Friday, 1 April 2022

(10.00 am)

DR ROBERT PERRY (continued)

Questioned by MS RICHARDS (continued)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Dr Perry, we had started talking yesterday afternoon about product warnings and that's the topic I want to pick up this morning.

A. Okay.

Q. We will see shortly how the terms of the leaflet or insert were submitted with the licence application to the licensing authority. Once the product licence had been granted, and presumably the form of wording approved, was there any system within PFC for reviewing what was said on the labels or the leaflets during the duration of the product licence, or was it a question of, "Well, it has been approved, we have got our product licence, we will look at it again when the licence comes up for renewal"?

A. I can't describe the details of a system but certainly when significant changes to the product specification -- and the best example of that is introduction of heat treatment -- was arrived at, then, yes, the labelling and the leaflet would have been reviewed. In some cases it remained unchanged

but in other cases, modifications would have been brought about, and I believe those modifications would have been notified to the licensing authority.

Q. So would it be right to understand, and I appreciate I'm asking you about events, obviously, a number of years ago, but do you think it is more likely that there wasn't a systematic process for re-examining the contents of the label but an *ad hoc* process, that as and when things came to PFC's attention or changes were made to the products, that the matter would be looked at?

A. I don't think -- I wouldn't describe it as *"ad hoc*". But it was clearly evident, certainly to myself and others, that when significant changes had occurred to the product and, if necessary -- and some review or labelling.

The first example we had of this was when we introduced the first generation heat-treated Factor VIII product, where we really didn't have the opportunity, because we wanted to do it so quickly, to substantially change the wording on the leaflets or the wordings on the label. So what we used in that situation was we simply over-stuck the packaging with notifications that this product had been heat treated and so on. My recollection is that we advised the

licensing authority that we had done that.

Q. I think you have said in one of your statements to the Penrose Inquiry that the wording that was used in relation to hepatitis was the wording -- I think you used the words "prescribed by the British Pharmacopoeia". We will look in a moment both at the wording used and at the wording in the British Pharmacopoeia.

Was it your understanding that the pharmacopoeia actually prescribed what had to be on the labels or that it laid down a minimum requirement or minimum recommendation?

A. I'm not absolutely clear after the passage of time whether it was a requirement to slavishly adhere to the wording that the pharmacopoeia had used but I think we took the view that the product that we made was presented as human anti-haemophilic factor. BP, then -- which is typical of some pharmaceuticals, you put "BPR", which means it has been made in accordance with the specifications of the pharmacopoeia. I think in that circumstance we fairly consistently applied the wording that had been prescribed by the pharmacopoeia.

I think there was freedom for manufacturers to diverge from that, but it is always a problem with

small vials of product, how much wording you can actually put on a label or in a product insert leaflet.

Q. I'm going to ask you to look at the leaflets and some of the information submitted to the licensing authority and also some of the labels. We did look at these with Dr Foster, but I'm conscious that there may be those listening who wouldn't have seen this material, so I'm going to take a little time going through it again Dr Perry.

If we start at PRSE0002726 and if we go over to page 5, I think, Sully. No, I had this last time. Try page 10. I think there are blank pages in the middle. Thank you.

This is the licence application submitted by Mr Watt in March 1978 for PFC's Factor VIII product, is that right?

A. Yes, yes.

Q. If we go to the second page and we look at the bottom half of the page, there's the -- sorry just up a little further, please.

So we have got the:

"Contra-indications.

"Precautions and Warnings."

We see it is written:

"... no contra-indications. Warnings include storage below 5ºC, reconstitution by addition of pyrogen free distilled water, the material should not be infused if a gel forms on solution and should be discarded if it is not used within three hours of preparation of solution. Product may carry the risk of transmitting serum hepatitis."

So that is the information in the application form.

If we go over to the next page, please, Sully, or, if it is blank, go two pages. Yes, thank you.

So we can see this is then, as I understand it, appended to the licence application form and it is PFC's proposed draft package leaflet insert, is that right?

A. For the 1978 application.

Q. For the 1978 application, yes.

Then if we go on to the next page, please. We can see in the second paragraph, as part of the description, it refers to:

"All plasma used for preparation of factor VIII concentrate is derived from blood collected from volunteer donors has been screened for the presence of the HB surface antigen ..."

And details given of the test:

"... preparation has also been examined by more searching techniques applied in at least two laboratories external to the laboratory of manufacture."

Do you know what that's a reference to?

A. No, but there would have been reference laboratories in both Scotland and England that had perhaps more sensitive assays available, and my predecessor Mr Watt I think always took the advantage of accessing those to -- either to confirm the results that PFC was getting or he was interested in a technique which could be more searching. I don't think they were routinely applied to every batch.

Q. Then it continues --

SIR BRIAN LANGSTAFF: Just one moment.

Do you actually know of a test being used in 1978 which was more searching than radioimmunoassay? I can understand that RIAs is and was thought to be at the time more searching than RPH, but RIA itself, more searching than that?

A. There may have been versions of it and different extraction techniques which increased the sensitivity. I think it is simply implying that. I don't think -- there was nothing like nucleic acid amplification technology then.

SIR BRIAN LANGSTAFF: No.

A. So it was -- my understanding is that this would have been a more -- perhaps a more sensitive assay, using more sophisticated extraction techniques for the product which may have picked up or had the capability of picking up much lower levels of contamination that could be detected by routine assay. That is my understanding, although I don't have on a clear view on it. And I'm not sure what Mr Watt meant in 1978 but that's my interpretation of his meaning.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: The leaflet continues:

"Nevertheless none of these tests are of sufficient sensitivity to eliminate the possibility of transmitting hepatitis. Methods for examination of this product continue to be developed but the risk of transmission cannot be disregarded."

That's part of the description.

Then over the page, under the heading "Side Effects", towards the bottom of the page:

"Complications in the use of factor VIII concentrate are rare. Apart from the general complications of hepatitis and intravascular haemolysis (see above) some patients may occasionally experience slight irritation at the site of the injection."

Then there is reference to transitory headache

or nausea being reported.

That is the information as at 1978. If we then go over the page to the application made also in '78, but I think in October '78, for Factor IX.

Can we go to the next page, please, Sully.

We can see at the bottom of the page, we see in the licence application form a similar heading "Contra-indications, Precautions and Warnings", similar to what's said in relation to Factor VIII, and then:

"Product may carry the risk of transmitting serum hepatitis."

Then there is reference to a "slight generic risk of diffuse intravascular thrombosis".

If we go to the next page we can see similarly we have an appendix containing the proposed package insert leaflet for the -- DEFIX, the Factor IX concentrate.

If we go to the next page. I won't read it fully aloud, but we have, in the second paragraph under the heading "Description", a similar explanation, recording in the penultimate sentence:

"... none of these tests are of sufficient sensitivity to eliminate the possibility of transmitting hepatitis ... the risk of transmission cannot be

disregarded."

Then if we go over the page to "Side Effects", it suggests complications in the use of the Factor IX concentrate DEFIX are rare.

Then there is the reference to the general complications of hepatitis and then it goes on to talk about intravascular coagulation or thrombosis as a potential side effect of Factor IX.

Can we go to the next page, then, please.

If we zoom in on this, is this, as far as you understand it, the final version of the leaflet, Dr Perry?

A. Unfortunately it hasn't got a date reference, but it's prior -- it's a leaflet that was used prior to the introduction of heat treatment. So I believe this is a faithful copy of the leaflet which was included with the product.

Q. So this is Factor VIII, and we can see in the second paragraph, under the heading "Description" -- I haven't checked word for word to see if it is identical to the form submitted to the licensing authority, but it certainly seems to be largely the same in relation to what's said about hepatitis, and under the heading "Side Effects", again, it seems to follow or be very similar to the language in the draft

submitted to the licensing authority. So reference there, do you see, to the general complications of hepatitis?

Then, next page, we have, as I understand it now, the leaflet in relation to Factor VIII heat treated. Is that right?

A. Yes.

Q. Would this then be a leaflet that would have been produced from -- well, are you able to assist us with when? There is a date in the bottom right which looks like it is April 1985, "5/4/85".

A. Yes, I think this is a date reference for this particular leaflet.

Q. Do you know what was done between December 1984 and April 1985 in terms of information provided with the heat-treated product?

A. I'm not sure what information was provided in addition to the leaflet. As I mentioned a few minutes ago, the action that we took as a result of introducing our first generation heat-treated product was simply to apply over-stick labels to the existing labelling. That was seen as the most efficient and quick way of getting the product to issue.

Q. In any event, by April 1985 we have this as the leaflet for the heat-treated Factor VIII?

A. Yes.

Q. We can see the second paragraph -- sorry, under the heading "Description" refers to a collection from volunteer donors, screening for hepatitis B surface antigen using radioimmunoassay. So just the RIA test. Reference again to the more sensitive techniques. And then:

"The product has been heat treated at 68ºC for twenty-four hours in the dried state but it cannot be assumed that the product is non-infective."

I think this is right, in this section, there is not any express reference to serum hepatitis or hepatitis beyond the hepatitis B surface antigen testing?

A. No, there is no explicit reference to any particular infectivity risk. And my recollection is that I think in discussions with Professor Cash, and probably the Haemophilia Centre Directors as well, we chose to give a more generic expression of "non-infective", which was intended to imply that there could be a risk of other viruses as well. So I think we moved from a situation where we were only referencing hepatitis and this was intended to include, particularly at this time, HIV as well.

Q. But I think it is clear on the face of it, there is no

express reference to HTLV-III or AIDS?

A. No. I think that was by design, at that stage.

Q. Yes, I will come back to -- once we have looked at the actual documents as to why that might be the case. There is reference under the heading "Side Effects" to general complications of hepatitis, and we can see that in the second sentence there.

Then, if we go to the next page --

SIR BRIAN LANGSTAFF: May I just ask, the references here, the references 1 and 2, at the bottom, they are copied over from the previous document. I think reference number 3, "MMWR Vol 33 No. 42 1984", is a new one. And if I'm --

A. Yes.

SIR BRIAN LANGSTAFF: I imagine, though I haven't checked, that may be the MMWR that spoke about the likely efficacy about heat treatment.

MS RICHARDS: The timing would be right but I haven't checked either, sir. I will do so.

SIR BRIAN LANGSTAFF: That can be checked and confirmed in due course.

A. The timing is certainly consistent, I agree.

MS RICHARDS: Then if we go to the next page, we've got what looks like the issued leaflet in relation to the unheated Factor IX concentrate.

A. Yes.
Q. And the description contains in the second paragraph a similar narrative to that in the draft leaflet submitted in 1978 with the licence application, and then if we look at "side effects", there is reference there in the second sentence again to general complications of hepatitis.

Then, the next page is the heat-treated Factor IX. Now, if we just look a little more closely, first of all, to the left-hand side, please, Sully. Thank you. If we look at the second paragraph under the heading "description", it reads:

"All plasma used for the preparation of Factor IX concentrate as derived from blood collected by volunteer donors has been screened for the presence of the hepatitis B surface antigen using a radioimmunoassay. The preparation has also been examined for this antigen by more searching techniques applied in at least two laboratories."

So that's similar to what had been in the earlier leaflets from 1978.

A. Yes, yes.
Q. "In addition, product plasma pools and individual plasma donations are tested for the presence of antibody to HTLV-III. The product has been heat

treated at 80 degrees C for 72 hours in the freeze dried state. This treatment is expected to inactivate viruses associated with the acquired immune deficiency syndrome (HTLV-III, LAV, ARV). The effect of this heat treatment of hepatitis B and hepatitis non-A, non-B has still to be elucidated and therefore this product cannot be assumed to be non-infective with regard to the hepatitis viruses."

Then, before I ask you about that, if we just look at side effects, we can see it records:

"Apart from the general complications of virus transmission (discussed above) ..."

Then it goes on to talk about the risks of intravascular coagulation or thrombosis.

Now, I don't think this leaflet is dated. Can we just go back to the whole leaflet, Sully. We don't appear to have a date on it in the way that we had for the heat-treated Factor VIII but does the reference to plasma pools and individual plasma donations being tested and the reference to the heat treatment programme enable you to tell us roughly when this would have been produced?

A. Yes. We may come on to discuss this, but the Factor IX product was not introduced -- the heat-treated DEFIX was not introduced for routine use

in Scotland until the autumn of 1985 because of our experiments and studies and to ensure that it didn't have any risk of thrombosis associated with it.

So, by that time we knew we were testing -- well, we were. We were testing individual donations and plasma pools for HIV.

Q. Which was, I think, the middle of October 1985?
A. Which was middle of October 1985, yes.
Q. This is autumn or end of 1985, this leaflet?
A. So the opportunity presented itself to update that leaflet but that opportunity didn't exist with Factor VIII which was introduced in -- the 24 hour heated product wasn't introduced -- it was introduced much sooner than that in manufacture in early 1985 and HIV testing hadn't been introduced then.
Q. Then if we just go to the next page, I'm not going to try and read this because we looked at it with Dr Foster and he helpfully reminded us that there were colour copies available which are easier for us to read. We can see these are vial labels.
A. Yes.
Q. If we go to CBCA0000065_010, I hope we will have a clearer -- yes, this is slightly easier to read. If we look first of all at the top label which is "unheated Factor VIII", I don't think again we have

a date. There's an expiry for this particular vial presumably, this particular batch, which looks like -- well, I'm not quite sure, 84?

SIR BRIAN LANGSTAFF: It looks like 12/84.
A. I'm sorry where are we?
MS RICHARDS: So the expiry date in the bottom right-hand corner of that label.
SIR BRIAN LANGSTAFF: SLC -- was it 2575m/12/84? It looks like 12/84. It looks as though there might be the operative date.
A. Yes. It seems a strange way of expressing the expiry date which is usually just a -- so I can't quite explain that, but it could well have been a sample label from a batch which did expire in December 1984.
SIR BRIAN LANGSTAFF: Well, whoever was using it would have to know when it was past its use by date.
A. Absolutely.
MS RICHARDS: In any event, we're told, and I think it is apparent from the label, that this is for Factor VIII and it's clear it's for the non-heat-treated Factor VIII. So it's for the product that was being used by PFC up until the end of 1984.
A. Yes.
Q. And we can see the label contains instructions about reconstitution and so on, and then says:

"This preparation is of human origin and cannot be assumed free of hepatitis virus."

A. Yes.

Q. And that is what I think we'll see potentially echoes the language of the British Pharmacopoeia. If we then just go to the next label, so this is the heat-treated Factor VIII and, again, looking at the expiry date it looks to me as though it's a date in 1985.

A. Yes.

SIR BRIAN LANGSTAFF: It looks like 2/85.

A. Yes, it's February '85 yes.

MS RICHARDS: Again, the label has instructions in relation to reconstitution, and then the last sentence says:

"The freeze-dried product has been heat treated but cannot be assumed to be non-infective."

So that echoes, I think, the term that PFC have chosen to use in the leaflet: not referencing hepatitis, not referencing AIDS or HTLV-III --

A. Yes but --

Q. -- using the terminology "non-infective"?

A. But recognising there were risks other than hepatitis by then. I think this curious reference in the expiry date actually is just a label-dating reference for when the label was drafted. I think typically under

the Factor VIII, the lot number and expires, there would have been a much clearer expression alongside. These are blank labels. So I think that reference down there, which is a bit curious, is a label version reference.

Q. Thank you. Understood.

Then if we look at the last of the labels, which is for the unheated Factor IX concentrate, we can see again it has instructions in relation to usage and then it says:

"This preparation is of human origin and cannot be assumed free of hepatitis virus."

So I think we can see from the material that we've looked at, Dr Perry, there's no express reference to non-A, non-B hepatitis in any of the material until we get to the heated Factor IX at the end of 1985.

A. Yes, that's right, yes.

Q. There is no particular description or account of either -- the seriousness of hepatitis, is there?

A. No, there's not.

Q. There's no reference to HTLV-III or AIDS again until we get to the heat-treated Factor IX towards the end of 1985?

A. Yes, but not an explicit reference to it. It's in --

Q. Only on the Factor IX there's an explicit reference to acquired immune deficiency syndrome and HTLV-III LAV.

A. And the confidence that the product is likely to be free of that particular -- of HIV risk, yes.

Q. Would you also accept, looking at this material, there's nothing which would inform a reader of what I think you yourself have described and others have described as the almost inevitability of infection or transmission of non-A, non-B hepatitis, even with NHS products?

A. No, there's not. There's not an extended narrative on those risks but I think as -- we may come onto discuss the purpose of these -- these were prescription-only medicines. The labelling, the leaflets and so on were primarily targeted at the prescribing doctor and, in a sense, they had a much closer working knowledge of risks of hepatitis non-A, non-B, hepatitis B and, latterly, HIV than the manufacturer of the products. So none of this information would have been a surprise to a treating doctor.

Q. Yes. I may come back to that, Dr Perry. But before I do that, just to complete the factual picture, the British Pharmacopoeia -- and we have extracts only for present purposes at SBTS0002189. So these are extracts provided by SNBTS and we'll obviously want to

look at the fuller pharmacopoeia in due course. We can see these are extracts related to Factor VIII, rather than Factor IX.

If we go to the next page, please, Sully.

So this is the extract. We're told at the top of the page it's from the British Pharmacopoeia for 1973. Then if we look down the bottom of the page to the heading "Dried Human Antihaemophilic Fraction", there's a description that I'm not going to read through.

If we go to the next page, if we look at the right-hand column, top half of the page, there's a heading "Labelling". We can see what's written here is:

"The label on the container states ..."

Now, just pausing there, this isn't, therefore -- is this right -- prescribing what should be in the package insert or leaflet? This is concerned only with what should be on the container itself?

A. Precisely, yes.

Q. And then we can see this is what the pharmacopoeia is contemplating, that the label will state: the number of units contained in it; equivalence to the anti-haemophilic activity of normal plasma; amounts of

fibrinogen; sodium ions; citrate ions, other added substances; point 5 is about reconstitution, as is 6, 7, 8. Then point 9 is:

"The number of donations in the pool from which the preparation was obtained."

So that's -- and then 10, 11, and 12 is about expiry, storage and use.

So it would appear from the British Pharmacopoeia extract, 1973, that we've got here, there isn't any express reference to hepatitis there but there is a requirement or a recommendation or an expectation that the label will state the number of donations in the pool?

A. Yes, clearly. I think that subsequently disappeared in the subsequent monographs.

Q. Yes, absolutely right. Yes, that is correct as far as I understand at least these extracts and that's why I wanted to go through them with you with some care.

If we go over the page, you'll see someone's written at the top there:

"British Pharmacopoeia 1973, Addendum 1977."

There's nothing of particular significance in the passage in the addendum relating to anti-haemophilic fraction. It is the one paragraph on the page that hasn't been crossed through. Then if we

go to the next page, someone has written at the top there:

"British Pharmacopoeia 1973, Addendum 1978, Pages 11-12."

Just before we look at the text, I don't know whether you can assist with this, Dr Perry. Is this right: there was a principal version of the pharmacopoeia produced periodically and then there would be, was it every year there was an addendum produced or ...?

A. I can't confirm whether or not that's the case but that was certainly the way they managed changes in pharmaceutical development if there was a -- because the pharmacopoeia, if you've ever seen these things, they're enormous volumes --

Q. Yes.

A. -- and republishing to make minor changes to certain monographs just simply wouldn't be possible. Well, it would be possible but at enormous cost and inconvenience to everybody, I think. So the system was that they would put out regular updates in the form of addenda, which were formal documents.

Q. Yes. Then we can see -- so this is recorded as being the addendum from 1978 and, if we go to the bottom right-hand part of the page then, under the heading

"dried human anti-haemophilic fraction", we can see there is a narrative here which refers to donor selection and donor screening in relation to hepatitis B. It says:

"Blood to be used for preparing ... Fraction is obtained from human subjects (a) who are, as far as can be ascertained by a registered medical practitioner after simple clinical examination and consideration of their medical history, free from disease transmissible by blood transfusion ..."

(b) there refers to testing for syphilis. (c) then refers to testing for hepatitis B antigen. Then I don't think I need to read any of the remainder.

Then if we go over the page and we look in the bottom right-hand part of the page, we have got the heading "Labelling".

Thank you, Sully.

Here we have got what's recommended for inclusion on the label: (1) number of units; (2) concerns concentration of protein, sodium ions and citrate ions, (3) any other substances contained in it. (4), (5), (6) and (7) are concerned with matters relating to reconstitution of the product. And then (8):

"... that the preparation is of human origin and

cannot be assumed to be free of hepatitis virus ..."

So that's the language which is similar to the language used on the PFC labels, is that right?

A. That is correct, yes.

Q. Then (9) is date, (10) and (11) concern storage and use.

So it would appear from this that between 1973 and 1978 -- or, sorry, by 1978, the British Pharmacopoeia recommendation that the label includes a description of the number of donations has disappeared?

A. It has. And they have added hepatitis risks.

Q. Yes, in the terms that we see here.

If we go to the next page, someone has written at the top:

"British Pharmacopoeia 1980."

Now the Inquiry will be checking this for itself and we hope, sir, to obtain full copies of the relevant pharmacopoeias, but this would tend to suggest that in 1980 a whole new pharmacopoeia was issued. So we had the 1973 one, then we had addendums being published, and then in 1980 there is a new version.

