragraph 81, he says:

"First [of all] there was uncertainty as to what was actually being produced at any given time."

And that's a reference to variability and quality of plasma and yield of Factor VIII.

Secondly -- this is his paragraph 82, he says, in terms of estimating demand, particularly in the early '70s, there were problems because it was largely cryoprecipitate that had been the basis for treatment, and there was a lack of exactitude in estimating international units of Factor VIII.

Then over the page, paragraph 83, there is a further discussion there in relation to what he describes as the compromise between yield of Factor VIII and purity of the product.

If we pick it up at paragraph 84, what he says is there is:

"The underlying problem (in retrospect) is that those involved were sometimes thinking of different things when considering self-sufficiency. For Dr Maycock and some of those in the DOH,

self-sufficiency was considered to mean the amount of plasma and concentrate produced from it which was needed to treat haemophiliacs in the way they were treated using cryoprecipitate. For others (particularly some clinicians), it was the amount wanted by their patients to lead as near normal a life as possible. Estimates arrived at on either basis were, as we now know, wrong."

Then what follows from paragraph 85 onwards, if we go over the page, is a discussion of a range of documents relevant to issues about estimates of demand, supply, and discussion of self-sufficiency.

As I say, I'm not going to go to each and every one of them or indeed to the vast majority of them, not least because some of the most important ones have already been flagged up by Mr Hill.

If we go over to page 33, we've got the heading "1974", and this is Dr Lane's summary, albeit a summary from the perspective of someone not directly involved with the issue at this time. He says:

"... the year was one taken up with discussions about the need to increase the production of Factor VIII, and although the then Health Minister, Dr David Owen, became involved, not much was achieved. The focus was very much on 1975 and the steps which

might be taken during that year."

Just note at the bottom of page 34, so over the page, paragraph 92, Dr Lane picks up on -- by reference to documents, but perhaps no doubt also informed by his own knowledge -- the need for investment in a new fractionation plant -- this is the fourth line of paragraph 92 -- and this requiring a policy decision by the Department of Health.

If we just go to page 36 now, paragraph 96. As I say, I'm going to skate over most of the documents themselves, but this is the first reference to a repeated theme in Dr Lane's proof. And then it relates to Dr Lane's relationship with Mr Watt, director of the Plasma Fractionation Centre in Scotland, and his scepticism, this is Dr Lane's scepticism, about what was being said in Scotland and his scepticism about whether the PFC could provide any assistance in fractionating plasma produced in England and Wales.

I'll show you a number of references in the course of the proof, but here we have Dr Lane saying this. This is reference to a -- I think a meeting of Haemophilia Centre Directors on 1 November 1974. It says this:

"Mr Watt ... chipped in on two occasions with

comments relating to Scotland. His tendency in these meetings (as discovered when I was employed by BPL) was to talk either in terms of what Scotland aimed to do, rather than what it was doing, or to try and score points wherever possible by stressing how much more advanced Scotland was compared with England and Wales. In practice, this was not too difficult given the disproportionate amount of money per capita which Scotland was receiving and spending on its transfusion service and associated fractionation installation at this time and for some years after."

In the course of looking at Dr Smith's evidence this morning, sir, I drew attention to Dr Smith's evidence about the good working relationship he had with Dr Foster, so the good relationship between the scientists involved in research and development, but there is distinct evidence of tension at a managerial level, in particular between Mr Watt and Dr Lane. And that's something that we may pick up on in the course of the presentation on Scotland next week.

But this is the first of a number of references in Dr Lane's proof in which he takes issue with what's being said by Mr Watt, or what's being put forward about the Plasma Fractionation Centre.

If we move to page 38, we get to Dr Lane's

comments on 1975. He deals with 1975 in paragraphs 99 to 109 of his statement. I just want to look at a couple of the paragraphs.

Firstly, paragraph 99. He refers to statements in Parliament from Dr David Owen. The second half of paragraph 99 is, as I read it, Dr Lane's own comment. He says this:

"Although the stated intention of the minister was to make the United Kingdom self-sufficient in two or three years, a one-off payment with a view to producing Factor VIII from some 275,000 donations was clearly not sufficient without continuing investment to increase the production of Factor VIII beyond this figure."

So I take that as a comment from Dr Lane.

Then if we go over the page to paragraph 104 -- sorry, page 40, Paul. My apologies. He refers in the preceding paragraph to a March 1975 memorandum, and then we get Dr Lane's comments in paragraph 104.

He says:

"This ... gives some clue to the mismatch between the 'target' of producing Factor VIII from 275,000 donations and what was actually required. My belief, as previously indicated, is that Dr Maycock and the DoH were concentrating on what was believed to

be the appropriate level of production to treat patients when a bleed occurred. Use of Factor VIII for home prophylaxis (which was to become the norm) was a significant factor which may in part explain some of the discrepancies between what BPL actually resolved to produce and what others estimated was actually needed."

Then he refers to:

"... a reference [in the memorandum] to Factor VIII yield from plasma being in the order of 30 to 40%."

And, again, this is Dr Lane's take on the document.

"This is frankly absurd even at the time this memorandum was produced. At the time, yields would have been in the region of 20%, and I'm somewhat puzzled as to why figures which were obviously very optimistic were not challenged by Dr Maycock at the time, since he obviously received a copy of the memorandum, and his manuscript note gives no indication of disagreement with this part of the text".

If we move to 1976 then on page 43. And 1976 is covered in paragraphs 110 to 131 of the proof. Again, I don't propose to look at them in their entirety.

You'll note the observation in paragraph 110 by Dr Lane is:

"This year was yet again punctuated by confusing statements as to 'targets' for the achievement of self-sufficiency."

If we go over the page, then, and pick matters up -- sorry, Paul, the previous page. Bottom of page 44. Paragraph 114. This is a reference to a practice introduced, according to the proof in December 1976, whereby:

"NHS factor concentrate was delivered to the Regional Blood Transfusion Centres in an amount proportional to the number of patients treated at the Haemophilia Centres of in that region in 1974."

Then if we skip down a few lines, picking it up on the fifth line on that page:

"Up until that point, I think it's fair to say that the distribution was somewhat *ad hoc*. The documentation from the earlier 1970s reveals correspondence from clinicians on behalf of individual patients seeking supplies direct from BPL, and there seemed to be no established and formalised procedure adopted with regard to the distribution of concentrates, particularly one which encouraged Blood Transfusion Centres to increase their supplies of FFP

to BPL."