We can see bottom of the page refers to the dried Factor VIII fraction.

If we go over the page to "Labelling", top left-hand corner of the page, I don't, I think, need to read through all of them. Again, it echoes what we saw from the previous addendum from 1978, so there's no reference to number of donations and then point (8) is the terminology of "the preparation is of human origin and cannot be assumed to be free of hepatitis virus".

So that is 1980. If we go to the next page, someone has written on the top there:

"British Pharmacopoeia 1980. Addendum 1986."

Do you know, Dr Perry, bearing in mind that this was provided by SNBTS, whether there were any addenda issued between 1980 and 1986 that related to Factor VIII concentrate?

A. I don't know.

Q. Well, again, sir, the Inquiry will be endeavouring to check all of the originals and find out for ourselves.

Bottom right-hand corner, in any event, we see the start of the monograph for "Dried Factor VIII Fraction". If we go over the page -- actually, no, can I -- sorry, Sully -- if we stay on the page that we were -- look at the bottom right-hand corner. It says:

"Dried Factor VIII Fraction is prepared from human

plasma obtained from blood from more than ten healthy donors who must, as far as can be ascertained after clinical examination, laboratory tests on their blood and a study of their medical history, be free from disease transmissible by transfusion of blood or blood derivatives."

Then there is reference to how it is prepared and so on.

Then if we go back to the whole page, Sully, "Labelling" is bottom right-hand corner of the page.

So here we have, as at 1986:

"The label on the container and the label of the package state ..."

Then I think I can skip over the first few -- well, in fact, no, actually I won't:

"... the label on the container and the label on the package state ..."

Then there are number of units, protein, heparin, information about preparation. Then the second paragraph says:

"The label on the container or a leaflet accompanying the package states ..."

Then we have the reference at (3) to "the preparation cannot be assumed free of hepatitis virus".

So it doesn't appear, as at the addendum of 1986, at least from these extracts, that there's any reference in the British Pharmacopoeia to HTLV-III or AIDS?

A. No, I don't think -- there is no reference to AIDS at this stage. This is 1983?

Q. This is 1986.

A. Oh, 1986. Okay. No, there is no reference by that time.

Q. Then the next extract we have is from 1988, which is the next page.

We will see in the description in the first paragraph on the left-hand side -- if we just go closer in to that, please -- again, there is reference to preparation from human plasma, and then it says:

"The examinations and tests to be carried out are decided by the appropriate national authority; in particular, tests for hepatitis B surface antigen and for HIV antibodies are carried out by suitably sensitive methods and give negative results in both cases."

Then if we go over the page, please, to the "Labelling".

So if we can just zoom in on the paragraph on the left-hand side, please, Sully. "Labelling", top half of the page. Thank you.

So we can see what's stipulated there for the label: number of units, concentration of protein, fibrinogen, heparin, other substances, volume of water, expiry dates, conditions for storage, and so on.

So there's no reference here to the label stating anything about infection?

A. No, no.

Q. Do you know why that might have been the case as at 1988? Is that reflecting the belief that products -- Factor VIII concentrates had been successfully inactivated?

A. I think so. I would make the general observation that pharmacopoeia monographs always tended to be produced after a significant period of time. You know, they weren't prospective; they were retrospective documents, reflecting best practice and developments and so on. My explanation, I think, is not dissimilar to yours: that it was -- by that time there was an expectation that clotting factor products should not transmit HTLV-III -- or HIV as it was then.

Q. Or non-A, non-B hepatitis?

A. Or perhaps non-A, non-B, but I think it is a little early for that. It is interesting that there is no reference to hepatitis virus because there were

products still transmitting non-A, non-B hepatitis at that time.

Q. Dr Perry, do you know from your own knowledge anything about how the British Pharmacopoeia in the 1970s and 1980s was compiled or who by?

A. Well, I did actually sit for a brief period, a few years, on the British Pharmacopoeia Commission subgroup on biologicals, and it met very infrequently and often by correspondence, and, as I have described, it was a highly retrospective exercise and prescribed absolute minimum standards. For instance, it talks about 10 donors, a minimum of 10 donors. Well, I know of no organisation that produced Factor VIII from 10 donors. But it was a document and a system that was widely used beyond the UK. So it was targeted, as well as at developed countries, at developing countries as well, so it could give them some guidance on how to make these products.

SIR BRIAN LANGSTAFF: On that point, it was plainly -- if we just go back to the start of this particular document -- thank you. The previous page.

It is the first paragraph. About halfway down:

"The examinations and tests to be carried out are decided by the appropriate national authority."

So it looks from that that this was designed to

deal with any Factor VIII fraction, whether it was of origin at the PFC or BPL, but also origin elsewhere --

A. Or any other country.

SIR BRIAN LANGSTAFF: -- that was being sold or distributed in the UK through pharmacies or through hospitals. And that might explain or fit with the reference to 10 you are mentioning possibly.

A. Absolutely. I recall being involved in discussions on some monographs and -- well, it was more than a tendency. It was a requirement to provide -- it provided a minimum specification for these products. It wasn't designed to be a state of the art document. It was designed, as I say, for other countries, and many other countries did use the British Pharmacopoeia as a reference document or a reference specification for products that they wished to make, not only plasma products but many other pharmaceuticals as well. So it was a -- I think it was an attempt to provide a useful body of knowledge for organisations that wished to produce products but for whatever reason couldn't -- were not able to provide state of the art pharmaceuticals, as it were.

SIR BRIAN LANGSTAFF: Just one further slightly different point in respect of these labels.

If we go to the very end of this document, so

the next page, please, Sully.

The very last words, which are not apparently to be put on the label as -- or not prescribed as minimum for the label, are repeated from edition to edition:

"Dried Factor VIII Fraction [which is what this is], after constitution, should be administered only with equipment that includes a filter."

A. Yes.

SIR BRIAN LANGSTAFF: It is not simply a question of reconstituting and putting into a syringe, there has to be a filter somewhere in the --

A. Yes, I think the conventional practice, as I understand it, and we introduced this in our products latterly, that the product and the insert leaflet and the outer package would contain a filter needle. So you would take the -- you would aspirate the reconstituted product into the syringe, you would -- and then attach a filter needle prior to infusion.

SIR BRIAN LANGSTAFF: I see. So that's how it would --

A. It wasn't a big sophisticated filtered giving set, it was a simple filter needle that took out any particulate matter that might be there.

SIR BRIAN LANGSTAFF: And that would be why it didn't need to be put on the label, is it?

A. Yes, yes.

MS RICHARDS: As you have explained, Dr Perry, these effectively then were minimum expectations. So there was nothing that would prevent someone producing Factor VIII, whether it is PFC or BPL or a commercial pharmaceutical company, from setting out more information, particularly in the package inserts and leaflets?

A. No, that's right. I think that's absolutely right.

Q. Can I then just look at some of the evidence you have given on this topic to the Penrose Inquiry, when you were asked to explain PFC's approach.

If we start with PRSE0002620.

This is a statement provided by you. I don't think it's -- oh, yes, it's the end of 2011.

If we go to the second page, I just want to pick it up -- so you've set out an extract from a range of the materials. We have looked at the originals so I don't need to trouble you with that. And then you say this:

"The above statements are designed to comply with regulatory and pharmacopoeial standards and to provide a warning to expert and experienced prescribers of the product (ie Haemophilia Doctors) of the generally recognised and understood infectivity risks associated

with the use of these products. It was reasonable to assume that these expert users would understand that these risks included NANBH. Explanation of such risks to patients was exclusively the responsibility of Haemophilia doctors.

"Notwithstanding that some patients (eg patients on home treatment) would have cited the information provided by the manufacturer this was not the target audience for the technical information which was required to be included."

Then you refer -- I think you gave evidence on this yesterday afternoon -- to a change in the 1990s when there was a specific requirement for patient information leaflets.

I think in fairness I should also read the third paragraph:

"Examples of leaflets held by SNBTS other manufacturers suggest that the statements included with PFC products were typical of products at that time."

I just wanted to go back to the first of those paragraphs that I read, Dr Perry, so the paragraph beginning "The above statements were designed".

Can we just have that? Thank you, Sully.

So, as I understand it, the explanation that you're giving here, Dr Perry, is that it was

reasonable not to have an express reference to non-A, non-B hepatitis because haemophilia clinicians would have that knowledge themselves?

A. I think that was the prevailing view, yes. In fact, the products that PFC made only went to five individual centres in -- Factor VIII products to five individual centres and haemophilia doctors are, you know, much more knowledgeable about the risks of coagulation factors with respect to non-A, non-B hepatitis, and it was certainly the case that the belief -- and that's not just my belief, that's the belief of RTC medical colleagues and so on -- that conveying and providing a detailed narrative and understanding of the risk associated with products was not the responsibility of the manufacturer. It was the responsibility of the prescribing doctor.

Q. On that basis, why say anything about hepatitis at all? Haemophilia clinicians would be even more familiar perhaps with hepatitis B.

A. Because that's what the regulation and the reference documents required us to do.

Q. Did PFC, as far as you know, ever actually discuss with haemophilia clinicians using its products (a) what their knowledge of non-A, non-B hepatitis was, because they're haematologists rather than virologists

or hepatologists, or discuss with them what information they were providing about non-A, non-B hepatitis to their patients?

A. No, I think, if anything, the flow of information was in the other direction. They would inform us on risks of hepatitis in their patients or incidents of transmissions and so on, but to the best of my recollection -- we would periodically, including myself, Dr Foster, others, Professor Cash, we would give talks, lectures, presentations on products and refer to matters such as hepatitis, but I don't think it was ever a view that the SNBTS was an expert on non-A, non-B hepatitis and, as you say, all haemophilia doctors are haematologists by trade but they do have, and increasingly had, an expert knowledge on hepatitis and its transmission and its implications for patients.

Q. Is it right to put it this way, that the PFC in taking its decisions about what it included on leaflets and so on acted on an assumption that information about non-A, non-B hepatitis was being provided to patients by clinicians without any actual knowledge itself that that was taking place?

A. Well, I think it's more than an assumption. I think it was an evidence-based belief that they knew the

risks of treatment with these products. They talked to us about it. They delivered publications. They studied groups of patients and so on.

Q. The "they" you're talking about there are the haemophilia clinicians?

A. I'm talking about haemophilia clinicians, yes.

Q. My question was slightly different. Forgive me.

A. Sorry.

Q. No, no, the fault's mine. Did PFC essentially assume that PFC, as the product manufacturer, did not need to spell out risks relating to non-A, non-B hepatitis because PFC assumed that clinicians would be spelling out those risks to their patients?

A. I think clinicians, as I understand it, would be trained in their requirement to have a sufficient knowledge of the risks associated with treatment, so that they could convey that to patients. And, like all other manufacturers, we were quite limited in the amount of information that it was appropriate to give to doctors or -- and certainly to patients.

So I think your assumption is -- it is an assumption but it's one based on a good knowledge of the people that we were working with and providing the products to.

Q. Looking at it now, and with the knowledge that,

certainly by a date in the early 1980s -- you referred yesterday to, I think, the Kernoff publication, it may have been the Fletcher publication you had in mind, but in any event a publication in 1983 which suggested a high risk of infectivity with non-A, non-B hepatitis from NHS concentrates and not just commercial concentrates?

A. Yes.

Q. So looking -- knowing that as at 1983 if not earlier, do you think PFC, rather than saying, "This product can't be assumed to be free of hepatitis viruses", that rather understated the risk, and there was a case for saying, "This product is likely to transmit hepatitis virus", because that was the state of knowledge, at least by 1983, wasn't it?

A. I think by 1983 there was increasing knowledge that the NHS products and commercial products did transmit non-A, non-B hepatitis in close to 100 per cent of recipients over a period of time. But the information that we gained or that our knowledge, actually, for instance, from that key publication from Peter Kernoff -- he was a member of the UKHCDO. These were topics that routinely and regularly were discussed by haemophilia doctors. So, in a sense, we got that information from publications provided by

experts dealing with haemophilia patients. And I think, to be honest, we didn't feel the need, certainly at PFC, to elaborate on that information. We would just be reflecting back to them the information that they provided to us.

Q. Looking at it now -- and I ask this question because this may be a submission made in due course to the chair, and it will be a matter for the chair obviously to decide. Looking at it now, do you think PFC made the wrong call in not stating sufficiently clearly the risks of non-A, non-B hepatitis on its product information?

A. No, I don't. I think PFC reflected the wider practice through the industry. We had many -- we used to have discussions with Haemophilia Directors on a frequent basis, and there was a legitimate concern that we should neither under-exaggerate or over-exaggerate the risks associated with the product. So the wording that was used was not just the wording that PFC developed, it was informed by our medical advisers, Professor Cash, RTC colleagues, haemophilia doctors and so on, plus satisfying the requirements of the regulatory authorities. And it may well have been, if we had been more explicit in saying we want now to say that this product will transmit non-A, non-B

hepatitis, it could well have been that the regulatory authorities said, "No, you can't say that". They might say, "It is not absolutely proven, so you cannot state something that's not absolutely proven scientifically and enjoys a large consensus."

Q. That, I think, is -- and I don't mean this as a criticism, but that's -- I think that is a degree of speculation on your part --

A. Absolutely.

Q. -- because, as I understand it, that conversation never took place. PFC didn't ask the licensing authorities for its view on whether there should be any explicit statement about either non-A, non-B hepatitis or about the likelihood of infection of non-A, non-B hepatitis?

A. No, that is right. That is right.

I do remember, and I think this has been raised somewhere in the evidence that's provided to the Inquiry, perhaps by Dr Foster, that he recalls a conversation either with Professor Cash or Dr Ludlam where we did suggest that we should be much more explicit about the risk of HIV in our products, and my understanding is that Professor Ludlam and his colleagues expressed concern at making such a statement. Not that he wanted to hide it but he

felt the wording had to be very, very carefully considered.

Q. Yes. I will check that. I think there certainly is a reference to a conversation with Professor Cash in the evidence somewhere. Whether it referenced Dr Ludlam or not we will check.

A. I'm not sure whether there is any documented evidence of this conversation, no.

Q. That leads then to the question of warnings about AIDS or HTLV-III.

If we could perhaps just look at PRSE0001885 -- no, in fact, I don't need to because you were just summarising in that document what wasn't in the leaflets about -- and we have looked at the leaflets themselves.

Can I take you to some of your evidence to the Penrose Inquiry on the issue of warnings in relation to AIDS.

PRSE0006038, please.

So this is your evidence on 24 June 2011.

Sully, can you go to page 98, please.

So you were asked at line 4 this question:

"I just wanted to ask you whether consideration had been given within PFC to include in the text information about the risks of AIDS or HIV from the products at any

stage in 1983 or 1984?"

Your answer was no. Then you go on to explain why that might have been the case.

Can I just ask you to confirm that that's correct. I think you say it elsewhere in the evidence as well -- you say it elsewhere in your evidence to Penrose -- that you don't recall there being any express discussion within PFC of the issue of adding information about AIDS risks in '83 or '84?

A. No, other than that which we just mentioned, about the possible conversation with Professor Cash and his proposal to Professor Ludlam. So I think the views expressed in that answer to the Penrose Inquiry I would still -- I still think are my views today.

Q. If we just read then what you gave as the reasoning there. You say:

"I think at that stage, with the state of scientific knowledge, it would have been highly improper for any manufacturer of a pharmaceutical product without good reason and without good evidence that the product may present a risk of HIV -- The sort of information that's provided in these package insert leaflets is highly controlled and highly regulated and I think in the absence of any information, the control authorities would have taken grave exception to us intimating

without any evidence on -- that this was the case. I'm not suggesting that there was no evidence. I know there was a body of evidence growing and so on but not to the extent that allowed one to place this as a standard warning in a pharmaceutical product."

Again, is it right to understand that there was no conversation with the regulatory authorities about this in 83/84?

A. Not that I was aware of. It may have been discussed, I don't know, on the Biologicals Committee on the Committee on Safety of Medicines, which Mr Watt was a member of at that time, in 1983 and 1984, but I don't remember personally having any direct conversation with the regulatory authorities about these issues. And indeed, I think my speculation there on what the regulatory authorities might have thought I think is still valid. Certainly in 1983 and 1984 we were aware of HIV and its risks but, at that stage, there was no evidence that our products were transmitting at that stage. And, therefore, to put in a leaflet that "this product may transmit", I think the regulatory authorities would have come back and asked for evidence of that. And at that stage there was no evidence.

This sounds very pedantic but this is how the

regulatory authorities work. They are very careful and very clear on what can and should be communicated to patients. And the manner in which it is communicated.

Q. It may be, I hope, that we will hear evidence from -- or hear or receive evidence from regulatory authorities in due course in relation to what their approach was at the time.

But is this right, then, your evidence is that you think that if a pharmaceutical manufacturer went to the regulatory authorities in the United Kingdom in the 1980s and said, "We think it is likely that HTLV-III -- or that AIDS is transmissible through factor concentrates" -- because that was, certainly by 1984, the belief?

A. Sure.

Q. It was, I think, the belief probably pretty early on in 1983, not proven but the belief?

A. Yes.

Q. "And we would like to say something about that in our -- not necessarily on the label, but in our leaflets", you think the regulatory authorities would turn to a pharmaceutical company and say, "No, you can't say that"?

A. I'd think they would want to see the evidence for the

statement that you are making. And in the same way that pharmaceutical companies, in the documentation that they provide, the insert leaflets and so on, they are certainly not permitted to make claims for benefits without evidence, and I think the converse of that is true as well, that they shouldn't be pronouncing risks where a sufficient body of evidence doesn't exist.

Now, that might sound a little complacent by the system, but that's my understanding of how it worked.

Q. As I say, it may be that we will have to try to pick that up with evidence in relation to the approach of the licensing authorities.

Can I then -- just continuing with evidence on this theme to the Penrose Inquiry, if we go to PRSE0001324, please.

Now this is another written statement to the Penrose Inquiry from you. If we go over to the bottom of the page -- sorry, bottom of the next page, my apologies, Sully.

You were asked by the Penrose Inquiry, the question of:

"What discussions were there amongst the staff of the PFC of the possibility of including reference to the risk of HIV transmission on package

inserts ..."

Your answer was there you can't recall whether or not in '82 or '83 you had any discussions with the PFC director, Mr Watt, concerning the inclusion of AIDS warnings, and you don't know if Mr Watt discussed the possibility with others including Dr Cash, as national medical director.

That's obviously the period prior to you taking up the directorship?

A. Sure.

Q. But you were -- I think, as quality control inspector, liaising with regulatory authorities, content of leaflets and so on was part of your role?

A. It was, it was.

Q. Then if we go to the next page. You say this:

"However I did lead a review of the packaging systems for PFC FVIII and FIX products during this period which resulted in the introduction of new multi-vial packaging. Product warnings on both product packaging and leaflets remained unchanged and continued to relate only to a hepatitis risk."

Just pausing there. Although we know there was no change in the product warnings, you say so there and we have looked at the underlying documents, what did the review that you describe there entail?

A. Well, I think the review was a response to feedback that we were getting that the existing presentation of the product in individual boxes was not the most convenient, particularly for patients increasingly being transferred onto home therapy. So we produced, as it is described there, a multi-vial. It was a small box with ten vials of products and ten vials of water for reconstitution, product insert leaflets and so on. And as part of that process, I think I also carried out a review of the -- because it was an appropriate time to do it, because we were making a change to the packaging, to check that the wording that was used particularly on the outer box packaging and on the vial label was still accurate and reflecting the current position. And during that process, as I think I have described there, Mr Watt was on the Committee on Safety of Medicines. He would have looked at these things on a number of occasions, and I don't recall him suggesting that we needed to change the warnings -- or, indeed, Professor Cash, because he would have also been involved in just checking the documentation and leaflets and the packaging and so on.

Q. Can I just pick up on the point you make about Mr Watt by reference to his membership of the Biological

Subcommittee. Of course, if that issue had been discussed as part of the proceedings of the Biological Subcommittee, Mr Watt wouldn't have been able to pass that on because those meetings were confidential?

A. It is a very good point, but he may have found a way to communicate that this was an emerging view.

Q. And then if we continue -- in any event, you have no recollection that he -- of him saying anything of the kind?

A. No, no, he didn't.

Q. Then if we continue with this passage you say:

"I cannot recall whether or not in 1984 (following my appointment as Director) I discussed with others in PFC or elsewhere the possibility or desirability of modifying our 'warnings' to include AIDS. I think it is possible that such discussions took place with eg Dr Cash, Dr Boulton and the Haemophilia Directors."

This, I think, is the reference that you were making earlier, Dr Perry:

"For example Dr Foster has advised me that he recalls that in late 1983 the SNBTS (Professor Cash) suggested, at a meeting between SNBTS and Haemophilia Directors, the inclusion of an AIDS warning but that this suggestion was rejected by those present in the belief that such action might cause patients unnecessary

anxiety. However the SNBTS has been unable to find any record of this."

Then if we look at the next sentence, please, Sully:

"In any event no action was taken to include any specific reference to AIDS or HIV until [heat-treated] DEFIX was issued in September 1985."

A. That is correct.

Q. Can we then just go over the page and I will just go through this with you before we break.

You say:

"However I am unable to find any reference to or evidence of a process which led any individual(s) to recommend in favour or against the introduction of AIDS warnings for FVIII products.