And essentially what he identifies is really three stages: the *ad hoc* position prior to 1976; the scheme introduced with effect from December 1976; and then the pro rata scheme, and we see a reference to that in paragraph 115. He says:

"The scheme introduced with effect from 1 December 1976 was a prelude to a later arrangement which I was instrumental in introducing after I became director of BPL which we called 'pro rata'."

Then he goes on to give a description of the pro rata scheme which I don't need to go to because we've heard lots of evidence about that.

But those, in any event, are his views about the position in relation to supply prior to the introduction of what he refers to as the prelude to the pro rata scheme.

If we turn on then next to page 47, just draw attention in paragraph 119 to a further reference to Dr Watt. If we pick it up halfway through paragraph 119, and this is Dr Lane commenting upon a meeting that took place on 11 March 1976. Halfway thorough that paragraph, Dr Lane says this:

"Typically, Dr Watt from PFC in Scotland suggested that Edinburgh's yield was in the region of

30 to 35% and that their aim at Edinburgh was to achieve a 70% yield. Not only was the yield of 30 to 35% much higher than I would have expected was possible at that time, but 70% was, frankly, ludicrous on any view. For the same reason, I would be suspicious about the costings contained in the same document where Mr Watt, again trying to go one better, suggests that the Scottish product costs 4.2p per international unit against the NHS product which seems to be estimated (I'm not sure how) at costing 6p per international unit."

Then the bottom of that page, paragraph 120, refers to a paper prepared by Dr Maycock. I'm not going to take you to the underlying paper -- I think it's probably one you've already seen -- but just to Dr Lane's commentary on it.

So he says:

"The figures in this paper look rather more satisfactory than some of those appearing in Dr Maycock's earlier calculations, although a 30% yield which he assumes is still, in my view, too high. 20% would have been closer to the real yield."

And then there are some further observations on figures in the following sections of the statement.

If we then perhaps turn to page 51 next. This

is, in paragraph 128, Dr Lane talking about a document produced by Dr Maycock. It's an account in fairly forthright terms. Dr Lane says this, picking it up perhaps in the fourth line:

"Clearly, the idea that 40 million international units was to be the target was pointless. It was, as far as anyone could tell at the time, the existing not the future demand, and any planning exercise needed to look well beyond existing usage to future demand and plan accordingly. The graph sketched out at the foot of the last page suggests that Dr Maycock believes the demand would flatten out quite considerably, not withstanding the extraordinary steep climb to the level of consumption as it then stood. This was unfortunately entirely bogus. In my view, there were no grounds for believing that the demand would follow the pattern shown on the graph."

Then he goes on to talk about his attempts at estimating likely demand when he joined BPL in 1977.

Again, I'm not going to go to the underlying accuracy or otherwise of the documents themselves, but it perhaps casts some light on some of the difficulties that appear to have been experienced at the time.

Then if we go over the page, we can see, in

paragraph 131, this is Dr Lane's summary about 1976. Obviously, he looking back, because he was not involved at the time, so he's looking at the documents, presumably bringing his own subsequent knowledge to bear.

And he says this:

"Summarising 1976, the year appears to have been dominated by the continuing cryoprecipitate debate, the implementation of increases in production facilitated by the £500,000 injection of finance, and debate about the 'target' necessary to achieve self-sufficiency and the confusion sown in all this by 'targets' which related to capacity to produce rather than volume necessary to achieve self-sufficiency, and to what was needed rather than what the patients and clinicians wanted. Throughout the debate, there is no intervention from the Department of Health. At the time, the mismatch between what was being achieved (with a struggle), what was required to meet the current self-sufficiency requirements in concentrate and what, had anyone looked beyond current usage, would be necessary to achieve self-sufficiency for the future was all too obvious. Decisive action would have been required (backed by considerable funding) to plan a facility which would be ready by the end of the

decade and of a size which would leapfrog sufficiently far ahead to cater for the burgeoning demand for Factor VIII concentrate."

So on one view of what Dr Lane is there saying, he's saying -- it could be said he's saying that in 1976, it was obvious what was needed, which was the provision of funding and the policy decision to rebuild BPL.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: We're now at 1977, page 53. We've still got quite a few years to come.

Paragraphs 132 to 166 of Dr Lane's proof deal with 1977. He now goes into rather a lot more detail because obviously this is the point in time at which he took up the position of Director Designate.

Mr Hill has referred to this already, but it's just perhaps worth looking again at what Dr Lane says in paragraph 132, in which he says in the third line:

"I should point out (and this will be apparent from any of the minutes of the meetings between April 1977 and September 1978) that Dr Maycock kept me very much in the background. He continued to attend Transfusion Directors meetings, etc, as representative of BPL/PFL without me, and although, as I explain below, I was given some specific work to do

in planning for the 'Stop-Gap' proposals to further upgrade the BPL facilities, it was not until Dr Maycock's retirement in September 1978 that I found I was able to exert much influence or control over BPL/PFL."

If we go next to page 55, paragraph 137. Now, this is, I think, a reference to a meeting of Haemophilia Centre Directors in January 1977. I'll double check that, but I think that is what he's referring to in paragraph 137. In any event, I draw attention to it because it's -- we again see a tension between Dr Lane and the PFC.

So there's a reference to, about six lines down:

"Dr Drummond Ellis ... [so he represented BPL at the meetings at this point in time] said that the maximum capacity for Elstree (including a proportion made in Oxford) was 14 to 15 million international units. It will be noted that Dr McDonald from the Royal Infirmary Glasgow said that Liberton had the capacity to make 60 million international units per year. He added that to reach this target, the centre would need about £25,000 for new capital equipment and money for extra running costs, including payment for staff operating a 24-hour shift system."

Then this is Dr Lane's take:

"This figure was nonsense but was not apparently challenged in the meeting if the minutes are correct. As I shall describe below, it subsequently became apparent that Scotland was not in a position to make any real contribution to the requirements in England and Wales for Factor VIII concentrate, but at this meeting, a comment was made that it seemed as if Liberton had capacity to supply Factor VIII for the whole of the United Kingdom."

Then there is a quote from what it's said Dr Waiter was saying at the bottom of the page, about plans to divert plasma from south of the border to Liberton.

Then if we go over the page, Dr Lane's take at the top of the page is:

"In fact, so far as I can tell, whatever plans the DoH may have had, nothing ever came of them."