"Prior to 1985, product information supplied by PFC/SNBTS reflected the background of knowledge and guidance available between 1982 and 1984 ie ..."

Then you have set out here a series of six points and I just wanted to, really in fairness to you, just go through those. The first is:

"... no requirement or advice from the UK licensing authority to include such warnings for products used in the UK."

Now, leave aside the British Pharmacopoeia

because we have already discussed those tended to be minimum recommendations or stipulations and after the event rather than being proactive.

A. Yes.

Q. So you are talking here about the UK licensing authority, essentially the medicines division of the Department of Health, is that really what you have in mind here?

A. Yes, the Medicines Control Agency, yes.

Q. Yes. I'm not sure it was called that then, but in any -- it may have been.

A. I think it was.

Q. You may well be right. You are talking about, in any event, something coming from the medicines division or from the Committee on Safety of Medicines or the Biological Subcommittee, some manifestation of the licensing authorities?

A. Yes.

Q. Other than through the process of submitting licence applications and having them approved, which would have involved, obviously, a degree of dialogue with the licensing authority -- and we have seen you would submit your proposed draft leaflet package insert to the licensing authority. So that was obviously one means whereby the licensing authority could give you

its views.

A. Yes.

Q. But that would only happen at application or renewal time. Was there -- did the licensing authority issue advice or requirements other than during the licence application process?

A. If there was a key development for any pharmaceutical that required them to provide an update or a revision, then they would have done that spontaneously. But they also -- if there had been an approach to the licensing authority, they would have responded, an approach by a manufacturer. For instance, it wanted to change its leaflet or it wanted to change its packaging or it wanted to change risk warnings, as you've discussed, then I think there was a mechanism for dialogue between manufacturers and the licensing authority.

Q. We know that no such approach was made by PFC, so my question was more really did the licensing authority proactively issue advice outside of dialogue with an individual manufacturer?

A. Generic guidance or industry --

Q. Generic guidance or advice in the early '80s?

A. I can't remember. If there was a particular risk arising from a particular drug, then it would have

issued a warning, perhaps to all manufacturers, to either keep an eye out for a particular new adverse event or if there was a requirement to change the specification of a product as a result of clinical experience, then, yes, they would have put out warnings or notifications and so on. I can't remember the detail of how it happened but it was -- I think there almost certainly was a formal system for maintaining an open dialogue between the regulatory authorities, the licensing authority, and the licence holders.

Q. In any event, is this right, that there was neither an approach by PFC to the licensing authority for advice nor anything issued by the licensing authority to PFC or anyone else, to your knowledge, about it?

A. I can't remember. I can't remember any such approach.

Q. The second point you make in this part of your --

A. Sorry. I would say that Mr Watt regularly attended meetings of the licensing authority on the Biological Subcommittee and there would have been opportunity at those meetings for him to discuss these issues with the secretariat of the Biological Subcommittee. But I have no record of him coming back and saying this is a topic which has emerged in discussion.

Q. Do you mean informal opportunities?

A. Informal opportunities, yes.

Q. The second bullet point is this:

"In contrast to products imported from the USA prior to October '84, there was no evidence that products manufactured from UK plasma had transmitted HTLV-III."

Now, I just wanted to explore with you whether you maintain that was a sufficient reason or a good reason not to include any warnings on PFC products. If you wait until a UK product has transmitted HTLV-III, isn't that rather too late?

A. I understand the question. But, again, in terms of the formal documentation that went out with our products, as I have said before, I think as far as the very formal and limited information that we provided with the products, and the requirement to get regulatory approval for that, there would have been at least disquiet that we were issuing a warning for which there was no evidence. But we didn't test that in practice.

Q. The next bullet point is:

"Prior to 1984 no consensus on the causal relationship between AIDS and treatment with coagulation factor products."

Is that essentially this -- is that a different point to the point you've already made?

A. No, I think it's slightly different. I think it's an arguable statement. I would acknowledge, and I think many would say, that there was consensus on the causal relationship but there were legitimate scientists and experts expressing slightly different views at that time.

Q. Do you need a consensus in order to be able to include a warning if you, as the manufacturer, believe that the risk is real?

A. Well, the only way the manufacturer knows whether the risk is real is by talking to the people that prescribed the products because that's where the information comes back from and so, in terms of its routine scanning of the environment in which it operates, it can only get the information that it needs to make statements from the people that are using the products and the publications that they make. So I'm not sure whether that answers the question.

Q. Well, that may be a matter for the Chair. But that leads to the next point, which is, you say:

"PFC and NBTS received no request or advice from haemophilia directors to receive such warning."

So just pausing there, I certainly think we've seen no evidence of that; so you may be right. But

you then say this:

"It is highly unlikely that PFC would have included AIDS warnings without their express agreement and support."

A. That's right.

Q. Why was the agreement and support of the treating clinicians a prerequisite to putting information on a product?

A. Because they -- I think there was an understandable sensitivity in this area. Well, it was an extraordinarily difficult period of time in which everyone operated, and I think we may well have discussed with haemophilia doctors whether we wanted to -- whether we should put more explicit warnings and I think the feedback that we got was that their preference was to be cautious.

I think certainly our view and Professor Cash's view would have been that it's no business of the manufacturer and the supplier to provide such direct warnings. Those sort of nuanced discussions, which are not absolutely clear, was the business of the doctor that's treating the patients, and our job was to provide as much information to the prescribing doctor and it is then for the doctor to prescribe what is known and what is best communicated and not

communicated to individual patients. And that was a clear view.

SIR BRIAN LANGSTAFF: Can you help me with this, particularly the reference that you've just made to what Professor Cash may have thought.

A few minutes ago we were talking about Professor Cash having had a conversation in which he was suggesting there might be a warning in respect of AIDS to SNBTS and clinicians, who were persuading him that he shouldn't do so, not because there were no risks or because a warning might not in itself be justified, but because it might cause unnecessary distress or anxiety amongst the patients who might be receiving it.

A. Yes.

SIR BRIAN LANGSTAFF: How does that fit with what you're saying here?

A. If I understand the question correctly, I think what I'm saying here is that this is an example of the clear demarcation which existed between the SNBTS and those that prescribed our products and Professor Cash was always emphasising the importance of not -- of the SNBTS, as a manufacturer, not trying to influence product use and so on. So I'm not sure I'm answering your question, sir.

But the emphasis for the PFC and for the wider SNBTS through its medical colleagues, Dr Boulton and Professor Cash and others, was to provide the best possible information we could to the haemophilia directors. One of the advantages of the SNBTS system of manufacture and supply is that it was a very collegiate group of people involving Regional Transfusion Centres, PFC as the operational manufacturing unit, and haemophilia doctors, and I think many of these discussions about developments certainly in the early and mid-80s, leading up to and during these terrible events, were always conducted collegiately.

So there would be an instinctive tendency in SNBTS to consult with haemophilia doctors so that they could judge whether, if the manufacturer put out a warning, a formal warning, on a particular product, whether the haemophilia directors would be able to support that or whether that would be consistent with the information they wanted to give to their patients.

Q. The reference to a concern about causing distress or anxiety, about there being a lot of sensitivity about this issue, I think it is picked up in the next bullet point where you say:

"There would need to be some measure of evidence

a genuine risk existed. It would be inappropriate for a manufacturer to provide warnings which could cause anxiety and alarm to patients and which might cause patients to reject life-saving treatment."

Would it be right to understand the evidence that you've given over the last few minutes and what we see reflected here as indicating that the message that was coming back to PFC or SNBTS from the haemophilia clinicians in Scotland was a message of "we don't want patients to be alarmed, we don't want patients to be caused anxiety, we don't want patients to be put off from accepting factor concentrates"?

A. I don't think I can say that that was their position.

Q. Was that the PFC's perception?

A. The PFC's perception was that it was our job and our duty to consult with haemophilia directors, which we did on a whole range of issues, and this was one of them and we would accept the advice and the feedback that we got, unless it contravened a particular regulatory requirement.

And there are other -- I don't think this was just a feature of SNBTS or Scotland. There are a number of examples throughout the world where there was a late reference to HTLV-III and AIDS in package inserts. The most striking example that I've seen

recently, or certainly reminded myself about recently, was the products that were supplied to Canada, where commercial manufacturers in -- they obtained their supplies of product from commercial suppliers from the US, and I think at some stage the commercial products did include perhaps AIDS warnings, but the Canadian authorities, who were supplying plasma for fractionation on a contract basis to America, said, "We don't want to include that warning". Now, I'm not saying that's the right outcome. But it's another example of this difficult area of what the manufacturer should say to the user of its products.

Q. It might be said, Dr Perry, that if the feeling that is coming from the Haemophilia Centre Directors is, "We don't want to cause undue anxiety to our patients by having some reference to AIDS on the products", that that should be ringing alarm bells for SNBTS and PFC that information about AIDS is not being passed on in practice to patients, which might reinforce the importance of you, as a manufacturer, setting it out when you release your product, because you can't have the confidence that the clinicians are actually, in their real life discussions with patients, providing that information?

A. Well, yes. And as I have described, the outcome isn't

as you have suggested it might have been. But there was no absence of discussion and there were certainly alarm bells ringing throughout this period. They were very loud and they were very persistent. But I can only repeat what I've said, that we did -- we consulted on this, we asked for their views and their feedback. Perhaps it is an issue that haemophilia doctors need to respond on how they were managing that important interface with their patients.

Q. They certainly have been asked those questions, Dr Perry.

Just the last, then, question on this point. I'm conscious we have gone into a time that would normally be for a break.

It might be said that there is something profoundly paternalistic about a system which says: we are not going to include information about a potential risk of a fatal virus because we don't want to cause alarm and anxiety.

Do you have any comment on that?

A. Well, only -- I'm not a medical doctor, I had no direct dealings with patients in terms of their treatment. And I think, by today's standards, it was as you describe it: it was a much more paternalistic system and the actions and inactions at that time were

quite different to those that you would expect today.

I'm not sure if -- god forbid -- another virus should enter the blood supply that there wouldn't be similar considerations, about: how sure we are of this? Do we know what the clinical outcome of this is? Do we know what the long-term sequelae are to the infections with this product? They are always difficult decisions. And I think, in that environment, the PFC, as a manufacturer of the products, put out the best information that it thought it was justified in doing.

MS RICHARDS: Sir, that completes my questioning on this topic, and I'm conscious I have gone 15 minutes over, into what would normally be everybody's break. So perhaps we could take the break now.

SIR BRIAN LANGSTAFF: Yes. It was just quite right that you should do so. We will take a break now until 12 o'clock. 12 o'clock.

(11.30 am)

(A short break)

(12.00 pm)

MS RICHARDS: Dr Perry, I'm going to ask you to look at a different aspect now of the evidence you gave to the Penrose Inquiry.

PRSE0001258, please, Sully, page 3.

So this is part of -- one of your statements on the topic of viral inactivation '85 to '87. Can I just pick up what you say on this page. At the top of the page:

"When it became known in 1984 that coagulation factor concentrates were implicated in transmission of HIV ... the SNBTS and Haemophilia Centre Directors' strategy to protect patients from infection with HIV included the following key elements ..."

You then set out three key elements. The first was:

"[Avoiding] the need to import commercial products through the already established programme to achieve and maintain 'self sufficiency'."

So that is essentially a continuation of what you were already doing?

A. Yes.

Q. The second was:

"... rapid and progressive development of manufacturing processes capable of inactivating HIV following the announcement that HIV could be inactivated by heat treatment."

I will come on to that in a little while. Then the third key element was:

"The development and implementation of a system of

'batch dedication' to reduce the exposure of patients to multiple batches ... Introduced in early 1985 ..."

Again, I will come on to that in a little more detail in a little while.

If we go back to the whole paragraph, please, Sully.

Now, it is right to say you were describing this as a strategy that included those key elements. You weren't suggesting this was the only thing that was under contemplation. But is it right to understand that the strategy within Scotland to protect patients from infection with HIV did not include a reversion to cryoprecipitate?

A. I don't recall there being -- from my perspective at least, I don't recall there being a significant reversion to the use of cryoprecipitate. I think it would almost certainly have been discussed at various levels and at various times but I don't think that actually occurred.

Q. I then just want to show you I think three documents where there is a discussion in the course of 1984 of the issue and invite your perspective. The first is PRSE0004741.

Now, these are notes prepared in January 1984 by Dr Cash, and we can see they are notes for "Scottish

Health Service Haemophilia Centre/Transfusion Service Directors' Meeting. February 1984". So prepared by him in anticipation of the meeting that was going to take place the following month.

A. The annual meeting, yes, of that group.

Q. Do you know, was that Dr Cash's practice, to prepare something in advance of the meeting --

A. Yes, he would always prepare a -- a briefing document, effectively, and also raising issues that he thought were important. So that was his practice, yes.

Q. And so if we can go on to page 4, under the heading "AIDS", so bottom half of the page.

He refers, first of all, to the introduction of the leaflet for donors, and then he says this:

"Clinical colleagues' attention is drawn to a leading article, published in the BMJ ... by Dr Peter Jones ... Dr Jones concludes ... 'For the moment, however, it seems sensible to treat very young severely affected children with cryoprecipitate rather than concentrates'. The SNBTS Directors would welcome comments on this proposal."

Then the next paragraph:

"It is noted that cryoprecipitate is no longer issued for haemophilia care at the Inverness and Aberdeen Centres and the size of current intermediate

stocks would normally lead to the consideration with the SNBTS of the introduction of similar practices in other regions."

Now, just if I may try and unpick that with you, obviously the paragraph referring to Dr Jones is self-evident and as I understand it, but Dr Cash is inviting the views of SNBTS directors on the proposal of cryoprecipitate for children.

A. And haemophilia directors.

Q. Yes. Then there is reference to two of the centres no longer issuing cryoprecipitate, one assumes at all. But it is that last part of the second -- of that last paragraph that I wanted your help with. "The size of current intermediate stocks", is that a reference to the volume of intermediate purity factor concentrate that's been built up?

A. I'm not with you.

Q. It is the paragraph --

A. The last paragraph in the AIDS --

Q. Yes, sorry, Dr Perry.

A. I can only try to construct a view on what Professor Cash meant by that. I think what he is actually signaling is that there are large stocks of intermediate -- I'm not sure whether -- what the stocks he is talking about actually:

"... the size of current intermediate stocks would normally lead to the consideration with the SNBTS of the introduction of similar practices in other regions."

I'm not sure I can help you. I was going to say that he was making the point that we have high stocks of a Factor VIII concentrate, which in normal circumstances would lead to a discontinued use of cryoprecipitate --

Q. That's what I wondered --

A. -- but I'm not sure he is saying that, because you wouldn't describe the stock of Factor VIII concentrates, national stocks of Factor VIII concentrates, as "current intermediate stocks". That would be a curious way of expressing it.

Q. If we go over two pages then. If we look at the bottom half of the page you will see the heading "Limitation of batch exposure to individual patients". I'm not going to read through the detail of that, but if we look just at the very bottom of the page he says:

"It is suggested to Directors that in view of the current significant national reserves of SNBTS intermediate factor VIII ..."

Top of the next page:

"... that the time is opportune to direct efforts towards reducing the number of batch exposures per patient per year."

Is that Dr Cash, in January 1984, identifying the possibility of having a batch dedication system or policy introduced?

A. Yes, I think so. I think he wrote to -- as we saw yesterday, he wrote a letter to regional transfusion centre directors in late 1983 asking for updated information on product stocks but also their views and ideas on a batch dedication type of system. So, yes. He was reiterating that here.

Q. If we then move to the actual meeting for which the document was prepared.

PRSE0001556, please.

So we can see it is meetings of directors of SNBTS and Haemophilia Directors, 2 February 1984. We can see that you were present.

If we go over the page, point 5 is headed "Review paper from SNBTS", and there's reference to Dr Cash introducing the paper he had prepared, which I take is a reference to the document we've just looked at?

A. Yes.

Q. Then, we see the discussion on cryoprecipitate at (ii)

which was:

"Members discussed the suggestion that the production of cryoprecipitate could now be reduced. Dr Ludlam said that cryoprecipitate was preferred in the treatment of children at present, because of the new danger of AIDS. Dr Hann concurred. A policy seemed to be emerging however to use less cryo for haemophilia A patients. It was agreed that a certain minimal amount of cryo was required and Dr Cash pointed out that TDs [Transfusion Directors I assume] could produce it in emergencies."

Dr Foster told us his recollection of the discussion about cryoprecipitate at that meeting. Do you have any recollection of the discussion and what the views were that were being expressed or what Dr Cash's position was?

A. I don't have any recollection from my memory. I can only interpret what is probably meant here, and it seems to me that what was agreed was that there was clearly an ongoing need for cryoprecipitate for treatment of some groups of patients, but it wasn't signaling a large increase, for example. But Professor Cash also made the point that if there was a large increase in the need for cryoprecipitate for children or other groups of patients then it can be

produced at relatively short notice.

Q. Then just still on the topic of cryoprecipitate, if we can go to SBTS0000615_042, please.

Now, this is a few days later in 1984, 7 February, and it is a special meeting of the coordinating group.

Can you just remind us what the coordinating group was?

A. I think the title of the meeting, which was established in the late 1970s -- or in the 1970s under Dr Cash's predecessor, and its role was -- it reflected the fact that he was not in charge but he had a specific role to coordinate the activities of the individual operation centres within the SNBTS. So this was a meeting -- I think it was held every three months or maybe more frequently -- for general discussion of topics that were important to the SNBTS.

Q. We can pick up the discussion on AIDS at page 4 of the minutes. Towards the bottom of the page we have the heading "AIDS". There is a reference to a report being circulated by Dr McClelland and then a number of matters being agreed. The first that Dr Cash will write recommending a single UK working group, with Scottish representation. The second refers to revisions to the donor leaflet.

If we go over the page to the top of the next page, please. If we just zoom in on the top half of the page, thanks, we don't need to zoom in any further.

There is then a reference to donor screening studies, a plasma processing policy, auto transfusion. Then this at (f):

"Small pool [Factor] VIII

"It was noted that small pool freeze dried [cryoprecipitate] for haemophilia therapy may have to be reassessed."

Just before we look at the next sentence, is it right to understand that's referring to the type of cryoprecipitate that had been manufactured in that project at the Law Hospital?

A. In the west of Scotland, yes.

Q. Which had then been abandoned --

A. That's my understanding.

Q. Then it says:

"Dr Perry said he could manufacture such a product (given the appropriate resources)."

A. Yes.

Q. Can you recall anything further about that discussion and assist us in understanding what the appropriate resources would have been?

A. I think I was simply signaling if that's what the service required, ie the haemophilia directors, if a decision -- by that stage I thought the discussion about freeze-dried cryoprecipitate was finished and the idea of producing it had been discontinued in 1983. I think I was simply signaling that if there is a reversal of that decision and there is a clinical consensus that we would need freeze-dried cryoprecipitate as a treatment option, then the PFC could produce that product but it would need, as I described yesterday, quite extensive re-configuring of the production facilities at PFC.

Q. Is it right to understand that this idea was never taken any further?

A. I'm not aware of freeze-dried cryoprecipitate emerging as a product from SNBTS.

Q. Can I then move to later in 1984 and the discovery of HTLV-III seroconversion in a group of Dr Ludlam's patients.

We can take the document down, Sully, thank you.

What's your best recollection of how and when you learnt of the first news that a PFC product may have transmitted HIV?

A. Well, clearly, this was a major and devastating event for SNBTS, and obviously for patients. My

recollection of the first time I heard this was on -- which may be wrong, because I think there is some evidence, though not conclusive, that it was known before this date -- but my recollection is that I learnt about this for the first time on my return from the meeting in Groningen, the conference in Groningen, on 5 November. But it may have been because the very early information that came through -- that Dr Foster has described, and he has a good memory of things, and he has kept scrupulous diaries -- is that the earliest information that the PFC might have known about it was as a result of a telephone call to Dr Cuthbertson. But that may have been about the very earliest reports of three patients having what he thought -- which may have -- three patients who may have antibodies to HTLV-III.

But I think at that stage, for those three patients, Professor Ludlam was looking for a confirmation of that because the assays that were being used were research assays. They weren't established, fully validated assays. So I think he -- he wanted -- but my memory is that the first time I heard about it was when I returned from the Groningen conference.

Q. Whatever the precise date, can you remember your

reaction and the reaction within PFC?

A. Difficult to describe it actually. It was a very shocking and devastating news. Not shock in terms of a major surprise (how could this ever have happened?) but it had a profound impact throughout the centre and that that point forward there was very little discussed in PFC other than its programme of work to actually deal with this.

Q. Would it be right to understand that in a sense it was not unexpected? I think Dr Foster had told us or we looked at some evidence Dr Foster had given to the Lindsay Tribunal reflecting the idea it was really only a matter of time. Do you remember that being the sense at the time?

A. I think that was a perfectly legitimate view and probably a view that I held myself. There was another view that the epidemiology of HTLV-III was still focused and concentrated in the United States and maybe it was more a hope than an evidence-based conclusion but that it had yet to enter in any significant way into the UK blood supply.

Q. Do you remember how and when you learnt of the possible -- any similar events having taken place in England?

A. No.

Q. If we just go then, just to pick up on a handful of dates to PRSE0000828, please, Sully.

This is a memo that Dr McClelland wrote to you, 20 November 1984, setting out events leading up to the recall of Factor VIII batch 023110090.