If we go to page 57 next, please, paragraph 143, you'll see there Dr Lane associating himself in terms of his agreement with a memorandum produced by Dr Gunson in May 1977, about the organisation of the National Blood Transfusion Service. And picking it up in the fourth line, Dr Lane says:

"This was a submission [this is the document produced by Dr Gunson] which embodied comments and

views of all the directors of Regional Transfusion Centres (including myself in my former capacity prior to joining BPL). As it transpired, it had very little impact. The thrust of the document was that there was a lack of central co-ordination within the National Blood Transfusion Service."

And then Dr Lane then elaborates upon that in rest of this paragraph. And if we pick it up in the last five lines or so, Dr Lane says:

"Notwithstanding the position, the problems identified in it persisted, and it was only in 1988 that a National Directorate for the NBTS was established."

Then he observes, and we've heard this from evidence from Dr Moore and others:

"The National Directorate remains mainly advisory and without regional executive authority."

Over the page to paragraph 144, we're on Scotland again:

"I have mentioned previously [says Dr Lane] that there appears to be a disproportionate amount of money spent on the Scottish Blood Transfusion Service, and this discrepancy in funding is exemplified on page 9 of the submission."

Then he identifies the figures:

"In 1975/76, expenditure on the National Blood Transfusion Service in England and Wales ... £15.8 million for a population of some 49 million, compared with expenditure of £3.5 million in Scotland, where the population was only 5.5 million."

And, again, the reference to the need for a central organisation for national planning if the NHS was to receive sufficient blood and blood products.

If we then just look at bottom of page 59 ... there's reference there to a report produced for the Advisory Subcommittee on Blood Products and Blood Group Reference Laboratories of the Central Committee for the National Blood Transfusion Service. That's paragraph 148.

And then Dr Lane sets out over the page a citation from it. It's been referred to in Mr Hill's presentation. What I wanted to show you is what Dr Lane says on page 61.

So having set out an extract from the document, paragraph 151, he refers to and sets out a particular passage which concludes with the sentence:

"Planning the future of BPL should not wait until the problems of PFC have been resolved."

Then we see at paragraph 152, Dr Lane says this:

"It was at my insistence that this paragraph was inserted. The indecision as to whether or not to redevelop BPL in line with what was clearly required by this time [and this time is now 1977] was becoming confused by DoH intentions to utilise PFC Liberton to some extent, a state of affairs which was not helped by exaggerated claims made by the director of PFC Liberton [that's Mr Watt again] for its operational capacity."

Dr Lane then sets out a reference to an appendix to the report. Again, this is a document you've already looked at, so I am not going to go over it.

But you'll see over the page at paragraph 155, Dr Lane sets out the conclusions he'd recorded in the appendix. If we just pick it up because it may be of relevance when you come to evaluate some of Dr Lane's broader statements about self-sufficiency. At the end of that first paragraph that we see on the screen, Dr Lane says that:

"The effects of shortage of finance can be mitigated in several ways which this paper seeks to show."

If we go to the next page, point (d) is:

"Adhering to the Department of Health's principle that the health service shall make all

possible attempts to become self-sufficient.

"The Director Designate of BPL [so Dr Lane] hopes the Central Advisory and executive bodies will reaffirmtheir intent to make the NBTS self-sufficient."

So it did appear to be, does appear to have been Dr Lane's view in 1977 that self-sufficiency was absolutely the goal, even though we've seen the earlier passage in his statement where he suggests it was a desirable rather than a necessary objective.

Just observe paragraph 156. He says:

"[That] report generated limited response from the Department of Health."

Let me just finish 1977 before we break. So if we go to -- if we go over the page to page 64, this is reference to a meeting in October 1977. Again, you've seen reference to this meeting elsewhere. If we go -- and Dr Lane was present at this meeting. If we go to the top of the next page, you'll see Dr Lane suggests by reference to the minute that:

"... the Department of Health made it ... clear ... no commitment could be made at that stage to any specific solution."

It then refers to Dr Lane's summary of three main problems.

If we go over the page -- sorry. Always a problem trying to take things too quickly.

Go to the bottom of the previous page, paragraph 161. There's an extract there again from the document referring to Mr Parrott explaining the Department of Health's thinking on future planning for BPL.

Then over the page, and this is just to give you Dr Lane's take in his proof on aspects of the meeting. Paragraph 162. Referring to Mr Parrott's use of the phrase "low-cost selective development", Dr Lane says this:

"I would comment this was not in line with Dr David Owen's objective as stated two years previously, that self-sufficiency should be pursued."

So that appears to be Dr Lane's understanding of what the position was, in terms of the policy.

And then, again, Scotland:

"It is also worth noting that the wheels were beginning to turn in Mr Parrott's mind as to the advisability of reliance on the Scottish plant. However, his manuscript amendment refers to 'not being totally reliant' on the Scottish PFC at Liberton. At this stage, Mr Parrott had not yet been to Scotland."

There is then, if we just look at paragraph 164,

a reference to Dr Maycock's first Stop-Gap paper. I don't need to take you to that, but if we just go to the next page, we see Dr Lane's observation:

"I am bound to say that the report itself was prepared without knowledge of Department of Health's intentions so far as Elstree was concerned, particularly with respect to the planned use of PFC Liberton."

So you'll have seen by now a consistent theme in the proof of evidence is Dr Lane's concern about what he says are the claims being made by Liberton but also his concern that somehow the consideration of the use of Liberton, which he thinks is essentially not a good idea -- and you'll have to evaluate for yourself in due course, sir, perhaps whether he was right or not. But his concern that that somehow having an effect on the decision-making process in relation to the Department of Health.

That brings us to 1977, the end of 1977, and time for a cup of tea.

SIR BRIAN LANGSTAFF: Yes.

Well, I think cup of tea will help us to reflect on that. 3.45.

(3.21 pm)

(A short break)

(3.45 pm)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Sir, we've reached 1978. As you heard earlier in the week, in April 1978 the announcement was made by the Lister Institute that it proposed to close its laboratories at Elstree.

That prompted Dr Lane to write a report addressed to Professor Mollison. He refers to it in his witness statement at paragraph 170, but here I'd like to show you the underlying document.

It's CBLA0000758.