A. Yes.

Q. We can just see some of the staging posts along the way to the decision in principle to recall. So paragraph 1 refers to Dr Ludlam phoning Dr McClelland in the evening of 26 October, reporting six haemophiliac patients having developed antibody to HTLV-III, three of whom he thought could be attributable to PFC products.

Sorry, Sully, could we have the whole section on the screen. It's slightly easier, thank you.

Point 2 refers to Dr McClelland just reporting that to Dr Cash on the Saturday. It says:

"We were both agreed that the information was insufficient to require any recall of PFC products."

Now, I appreciate that Dr Cash obviously was the overall director of SNBTS, but there doesn't appear to be recorded there any communication with you or with Dr Cuthbertson or anyone else directly at PFC at that early stage. Is that your recollection as well?

A. That's my recollection. I think that's right. At

that stage all that was known was that were three patients that had produced this positive result in a research HTLV-III assay run by Dr Tedder and I don't think PFC had any further information. At that stage, the analysis of the batch consumption hadn't been done, so there was actually -- there was no idea which batches might be implicated. That work was carried on over the weekend and on 29th and 30th October, I think.

Q. We can then see on the Friday of 2 November (so essentially a week later) there's a reference to Dr Ludlam telephoning Dr McClelland at home, having received further data from Dr Tedder, and Dr McClelland records that:

"An initial look at these data indicated that either 15 or 16 of these patients had received the above batch."

Then paragraph 5 says "October 3rd". I think someone has written: "I am sure this should be November!", so I'll assume that's right, I think. November 3 records Dr Boulton and Dr McClelland contacting all the Scottish transfusion centres and the Northern Ireland transfusion centre to notify them "that the above batch should be immediately recalled". Also contacting the duty officer at the PFC to let him

know of the action that had been taken.

Do you know, would that have been Dr Cuthbertson at that stage?

A. I think that would have been Dr Cuthbertson.

Q. Were you in Groningen at that time?

A. I was in Groningen at that time, yes. Well, that's my recollection. I was certainly at the meeting, so I would have been in Groningen.

Q. So it's just over a week from Dr Ludlam first contacting Dr McClelland to Dr Boulton and Dr McClelland notifying the Regional Transfusion Centres that that particular batch should be recalled.

Did you think it was, from your perspective as director of the PFC, that that was done quickly enough or whether it could have been done any quicker?

A. The only delay that was injected into the overall timescale from the initial results was the need to analyse effectively manually, because there were no computers around at that time, the batch to try and identify which patients had received what batches and then come to a conclusion as to which might be the implicated batches because there were many, many batches that had been used to treat those patients. And that would clearly take, yes, a matter of days to collect the data from patient records and so on.

Q. If we then go to LOTH0000005_052, please. This is a letter from Dr McClelland on 15 November 1984 to Dr Cash. The first paragraph says:

"I have had several discussions with Dr Christopher Ludlam following the discovery that some recipients of PFC Factor VIII have developed antibodies to HTLVIII ... which must at present be attributed to infusions of PFC product. I spent several hours this morning with Dr Ludlam and Dr Perry ... reviewing the data and write now to report to you, as National Medical Director on our conclusions."

Can you recall that meeting and what the process was that was being undertaken?

A. What was the date of this letter?

Q. 15 November.

A. 15 November. I think it was a meeting with Dr Ludlam, myself and Dr McClelland really just going over again the -- I have a faint memory and recollection of sitting down and examining not the individual patient records, but an analysis of the patient exposures to different batches and the rationale for concluding that it was batch 3-009 which was the most likely candidate batch that had transmitted HTLV-III.

Q. We can see from the third paragraph the analysis had been that all but one of the patients had received

that batch. There's then a description of looking at batches received -- sorry -- yes, batches received by -- other batches received by the patients.

A. Yes.

Q. If we go over the page, just picking it up below the paragraph numbered 6, it refers to one patient who didn't receive the implicated batch and was not known to have other risk factors.

Now, obviously we're not going to say anything which potentially identifies any individual patient and you, I suspect, probably wouldn't have that information to hand anyway.

A. Of course.

Q. It is right, isn't it, I think, that it was never established how that one patient who hadn't received that batch had been infected?

A. I'm not absolutely clear on the final outcome. What I do know is in subsequent analysis of data, there was found to be a total of 18 patients in Scotland.

Q. Yes.

A. And I think our conclusion from the analysis that was done by Dr Cuthbertson and others of the detailed information we had was that there were probably three batches that had -- that could be described as being suspect for the transmission of HTLV-III.

I don't think any of those three still account for the sixteenth patient in that patient cohort.

Q. So potentially there may have been a fourth batch but --

A. There may have been a fourth batch, yes, or a ...

Q. At this point in time there were no other batches that were withdrawn?

A. No, it was only batch 3-009.

Q. We can take that down.

A. Well, batch 3-009 had been consumed. It had all been used up in Edinburgh, and there were about 40 or 45 vials left in Aberdeen.

Q. Yes.

A. So the only physical material that came back was from Aberdeen.

Q. Was the Aberdeen.

Now, we know that from your evidence and the evidence of others that what happened over the following weeks was a process of heating, dry heating, the stock of Factor VIII concentrates that the PFC had built up with a view to issuing that then to patients from, I think, late -- from a date in December 1984?

A. 10 December.

Q. Can you recall what the process was for receiving back in from centres or patients unheated concentrate?

A. I can't describe the details of the process other than to say that when we initiated the recall or we instructed the Regional Transfusion Centres, they were already aware of this issue, of course, and the instruction was to recall product held in the Regional Transfusion Centres, to recall product that may have been held in haematology departments or haemophilia directors or in haemophilia centres and also from patients' home stocks as well. So it was an in-depth recall.

Q. Was it a formal product recall or was it essentially a product exchange programme whereby people were asked to bring in such stocks that they had? I'm thinking in terms of the patients here. Sorry, I should have made that --

A. I hope I've not lost the thread here. Are we talking about the recall of batch 3-009?

Q. No, I'm sorry --

A. Oh, you're talking about the exchange of --

Q. Yes.

A. I'm sorry.

Q. We'll leave aside that batch because you're absolutely right as to what happened in relation to that batch. Edinburgh had used up all of it, as I understand the position. Aberdeen had not. There was a formal

recall of the remaining vials from Aberdeen.

No, I'm talking about what happened in order to give effect to the decision to now issue only heated product.

A. Yes, I understand.

Q. What was the process that was undertaken to try and get back as much unheated product and replace it with heated product?

A. Well, it was not -- in all practical respects. It was a recall but we described it as a "product exchange" because recalls are usually associated with a known defect or a known issue and so on and, other than the batch that we recalled, there was no reason to suspect these other batches or the rest of the stock.

So we called it or we have subsequently described it more as a product exchange and the process was very similar to that which we used for any recall, except on this occasion we once again drilled down into the detail of the supply chain and, as far as I recall, the instruction was that, coordinated by Regional Transfusion Centre staff because they were responsible for distribution, they should recover stocks from Haemophilia Centres, haematology, any stock, any place where the product was stocked and also from the stocks held by patients in their homes.

Q. So in terms of the process of getting any stocks held by patients in their homes, do you know whether that was coordinated or was it intended to be coordinated by the transfusion centres or by the haemophilia centres?

A. Well, it would have been coordinated by the transfusion centres but they would have clearly corresponded or discussed the requirements with the haemophilia directors and it would be for the haemophilia directors then to speak to their individual patients. To the best of my knowledge, that process worked perfectly well. We didn't get any, for instance, late returns of product that should have been sent back.

The intention -- the system was set up so that by 10 December every patient in Scotland and Northern Ireland should have access to heat-treated Factor VIII and, to the best of my knowledge, that was achieved.

Q. Can we then just look at --

A. Sorry, I've slightly misled you. The recall that I've described didn't take place until January.

Q. That makes a little more sense.

A. Clearly you can't do the two things simultaneously; you can't fully recall and issue new stock at the same

time. It would have been too confusing. So we put a hold on all use of -- the first step was to issue product that had been heat treated to every centre in Scotland so that that could be distributed throughout the centres and, where necessary, to patients' homes. When that was complete and we'd built up further stocks of heat-treated products, we then did the formal recall in early January.

Q. Can we then just look at one further meeting at this time which is PRSE0002066.

So this is a meeting of haemophilia directors and SNBTS directors, 29 November '84. You were present. We can see from paragraph 2 the purpose of the meeting:

"... convened to discuss the implications of the recent finding of HTLV III antibodies in Scottish haemophiliacs ..."

Then, if we go over the page, there is an update in paragraph 6 from you of what's being done by PFC in terms of heat treatment. And it is explained that the measure that was being implemented in terms of heat treatment of existing stocks at 68 degrees for two hours.

If we then go further down the page, I just wanted to pick up on paragraph 8 and whether you have

any recollection of this:

"Views were exchanged on the very difficult ethical problems which had arisen. These included whether patients and patients' relatives should be informed and perhaps subjected to needless worry; whether publicity additional to that already provided should be given, and how directors should respond to direct enquiries or requests for advice. The chairman advised members that ministers had been informed and that SIO had been briefed. While a press statement would not be issued by the Department at present any enquiries would be answered. It was agreed that every effort should be made for patients to have the situation explained to them before the impending publicity."

Now, I'm not suggesting that informing patients was the responsibility of PFC, Dr Perry, but you were present at this meeting and it appears to be suggested that there was some question mark over whether patients and their relatives should be told or not, and this was described as a very difficult ethical problem. It might be thought fairly obvious that they should be told. Do you have any reflection or any recollection of that discussion?

A. I don't have a detailed recollection. My focus and emphasis at the time, and probably during this

meeting, was making sure I clearly communicated what the PFC was doing in its response. I think I would have regarded this very much the business of haemophilia directors in describing the issues that arises in terms of their conversations with patients. And I would have noted it, I would have understood it, I would have understood their concerns, but I would not have had any further input into that particular decision.

Q. We know a meeting took place, a group meeting, at the Edinburgh Royal Infirmary in December. We heard evidence about that from Dr Ludlam and from attendees at the meeting. Were you present at that meeting?

A. No, I wasn't. Dr McClelland, from South East Scotland BTS, and I think the haemophilia director from Glasgow also attended. I think that was Dr Forbes at that time.

Q. But you did not?

A. I didn't attend it, no.

Q. Then I won't ask you anything further in relation to that.

Can I just ask you to look then at one document from the evidence submitted to Penrose.

PRSE0002801, please.

I'm not proposing to go through the detail of

this. It is a report describing actions surrounding batch 3-009. If we go to page 5.

We will see that there is a fairly detailed narrative of the actions taken. Over the page. There's then a description of the history of this particular batch, when it was manufactured and so on.

I'm not going to ask you about the detail of that because we have got it set out in the report.

But there's just one passage I wanted to ask you about, if we go to page 10. It is this, under the heading "Introduction of Heat Treatment", it says this:

"It should be noted that the finding of HIV infection in Scottish haemophiliacs was unexpected, since until that time, the belief was that the infection was largely confined to donors in the USA."

I don't know whether you were an author or co-author of this particular paper, Dr Perry, but if I can perhaps ask you more generally, do you agree with that sentence that it was unexpected?

A. I didn't author this paper, although I think I was involved and I had input into it. It is probably not the word I would use now. I think it was perhaps (and Dr Foster has explained and, to an extent, I would agree with him) that it was just a matter of time.

I think it was unexpected in the sense that we did believe or at least we had an evidence-based hope that the epidemic was mainly confined to the US at that time.

Q. One of the issues explored with Dr McClelland, Dr Brian McClelland, when he gave evidence to this Inquiry, was whether there were particular risk factors perhaps associated with Edinburgh in terms of high-risk donors.

A. Yes.

Q. As a centre of international travel, location of the Edinburgh Festival, population in terms of drug use, and so on?

A. Yes.

Q. Do you remember that being something that was explicitly discussed back in '83/'84? So prior to the October '84 discovery of the seroconversion of this particular cohort of patients, do you recall PFC ever giving any particular thought to that or there being any discussions between PFC and SEBTS?

A. There could well have been discussions. It would have been -- the discussions would have taken place at the coordinating group or directors' meetings because they were the people involved in the interface with donors and so these issues were constantly on the agenda.

Donor selection.

But I'm afraid I can't recall any specific issues. I think at that stage it was -- although what you have described as the potential risk factors of drug use and so on and it being a fairly international city, at least for one month in the year, I think the general view was that we simply didn't know the nature of the epidemiology of HIV at that time. There were no assays. The diagnosis was only available through patients presenting with clear signs of AIDS.

Q. Then just going briefly back to the implicated batch from the autumn of 1984, is this right, that it was possible to identify from records all the donors who had contributed to that batch, which was I think approximately 4,000?

A. About 4,000, yes.

Q. But it was never established which particular donor or donors had transmitted HIV?

A. That was certainly my understanding when I left the SNBTS and I don't think there's been any further clarity on that using the assay systems that were available at the time -- none of the donors. And, yes, I think, as you probably already know, the PFC had a complete traceability system associated with these products.

Q. Yes. Then just a handful of further questions about seroconversions if I may.

Can we just start, first of all, at CBLA0001919.

Now, this is not a meeting in which you were involved, Dr Perry. It's a meeting of the Central Committee for Research and Development in Blood Transfusion, November 1984 -- 9 November 1984 -- but you will see Dr Brian McClelland was there.

A. Yes.

Q. If we go over the page, the third paragraph, under the heading "Developments with respect to AIDS", says this, and this is a particular point I've been asked to see whether you can help us understand or clarify, Dr Perry:

"Dr McClelland referred to a batch of Factor VIII in Scotland, fractionated in November, 1983, which was discovered to contain anti-HTLV3 in August, 1984."

Then there's reference to the remainder of the product having been withdrawn:

"... but the incident served to highlight the difficulties which lay ahead ..."

Was there a discovery in August 1984 or is that, to the best of your knowledge, simply an error in the minutes?

A. I think it must be an error in the recording of the minute. We had no knowledge of HTLV-III being in any batch of PFC product in August 1984.
Q. Thank you. That's what I wanted to check with you.
A. I don't know the genesis of that statement. It seems like it is just an error of reporting.
Q. Now, the next document, please, is at BNOR000177. If we go to the second page, please.

So this is a letter from Dr Snape at BPL to Dr Jean Harrison, the Northeast Thames Regional Transfusion Centre, 26 July 1985, and we can see from the bottom right-hand corner, it was copied to you.

If we then just go up the page, please. We can see it is headed "Advice of Transfusion Incident and Product Recall Notice". Then there is a reference to a BPL product and then PFC 795. Then the letter says that:

"[Dr Snape] has been informed by Dr Craske ... that a patient treated at the London Hospital ... has developed ..."

An illness consistent with HTLV-III infection.

"The batches implicated are HLA and HLB3185 and [then] PFC batch 795."

It's described that the Regional Transfusion Centre had received 947 vials of PFC 795 as their

September allocation.

Now that presumably is a reference to the distribution of PFC products when you were sending part of the stockpile or surplus to BPL which we looked at yesterday. That would be consistent with the timing?
A. That is right.
Q. Do you know what, if any, follow up was done or what, if any, investigation was done into PFC 795?
A. No. I think just for clarification, where it describes the batches implicated doesn't necessarily imply that there's a causal association with batch 795 or any of the other batches. It's just a description of what the patient's received.

I'm afraid I only -- I think this -- I only saw this letter again recently in the bundle of results, so I haven't had the opportunity of researching it. I can only say that when that was received at PFC, that would certainly have been subject to evaluation and follow up and so on. But I don't think batch 795 was ever identified as a batch that either contained an HIV positive donation or not.
Q. Then if we go to PRSE00001773, please. There is an exchange of correspondence here between -- this particular letter is Dr Forbes to Dr Cash,

February 1986, referring to having become aware of three seroconversions in the past year in patients receiving blood products. And then there's, I think, a follow-up letter if we go to MACK0001870_01.

You then wrote to Dr Madhok in Glasgow in July of the same year:

"HTLV III seroconversions in west of Scotland haemophiliacs.

"You will recall our discussions regarding the seroconversions of 2 haemophiliacs in your region.

"I can now enclose a brief report on our findings which attempts to relate these 2 incidents to the seroconversions in Edinburgh. As you will see, we can draw no definite conclusions."

Then I think the report that is referred to in this letter is at PRSE0003506.

And we can see it is headed "HTLVIII seroconversions related to SNBTS [Factor] VIII, An interim report". The first paragraph refers to the Edinburgh seroconversions and then the second paragraph says:

"Follow-up of West of Scotland haemophiliacs, has revealed two patients receiving SNBTS [Factor] VIII who seroconverted in 1983 and 1985 respectively."

Then we can skip over the details of the two patients. It then says:

"The batches of product received by the South-East and West of Scotland seroconverters are summarised in the Table."

Point 1:

"Neither of the West of Scotland patients received the batch ... implicated in the South-East Scotland seroconversions.

"2. No batch is common to the two West of Scotland seroconversions.

"3. If SNBTS FVIII was responsible for each of the 18 seroconversions, then at least three contaminated batches must have been issued."

There is then an identification of batches common to both seroconversions.

Then, if we go over the page, it says:

"5. None of the batches received by any of the seroconverters are known to have contained an HTLV-III positive donations."

"Further action:

"At this time, no information is available (at PFC) on the quantities of each batch received by the two West of Scotland seroconverters."

Do you know -- other than identifying that there

were potentially at least three contaminated batches that must have been issued from PFC on the basis of the information you had about those seroconverted, do you know whether there was any particular follow-up to this investigation or whether any conclusions were reached as to which other batches and how many were implicated?

A. I have no recollection of any additional data or evidence coming to light beyond that which has been reported here. My memory is that there were -- it was established fairly early on that there were at least three batches, but I don't think there are -- I think we requested further information from Dr Madhok in my letter. I'm not sure whether that was received or whether it was significant.

Q. Then finally on this topic, can we go to MACK0002301_022, please.

This was an email from Dr Foster to you, January 2000. I don't need to go through the detail of most of it. If we go to the bottom half of the page, you'll see there's a list of pharmaceutical companies and viral transmissions reported.

In relation to Armour it refers to there being:

"18 HIV transmissions published in 1988 & 1990 (+ 2 in Scotland not published) ..."

And, if we go to the very bottom of the page, it says -- it's referring to, I think, Dr Mike McGovern here:

"... Mike seems not to be aware that Armour's FVIII was withdrawn from the UK ... following HIV transmissions in the UK (4 cases in Birmingham and 2 in Glasgow's Royal Hospital for Sick Children)."

Then it refers to that product also transmitting HIV in the USA and Canada. I appreciate that this is not talking about SNBTS product, it's talking about seroconversions from the heat-treated Armour Factor VIII --

A. Yes.

Q. -- said to be two in the Royal Hospital for Sick Children. But do you have any further knowledge about those seroconversions?

A. I don't think I do. I would have probably had more knowledge and recollection closer to the time but after the passage of time. I'm aware, of course, that there were reports of commercial products in particular continuing to transmit HIV. But I can't recall who Mike McGovern was.

Q. Based, I think, at the Department of Health.

A. Oh, okay.

Q. I think that's right.

A. Okay, thank you.

Q. The next topic I wanted to move to is just batch dedication. We saw it touched on in that report from Dr Cash, January 1984 --

A. Yes.

Q. -- for the February 1984 SNBTS and Haemophilia Centre Directors' meeting.

Now, the evidence shows -- your own evidence explains this -- the batch dedication system was introduced from early 1985.

A. That's correct.

Q. Can you assist us, first of all, by explaining how the particular batch dedication system introduced worked?

A. When it was fully implemented?

Q. Yes.

A. It was a system whereby -- and it was predicated and necessary to have large stocks of product to make such a system work, and it involved dividing the patients, all the patients in Scotland who were treated with Factor VIII, into patient groups on a regional basis. So there might have been three patient groups in Edinburgh, six patient groups in Glasgow, one in Aberdeen, Dundee, Inverness and so on, and I think we called them "lanes", patient "lanes". They were allocated, I think, simply on the basis of their

alphabetical surnames. And the PFC's role in the batch dedication system was to provide these so-called lanes with whole batches of product.

The patients, when they received their product for treatment from the Haemophilia Centres, would draw upon the stocks that had been particularly -- from the lane that they had been allocated and when that lane was empty, ie the patients had used up all the product in that lane, that batch would be replenished with another whole batch.

I'm not sure how many patients were in each patient group but I would estimate it would be in the region of 20 or so, maybe more, depending how many lanes had been established and that system was designed to minimise patient exposure to donors. It worked very well. Once it was implemented, it worked very well.

Q. There are various documents and correspondence relating to it but I don't think we probably need to go to those, but can you assist with this: why was a system only introduced in early 1985 (at which time you've got a product which, in fact, inactivates HTLV-III, albeit not non-A, non-B hepatitis), given that it was certainly under contemplation beginning of the previous year and presumably is something that

could have been thought about earlier even than 1984? Wasn't it done really too late?

A. Well, I don't think it was done too late but I think, you know, as perhaps an opening comment I think this is a topic that could have been addressed earlier. I've thought quite extensively about this particular topic because it's become an important issue.

I think my conclusions are that it was perhaps not well defined who was -- where the centre of responsibility or the leadership for such a process existed. The operation of it was primarily dependent on the Regional Transfusion Centres and the Haemophilia Centre Directors identifying the patient groups and setting up the operational systems for making sure that individual patients only got the batch that they were allocated to, and the PFC had no involvement or role in that. The PFC's role was simply to provide the number of batches necessary to sustain the system.

So it was never quite clear, I think, even in the minutes of the annual meeting of Haemophilia Centre Directors and Transfusion Directors, that it was -- that it was not defined who, if anybody, should take the lead in that. It was a sort of call to arms I think, in some respects, to begin thinking about

this and determine its feasibility.

My analysis of the situation is that it certainly had the product stocks in 1984. And I think it is fair to say that had it been identified as a -- I had only just become acting director at that stage and I think my priorities lay elsewhere at that time, but had it been identified as a high priority topic by transfusion centres or haemophilia directors or indeed myself, then, I think it could have been introduced earlier.

What I'm not clear on though is whether, had it been introduced in 1984, the infective batch that we have just talked about would have been included in one of the patient lanes for a batch dedication system in 1984. And so there would have still been a tragic outcome. Whether it would have resulted in more patients being infected or less patients being infected, I'm not sure, but I think I have described it in my witness statement as a lost opportunity. We could and should have done it sooner.

MS RICHARDS: Sir, I'm going to move on to another topic now. Given the time, perhaps we could pick that up at 2 o'clock.

SIR BRIAN LANGSTAFF: Yes, let's do that. 2 o'clock.

MS RICHARDS: Thank you, sir.

(1.00 pm)

(Luncheon adjournment)

(2.00 pm)

MS RICHARDS: Dr Perry, I'm going to move to the question of viral inactivation now, heat treatment work.

This has been largely covered in the evidence of Dr Peter Foster so I'm not going to go through the detail of it at all with you. I've a handful of general questions which reflect, I think it's probably fair to say, concerns of some Core Participants or issues which some Core Participants have asked to raise.

So the first question is this: what was your understanding of the weight attached to viral inactivation as a research and development goal for PFC in 1981/1982? In other words, how much of a priority was it for the PFC at that stage?

A. I think it was top priority by '81/'82.

Q. In terms of the establishment of the Factor VIII study group, do you know of any reasons why that couldn't have been set up earlier than it was?

A. No, I don't think there's a particularly good reason why it couldn't have been set up sooner. I think it was set up when I think the body of evidence and opinion and so on drew us to the conclusion that it

was necessary and it was necessary to draw upon, not just PFC resources, but the wider resources of SNBTS to address the issues. And it wasn't just about virus inactivation, the Factor VIII study group, it was about maintaining self-sufficiency as well.

Q. Can I then ask you about one passage in your witness statement, WITN69200001, and if we could go to page 37, please, Sully. So, in paragraph 106, having referred to the work of the Factor VIII study group, you say that PFC continued to research and progress methods for pasteurisation of Factor VIII as its preferred option. You refer to the development of in-house methods for testing the efficacy of inactivation processes and then say this:

"However there remained concern, including internationally, that the modification of [Factor] VIII manufacturing processes to include steps for virus inactivation could lead to the development of inhibitors in recipient patients, leading to potentially catastrophic consequences for the treatment of haemophilia."

The question arising out of that, Dr Perry, is this: what weight was given to that hypothetical theory as opposed to the known real risk of hepatitis which, equally, could lead to catastrophic

consequences?
A. I think there was very significant weight. It wasn't completely hypothetical, either. I think it was based on admittedly rather scant knowledge of the Factor VIII molecule and what heat might do to it, and the consequences that it might have in invoking or potentiating inhibitors in patients.

It was a very serious risk. I wouldn't describe it as a hypothetical risk. Indeed, latterly, there were a couple of organisations, I think the Dutch Red Cross (the CLB, as it was then) and Octapharma did actually produce heat-treated product which generated very high levels of inhibitors in a large number of patients. So it was a very real risk. I think that postdated '81/'82 but it was still -- it has still been identified as a risk then, and I think part of the Factor VIII study group actually tried to develop ways of examining whether there was any physical damage to Factor VIII after it had been subjected to a heat treatment process.
Q. Now, more generally, it might be said in relation to the work of PFL and BPL, having regard to the evidence the Inquiry's examined from Dr Smith and Dr Lane, that the work on heat treatment, whether pasteurised or dry heat, which had been started because of a desire to

address non-A, non-B hepatitis, was really given urgency, galvanised by the advent of AIDS and it was that which injected a greater sense of urgency into the work that was being undertaken. That might be a submission that's advanced.

Is the same point applicable to the work of the PFC, that it was AIDS that injected the real sense of urgency, and at a relatively late stage, and perhaps a greater sense of urgency having been engendered by non-A, non-B?
A. It was certainly the case that the major concern when this group was set up in 1982 was how to address the universal risk of non-A, non-B hepatitis by its coagulation factors and I think it's probably true to say that, following the events in late 1984, it did inject a much ... I don't know how best to express it -- a substantially greater sense of urgency and also a slight change of direction. This became the target HIV, not non-A, non-B hepatitis anymore.
Q. Again, this is a question I've particularly been asked to put to you, Dr Perry. Why did it take patients in Scotland being infected with HIV to bring about this change of direction and this greater sense of urgency?
A. I think there are a number of reasons. I think our work on non-A, non-B hepatitis was still very valid

during -- if we talk about the period of 1984, for instance, leading up to the patient cohort in Edinburgh, there was -- I think, as I say, there are a number of factors.

We didn't -- nobody knew what the -- it hadn't been discovered or identified or isolated, the HIV virus or the HTLV-III virus. We didn't know its physical characteristics. We didn't know whether heat treatment would do anything for it at all. There was the risk of inhibitors, which was very real, and we had correspondence, or Professor Cash certainly had correspondence, with a number of haemophilia doctors who advised him that they were very concerned (Professor Ludlam was one of them) about the risk of inhibitors following the application of heat treatment and, indeed, for really quite extensive, and probably quite lengthy, clinical trails before it was introduced.

So I think those two main factors -- and I think had we suggested -- this is my own view -- had it been proposed to introduce heat treatment in 1984, for instance, at the beginning of 1984, in a similar way to which we did in late 1984, I'm far from convinced that would have enjoyed the support of haemophilia doctors, because I think they may have regarded it as

premature. They had no evidence that patients were or had been infected with HIV at that stage.
Q. And then can I ask you to help with one particular document from November 1984.

PRSE0004148.

So it's a meeting chaired by you, Dr Perry, on 13 November 1984.
A. Yes.
Q. Minutes of a meeting of heads of department/section managers. So it's an internal PFC meeting; is that right?
A. It's a local management team meeting, yes.
Q. If we go to the second page, towards the top of the page, under the heading "AIDS Minute", the minutes record as follows:

"Dr Perry advised the meeting that as a result of the amount of information being publicised through the press on the subject of AIDS, there was an immediate requirement for PFC to render all [Factor] VIII free from HTLV III virus."

Then there is an explanation of the work that was being undertaken to that end.
A. Yes.
Q. Now that might be said to read as though this sense of urgency, this change of direction in the autumn of

1984 is because of publicity. That's how it reads. Are you able to assist us with that?

A. I agree it could be interpreted like that. I didn't write the minute of the meeting, but I would have approved them. I think the minutes tended to be written by the head of the administration department in PFC.

But it is certainly the case that the impetus and the momentum and the requirement for inactivation wasn't simply to do with publicity. It was, as I say, the devastating news received earlier that month of the transmission episode.

Q. I then want to move beyond 1984 into 1985, and in particular 1986. If we get to, as it were, 1986, I think it is right to say that, in terms of domestic Factor VIII concentrates, there are two products, both of which inactivate HIV, that is BPL 8Y's product and PFC's NY product?

A. Yes.

Q. 8Y inactivated non-A, non-B hepatitis. NY did not. That is correct, isn't it? I leave aside the question of when that became known.

A. I don't think it was certain at that beginning of '86 that 8Y was effective against non-A, non-B, but there was the early -- there was reason for optimism,

I think.

Q. Yes, I will come on to, as it were, date of knowledge in the moment. On any view, that's correct as a matter of fact, I think, 8Y had that advantage over NY?

A. At that point in time, yes. Yes.

Q. Obviously PFC then introduced Z8 in 1987, and Z8 did inactivate non-A, non-B hepatitis?

A. But that conclusion can only be drawn with hindsight, as it were.

Q. What I want to do is just look at what was known and what was happening at the time then, so that we avoid hindsight.

So if we just perhaps pick it up at PRSE0001258.

So we can see this is, again, one of your statements to the Penrose Inquiry.

If we just go a little further down the page, please, Sully. So below the passage, or the question in italics, you say:

"I am unable to precisely identify the date on which the SNBTS/PFC first became aware of the BPL/PFL 8Y development."

Then you refer to a paper put together by Dr Foster which you say:

"... indicates that we were first briefed by

Dr JK Smith ... on their 8Y developments in February 1985."

If we then go over the page. You refer to the clinical trial of 8Y commencing around April 1985. Then, if we pick it up in the second paragraph, you say this:

"Therefore, although early results in a relatively small group of patients were reported by Dr Rizza as encouraging ..."

Just pausing there. Can you recall when that was being reported by Dr Rizza?

A. No, I can't recall the date, but it would have obviously pre-dated 1986. It might have been late 1985.

Q. My understanding is it was 1985, but I'm afraid I've mislaid the reference that gave me a precise date.

A. It was probably in a study that didn't quite meet the international guidelines for conducting these studies.

Q. I am sure we can check that in any event. You then continue:

"... it was not until the interim review point in this study (March 1986), reported in October 1986, to the UKHCDO, that the freedom of NANBH ..."

I will skip over hepatitis B or HTLV-III:

"... would have been described as likely."

Now that, at first blush, makes it sound as though the point in time at which it would have been regarded that 8Y was likely not to transmit non A, non B hepatitis was when the results were published, in October 1986. But I think it is right that you would have been aware of the interim results in March of 1986, is that correct?

A. I think so, yes, absolutely.

Q. And I think we can just look briefly at the meeting.

PRSE0003764.

Sir, it is a note of a meeting held at PFC on 17 March at 1986. We can see that there are a range of representatives from BPL and a range of representatives from SNBTS present.

If we go to the third page, please, Sully.

We can see this is your note of a meeting, 24 March 1986, and it is paragraph 5 on this page in which we see:

"Dr Smith outlined clinical trial results of the 8Y [Factor] VIII products 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."

That is the significance, I think, of

March 1986; is that right?
A. I think that is correct.
Q. The earlier indications had been promising but this was a greater degree of confirmation, albeit it obviously fell short of conclusive --
A. Yes, I think it became likely at this stage, I think. I think my view of these reports was more optimistic than Dr Smith's actually. He was always very cautious not to overestimate or be too optimistic about outcomes before the data was confirming it.
Q. So by March 1986, or by the date of this meeting, by the time of this meeting in March 1986, you and your colleagues, within Scotland -- if we just go back to the list of attenders on the first page.

So we have a range of colleagues there, although I'm not sure whether we can tell if all of them were present for the whole of the meeting -- sorry, for the relevant part of the meeting.

But, in any event, you and your colleagues would know that there was a good chance, if I can put it that way, that 8Y was successful in terms of not transmitting non-A, non-B hepatitis?
A. Yes.
Q. And at that time, in terms of NY, the feeling was it did transmit non-A, non-B hepatitis?

A. I'm not sure that we had any data on that but we had no reason to expect 24 hours at 68 degrees to inactivate non-A, non-B hepatitis.
Q. What I want to do next then is just go through a chain of correspondence in June, July and August involving the efforts made to obtain some 8Y from BPL for use in virgin haemophiliacs or minimally treated patients.

If we start with PRSE0003845.

What I'm going to do, Dr Perry, is go through the correspondence and then ask you some questions about it.

We can see this is Dr Boulton to you, 27 June 1986 passing on some comments from Dr Ludlam, and the first main paragraph reads -- sorry, it's the second paragraph:

"A young haemophiliac who previously had minimal therapy with factor VIII received an infusion of the current heat-treated product a month ago. He now shows signs of liver enzyme rises indicating non-A, non-B hepatitis. Christopher is a bit ruthful with his own staff about this because he feels that this patient should have received VIIIY or an equivalent product."

I think that's the first communication with you on this particular issue.
A. On this topic, yes.

Q. And then if we go to PRSE0003030, please.

You responded to Dr Boulton on 2 July 1986. If we look at the text of the letter, you don't deal with the particular case that has been flagged up but you say, in the second and third paragraphs, that the PFC is, you say, "poised to introduce ... another [Factor] VIII product". I'm not sure whether -- I think it's April 1987 by which time you were actually --
A. I think our expectation in our plan at that time was it should have been -- it would have been available by September, I think.
Q. But, in any event, what you're doing is flagging up that there will be a PFC product --
A. A comparable product --
Q. -- equivalent to 8Y in due course?
A. Yes.
Q. If we then go, please, to PRSE0001784.

We can see Dr Boulton wrote to you on 4 July 1986, and it reflects -- or refers to a telephone conversation that the two of you had had the previous day. And then the attached record of the conversation is actually on a different reference.

PRSE0002783. If we turn the document round, please.

Now I think most of this page, as I understand it, Dr Perry, is describing the intended progression towards the release of the PFC's own new product, Z8; is that right?
A. Yes. I think the phase 2 product refers to the 68 degrees for 24 hours and phase 3 refers to Z8.
Q. Yes. And so we can see a timescale being given in relation to that which I don't need to trouble you with. But the bottom of the page says this:

"In the meantime any Edinburgh 'virgin' haemophiliacs requiring therapy could be given BPL 8Y."

Is it right to understand from this note you and Dr Boulton have had a conversation on 3 July, and part of the conversation involves a plan for 8Y to be given to any virgin haemophiliacs who may require treatment?
A. Yes.
Q. So I think we see that then picked up next in a letter at PRSE0004097.

This is again Dr Boulton to you, 7 July:

"Sorry to be pestering you again.

"Last week Dr Ludlam wrote to Brian ..."

That's presumably Dr McClelland?
A. Dr McClelland, yes.
Q. "... asking you if it would be possible to obtain some of the BPL products for use if a previously untreated

haemophilic presented for replacement therapy."

Then the letter continues by a discussion of how much and Dr Boulton says he thinks the amount that Dr Ludlam had suggested might be too much, essentially.

If we just look at the whole letter, please, Sully.

In the last paragraph, Dr Boulton says to you:

"... would it be possible for you to obtain perhaps 10,000 units -- ie 50 vials ..."

A. Yes.

Q. So that's 7 July.

Then if we go to PRSE0003814.

We can see a letter of the same date from you back to Dr Boulton, and you're responding, I think, to the note, the handwritten note, I'm assuming is what's referred to in the first paragraph. And then you say in paragraph (b):

"While there will be no PFC product virucidally comparable to 8Y until September '86 ..."

Then you refer to the Phase III product. Then you say this:

"However, in the immediate future (July-September '86), we could probably get supplies of 8Y for special cases. It would of course be preferable

if these were obtained and supplied through PFC."

Why would it be preferable for them to be obtained and supplied through PFC?

A. With hindsight, I'm not sure actually. Perhaps I felt that it would have -- it would just have fitted in with the distribution system and we could have held the stock at PFC.

Q. In any event, is it right to understand that this is a suggestion that in the intervening period before the PFC equivalent is capable of being available, rolled out, you think you'll be able to get supplies of 8Y for what's described as "special cases"?

A. In response to a specific request by a haemophilia director, yes.

Q. And by "special cases", I assume that's meaning minimally or previously untreated patients?

A. I think it would be, yes, exactly those two categories of patients, yes.

Q. If we --

A. If -- my understanding is the guidance produced by UKHCDO at that time did have a prescribed policy for minimally treated patients or previously untreated patients, which was the use of cryoprecipitate. So that was the standard treatment for those groups of patients. That's my understanding.

Q. If we then go, please, to PRSE0004383.

We can see that you wrote on 10 July to Mr Pettet at BPL. The first paragraph of the letter refers to:

"Very occasionally a haemophiliac without previous exposure to Factor VIII Concentrate presents in Scotland for treatment."

You refer to one such patient presenting very recently being:

"... treated with our current product ... and subsequently developed markers for NANB hepatitis ..."

You then refer to the intention to introduce PFC's own product in due course.

Then the second paragraph:

"Pending the introduction of this product in Scotland and Northern Ireland, I write to ask if it would be possible for you to supply PFC with a very modest quantity of 8Y (50 vials) to cover the treatment of similar virgin patients who may appear between now and September. This request originated from our own Haemophilia Directors and, in the light of our imminent introduction of a product comparable to 8Y, does not seem unreasonable and should not place an overwhelming burden on your supply."

I think that's you to Mr Pettet on 10 July.

Then, if we go to PRSE0001397.

It appears you wrote to Dr Smith at PFL on 24 July, referring to a discussion you'd had and asking for a supply of 50 vials of 8Y as a contingency in the event that a virgin haemophiliac presents for treatment. You say it:

"... will be issued on condition that [the] clinical trial protocol is observed."

What would that entail, the clinical trial protocol?

A. I think there's a little correspondence in between this where Mr Pettet wrote back to me and said he'd discussed it with Dr Lane and he'd discussed it with Dr Smith, this was an unlicensed product, and they could assist, they thought it was a reasonable request, but what they would prefer was a slightly more win-win situation where, if we did have a previously untreated patient, they could be entered into the trial, the clinical trial of 8Y, which was ongoing, to study the absence of infectivity in that product.

Q. I think that's probably a reference to a letter of the same date, but it essentially crossed with yours, from Mr Pettet to you, PRSE0003693, where he says:

"Following your letter on your requirements for

'virgin' haemophiliacs in Scotland and Northern Ireland, I tried to contact you by telephone last Thursday in order to begin supplies as soon as possible."

The next paragraph refers to Dr Lane's agreement:

"... I had spoken to Jim Smith and he hoped to see you last Friday with a novel proposal: perhaps Scotland would like to participate in our trial of Factor VIII Y!

"Provided that you were agreeable that the patients met the criteria, and given agreement by the Haemophilia Directors involved, Jim can provide 8Y from batches set aside for trial purposes."

The next paragraph says:

"In case there are some patients who do not strictly meet the criteria for trial, now or in the future, I have put aside some 8Y for immediate despatch to PFC (or any other destination), if you require it. I can arrange same day delivery if necessary. Would you like this additional product to be sent to PFC now, or have you made adequate arrangements for cover with Jim?"

That letter reads as though saying there are two routes to getting a small supply of 8Y for Scotland. There's the proposal that any Scottish or Northern Irish patient who might need it could be entered in

the trial and get 8Y that way?

A. Yes.

Q. And then Mr Pettet saying, "But we can also put aside some 8Y for you and send it to you by same-day delivery"?

A. Yes. If there were similar patients that didn't quite meet the criteria for entry into the trial, they weren't going to be too rigid about which in patients it should be useful.

Q. Then we can see at PRSE0003143 -- now, you wouldn't have received the letter we just looked at because these are all letters written on the same date, so I suspect you wouldn't --

A. Okay.

Q. You might have had the earlier letters. But this is you writing to Dr Boulton, 24 July:

"I have now confirmed that BPL are happy to supply 50 vials of 8Y to PFC on the understanding that, in the event that the material is used in suitable virgin patients, appropriate serial samples would be taken to contribute to their overall infectivity study."

That is 24 July.

Then, just to complete the chain of correspondence, if we go to PRSE0004146, this is you now responding to Mr Pettet's letter of 24 July.

You're writing on 28 July. You confirm -- if we just zoom in on the text, Sully, thank you -- that you've spoken to Jim Smith. You've confirmed locally that the supplies of 8Y should be conditional on users participating in the clinical trial, and you've asked if someone can send -- sorry, if Jim can:

"... send (immediately) 50 vials ... as a contingency stock of non-infective material in the unlikely event that a virgin haemophiliac presents for treatment in the near future."

Then we can see, if we then go to PRSE0002616, here's Dr Smith sending 50 vials of 8Y on 1 August 1986 to you.

Then PRSE0002643, we can see on 5 August you wrote to Dr Boulton. You told him the 8Y had arrived and you've sent 20 vials to the Regional Transfusion Centre in Edinburgh. And you say:

"There is more here if [you] need it."

Now, is it fair to say, having regard to that correspondence, that certainly once the issue had been raised with you, it was fairly simple and straightforward for you to obtain a supply of 8Y from BPL?

A. I think the incident that triggered this was the one that you've described -- or the one that was described

in Dr Boulton's original letter, and I guess I set out on this short journey not necessarily with an expectation it would be successful. I think Factor VIII was in short supply in England and 50 vials for Scotland would mean 50 vials less for England and those sorts of considerations.

So I was quite surprised, but also delighted, when they responded so positively and I guess, in Jim Smith's usual way, he found quite an elegant way of dealing with this, which was providing product and if it was a previously untreated patient or somebody that met the criteria for entry into the trial, then it would be a good way of meeting the clinical need but also supplementing the data that they had for their clinical study.