Sir, you can see there it's headed "Closure of the vaccines and sera laboratories of the Lister Institute, Elstree, and the implications of the Blood Products Laboratory", to Professor PL Mollison. And we know it's from Dr Lane from his statement although the signature is somewhat indistinct.

If we go to the bottom of page 2, we see a heading "The future of BPL at Elstree" and the various implications which Dr Lane then sets out. What I wanted to do, however, is take you to page 4 under the heading "Future administration of BPL". Dr Lane says this, picking it up in the fourth line:

"BPL is expanded to become a considerable international resource within the Health Service and

must increase much further to meet the projected requirements for blood products scheduled over the next ten years. As an operation within the health service it stands alone, by its own development, contains the expert opinion needed to guide and plan future running and redevelopment. BPL should now have its own administration so that it can function as a complete unit."

Then Dr Lane sets out some suggestions as to what the constitutional arrangements should be for BPL.

Then if we go to the top of the next page, this really the observation I wanted to draw attention to. At the beginning of the page it says this:

"Development of BPL is hampered predominantly by the inordinately slow process of decision-taking by DHSS."

So that's the general observation Dr Lane there makes. Then he goes on to again to talk about what arrangements could be put in place for the running of BPL in the future. He says:

"By interposing professionally inappropriate controlling bodies between management of BPL and DHSS merely serves to delay planning and to remove from DHSS the need to maintain an essential and close

contact with BPL so that its administration is always fully informed. BPL is a DHSS Central Laboratory in the Transfusion Service -- it would not benefit from the constraints of a governing body poorly represented in blood transfusion skills."

Then the last paragraph on that page talks about the advantage of fully constituted managing subcommittee.

If we go back to the statement then, at CBLA0000005_002, page 70, you'll see in paragraph 170, Dr Lane refers to the report we've just looked at, his report to Dr Mollison, and sets out how he viewed the Lister's closure as a unique opportunity for the development and future of BPL.

Then paragraph 171 he then talks about the significance of the closure of the Lister Institute, for a number of reasons:

"... jeopardised the status of the 1978/79 budget ... Stop-gap proposals needed review because the future of existing building was unknown. Activities had, therefore, to be diverted to such questions as the future of the site, the future of BPL and the question of long term management. As the position presented itself, operations could have ceased."

Reference to Dr Maycock's retirement.

"It was possible that the DoH would ..."

Then we see another constant theme:

"... perceive an immediate need to resort to Scotland for Factor VIII concentrate if the Scottish figures were to be believed."

Then he says:

"As it turned out, the closure could not have come at a better time ... The Department decided to buy the Lister site ..." et cetera.

Then if we go down to paragraph 173, on the same page, you'll note the reference to a Regional Transfusion Directors meeting on 5 July. I don't propose to take you to the detail of that and, again, I think some of it you've seen from Mr Hill's presentation, but you'll note that Dr Lane says, as he recalls this was the first meeting of the Regional Transfusion Directors which he was permitted to attend, notwithstanding that he'd been director designate for over a year by that time.

There's just a reference at the very bottom of that page to the "Single Bag" committee. I'm not going to go into that topic in any detail but, if we go over the page, you'll see there the tension with Scotland, with Dr Lane saying:

"Its formation and work was criticised by Scotland."

And then there are some observations in paragraph 174. Dr Lane says:

"... I think it is worth making the point that so far as FFP production was concerned, three opportunities presented themselves during the period relevant to this litigation. The first was that resulting from the David Owen £500,000 injection. This enabled BPL to effectively double its production of Factor VIII concentrate ... The second was the development of optimal additive solutions permitting blood to be totally separated resulting in an increase of 30% in recovered plasma volume ... The third opportunity to increase FFP could have resulted from more use of plasmapheresis, enabling donors to donate a greater plasma volume. The introduction of single plasma donations and pro rata return to RHAs of products in relation to volume of plasma supplied to BPL were further contributory factors."

So there is summary from Dr Lane of a number of factors which he identifies as significant in terms of the ability to increase the supply of plasma.

Then if we go to the bottom of page 73, this is following a discussion about Dr Maycock's report,

which again was covered in Mr Hill's presentation.

At the bottom of the page, paragraph 179, Dr Lane makes this observation:

"In retrospect, however, the Owen initiative rebounded on the Service in that it supported growth in demand for Factor VIII but only a basis for limited supply and growth in output from NBTS and BPL sources. The growth at BPL focused attention on the effects of transition from a development laboratory to a manufacturing enterprise, now seriously below pharmaceutical standards.

"180. The problem was that the basic infrastructure of BPL remained one which was appropriate to a laboratory engaging in research and relatively small scale production. The buildings dating back to the 1950s were old, small and not appropriately designed for manufacturing. In 1979 the Medicines Inspectorate condemned the facility. However, whilst still inadequate, it was now a facility making a significant contribution to the increasing in requirements to haemophiliacs for Factor VIII concentrate. In retrospect it would have been less disruptive to the NHS if the consequences of inspection had been met in 1976 when the Licence Application to manufacture was submitted to the DoH."

So that appears to be, in part at least, a call or a suggestion that earlier inspection and the consequent decision-making might have been a better course.

I'm going to move to 1979 next, page 79.

Dr Lane deals with 1979 in terms of self-sufficiency in paragraphs 187-238 of the proof. What he says in paragraph 187 is this, and this is obviously an expression of opinion:

"In terms of self-sufficiency, by 1979 it was too late, (having regard to the four to five years it would take to plan and build a new facility), for a decision in this regard to have made any difference if, as I would submit, the majority of severe haemophiliacs were infected with HIV before 1985. That said, 1979 saw the Medicines Inspectorate carry out their inspection of BPL's facilities in April, and the publication of their findings severely criticising virtually every aspect of the BPL facility in the summer. From my discussions with the Inspectors during the course of their initial inspection, I was fairly clear in my own mind what the outcome would be even before the report was available, and this prompted me to press for a decision by the DoH on the future of BPL."

Then Dr Lane goes on to consider, at the bottom of that page, his paper on the function of Stop-Gap and phased redevelopment of the Blood Products Laboratory. I don't propose to go to that. However -- and indeed it's been looked at I think in the course of Mr Hill's presentation.

If we go to page 81, paragraph 193 is Dr Lane's brief reference to the inspection itself in April 1979, and he says:

"From my discussions with the Inspectors during the course of their visit, my expectation that they would be severely critical of the facility was confirmed by their comments. So much so that, on the 2nd May 1979, I wrote to Mr Dutton at the DH ... setting out my observations on their visit prior to the publication of their first formal report."

That letter is at CBLA0000938.

2 May 1979, addressed to Mr Dutton in the DHSS, and he says in the last part of the first paragraph that he believes his own views will "differ but little from the Medicines Division report".

And then in the second paragraph he says this:

"I would like to reiterate that from my point of view as the new director, the visit of the Medicines Division describes the laboratory very much in the

condition in which I took it over. Mindful of the shortcomings of the existing system and somewhat contrary to the previous director's feelings, I both welcome and encourage this inspection since I believe it is quite contrary to good manufacturing practice to use a privileged situation to hide the considerable deficiencies of BPL. In addition, and also contrary to the previous director's views, I believe that Medicines Division, through their Inspectorate and acting on behalf of the Secretary of State for the Health Service, have a responsibility to assist a central Health Service production laboratory like BPL to carry out its function in the best possible way. There is, within the Division a considerable wealth of experience and information which should be made available to us quite normally through the Health Service."

Then I don't think we need to look at the detail.

If we go over the page, just so that you know, Dr Lane sets out -- well, actually, we will just look at the first paragraph, I think, on that second page, and the rest really flows from it. He says:

"At the outset of the Inspectors' visit, I observed that they would find little in this

laboratory which did not stem from three things: first, intrinsic deficiencies of the building and the constraints arising primarily out of the leasehold arrangements which govern BPL's development; second, a quantitative and qualitative deficiency in staff arising from our inability to compete with industry at the level required to recruit process/technical and scientific staff which are needed; third, the fact that the laboratory is in the transitional stage between what Malcolm Harris chose to call, quite aptly, a 'cottage industry' into a major production process moulded along commercial industrial lines."

Then Dr Lane goes on to develop a number of those points further in the course of the letter.

If we go back to his witness statement, draft proof I should say, CBLA0000005_002, and go to page 86.

So he is here commenting upon a discussion of a paper he'd authored about the continuation of Stop-Gap at a meeting of the Scientific and Technical Committee in June '79, and he says in paragraph 206:

"... discussion eventually led to the conclusion that the DoH should proceed to prepare a complete appraisal of the various possibilities open and their cost effectiveness for consideration by the Committee

in September, and that this should precede any approach to Ministers regarding the future of BPL."

Then this observation from Dr Lane:

"It seemed to me at the time that matters were still drifting, and likely to continue to do so for some months, and I expressed the hope that there would be an early decision in principle on the development of BPL."

The next few paragraphs of his statement really deal with meetings and reports which are covered in Mr Hill's presentation. And so I think if we go to ... well, I will just ask you to note -- I don't think we need to go to it -- paragraph 220 of the draft proof. Dr Lane refers to concerns he had about his liability as director of BPL, if there was an adverse event. And how he was unable to get a clear answer from lawyers as to the extent of his responsibilities.

If we then go to page 93, now in the autumn of 1979, paragraph 223 refers to a report at which he prepared. We don't need to look at the report but just see why, according to the proof, Dr Lane thought the report or the paper was necessary. He says:

"This paper was prompted by the need, as I saw it, to ensure that we did not attempt to resolve the problems faced by BPL without regard to those which

were faced by the Regional Transfusion Centres who were providing raw materials. The DoH would have received my paper and I feel fairly sure that, at the time I wrote it, I was also preparing myself for another attempt to lift the hold on Stop-Gap."

Then you'll see he refers again to his view that there should be an entity which took responsibility for the National Blood Transfusion Service.

We can see then at the bottom of page 95, this is a discussion which flows from a meeting of the Scientific and Technical Committee on 26 September 1979 at which Dr Lane was present, and we return to the theme of the use of PFC to fractionating *(unclear)* plasma:

"Dr Dunnill, who was very much an advocate for the Scottish PFC ... raised ... the question of the absence of PFC representatives on the Scientific and Technical Committee. I remained concerned about the claims made of PFC by Mr Watt. Mr Smart suggested that to clear the path for a decision to redevelop BPL, the claims for PFC be tested. Mr Watt and Mr Cash ... were required to agree to a trial of fractionation. I deal with this in more detail below."

And that's a reference to the events that we've

discussed on a number of occasions, not least during the evidence of Dr Walford.

I then just ask you to note, in relation to paragraph 230, Dr Lane refers to a paper put together in 1979 by Professor Mollison, and then he refers to "reasons for the Committee rejecting the idea of abandoning production at BPL". He sets out three reasons. I just want to look at the third, which is subparagraph (c), just go further down the page:

"Plasma from paid donors is known to be more likely to transmit disease (particularly hepatitis) than is plasma from volunteer donors."

So that's what the document that Dr Lane is commenting on said.

What Dr Lane then observes in paragraph 231 is that he says:

"... I think that this last point is an over simplification and probably not correct so far as hepatitis NANB is concerned. It was most probably true of HIV."

We'll pick up on Tuesday morning some of Dr Lane's observations in his proof about hepatitis. But you'll see reflected there a view that hepatitis was not necessarily more likely to be transmitted by paid donors, is what he was setting out there.

If you move now to page 99, we get to 1980. Dr Lane deals with events in 1980 from paragraphs 239 to 288 of the draft proof.

We can see in paragraph 239 Dr Lane's recollection of the discussion of the future of BPL at a meeting of the Scientific and Technical Committee in January 1980. We don't need to look at the detail of it, which is the discussion which is set out in the documents, but if we go towards the bottom of that paragraph, we can see -- perhaps we pick it up where it says -- there's mention of "co-operative ventures with industry":

"I pointed out that it was necessary to ensure that the Minister, Dr Gerrard Vaughan, appreciated the inter-dependence between the Laboratory and the Regional Transfusion Centres ... the measures proposed fell somewhere short of Stop-Gap and of course did not include any commitment to redevelop BPL. Since I saw Stop-Gap merely as a stage in the comprehensive redevelopment of BPL, I was disappointed."

Then he refers in the last sentence to seeking a firm policy statement from the Department of Health and the planning work for the redevelopment of BPL.

So you will have seen, sir, by some of the references to which I've taken you, a theme in this

part of Dr Lane's proof is a theme of his concern, disappointment, at the speed or lack of speed in the decision-making on the part of the Department of Health in relation to the redevelopment of BPL.