Q. Now, we can see from this, and indeed from the document on screen, having received the 50 vials from England, you sent out 20 to Edinburgh and obviously Dr Boulton knew what the plan was because you'd been having these earlier discussions with him --

A. Sure.

Q. -- and we saw the handwritten note of your conversation in early July. Did you notify other regions that there was a small supply of 8Y in stock in case they had a virgin haemophiliac or minimally

treated haemophiliac?
A. No, I didn't.
Q. Should you have done?
A. This topic was discussed in the Penrose Inquiry -- and I'm not suggesting that's not a reason to discuss it here. I think my understanding and my response to this particular request was that we were responding to a specific request from a specific haemophilia director and, although I framed the correspondence with BPL to reflect a Scotland-wide potential requirement, it was designed to maximise the chances of success of getting this product for Scotland.

I think, with hindsight, what should have happened -- or maybe I can go on to explain why I didn't.

It was not a licensed product. I think if another haemophilia director in Scotland had requested a similar product for treatment, then I would have acted in the same way and sought further supplies. But my view at that time, which wasn't an overly hard view, but it was that the fractionator or the manufacturer has no business in selecting products for treating specific groups of patients; that's a doctor's job. And what I was doing on this occasion was responding to a legitimate request from a close

haemophilia director colleague and there, for me, I think the matter rested.

And also the issue about not being seen to promote unlicensed products, and if I'd have started broadcasting to all the haemophilia directors in Scotland that, "We have this product available should you need it", that could be interpreted as promotion of a particular product, an unlicensed product.

My view with hindsight, and I've reflected not only during the Penrose Inquiry but subsequently on this topic, because it started out as a relatively small -- a response to an individual request from a haemophilia doctor. It was not a major issue for me. And, you're right, it went very smoothly in the end.

I think what should have happened or what could have happened is -- on a UK-wide basis, because there was this difference in availability -- or 8Y was proving to be a world-class product capable of inactivating not only HIV but non-A, non-B hepatitis, it seems to me -- and this is with hindsight but it's still a valid view -- that the UKHCDO organisation, if they'd have recognised that, it would not have been difficult for them to come up with a policy, which may have had to involve discussions with PFC and BPL, for

identifying -- for any patients in the UK that were appropriate, that were previously untreated, whether they were in Scotland, Northern Ireland, Wales or England, to access 8Y. And an operational arrangement could have been made so that the 8Y that was used (for instance, for treatment of patients in Scotland) could have been replaced with some PFC product for routinely treated severe haemophiliacs in England.

I think that would have been possible, I think, a bit like the batch dedication, it was a lost opportunity. It would have only appropriately come, I think, from the haemophilia doctors' organisation, because they had the knowledge, they knew how many patients there were likely to be, and I think that would have been well received. As it was, my response was limited to a particular response to a particular request from a doctor.

I think the other big centre in Scotland where it was likely that a previously untreated patient would emerge was in Glasgow, in the West of Scotland, and Dr Forbes, I think, was the director of that centre at the time, and he was chairman of the UKHCDO at that time as well. So he would also have been very aware of the data on 8Y and could, and perhaps should, have made a similar request, but in the event he

didn't. It could be that he chose to continue using cryoprecipitate for such cases, because that was the official UKHCDO guideline at the time I think.
Q. Did you have any direct discussions with Dr Ludlam yourself on this issue in 1986?
A. I don't think I did. I think it was -- it wasn't always done like this but I think this arrangement was brought about via Dr Boulton. He was, if you like, the go-between between Professor Ludlam and myself.
Q. Does that reflect, I think, what you told us yesterday, Dr Cash's preference that the Haemophilia Centre Directors would liaise with the RTCs rather than directly with PFC?
A. Yes, yes.
Q. So there was this slightly cumbersome route of Dr Ludlam going to Dr Boulton, who came to you and you went to Dr Smith or Mr Pettet?
A. Yes, yes, that's right.
Q. Leaving aside the question of whose individual responsibility it might have been, who should have come up with the idea --
A. Yes.
Q. -- would you accept this as a general proposition, that it should have been apparent to somebody, to the appropriate bodies in Scotland, and whether that's

just the Haemophilia Centre Directors or SNBTS or both, by March of 1986 -- leave aside for present purposes the earlier period and Dr Rizza's early promising signs, but by March 1986 it was known that there was this disparity between, or that there was likely to be a disparity between, 8Y and NY. It must have been capable of being foreseen that minimally treated or virgin haemophiliacs might present for treatment and that therefore somebody, maybe the Haemophilia Centre Directors, should have taken the lead, but somebody should have thought about this rather than for the solution to be triggered by the actual infection of a patient?

A. Well, I think I would probably agree with you, which is why, with hindsight, I think the ideal outcome would have been for the UK Haemophilia Centre Directors organisation to -- in the knowledge that they had a product which was likely to be non-infective with respect to non-A, non-B, there was an opportunity for wider UK co-operation between Scotland, England, Northern Ireland and Wales, and on -- and that could have been fairly simply put in place.

I'm not trying to distance myself. I was in a position perhaps to create more influence or to

drive this forward but, as I say, these decisions on choice of product for patients were quite well defined, for good reason, and, as I say, I don't think it was at the front of my mind that it was a PFC responsibility to then circulate a proposal to the Haemophilia Centres in Scotland that they might want to -- they might wish to consider using 8Y for the treatment of previously untreated patients. That's their business.

Professor Cash also took the view that this was perhaps was not an appropriate thing to be doing anyway. England and Wales were so short of Factor VIII from the NHS that I think he perhaps -- I'm not sure why, but he took the view that we shouldn't be stealing resources from England and Wales. Which was a slightly extreme view, I think, for the relatively small quantities involved.

So that's my view now, and I think it sort of concurs with your view that somebody or some organisation or some part of the network of care for haemophilia could have identified this as an opportunity.

SIR BRIAN LANGSTAFF: And the way you put it just a little while ago in your evidence, talking about Professor Forbes, was that he could have and perhaps

should have.

A. Well, yes, but only in the context of the short discussion we've just had. Again, I'm really not trying to distance myself from this, but for me to say that Professor Forbes should have done something in terms of selection of products for his patients is really not my --

SIR BRIAN LANGSTAFF: I appreciate there are a number of people who might have done something. You happen to be a person who had realised there was something perhaps to be done because of the position that Dr Ludlam had put you in. Plainly, it was a matter for him to raise too should he wish to do so. And you could have perhaps spoken informally to Dr Forbes because of his position in the UKHCDO and said, "Have you thought of this? It's not my position really to mention it but, you know, we're talking about children here. They're the likeliest people to come forward as newly diagnosed people with haemophilia. Perhaps you might want to discuss whether something can be done about it?"

A. Yes, indeed, that is the case. I could have done that. I wouldn't want to --

SIR BRIAN LANGSTAFF: And you didn't.

A. I wouldn't distance myself from that and I didn't do

that. But I think what I -- my more likely position would have been that Dr Ludlam, who had succeeded in obtaining this product through the good offices of PFC, if you like, and via BPL, I would have thought would have communicated to his fellow haemophilia directors in Scotland because they met regularly, they discussed issues regularly, they had common problems in terms of previously untreated patients and how best to treat them and so on.

So that seemed to me at the time, or subsequent to this issue, a more likely and appropriate mechanism for wider use of this product. I think, in the event, the product that we did get never got used for previously untreated patients. I think it was ultimately used for a patient under Dr Ludlam's care who had an allergic reaction to some other products and 8Y didn't produce that allergic reaction. So it never got used because previously untreated patients didn't come up very often.

And the other factor is that this was only -- it was only envisaged at the time of it taking place to be in place for about two or three months because the PFC equivalent product would have been available then. In the event, it was delayed for reasons of clinical trials and so on.

MS RICHARDS: I'm going to move now, Dr Perry, to a completely different topic. I just want to ask you very briefly, first of all, about your role on the Biological Subcommittee on the Committee on Safety of Medicines.

I'm not asking you about any particular aspect of the decisions or the Committee meetings that you attended between 1986 to 1990. It's just really to ask you to illuminate the process a little.

First of all, the confidentiality of meetings of the Biological Subcommittee, I think described by you in your Penrose evidence as "rigorous and formal". So members of the committee were expected not to share information about committee meetings --

A. This is the Committee on Safety of Medicines?

Q. Committee on Safety of Medicines, that's right. So there was a high expectation of confidentiality?

A. I think I had to sign a formal document declaring that I would keep the contents of the meeting and the discussions strictly confidential.

Q. Can you recall how potentially conflicts of interest were managed because you were and Mr Watt had been effectively fractionators, producers of blood products, at the time of sitting on the meetings. That could be said to give rise to a potential

conflict of interest when considering applications or issues relating to similar products produced elsewhere. But was there a system for managing that?

A. The solution to that very real problem that you described was fairly simple and straightforward, that both myself and Dr Snape, who was on the committee at the same time, were asked if we would care to resign because of potential conflict of interest.

So when that was recognised I think it was following the removal of Crown immunity. I think prior to that date, I think the Committee on Safety of Medicines, the Biological Subcommittee, felt that they needed people who had expertise in fractionation to advise the secretariat and the people that assessed product licence applications from other organisations to be part of that decision-making process.

I think I was always aware of the conflict of interest and I was extremely rigorous about never divulging any information or knowledge that I gained from reading a manufacturer's licence application. But I think, with hindsight, it was probably the correct outcome, that it was a conflict of interest but during our -- certainly during my time on the Committee on Safety of Medicines, I think both Dr Snape and Dr Lane, who preceded Dr Snape on the

committee, made a very real contribution to the work of the committee.

Q. And in terms of the issues that were considered at meetings, would it be right to understand that the majority of the consideration would be of actual licence applications or licence renewal applications? Was that most --

A. Yes, the way the system worked was perhaps a month before the meeting, a very large bag would arrive at my house, or it may have come to PFC as the point of delivery, containing the full dossiers that had been submitted by product licence holders and the job was to go through those and then present any views that we might have on safety or quality issues to the Committee when it met.

Q. Were there ever, as far as you can recall, subcommittee meetings which were looking -- in which *ad hoc* advice was sought on issues other than licence applications or licence renewal?

A. A generic issue?

Q. Yes.

A. No, but I think they did take place. I think they did occur. I can't give any really meaningful examples during my tenure, but they may well have done. But the bulk of the work was to address specific licence

applications and so on, but nothing comes to mind regarding more generic considerations.

Q. Now, the next and the sort of final main topic I want to turn to is your role on the Advisory Committee for the Virological Safety of Blood and its consideration of issues relating to the introduction of hepatitis C screening.

I just want to ask you before we look at any particular documents just for some general assistance with this particular committee. You were on it from its inception and the first meeting was April 1989. Did you gain any understanding or sense of why it hadn't been set up earlier than 1989?

A. Not really. I think it was -- my understanding, and I'm not sure I have a good evidence base for this understanding, but it was a result of some disquiet over the processes that were in place during the implementation of HIV testing in blood because it wasn't a straightforward process and it was -- there were multiple organisations involved in policy-making and so on and, as with so many things in government, it took them a few years to actually find the solution to this, which was to create an advisory committee whose purpose was to advise ministers on this.

Q. And it's right to understand, I think, that was

precisely its role. You would advise -- when I say "you", the Committee would advise -- the Department of Health through -- I think there's a suggestion in one of the documents it would go first to the Chief Medical Officer, but leave that aside, and then for Ministers to take the final decisions?

A. Maybe it's the passage of time but I'm not sure I know of the precise mechanism. It was certainly an advisory committee to advise Ministers. Whether it got -- whether the decisions and the considerations were passaged through the Department of Health, I'm not sure. But it was always chaired by the Deputy Chief Medical Officer. So it was a fairly senior official within the Department of Health and, indeed, the other four territorial countries, as they were called, had representation on the Committee as observers.

Q. Around the same time, there was another committee formed which was the Advisory Committee on Transfusion Transmitted Diseases. What was your understanding of the different roles or respective roles and remits of the two bodies?

A. Well, the ACVSB was set up to advise ministers on policy and I think that was emphasised. Its stated aim was not to get involved in detailed operational

issues, however important, these were matters for the professional services, the blood services and public health organisations to deal with. And ACTTD, the Advisory Committee on Transfusion Transmitted Diseases, was set up within or amongst the four blood services within the UK to consider those operational details. But also to advise the ACVSB on particular issues. And Dr Gunson, who chaired the ACTTD, sat on both committees, so there was overlap, but it was always reinforced at the meetings that I went to of ACVSB and also NSBT that it was their role to create policy and to decide policy, not the ACTTD.

So there was a little tension between the two committees but they worked very well together overall.

Q. You told the Penrose Inquiry when you gave evidence on this topic that the agendas for ACVSB meetings would be put together by the Department of Health secretariat, is that right?

A. Yes.

Q. If we can just pick up your Penrose evidence at PRSE0006068, please. If we go to page 116.

This is evidence given in November 2011.

So page 116, please, Sully. Bottom of the page.

You say this:

"It was always the case at these meetings that

Dr Metters ..."

He was the Deputy Chief Medical Officer, I think --

A. He was.

Q. -- who took over from Dr Harris, who chaired the first three meetings?

A. Yes, that's right.

Q. "... always emphasised that the views of the committee were advisory. It was an advisory committee and it didn't have the final say. So it always carried the caveat that ministers may or may not agree."

And that was your understanding at the time?

A. That was my understanding at the time, yes.

Q. Then, if we just go, by way of example --

A. I can't actually recall any instance where a carefully worked out strategy or policy presented to ministers was rejected, I think. By and large, at least in 99% of the time, the advice was accepted.

Q. Now, if we can go to the minutes of the second meeting, which was 22 May 1989. And it is NHBT0005019, please.

We see there the membership of the committee. We have got still Dr Harris here, before Dr Metters takes over. We have then got a number of members listed, yourself included, a number of names familiar to the Inquiry: Professor Zuckerman, Dr Tedder,

Dr Tuddenham, Dr Mitchell, Dr Mortimer, Dr Lane, Dr Minor, who I think represented NIBSC?

A. Yes, he was a well known and respected virologist at NIBSC.

Q. Then we have the secretariat, Dr Rejman, Mr Canavan, so they're from the Department of Health. Then we have observers, of whom I think, on the left-hand side of the observers, Dr Pickles, Dr Rotblat, Dr Purves, are from the Department of Health?

A. Dr Pickles was from the Department of Health. Dr Rotblat was a medical assessor for the Medicines Control Agency. And Dr Purves was a pharmaceutical assessor for the Medicines Control Agency.

Q. Then the other observers we have listed represented Scotland, Wales and Northern Ireland. I might have got the Northern Ireland and Wales the wrong way round, I'll need to double-check --

A. Yes, Dr McIntyre was the Scottish representative and I think Dr George was the Northern Ireland representative and Dr Flett perhaps from Wales, but I can't be sure.

Q. Now, you said in your Penrose -- or it was put to you in your evidence to the Penrose Inquiry, and you agreed, looking back, that there may have been insufficient public health expertise or perspective in

terms of the membership of the ACVSB; is that right?
A. This was in a briefing note I supplied to Professor Cash, wasn't it? Is that where that came from? Or is it in my evidence?
Q. It is in your evidence. I think if we go to PRSE0006068.
SIR BRIAN LANGSTAFF: That's it on the screen, I think.
MS RICHARDS: No, PRSE0006068. Oh, my screen still has the minutes.
SIR BRIAN LANGSTAFF: -- (overspeaking) -- 5019 on the screen I think.
MS RICHARDS: I don't have the transcript on the screen. Thank you.
Page 137. I should perhaps just pick it up on the previous page, 136, just so that we can see the context in which you then give an answer. So Professor James in the Penrose Inquiry explores with you issues about the composition of the committee. He says -- he suggested it:
"... didn't contain enough sharp end transfusionists ... and they were outnumbered by strong-minded and authoritative 'virologists' for example, so that the committee might have paid rather more cognisance, in that important period in 1990 in particular, and the beginning of 1991, to the

virology, as against the public health/needs of the screening service."
I want to remind you of your answer, which is at the top of the next page. You say:
"Answer: ... I think I agree with your analysis to an extent, and the reason I was hesitating was because this was something that I considered before I wrote my statement. I thought composition of the committee was, perhaps with hindsight, unduly biased to the science, the expert virologists, who are very authoritative people. I have to say this, it is not a criticism of them. But, standing back, and perhaps 20 or 30 years on, the public health perspective was not as dominant in fact as it possibly could have been."
Does that remain your view, again, looking back?
A. Yes, I think it does. Well, I would just underline, this is not a criticism of the virologists but it seemed to me that the best became the enemy of the good, as it were, as the expression goes. That they were searching for perfect outcomes rather than good outcomes that could meet a public health need. And that was -- for me, that came to the fore when data was presented that said the first generation hepatitis C antibody test would have picked up 60% of HCV positive donors. And I thought that's -- just on

that basis alone, that was a reasonable justification for implementing the Phase I test rather than delaying it by a further year.
Q. Then if we go to page 14, please, of this transcript.
If I can pick it up from line 10 onwards, you were asked about the contribution of the secretariat to the meetings. Did they contribute to meetings, those individuals? And your answer:
"Yes, there were -- certainly Dr Rejman and Dr Pickles -- and I'm trying to recall if there were others ..."
Then you refer to Dr Purves.
Then line 18:
"Yes, periodically they were called upon specifically to report on a particular issue, but also took a full part in the discussions of the committee."
So that is your recollection of the role of the Department of Health secretariat, that they weren't simply there to put together the agenda and take a note; they participated actively in the discussions?
A. No, they had quite senior medical officers from the Department of Health that were part of the committee. They weren't full members of the committee, but then it wasn't a voting committee. It didn't used to vote on issues and so on. There was a process that I never

really understood what the detail was, and we would have the discussions at the meeting and then those discussions would get taken away to the Department of Health for further consideration and perhaps a revised position might come back from the Department of Health for consideration. So they were very much an integral part of the process as far as I recall.
Q. Then you continue:
"I think that was probably less the case with the Welsh, the Northern Irish and the Scottish departmental representatives, who tended to be, as they were described there, more observers than participants."
A. That's my impression, yes.
Q. Now, confidentiality, I don't think we need to look at the minutes to see this, but in -- a number of the minutes record the chair, so the deputy CMO, emphasising the confidentiality of the proceedings.
If we go to page 16, please.
I want to pick up the way in which you put it in your Penrose evidence. At line 6, you were -- so your attention was drawn to the minutes referring to confidentiality, and then you said this:
"Yes, I think the minutes slightly understate what was actually said at the meeting and I remember this -- there are a few moments in one's life that you do

remember and I think Ed Harris, who was the deputy chief medical officer at the time, did really underline and emphasis this point, almost threatening you with the tower of London if you were to breach that confidentiality."

So it was expected that members of the committee would keep what was being discussed absolutely confidential and secret?

A. That was certainly the message that was delivered very forcefully at the first meeting and subsequently underlined periodically. There wasn't a -- it wasn't reinforced vigorously at each meeting but we were reminded that discussions were confidential and if there was a particularly controversial topic or a topic with a very wide and active public health interest associated with it, which was controversial, then we were always advised that the discussions of the meeting should remain confidential.

That was always a problem, of course, because some of the discussions had really quite short-term impacts on the work of the transfusion services. So I think I did find ways of communicating some points of information that I gleaned from the meeting to senior colleagues. But it was never a satisfactory process. The minutes were never released to a wider

audience.

Q. You say later in your Penrose evidence, I don't think we need to go to it, but it is the same transcript, at page 141, you said:

"... there was undue emphasis on this [that's the confidentiality requirement], for reasons which were never really clear."

Is that right?

Sorry, it is a different page. I can take you to it.

Page 141, please, Sully.

Bottom of the page, line 21, you were being asked about confidentiality, and you say:

"I think there was undue emphasis on this, for reasons that were never really clear."

So is that right, it was never really explained to you as a member why there was this requirement of confidentiality?

A. I think the world was generally much more confidential then, and perhaps less transparent than it's required to be now. But periodically it did concern me that some of the issues that were being discussed I knew would be very important to those planning the work of the transfusion services back in the Regional Transfusion Centres in Scotland, which I knew more

about than England, of course. So, yes, it did concern me.

But the process as prescribed by the committee was that the -- nothing can be said to anybody until the formal position had been solidified and approved and so on.

Q. Can I suggest to you for your comment two problems that might arise as a consequence of the requirement of confidentiality. The first, which I think you have already alluded to, is that it means you, as a member of the committee, or any other members of the committee, could not report back to others and share with them information which might be highly relevant to what others are doing --

A. Yes.

Q. -- or might need to know?

A. Or equally, because I was a representative, effectively, I was on the committee because I was part of the SNBTS, but, equally, colleagues from SNBTS could inform my views much more substantially if I knew there was a particular topic on the agenda, but I couldn't go to them and say, "This particular topic is coming up on the agenda, can you please brief me?"

Q. I think that essentially picks up on what I was going to suggest was the second problem, which --

A. I think I found ways of managing around that, but it was a constraint, yes.

Q. Because if you have minutes that are publicly accessible and can be shared, it means that those who are not the eight, nine or however many members of the committee, but who might have a great deal of informed opinion and expertise to bear, they are not in a position to influence or inform or shape the decision-making, are they?