If we move on to page 103, paragraph 252, this is Dr Lane's reference to the visit to BPL by the Minister of State, Dr Gerrard Vaughan, on 21 March. Six lines down Dr Lane says:

"My own impression at the end of the visit was that having heard the views from the staff and from management regarding BPL being commercially run (all expressed reservations about this), the Minister was convinced of the need to upgrade BPL in the short-term and redevelop it thereafter."

So that was his impression, as he is saying in this statement, from the visit.

"However, the Minister decided to reduce available funds which were already inadequate for the task of satisfactorily upgrading BPL in the short-term, on the understanding that a decision would be taken about long term redevelopment. No actual commitment was made to the latter."

Again, we've explored a number of these stages in the decision-making process in earlier hearings, but this is Dr Lane's take on it.

He then refers in the next paragraph to the meeting of the Scientific and Technical Committee on 23 April. Picking it up in the third line he says:

"Paragraph 4 is a very brief (and in retrospect perhaps a somewhat optimistic) record of the Minister's visit to BPL in March, but paragraph 5 on page 3 of the minutes contained what, at the time, was something of a bombshell as far as I was concerned."

Then there is the quotation from the minutes about BPL.

If we go over the page, the citation from the minutes continues for the whole of that page, and you'll see in particular at (iv), the penultimate paragraph, there's a reference there to the possibility of commercial partnership.

It may be that that's what Dr Lane is referring to as a "bombshell".

In any event, on the next page, this is again Dr Lane's take:

"To me the implications were clear enough. We had already, prior to the Minister's visit, been promised a sum of money which was inadequate to meet the very modest targets of Stop-Gap, which sum of money was to be spent in a somewhat piecemeal fashion with one eye on the Medicines Inspectors'

requirements."

"255. Now, it seemed that the Minister was saying that even this sum was to be reduced. The Stop-Gap programme originally envisaged was intended to improve the existing BPL facilities and enable us to make reasonable increases in our production output pending a major redevelopment of the BPL. The Medicines Inspectorate had effectively put a cap on any increases in production and had set a series of (not unreasonable) requirements for BPL. Since the appeared we would not be allowed to pursue Stop-Gap as originally perceived, (which would have taken care of most the Inspector's concerns), future manufacturing requirements would be more compromised by lack of resources, than envisaged even before the Minister's visit."

So that's Dr Lane's assessment. There's then in the following pages -- and Dr Lane recounts various other meetings, but really largely by reference to the content of the documents themselves.

If we go then to page 109, we can see, in paragraph 263, Dr Lane's reference to the meeting in June 1980 to discuss further the question of expenditure on the upgrading of BPL. And he refers to being asked to provide a list of what he would have

invested if given only £500,000.

This is Dr Lane's take on that.

"I can only liken the situation to one where you are told you may purchase a motor car and subsequently informed that you only be allowed a sum of money which is materially less than the purchase price and should decide which bits of the car you would like to buy."

Then paragraph 264, the next paragraph, we're back on the PFC, and fractionation in Scotland. Reference to an *ad hoc* meeting of Regional Transfusion Centre Directors, 18 June:

"... at which it was noted that the Director of PFC ... had indicated that he was in a position to fractionate any plasma that the Birmingham [RTC] might care to send to him. The Regional Transfusion Directors agreed that the aim should be to see that the PFC was in a position to fractionate all the Birmingham Regional Transfusion Centres' and for that matter other Regions' plasma."

Then if we go on page 111, we pick it up at paragraph 270. There's reference to a letter, 4 July, from Dr Dunnill to Dr Gerrard Vaughan, in which -- or in respect of which Dr Lane makes this comment:

"It is interesting to see him [Dr Dunnill] making several points which I was in agreement with at

the time and one which I was not. First, Dr Dunnill sought to stress that the expenditure required to maintain production at Elstree pending the building of a new facility (which for the purpose of his letter he took as given) was not to be regarded as somehow transitional wasted expenditure but rather an integral part of the development of the new production facility."

So that's what Dr Dunnill was saying. And then this is Dr Lane's comment:

"I had been advocating this for a little while, but as I have indicated above, I expressed concern from time to time that this point did not appear to be accepted by the DoH."

Then over the page, the second point made by Mr Dunnill with which Dr Lane is agreeing, was the expression of regret that there was not going to be a Special Health Authority to manage the overall affairs of fractionation of human plasma.

Then the third point, and this is where there is disagreement, relates to collaboration between England and Scotland, so paragraph 237 [sic], Dr Lane says this:

"... Dr Dunnill makes a case for closer collaboration between England and Scotland.

Throughout this period I was unconvinced that Scotland had the ability to assist England to any great extent despite what I regarded as excessive claims made from time to time by Mr Watt. Dr Dunnill, as I have mentioned, was involved in developing some of the equipment used at PFC ... and therefore sympathetic to the continued Scottish involvement and participation through PFC. As his letter makes clear, he was sensitive to the fact that this was certainly not an opinion I shared."

There's further reference in paragraph 275, top of page 113, to Dr Dunnill pursuing closer links between England and Scotland. So this is the second half of the paragraph:

"He knew that proposing the participation of Mr. Watt in the Working Party was likely to cause some difficulties as far as I was concerned (and, for that matter, some others,) but his perseverance eventually resulted in Mr. Watt joining the Working Party."

I think that's all I need to show you in relation to that year which hasn't otherwise been covered elsewhere or can't be picked up from a reading of the statement.

If we then turn to 1981, page 120, Dr Lane's proof addresses 1981 in paragraphs 289 to 334. In

paragraph 289 you'll see he says:

"There were several events during the course of the year which are relevant to the issue of self-sufficiency."

He refers to concentrate usage climbing, BPL having received the go-ahead for MARP01.

Then if we go to the bottom of page 291, there is reference to a letter in The Times, January 1981, raising the issue of the future role of PFC Liberton.

The author of the letter, who was I think an academic based at the University of Bath, is recorded there as suggesting that the insufficiency of blood products in the UK was largely self-imposed by bureaucracy.

Then there's a quotation from the letter on the next page, a criticism, it might be said, of the output from Elstree, described as "limited by the plant and process, which are largely outmoded and inefficient by modern standards".

Then it said:

"In contrast, production in Scotland is limited by the blood supply; the plant in Edinburgh is seriously under utilised, working at less than one third of its current capacity."

Then there's a reference to blood not being sent

across the border because the health departments for England and Wales and Scotland are independent. Then the author of the letter writes this:

"In my view this state of affairs is nothing less than scandalous."

Paragraph 292 is Dr Lane's riposte:

"This was incorrect. PFC Liberton's equipment was designed for continuous operation and one stage in a multi-stage process had a potential capacity of an estimated 6,000 litres per week. This capacity [...] was not matched by capacity in other stages which both preceded and followed; likewise the stage in question required 24-hour manning -- a situation never agreed or accepted by the workforce."

Then he refers to there being a detailed comparison in the course of 1981 of the products, and says:

"My impression, to the extent that we could get to the truth of the matter, was that the PFC products were of lower specification."

Dr Lane then refers to the trial that took place at Liberton and says:

"This trial clearly showed that without substantial investment in building new facilities and installing additional plant and equipment up and

downstream of the central processing plant and equipment, PFC Liberton could not operate to the stated capacity."

And then you'll note paragraph 293 sets out Dr Lane's view that this letter to The Times was also inaccurate in terms of plasma supply. And he concludes at paragraph 293 by saying:

"At the time in question there was no material surplus of plasma which, for want of fractionation capacity, was being wasted and therefore no immediate role for PFC Liberton to play, since they would merely be taking plasma which BPL/PFL needed".

Then you'll see he refers in the next paragraph to a response from Dr Harris, a DCMO, to the letter in The Times.

SIR BRIAN LANGSTAFF: By talking about "upstream and downstream of the central processing plant and equipment", he is talking about before and after.

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: He's not actually criticising the ability to produce -- the ability do so, apart from the question about staff?

MS RICHARDS: I think that's right.

SIR BRIAN LANGSTAFF: So it's a question in the terms of which I was talking to Mr Hill about it, of the

refrigeration of plasma coming in, and the warehousing of stock going out, is it? Is that what he probably means?

MS RICHARDS: It may be. I'm afraid I can't shed any further light on what was in Dr Lane's mind other than what's in the proof. We'll be able to see whether Dr Foster has any particular understanding next week.

SIR BRIAN LANGSTAFF: Yes. It'll be quite interesting to explore what he has to say about that.

MS RICHARDS: Yes, exactly.

Then, if we go to the bottom of page 125, paragraph 302, picks up a document prepared by Dr Dunnill in February, which again deals with PFC Liberton. So if we go over the page, we can see there's a citation from the document itself, but Dr Lane describes these as "partisan comments" by Dr Dunnill. And then I'm not going to read through what Dr Dunnill himself said, that's set out in the document itself, but if we go to the bottom of the page, we can then see this is Dr Lane's response:

"In these various comments, one glimpses Dr Dunnill's sympathies. Whilst automation had been brought into the plant at Liberton (a plant designed in theory for continuous operation), the laboratory was, nevertheless, plagued by manpower problems and

the refusal to work shifts."

Reference in the third paragraph to "coherent management" which Dr Dunnill was suggesting was a way of addressing the issue: "... was an unrealistic proposition: the real problems lay in the terms and conditions imposed by the Union, and the structure within the NHS itself."

If we go next to page 134, bottom of the page, paragraph 319. We're now in August 1981 and the first meeting of the Policy Steering Group formed to assist in relation to the redevelopment of BPL, and paragraph 319 says:

"It was reported that the potential for PFC Liberton to fractionate a proportion of English plasma had not yet been determined."

Then if we go to the next page, there's a little further information set out. And then the last sentence of that paragraph, Dr Lane observes the role of PFC Liberton is mentioned again:

"This reference marks the slight shift in thinking. Dr Walford suggested that it might prove uneconomical to send plasma to Liberton to fractionate."

And you'll recall this was an issue that was explored with Dr Walford during her oral evidence.

If we go over the page, page 136, paragraph 322 contains Dr Lane's comments on a meeting of the Advisory Committee on the National Blood Transfusion Service in September 1981. You'll see, if we pick it up -- well, actually, we'll pick it up in the third line, because this is really comment by Dr Lane:

"Dr Tovey ducked the issue of keeping Regional Transfusion Directors informed of commercial purchases made by Haemophilia Centre Directors. There was clearly no way all the Haemophilia Centres would give up their budgets. Also, no procedure was implemented to ensure that Regional Transfusion Directors were kept informed of commercial purchases. As I had mentioned previously, this question of control over Factor VIII concentrate was a perennial theme."

And he continues observing how Haemophilia Centres were protective of their position in terms of controlling their own purchases of commercial Factor VIII.

There's then, at the end of that paragraph, a further reference to the potential use of PFC Liberton, where it says:

"Mr Harley again hinted that PFC Liberton might be jointly meeting the UK's needs for blood products with any redeveloped BPL."

The issue is picked up on the next page, paragraph 324. Picking it up in the third line, end of the third line, Dr Lane says:

"I discussed the problems associated with PFC Liberton and the claims made for it with Mr Smart [the chairman of the policy steering group]. He suggested that we should again try to resolve the extent of PFC's role by a trial of fractionation."

If we go to the bottom of the page, there's then comment by Dr Lane on a letter from Mr Watt, in terms of data that was being produced regarding PFC Liberton products. And Dr Lane says:

"PFC Liberton did not in the course of time produce all the relevant data."

Over the page, top of the page, Dr Lane suggests that Mr Watt mis-describes the English albumin product, deliberately obscures the true nature of the albumin products produced in England and in Scotland.

We pick it up then down the bottom of that page, paragraph 330, now a policy steering group meeting of October 1981, there's a further discussion about the proposed trial at PFC Liberton, and Dr Lane says they:

"... had not been receptive to the idea that we send observers (an idea [he says] which originated with me)."

Then next page, 139, paragraph 333, there's a further description in the Scientific and Technical Committee meeting in November 1981 -- sorry, a further discussion -- about the use of PFC Liberton. It's recorded the shift-working experiment had been carried out, and Dr Lane says that:

"The PFC trial related only to an evaluation of continuous production of SPPS: Factor VIII production was not included ..."

Dr Lane then records various matters being set out by Dr Dunnill. Over the page, we can see in paragraph 334:

"Further consideration about the PFC trial."

And if we pick it up about halfway down that paragraph, we see, consistent with what we've seen from Dr Lane's statement so far, he expressed reservations regarding the experiments. He said:

"The study had concentrated on one stage only of what was a complete production process."

Then we get a reference to the facilities both up and downstream.