A. No.

Q. Because they simply don't know what's being considered and why?

A. Yes, that's right that is right. I think, to be fair to the process, I think it over the -- as the years passed, it loosened up a little in terms of ability to communicate outside the Committee on particular issues.

Q. Now, what I'm going to do next is -- I'm not going to take you through each of the meetings. I'm going to just read the references and the dates for the meetings, so they're collected in one place on the transcript. Then I just want to take you to just a handful of observations you made either to Penrose or in your statement to this Inquiry about the decision-making process on hepatitis C screening.

So the dates of the meetings and their URNs are as follows: first meeting from April 1989 is NHBT0000041_003; second meeting, 22 May 1989, NHBT0005019; third meeting, 3 July 1989, NHBT0000072_025; and then, fourth meeting, 6 November 1989, NHBT0005043; fifth meeting, 17 January 1990, PRSE0001477; sixth meeting, 24 April 1990, NHBT0000072_098; seventh meeting, 2 July 1990, PRSE0000976; eighth meeting, 21 November 1990, NHBT0000073_018; ninth meeting, 25 February 1991, PRSE0002280; and then tenth meeting, 21 May 1991, NHBT000042_080.

Now, obviously meetings continued after that date but those are the meetings at which the issue of hepatitis C screening were considered.

Can I then come to just a number of general matters about the decision-making process. First of all, it appears to have been understood that the ultimate decision on hepatitis C screening was going to be a decision for the Department of Health or the Secretary of State for Health?

A. Departments of Health.

Q. So for the four departments; is that your understanding?

A. Yes.

Q. So it was a government decision, in any event?

A. I think so. And the DoH, the English Department of Health would have --

Q. Was in the lead?

A. Was very much in the lead, yes.

Q. The question both of whether to introduce screening, when to introduce screening, was going to be a matter centrally determined in that way?

A. That's my understanding of the process, yes.

Q. Was that just taken as read, as it were, because it might be said there was actually no real obstacle to individual transfusion services taking their own decision. They were autonomous bodies, funded in Scotland by the CSA, funded in England and Wales by their Regional Health Authorities. They didn't require the permission legally of the Departments of Health.

A. I can't comment on the legal aspects, but what I could say at the outset of both HIV testing and hepatitis C testing, it was a fairly consensual view that a single date for implementation of testing was desirable to avoid the situation where one hospital in a particular region was testing and another hospital was receiving untested blood. I think it would have caused really quite serious concerns and problems, not least amongst

patients, starting to choose hospitals or where they would have their transfusion according to whether they were testing for hepatitis C.

So I think there was -- amongst the professionals, there was no dissent from the notion that it should all be done on a single date. I think the problem in Scotland arose when I think colleagues in Scotland felt that this process was being delayed over and over again for no good reason for us in Scotland because all the systems are in place, the funding was in place, the expertise was there, the counselling algorithms for the donors was all in place, and there was very serious concern expressed by the then general manager, Mr Mackintosh, that actually we should be implementing this. Our line of accountability is to the Secretary of State for Scotland. That was always his argument. But I think SHHD came back and said no, this is a UK-wide decision.

Q. Now, one of the matters which I think I know you're now aware of, because you refer either in your Penrose evidence or your evidence to the Inquiry to having read the judgment of Mr Justice Burton in *A v National Blood Authority*?

A. Yes.

Q. So you will know now that a number of other countries introduced hepatitis C screening significantly earlier in some cases than the United Kingdom did. The judgment lists the dates for various different countries starting, I think, with Japan in November '89.

There's some reference in the ACVSB minutes from time to time to the position in other countries. Do you recall that being a focus of discussion or anyone asking the question, "The States have done it, Australia's done it, France has done it, Finland's done it; Canada's done it. Why aren't we doing it?"

A. I think it was discussed. I can't remember the specific conversations. I can certainly remember at one point in time at one of the meetings, I think it would have been in 1990, where we learnt that the Phase I product, Phase I testing system, had been implemented in many countries (including USA, France, Finland and so on) and, whatever problems were considered to remain in the UK, many other countries, not dissimilar to ourselves, had managed to resolve these.

So my view was -- although I was not an expert virologist, my view was, well, if they can resolve these issues and still implement the test system, then

even with only a 60 per cent specificity rate, then there's absolutely no reason why we shouldn't do that. So that was my evolving view. But it was discussed but perhaps not at the top of the agenda.

Q. Then if I can just pick up another general observation you made at PRSE0006068. This is back in your oral evidence, page 50.

Now, you were here, I think -- you were taken through during your Penrose evidence a number of the sets of minutes for the ACVSB. I'm not going to replicate that process. I think you were here commenting upon the November '89 meeting, but I'm really interested in whether this is a more general observation.

At line 10 you say this -- you talk about your recollection being:

"... Dr Metters ... was very anxious that the policy decision should not be taken until it was absolutely clear that all the various details associated with the test had been resolved."

Then you go on to say in line 17 that you thought:

"... fairly early on in the process, that there could have been a point earlier where ... the Department of Health ..."

Then I think there might be some words missing, but it talks about "the testing would go ahead".

Then, top of the next page, I think you're contrasting at the top of the next page, Dr Gunson's position, "urging the government to make a policy decision", with the position of the Department of Health taking what you describe in line 5 as "a slightly less enthusiastic view".

Leaving aside the particular meeting in question, is that a general theme that ran through it, a reluctance or anxiety on the part of Dr Metters that all the details had to be got right before the bigger decision could be taken?

A. From my perspective, that's a reasonable view. I took the view I think there were three conditions that were established during the work up to implementation of hepatitis C that had to be satisfied. One was FDA licentiateship of the test system because they licence diagnostic tests in the US.

Satisfactory operational experience of the transfusion services and a suitable confirmatory test and much earlier than September 1991. Those conditions had been satisfied.

Q. Then if I can just, to conclude this topic, go to your witness statement to this Inquiry.

So WITN6920001, and if we can go to page 146, please, Sully.

If we can pick it up towards the bottom of the page, paragraph 458. I'm just going to read what you say and then ask if you have any further comments. You say this:

"In brief summary I believe there were a number of shortcomings in the overall UK management process ultimately leading to a relatively late implementation of HCV testing in Scotland and throughout the UK. These included:

"i. Unnecessary secrecy and confidentiality associated with the considerations of ACVSB and other 'behind the scenes' discussions.

"ii. Absent or confused processes for communication of ACVSB decisions to operational managers.

"iii. A late recommendation in principle (in my view) by ACVSB and DOH for the introduction of HCV testing. This appeared to be driven primarily by scientific rigour rather than urgent public health considerations."

If we go to the top of the next page, please:

"iv. The apparent absence of a clear plan, timescale, strategy or policy guidance (from either DOH or SHHD) for the introduction of testing,

following the decision in principle by ACVSB in July 1990 to introduce testing.

"v. The progressive (and largely unexplained) deferral of the UK start date from April to July to September 1991, believed to have been caused at least in part by administrative and funding issues between the English services and DOH rather than operational readiness.

"vi. With hindsight, and given its readiness (both operational and financial) to introduce testing in early 1991, the failure of SNBTS to robustly argue a case for earlier introduction of testing in Scotland with SHHD/Scottish Ministers including the public health consequences of delays. Equally an SHHD apparent reluctance to consider such an option preferring instead to be guided exclusively by timescales determined by DoH."

Now, you've set out in your Penrose evidence some more detailed observations by reference to the various stages of the decision-making process and, as I say, I'm not going to repeat those. But does that represent your considered view now as someone who was a member of the ACVSB and involved in the contemporaneous decision-making?

A. Yes, I think those observations, which are my personal

observations (there may be others that disagree with some of those issues), but from my perspective they seem to be the main problems that emerged from the rather turbulent period during 1989 to 1991 when it was eventually implemented and, in particular, there were important meetings that were held in SNBTS and they were quite robust discussions about what Scotland should be doing. I certainly remember that the then general manager felt very, very passionately that Scotland was ready to go, so it should go. But SHHD flatly refused, I think is the best way of expressing it, to entertain such an event.

MS RICHARDS: Sir, just noting the time. I've probably got another, I think, only five to ten minutes of my own questions for Dr Perry.

SIR BRIAN LANGSTAFF: Then let's go ahead with them, shall we?

MS RICHARDS: Thank you. Then we can perhaps break and have the opportunity for Core Participants to suggest any further questions. We can take that down, thank you, Sully.

I just wanted to ask you next about your involvement in the Better Blood Transfusion programme, 2005 to 2007. Can you just tell us what, in broad terms, that entailed, what the objective was of the

Better Blood Transfusion programme in Scotland?

A. I think I can, yes. The Better Blood Transfusion programme, its slogan was "Right Blood, Right Patient, Right Time". It was about getting appropriate prescription of blood transfusion, making sure the right blood was transfused to the right patient because that was always an issue. Many of the adverse reactions associated with transfusion were associated with mismatched blood or the wrong blood going to the wrong patient, and so on.

But the -- so it was about clinical practice, about actual delivery of blood transfusion in a safe and appropriate way. But I think it also reflected the increasing observation that one of the most effective ways of reducing the risk of blood transfusion was to reduce the use of blood in inappropriate situations.

So if you could eliminate the use of 10 per cent of the blood used in a particular procedure, then you are at a stroke reducing the risk by 10 per cent. That seemed to be an important reward.

That process was put in place. The Better Blood Transfusion programme had a number of elements to it, including one of the major elements was training, building training programmes for specialist nurses to

go out and deliver training to nurse practitioners and in hospitals, and so on, and to haematology departments.

Another aspect of the programme was data collection to better understand how blood was being used. The Better Blood Transfusion programme was really only about blood components. It was nothing to do with plasma products.

Q. No, I understand.

A. So one of the key targets was understanding how much blood was being used for a hip replacement or a knee replacement or a standard high blood using procedure, because until you have got that and were able to feed that back to practicing doctors, it was very difficult to control demand or to ensure appropriate demand. So it sort of built as a peer review system, and I think the people that used blood most extensively, certainly in the surgical area, were quite interested in these data because they would look at it and say, "Well, I'm using twice as much blood as my colleague". And there was no data before that on that particular topic.

So the SNBTS set up what it thought was a -- what it thought and I still think today is still a very important programme.

Q. Was that set up in 2005 when you became involved or

had it been running before then?

A. No, it was set up before then.

Q. Do you know when it was initiated in Scotland?

A. No. Probably about 2000, maybe. 2001. Dr McClelland was closely involved in this programme.

Q. Can I ask you then to look at two separate unrelated documents.

The first is LOTH0000045_002. LOTH0000045_002.

This is a letter, 11 November 1991, from you to Professor Cash. It picks up on a letter that Dr Foster had written to Professor Cash on 5 November expressing some concerns about what Dr Ludlam had said at a meeting. And we looked at the letter with Dr Foster when he gave his evidence.

I just want to ask you about what you say here. You say in the second line:

"... I share Peter's disappointment at the presentational aspects of Christopher's talk. His comments seem to provide no useful purpose and have only served to undermine our claims of a unique and constructive relationship with our "customers".

"Perhaps of more concern is the effect of such public statements at a time when HIV infection of haemophiliacs is very much under continued public scrutiny:

"Indeed, a central feature of our own position with regard to the tragedy of HIV is the early introduction of heat treatment and other measures such as batch dedication. The scientific value of these measures cannot and will not be proved but they were introduced as a collective response (including Haemophilia Directors) in 1984."

Then it is this sentence I wanted to ask you about, please, Dr Perry:

"I think the public denial of the value of these actions should be carefully considered lest we undermine our collective security on this issue."

What does that mean, undermining our collective surety on this issue?

A. I'm not sure. I think I was referring to -- oh, I can't remember the detail of this little transaction that occurred, but the source of it was Dr Foster attending a lecture given by Professor Ludlam, where I think his view was -- quite clear view -- that Dr Ludlam had minimised the importance of the actions that we took in response to HIV. He wasn't criticising them, he was simply I think -- I might be thinking about another thing now but he sort of described the early PFC's product as gentle warming, for instance, and --

Q. You are correctly remembering, yes.

A. Is that a correct reference? Yes.

And I think Peter's view, and certainly mine, underscored by this letter, was that making such statements were not helpful to the SNBTS or, indeed, for patients either. So I think it was a concern about -- this was a specific concern about the presentation.

Q. Then if we can look at WITN3431004.

This is an email exchange between you, Dr Foster and Dr Douglas in July 2000 in the context of the Lindsay Inquiry in Ireland.

Can we look at the bottom of the page, first of all. So we see at the bottom an email from you to Drs Douglas and Foster, 20 July:

"Have just heard that Terry Snape ... is acting as an expert witness in the Tribunal. I think we need to take steps to ensure that there is no major conflict between our report of events (which will soon be in the public domain) and what Terry is planning to say. He has already provided written witness statement.

"I will contact him."

Then if we go up a little, we see Dr Foster emailed you back, saying:

"Although it will be useful to learn what Terry has

provided, it is always possible that different experts will have different opinions. I don't think we should 'interfere' with Terry or ask him to change his statement (should there be any differences between us), nor should we change ours to fit a BPL view."

I won't read out the rest of the email. But he continues. Then if we go to the top of the page to your response, you say:

"I disagree slightly!

"Not because I do not trust the competence of the Tribunal to make decisions based on different witness statements but because the Tribunal is a public process in which perceived differences can be exploited by media and other interested parties.

"I am not interested in spinning the two statements together or ensuring that the detail is identical, but I am interested in seeing that our respective positions are consistent."

Then you say you think it would help the Tribunal if any major conflict/differences were dealt with beforehand.

Why were you keen to avoid inconsistency between the picture that might be painted by the evidence of Dr Snape and any evidence that might be presented to the Tribunal from Dr Foster or others within SNBTS?

A. I don't really know I can answer that. I certainly wasn't aware of any major problems, but I think I took the view that, although Dr Foster and Dr Snape were both there in their personal capacities attending the Tribunal, they were, in a sense, representing SNBTS and BPL or at least a UK-wide position.

So I think both for the purposes of the Tribunal itself, I thought it would be useful if there was consistency between the two statements. I think the outcome of this short exchange was no action was taken by anybody.

Q. Yes. Was it the case that you were keen to avoid there being public criticism of SNBTS?

A. No. I think it was -- well, yes, if that criticism was based on an unclear comparison between England and Scotland, for instance. So yes, I was concerned that there could be criticism. But I think my statement really is as it is. I was definitely not interested in spinning the two statements together or trying to influence the outcomes.

Dr Foster is very able and competent and Dr Snape is very able and competent. But they were -- in a sense, Dr Foster reported to me and he was representing the environment in which I was operating. So at that time on that day I felt I had a legitimate

interest in what he might be saying and what Dr Snape might be saying.

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

Just one final question then for now, Dr Perry. A theme of your evidence, in particular yesterday when we were looking at self-sufficiency, was the importance of minimising the use of commercial concentrates in Scotland because commercial concentrates were seen as risky products in terms of viral transmission. Is that fair?

A. Yes, I think that's fair.

Q. Do you think that may have led to a sense of or a degree of complacency within SNBTS and PFC that the domestic product was safe as opposed to the domestic product being less risky than commercial concentrates?

A. I don't think that was a conclusion that we drew. I think certainly after, as we've discussed this morning, the publications by people like Peter Kernoff and so on which demonstrated that UK products from voluntary donors still had the capability of transmitting virus to patients, and they did, it was certainly not a view in my mind, or indeed other people's minds, that the products were necessarily safer with respect to non-A, non-B, although there was still a belief that the severity of disease in the

acute phase was lower and the duration of disease was lower and so on.

Where I think that changed dramatically was with the advent of AIDS, where I think there was a very clear view then that SNBTS, and indeed UK products and indeed voluntary products based on the voluntary donor principle, were almost certainly going to be safer in terms of the number of virus-infected donations entering a plasma pool. I think all the data that's come out from that particular period in terms of incidence of AIDS and incidence of HIV in plasma donors and so on bears that out.

But it didn't make us complacent. It reinforced the view that SNBTS products, and indeed BPL products, were going to be safer. But not safe.

MS RICHARDS: Sir, those are the questions or topics I'm proposing to cover with Dr Perry, but we now need to give an opportunity to Core Participants to suggest any further issues arising out of Dr Perry's evidence.

SIR BRIAN LANGSTAFF: Do you have any sense of how long a period of break you might need?

MS RICHARDS: I don't know but I think it is probably safe to ask for half an hour.

SIR BRIAN LANGSTAFF: If I was to suggest not before 4.15 pm?

MS RICHARDS: I think that will be sufficient, thank you, sir.

SIR BRIAN LANGSTAFF: Let me explain to you, Dr Perry -- you may have heard me say this before, I don't know, but I'll say it again anyway -- those who are represented as Core Participants have the right, through their representative, to ask counsel to put questions to you. Many will have been watching online. Those questions may not yet have been formulated, though people may have been thinking about them. Counsel must have a chance to collect those questions, consider them and then put the substance of them to you in due course. It takes time. That time is very usefully spent having a cup of tea, so we will take a tea break now and come back at 4.15 pm.

A. Thank you.

(3.38 pm)

(A short break)

(4.15 pm)

SIR BRIAN LANGSTAFF: Yes, Ms Richards.

MS RICHARDS: Dr Perry, because the questions I'm going to ask you now have come from Core Participants, or their legal representatives, over the break, they will leap around from topic to topic a little because of the multiple sources. Apologies for that.

A. Okay.

Q. The first question arises out of your evidence earlier today when we were discussing the question of product warnings and leaflets, and it is this: at the time, so in the early 1980s, did you think that the PFC had a responsibility to patients to provide accurate and clear information about the risk of hepatitis B and hepatitis non-A, non-B on its labels and leaflets, or did you think the PFC had no responsibility in that regard because it was the responsibility of others, such as treating clinicians or the licensing authority?

A. I think it was the former. I think that PFC did feel it had a responsibility to provide appropriate warnings but, as we discussed, I think those warnings to an extent are prescribed or proscribed by the regulations that we operated in.

So, yes, of course the PFC had a responsibility to communicate to patients, although at that time the communication was not directly to patients, it was to the doctors that treated the patients and, as I think we noted, that changed in 1994, when patient information leaflets which were much clearer, much more explicit of risks and so on, came into force.

Q. Did the PFC ever, to your knowledge -- again I'm

talking about really the first half of the 80s here -- ever explicitly consider the position of patients on home treatment who might essentially just be taking the products home and using them there rather than having the products administered to them by their clinicians?

A. I'm so sorry --

Q. In the context of labels and what should be on the labels or in the leaflets.

A. Providing special information to patients on home therapy?

Q. Yes, or ensuring that whatever information was provided took account of patients on home therapy.

A. It may well have been that PFC did provide information like that but never directly to patients. We may have provided background information for haemophilia doctors to decide whether they wanted to include it in information that they provided to patients, but I don't think it would be appropriate -- I would hesitate to say illegal, but I'm not sure of the formal regulatory position of a manufacturer providing detailed information to patients which could be of a clinical nature or identify risks. So we may well have produced information for home therapy -- patients on home therapy, but that would never have been

directly with patients. Nor would it be appropriate to do so now, I don't think.

Q. You are not aware of any particular documents or discussions or meetings which canvass that issue and what might be the information requirements of home therapy patients?

A. No, it was quite clear that if there was a requirement for such information, PFC and the wider SNBTS would have always responded positively to requests for detailed information that could then be provided by their doctors to their patients.

Q. In broad terms, what measures were taken to protect those working at PFC, in the processing and manufacturing plants, from hepatitis?

A. I think it was a process of just continually underlining awareness of the materials that they were dealing with that -- and I think in some of the documents that I have seen referenced by the Inquiry, there are memos that I have sent out to all staff. We had active health and safety committees. And the underlying principles of everything that we did was to assume, for the purposes of health and safety, that the plasma that we were dealing with had infectious agents in it and people should respond accordingly. Of course, systems and manufacturing

environments were made as safe as possible but nonetheless, on occasions, there were inescapable situations where you have open systems where large pools of plasma are being held.

Q. When the risks of -- potential risks of viral infection leading to AIDS emerged, did the PFC change the measures it took to protect the plant workers?

A. No, there wasn't much that we could do. The immediate measure that we took was to reinforce the importance of the existing practices, to further encourage staff to make comments and suggestions about safer methods of working. And the documents that -- some of the documents that were provided to staff to assist in that I think the Inquiry has access to. But there weren't any specific -- there was no vaccine, there was no way of protecting staff working at PFC from the risks of infectious agents. Although, to the very best of my knowledge, and I think it is fairly accurate, there were never any instances of transmission of either hepatitis viruses or HIV to any staff working at PFC. And probably BPL. I think we would have known about it had there been such a case.

Q. The next question then relates to the use of red cell concentrates as part of the strategy towards self-sufficiency. Do you know how Professor Cash

managed to get clinicians to adopt a much more widespread use of red cell concentrates rather than whole blood? Was it force of personality or particular initiatives or steps that he took or both?

A. I think it was a combination of all of those things. I think -- if I can sort of picture the scene in the late '70s when he was director of the Blood Transfusion Service in Edinburgh, I would imagine part of his working day would have been visiting, speaking to colleagues, harassing them, if you like, to actually perhaps review their clinical practice. He would have never prescribed and said you were only getting red cells. He would have done it by consensus.