He says:

"The experiment at PFC Liberton was inconclusive ... the commitment of the SHHD to PFC Liberton would be critical to the mode of its future use."

That brings us to the end of 1981.

If we just go to the top of the next page, 1982, which Dr Lane addresses in paragraphs 335 to 365 of his proof. He sets out -- or he discusses there the report on the PFC Liberton trial, and he says in the third paragraph -- sorry, third line:

"It seemed to me that the report supported my concerns about PFC Liberton's ability to assist England and Wales in the production of Factor VIII ..."

And he goes on to describe that further and set out his own feeling that the experiment was inconclusive.

There's a further account in this part of the statement if we go over the page. Paragraph 336 deals with the issue relating to PFC.

And then if we go to the next page, paragraph-page 143, paragraphs 338 to 339 refers to a letter from SHHD, so from the Scottish Home and Health Department, to the Department of Health, January 1982, about the contribution PFC could make. And you may recall, sir, we looked at this letter, I'm pretty sure, during the evidence of Dr Walford. And you'll see there the reference to the need for substantial investment.

Dr Lane's summary of this over the page at paragraph 340 is -- he says:

"In summary, it was clear that without substantial changes in working practices, an investment of ... £6 to £7 million (but with no guarantee this was an accurate estimate), a delay of some two and a half years (again with no guarantee that this was an accurate estimate), PFC Liberton would be in a position to fractionate sufficient amounts of English plasma but at a cost which no one could predict."

Then there are further discussions in relation to Liberton in paragraph 342, bottom of this page and over on to page 145. But I don't think they add to the underlying documents.

We can then, I think, pick up the position in relation to 1982 at the bottom of page 152 where Dr Lane has now reached the point in his chronological overview where the CBLA has been established, and so he refers to what was -- I think must have been the first meeting of the CBLA on 3 December 1982. Yes, in fact, if we go over the page, he refers to the members meeting for the first time.

And then if we pick it up at 363, this is Dr Lane's I think take on 1982. He says:

"Thus the year closed with CBLA in the management driving seat and with DoH Treasury approval for the redevelopment of BPL on the basis of a capacity which it was generally agreed amongst all the interested parties would be enough to achieve self-sufficiency."

At 364 he says:

"It was not expected that the redeveloped BPL would be available to produce Factor VIII before 1985/6 (in the event, it was commissioned in 1987/1988). By this time, HIV transmission in coagulation products had been effectively controlled."

Then the next paragraph:

"It can be seen, therefore, that the CBLA was established too late to have any influence over the primary definitions of self-sufficiency ..."

So there we see again the response, effectively, on behalf of the CBLA to the claim. But that, of course, doesn't answer the question of whether bodies, organisations, individuals other than the CBLA could have influenced matters differently.

Sir, in relation to the years that follow in the proof, there isn't any particular passage I wanted to take you to, so if I could have the indulgence of two minutes, we can finish, I think, the issue of

self-sufficiency.

SIR BRIAN LANGSTAFF: Yes, certainly.

MS RICHARDS: I'll just give the paragraph references in the draft proof.

Dr Lane deals with 1983 in relation to self-sufficiency in paragraphs 366 to 377 of the proof; 1984 in paragraphs 378 to 389; and 1985, which was the last year his proof looked at, paragraphs 390 to 398.

And so what we then get to is a summary of the position in relation to self-sufficiency from Dr Lane's perspective.

Sorry, Paul, if we could have the statement back on the screen. It's page 168. And you'll see there it's headed "Summary of self-sufficiency claims and CBLA rebuttal". So that's really the point of this part of his proof. He's responding on behalf of the CBLA to the particulars of negligence and/or breach of statutory duty in relation to the issue of self-sufficiency.

He sets out each of the allegations in the re-amended main statement of claim. And if we just go a little further down the page, we can see here the essence of the point that Dr Lane was seeking to make, which was by the time the CBLA took over

responsibility, the decision had, to all intents and purposes, been taken, and that had been a decision for the Department of Health.

And really, that's what -- he essentially runs through what he says in the next -- or, sorry, in his responses to each of the allegations on the issue of self-sufficiency.

So if we just look at page 170. The allegation there set out is the allegation of a failure to co-operate with the Regional Health Authorities sufficiently in providing a National Blood Transfusion Service, and his observation is CBLA is not responsible for providing the National Blood Transfusion Service. That's the responsibility of Regional Health Authorities.

Then he goes on to talk about in -- to go back to and pick up on some of the themes about the lack of co-ordination, the lack of a structure, the lack of control over funds, and so on.

Then next page, 171, paragraph 404 refers to the allegation of a failure to assess future needs of Factor VIII. Again, the key point is -- that he makes is that by the time the CBLA was established, December '82, he says the future needs had been accurately estimated and formed the key to the planned

redevelopment of BPL.

So, again, his essential point is, this isn't something you can lay at the door of the CBLA because of the issue of timing.

And then if we just go to page 173, this is the issue of the allegation of the failure to use the spare production capacity in Scotland. We've seen Dr Lane's views fairly clearly set out in the proof so far. His short answer is:

"This issue had been run to ground surely before CBLA took over BPL."

And then he gives a slightly more detailed account of why he thought that was not a realistic option. To the extent that if we go towards the bottom of that paragraph, he says this:

"The belief that there was any significant spare capacity immediately available for fractionating English and Welsh plasma at PFC Liberton was, I believe, a myth."

Then there are a number of allegations which he deals with very shortly on the next page, in which, again, he essentially says that these are not matters that were the responsibility of the CBLA or are not particularly relevant to the CBLA.

And that concludes his proof insofar as the

issue of self-sufficiency and, indeed, the organisation of the Blood Transfusion Service and its relationship with BPL was concerned.

He then goes on to look at issues relating to viral infection, responses to that and heat treatment and, although they still account for several hundred pages in his statement, I should be able to deal with those much more shortly.

Heat treatment we've effectively covered through Mr Hill's presentation. The evidence of Dr Smith I've already referred to. So I'll take you to a handful of references, but Dr Lane doesn't add an enormous amount in that regard. But I will show you some of what he says about hepatitis and other viral infections on Tuesday morning.

SIR BRIAN LANGSTAFF: Very well.

Tuesday morning it is, then, at 10.00.

10.00, Tuesday.

(4.36 pm)

(Adjourned until 10.00 on Tuesday, 22nd March 2022)

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