Q. I asked you yesterday about pool sizes. In relation to HIV, do you accept that pool size did matter when it came to HIV, in contrast to what you've said was the position in relation to non-A, non-B because of what you described effectively as the inevitability of infection?

A. Yes. After so many batches, yes. I think it was a much -- it had much more significance and importance when HIV emerged.

Q. And when HIV did emerge, HTLV-III/AIDS did emerge, end of '82 through into '83, and we heard from Dr Foster

last week about the information he gathered at the Stockholm conference in the middle of '83, was any consideration given to reducing pool sizes at that point in time, even as a temporary measure to try to reduce the risk of HIV transmission?

A. I think in all honesty there wasn't, for the reasons that I have described: reducing the pool size would have reduced the batch size, it would have reduced our capacity, output would have not met demand, and the outcome of that would have increased commercial product purchase. So that -- I don't recall any discussions being held about reducing pool size.

Q. Do you recall the context for Dr Crawford's suggestion of the creation of individual donor pools?

A. No, I don't, sorry.

Q. NIBSC, the testing that was undertaken before anti-HIV testing became available, was that focused on potency?

A. Potency and perhaps hepatitis B surface antigen testing and -- but I think it started out -- its genesis was concern that the vial potency of Factor VIII concentrates being used in the UK were particularly -- though not exclusively -- from commercial organisations, were carrying potency which didn't seem to accord with the measurements that were being made by clinicians and by NIBSC itself. So they

set up a system of -- I think it was -- I don't know -- I'm not sure whether it was absolutely mandatory but licence manufacturers were required to submit samples and NIBSC would either confirm the potency or suggest that they assign a different potency to a particular batch.

Q. Before HIV testing became available, roughly what proportion of PFC batches were tested by NIBSC?

A. Sorry, before?

Q. Before HIV testing became available, what proportion of batches were tested?

A. Before HIV testing?

Q. And then the next question is: did it change after HIV testing became available?

A. Before HIV testing became available, there were no batches tested for HIV --

Q. No, sorry --

A. But for -- for hepatitis B surface antigen?

Q. Yes. So what proportion of PFC batches were submitted to NIBSC for whatever tests they wanted to carry out?

A. This would be prior to 1985, of course.

Q. Yes.

A. I don't think I can answer that. When we did have arrangements for NIBSC undertaking testing on our products, it would probably have been all the batches.

But there was a short period when NIBSC said, "We are too busy to handle your material", so they suspended this arrangement where we submitted batch samples for testing. But that was reintroduced about a year later I think.

Q. In terms of the accumulation of or stockpile of material at PFC, you said in your evidence you were shocked to learn that that amount had been accumulated whilst operating a pro rata distribution system. Do you know how it happened that PFC was able to accumulate such a large surplus?

A. I think it was increased plasma supply, which was going up quite steeply at that time, and it was the product of the research and the development that Dr Foster had done to increase the process yield. So I think a combination of those two factors led to an increased product stock. I was surprised that it had accumulated to such an extent and nobody had noticed.

Q. That was really going to be my next question. How was it that nobody had noticed, and could it have been noticed rather earlier than I think late 1983?

A. Yes. I think if we had had -- but that was the purpose of me introducing a different stock control system and product supply system.

Q. Then can I just ask you to look now at PRSE0000040.

This is your note of the UKHCDO meeting, 17 October 1983.

Yes, PRSE0000040. Bottom of the page.

We looked at this passage before. It is just above the heading "Pasteurisation in Liquid State". It records you asking whether any viral inactivation data was available. Then it gives the example "vaccinia data". What is that data that you are referring to there as a possible indicator of non-infectivity?

A. Vaccinia is a virus that can be used in model -- it can be cultured in test tubes, if you like, and used to do model virus inactivation experiments. So when I say "eg vaccinia data", I think we used mumps virus and various other viruses to try to calibrate our processes using model viruses. And we did that on behalf of both BPL and PFC.

Q. If we go to you witness statement, WITN6920001. Page 37. Just looking at paragraph 106, which we looked at earlier for different purposes, where it says in the fourth line:

"This included the development of in house methods for testing the efficacy of inactivation processes using 'model' viruses."

My next question was going to be what were the model viruses you used at PFC. I think you have just referred to a couple?

A. Yes, I think we used vaccinia mumps. We also used -- on some occasions we used phage, which are bacterial viruses which are very easily grown and utilised and can be useful as models. But I -- there were others, but I can't remember what they were. But they were viruses that selected, especially when we were looking at heat treatment, for their thermal stability. So we tried to access viruses, for instance, that we knew were resistant to heat treatment and use those as part of a process. And then there will be other viruses that selected for different processes, like immunoglobulin preparation, where you wanted viruses that -- in which you could demonstrate the ability of low pH to inactivate viruses. So you use different viruses for different circumstances.

Q. In the same document can we go to page 133. Different issue.

Top of the page refers to a vial of the particular implicated batch from autumn of 1984, NY 3-009, being found in 2008 and submitted to NIBSC for testing.

How did a vial of the implicated batch come to

be found in 2008 do you know?

A. This postdated my retirement from SNBTS but I think I'm familiar with the context from my involvement in writing this particular report. It was a vial of product that was sent to, at that time a close colleague of PFC and SNBTS, a virologist, Dr Peter Simmonds, and he was doing some work on identifying HIV, and we sent him -- I think we sent him some of the vials that were returned from Aberdeen associated with batch 3-009. And this was when -- in the run-up to the Penrose Inquiry, we knew this topic was an important topic, the transmission of HIV by this particular batch, and so we -- the SNBTS circulated everybody it could think of who might have access to any samples of this product and Dr Simmonds wrote back and said, "Yes, I have found one actually". It hadn't been held in appropriate storage. It had been held at room temperature. But we were able to gain some useful information from it.

Q. You can take that down, thank you.

Then, last question. In relation to the rollout of heat-treated concentrates from 10 December 1984, and given the potential for heat treated concentrates to cause problems such as the development of inhibitors that you mentioned before, what in vivo or

in vitro trials or testing of the heat-treated NY was done before the rollout?

A. I don't think too much. I think it was -- I can't remember exactly how many patients but they were infused with the product and carefully followed up to ensure there were no short-term or long-term adverse events, but in one sense it was an advantage of operating out of a very tightly and formally controlled regulatory system, because we were able to introduce developments like this very quickly. I think by today's standards you would have done a much more extensive study before implementing such a change. But I think it is a good example of the urgency with which we thought this process step was required.

MS RICHARDS: Sir, those are the questions I'm proposing to ask from those submitted by Core Participants.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Do you have any questions?

Questions from SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: Just one area really. It arises out of the questions which a Core Participant invited you to ask.

You said that, as far as protection of staff were concerned, you assumed for the purposes of health

and safety that the products you were dealing with had infectious agents in them?

A. Yes.

SIR BRIAN LANGSTAFF: Did you tell the staff of the risks that there might be?

A. Yes, we did. And as soon as hepatitis B vaccination came in, all staff of PFC were vaccinated for hepatitis B.

There was little other action that was taken but they were certainly informed of the risks of needlestick injuries or abrasions or cuts and so on. And on those occasions where staff -- and they were encouraged to always report those incidents, and we had the services of a GP close by who used to attend the centre periodically, and the staff would be injected with a dose of immunoglobulin following any needlestick injury or suspected needlestick injury.

I'm not sure how effective that was, but that was the extent to which one could make a material intervention for staff that might have been exposed to a virus. But I think generally staff at the centre were very carefully advised and trained to -- as I say -- the underlying principle of the training and the behaviour control was to -- really just to emphasise that they had to assume that everything was

infective, because we didn't know otherwise. We couldn't identify which batches might be infective or which particular -- so you assume everything is infective and behave accordingly.

SIR BRIAN LANGSTAFF: They were heavily unionised.

A. Yes.

SIR BRIAN LANGSTAFF: So the union would have been told of the health and safety risk and pass that on as well?

A. Yes.

SIR BRIAN LANGSTAFF: But you didn't rely just on the union to tell them?

A. No, we didn't rely on the union. The union -- we had all the appropriate safety committees in place and safety advisory groups and so on. But no, we always felt that it was not the business -- it was the management's responsibility to do appropriate training and information provision on health and safety issues. And I think we had a very co-operative relationship with the health and safety officers of ASTMS, I think it was at the time.

SIR BRIAN LANGSTAFF: And although in one sense they couldn't avoid exposure to some risk because, after all, the product was there, you ensured, I take it, that their working practices were safe through standard operating procedures and that they had PPE

which was appropriate?

A. They didn't have such things as -- I'm not sure whether they're called hazmat suits or -- but it was PPE. They were dressed in Tyvek suits. They had appropriate face coverings and head coverings and I think we did the best that we possibly could with the materials and products that were available.

SIR BRIAN LANGSTAFF: Once you were aware, not of the certainty that blood products might transmit the whatever it was that was causing AIDS, but that there was a risk that it might, and you and Dr Foster both thought, as you've told us, that it was only a matter of time before what was in American pitched up in what you were dealing with in Scotland, you would have passed that on as a risk that people needed to be even more aware of and more cautious, did you?

A. Yes. I think we saw a document that I wrote, a memorandum to all staff which was one of my methods of communicating to staff on such things, to put out a memorandum to all staff and put it on the notice board, and that certainly immediately followed (I think it was mid-November 1984) after the report of the Edinburgh cohort.

SIR BRIAN LANGSTAFF: But you'd been a year before on 17th October 1983 to the meeting of the UKHCDO. Now,

at that meeting was it not a topic of conversation at least around the --

A. HIV?

SIR BRIAN LANGSTAFF: Yes, the fact that somebody had just died, who had haemophilia.

A. Yes, I think even at that stage, though -- I think I'm right in this but I can't be absolutely sure -- the cases of HIV in haemophilia patients in the UK at that time were, primarily or at least in the majority of, patients that had been treated with commercial Factor VIII concentrates from the US. So there was still a view at that stage that the UK plasma -- that the epidemic had yet to transmit completely to the UK.

SIR BRIAN LANGSTAFF: Although by then, as my memory serves me right, the Terry Higgins Trust as it was first known, was established in the middle of 1982. So plainly there was some public awareness of --

A. Of HIV --

SIR BRIAN LANGSTAFF: -- HIV as such.

A. Yes, yes, I think that's right. I think that's correct. It may be -- I gave the example of the memo that I wrote in mid-November 1984. It is quite possible that other communications to staff were made or the topic discussed. I think it was probably a regular topic on the agenda of the regular health

and safety meetings about safety with respect to infectivity.

SIR BRIAN LANGSTAFF: Well, that's where these questions were leading. Presumably there was some discussion about it. Did you hold back on any of the risks which you saw because you might alarm or upset members of the staff?

A. No. No, we explained -- people knew the environment they were working in. They knew that they had 4,000 bags of plasma from 4,000 individual donors and so it was not difficult to explain the risks, and we would talk about hepatitis B, and I think increasingly we would talk about non-A, non-B as it became better understood, and certainly when HIV -- when we knew HIV was in the blood supply, as it were, we certainly included that. So no, there was no caution in presenting those risks to staff.

We were concerned that staff would become extremely anxious about this but, in the event, we found they were -- they were sensible, they were co-operative, they knew the environment that they work in and they behaved accordingly. I don't think we collected any data on the number of needlestick injuries or abrasions that happened post-HIV to measure that. But I think, with hindsight, we were as

vigilant as we could be in terms of health and safety and it was always an important topic.

SIR BRIAN LANGSTAFF: Yes, thank you very much. I don't know if any questions arise out of that at all?

MS RICHARDS: No, sir.

Dr Perry, is there anything further that you would wish to add?

A. Well, I would just like to make a couple of final comments, if I may, just to -- in general and it's really no more than -- and I've actually just drafted a few notes to make sure I say what I need to say.

I would simply like to record my acknowledgement and recognition of the scale and the depth of impact that events explored and being explored in this Inquiry have had on so many patients. And these events are even more tragic, having been caused by developments in my field of work in SNBTS which held the promise of being so transformational for the treatment of haemophilia patients but which, at the same time, we now know had such tragic consequences for so many patients and their families.

My last thought is that I sincerely hope that this Inquiry will provide a complete as possible understanding of the events and the rationales for the decisions made by all those who were entrusted with

a duty of care for the patients they served.

Thank you.

SIR BRIAN LANGSTAFF: Thank you, Dr Perry. We will certainly try to get it as right as the evidence permits. Can I thank you in particular for coming. You've been here for two days. You've come down from Scotland. So, thank you for that. In many ways, it's been most informative. So thank you.

If you wait there for a moment or two, we have some little business to deal with since this is the last session before we have a bit of a break from sitting.

Ms Richards, we come back, do we, in May?

MS RICHARDS: We do. Sir, we come back on 10 May.

We will be publishing on the Inquiry's website imminently our proposed timetable for the rest of the year. Some of it, we're able to populate with names of witnesses. Other days or weeks we'll populate as the following weeks come on. But I just wanted to explain where we've got to so far so that those listening know who they'll be hearing from in May, June and July.

So we will start on 10 May, continuing on to 11 May with evidence from Dr Andrzej Rejman, Senior Medical Officer in the Department of Health 1989 to

1997.

Then on 12 May we will be hearing from Dr Hilary Pickles, Principal Medical Officer in the Department of Health, in particular in the Med SEB division, 1998 to 1991. Of course, both those names were mentioned in the course of the evidence this afternoon looking at the ACVSB.

On 13 May, Friday of that week, we turn to the first of these witnesses concerned with CJD and, in particular, vCJD. We will be calling Professor John Collinge on 13 May, Director of the NHS National Prion Clinic and MRC Prion Clinic.

In the following week, on 17 May, we will then be calling Professor James Ironside, a professor of clinical neuropathology and I think head or based at the National CJD Research and Surveillance Unit in Edinburgh.

The vCJD evidence continues on 18 May, hearing first from Dr Nicky Connor, a consultant epidemiologist and head of the CJD section of the Health Protection Agency. Then we will have a presentation by counsel to the Inquiry on a chronology of key events relevant to vCJD.

19 May we then return to Government evidence, where we will hear from David Mellor, Minister of

State for Health '88 to '89 and Chief Secretary to the Treasury 1990 to 1992. And then, on 20 May, from John Patten, Lord Patten, Parliamentary Undersecretary at the Department of Health and Social Security, 1983 to 1985.

There will then be two weeks when the Inquiry is not sitting and the Inquiry will then resume again in the week of 6 June, calling on 7 June, Professor Sir Michael Rawlins, professor of clinical pharmacology, but particularly for our purposes, member of the Committee of the Safety of Medicines from 1980 through to 1998.

On 8 June we will be calling Charles Lister, head of blood policy at the Department of Health, 1998 to 2003.

On 9 June we will be calling Justin Fenwick QC, who was instructed by the central defendants in the HIV Haemophilia Litigation.

And on 10 June, Richard Gutowski, head of blood policy at the Department of Health, 2003 to 2005.

There will then be a further two weeks when the Inquiry is not sitting, and then it will resume on 27 June, and then there will be five weeks when the Inquiry sits week after week.

So in the week of 27 June, we will be hearing

first from Sir John Major, Chief Secretary to the Treasury, Chancellor of the Exchequer and, obviously, Prime Minister.

On 28 June, Baroness Virginia Bottomley, Minister of State at the Department of Health and Secretary of State for Health the period 1989 through to 1995.

On 29 and 30 June, we will be hearing from Professor Richard Tedder, whose name obviously has come up in multiple documents, in terms of his involvement in relation to matters of virology in particular in the 1980s.

Then, on 1 June we will be hearing from Gloria Hooper, Baroness Hooper.

SIR BRIAN LANGSTAFF: 1 June?

MS RICHARDS: Sorry, 1 July -- who was Parliamentary Undersecretary of State for Health, 1989 to 1992.

In the week of 4 July, we will be calling William Waldegrave, Lord Waldegrave, Secretary of State for Health, 1990 to 1992, Chief Secretary to the Treasury, 1995 to 1997, and that will be on 5 and 6 July.

On 7 July we anticipate a counsel to the Inquiry presentation on the role and the decision-making of the Chief Medical Officers of the Departments of

Health in the 1970s and the 1980s.

In the week of 11 July, on the Monday and Tuesday of that week, so 11 and 12 July, we will be calling Sir Robert Francis to talk about and answer questions about his Infected Blood Compensation Framework Study.

The witnesses for 13 and 14 July of that week are yet to be confirmed and as soon as we have confirmed the position those details will be published on the Inquiry's website.

On 15 July we will be calling Andy Burnham, Minister of State at the Department of Health, 2006 to 2007, and Secretary of State for Health, 2009 to 2010.

In the week of 18 July we intend calling evidence relating to Government decision-making and the response of governments in Scotland Wales, Northern Ireland and England. We are yet to fully flesh out that week.

We will be calling, however, in the course of that week, John Reid, Lord Reid, Secretary of State for Health, 2003 to 2005. Also occupied positions as Secretary of State for Scotland and Northern Ireland. And we will be calling Hazel Blears, Parliamentary Undersecretary of State from 2001 to 2003.

In the week of 25 July, the focus will be in

particular on decision-making and the response of governments in Scotland, Wales and Northern Ireland.

Again, we will need to confirm the details of who will be called, but one of the witnesses will be Professor Aileen Keel, Deputy Chief Medical Officer for Scotland and, prior to that, a medical officer in the Scottish Home and Health Department.

That will conclude the summer evidence, that week of 25 July. The Inquiry will then resume in the week of 12 September. So some of these are additional weeks to those previously published on the Inquiry's website. The focus of the evidence called and examined in the week of 12 September will relate to issues of candour, openness, cover-up and recordkeeping.

On 12 September, so the Monday we will be calling Nigel Crisp, Lord Crisp, who was permanent secretary at the Department of Health from 2000 to 2006.

We will also be calling Zubeda Seedat, a civil servant in the blood policy team at the Department of Health.

On 13 September, we will be calling William Connon, who was head of blood policy at the Department of Health 2005 to 2009.

There will then, in the afternoon of 13 September and 14 September, be a number of presentations by counsel to the Inquiry on matters relevant to transparency, cover-up and recordkeeping.

On 15 September, we will be calling in the morning Susan Douglas who was the political correspondent to the Mail On Sunday in 1983 -- obviously many other journalistic roles during her career. Then there will be further presentations to the Inquiry.

16 September, we'll be calling Caroline Flint, Parliamentary Undersecretary for Public Health, 2005 to 2006, and Minister of State for Public Health 2006 to 2007, and there will be further presentations by counsel to the Inquiry.

In the week of 19 September, we anticipate having further evidence about government decision-making and the response of governments, a combination of witnesses and presentations, but we do not yet know exactly what that week will comprise.

We then move to the week of 26 September where we hope to have panels of people who were infected and affected giving evidence, and the week of 3 October where we will be hearing further expert evidence and also panels of people infected and affected.

Currently, it's then envisaged that the weeks of 7 and 14 November we will hear evidence relevant to the making of recommendations by the Inquiry and then the indicative weeks for the making of oral submissions remain as previously indicated, the weeks of 28 November, 5 December and 12 December.

So that, I hope, is a useful update of the Inquiry's future hearing plans for the remainder of this calendar year.

SIR BRIAN LANGSTAFF: Thank you very much, Ms Richards.

Let me add a few words of my own. I know that it can be all too easy to become so focused in some of the detail of what we have been hearing as to lose sight of how what we have already heard may fit together with what we are next to hear. But witnesses and topics are not heard at random. I hope you have recognised that there is some pattern with what the Inquiry is doing. Everything starts, everything started, everything will finish with the experiences of those infected by blood and blood products given to them by the NHS. Building on what we heard earlier, in the last six months we've heard how that blood was collected, transfused, turned into blood products and of blood products which were administered by the NHS but came from abroad.

We have heard how palliative care, properly delivered, can assist. In the next three months, as you've just heard, we're turning to government, which oversaw and had ultimate responsibility for what happened. I'm looking forward to hearing what civil servants and former government ministers have to say and, like many of you, to what Sir Robert Francis will have to say.

It is going to be an intensive timetable as we get closer to the end of the hearings, but I want to highlight two things which mustn't go unnoticed. First, I know that some statements which are in the pipeline have not yet been submitted to the Inquiry. It would be of real assistance to me if those statements could be provided by the end of September. I'm determined to read each and every one of them. Legal representatives, this is particularly for you: let the Inquiry have them as and when they are ready and not just in an avalanche all at once. That is a firm request rather than an absolute deadline but the second matter does relate to deadlines.

Legal representatives, please don't forget that 20 June is the deadline for suggesting recommendations that you'd want me to consider making and this allows time to consider if further evidence and, if so what,

is needed concerning those recommendations. I shall remind you again of the second deadline but I make no apology for mentioning it now and that's 24 October. Core Participants may address the Inquiry through their representative if they have one at the end of the hearings which come later. 24 October is the date by which anyone taking advantage of that opportunity must supply written detail of any closing arguments -- we've called them submissions which is a lawyer's phrase -- so that anything that is said can be properly focused. Now, there's further detail in the statement of approach to submissions on the website.

Finally, and looking to the more immediate future, I would like to wish everyone here and everyone listening a refreshing break over Easter.

Thank you.

(5.00 pm)

(Adjourned until 10.00 am on Tuesday, 10th May 2022)

INDEX

F:

F:

F:

F:

F: