Tuesday, 20 July 2021

(10.00 am)

DR DIANA MARION WALFORD (continued)

Questions by MS RICHARDS

MS RICHARDS: Dr Walford, we left yesterday having looked at Dr Waiter's memo on leaving office.

A. Yes.

Q. Just before we look at your memo from September of 1979, I want to ask you to look briefly with me at paper produced by Dr Lane at the same time, or around the same time. It's CBLA0000998 and we can see it's entitled "Future preparation of plasma protein fractions by NBTS, A reassessment of requirements". I'm not going to ask you to consider the detail with me but just a couple of the broad points that Dr Lane makes.

If we go to page 2 and if we look at the paragraph at the bottom half of the page, so the penultimate paragraph beginning:

"The problems that exist now in the [National Blood Transfusion Service] are not new, but have been accumulating in severity over several years in both regional transfusion centres and at BPL. The difficulties have been accentuated by the growth in requirement during the 1970s of plasma products,

see, under the heading "Reorganisation of NBTS", he makes a proposal for reforming it, setting up a special health authority, and so on.

Again, Dr Walford, it was really from your perspective of the years when you were involved whether you agree with or have any observations about his concern about the organisation of the National Blood Transfusion Service?

A. Well, it's fair to say that the National Blood Transfusion Service was not really organised in any choate form that one could see. It was a loose federation of Regional Transfusion Directors. Each regional transfusion director had an accountability to the Regional Health Authority, either through the Regional Medical Officer or in some other way but, basically, they were little fiefdoms under themselves. They were not centrally co-ordinated. The Government's initial central co-ordinating committee for the NBTS really didn't seem to co-ordinate anything and, as we saw, stopped in about 1978. So it was obviously not doing any good.

It was then replaced by the advisory committee on the NBTS and I think if you say to yourself here's an advisory committee, how likely is it it's going to be able to manage an organisation like the NBTS.

an exercise in production maintained without adequate planning, co-ordination or finance from the outset."

Do you agree with what Dr Lane was observing there, to the extent that you're able to?

A. Indeed. Basically, I think he's trying to refer to the fact that the UK was aiming for self-sufficiency but there appeared to be no overarching plan in order to achieve it and, to that extent, he's right.

Q. If we go to page 5 -- no, I'm sorry, page 6, there's just a particular observation about the organisation of the National Blood Transfusion Service I wanted to ask you about. Again, it's the bottom half of the page, it's a section entitled "The Central Defect in [National Blood Transfusion Service] Organisation", and then he says this:

"In spite of the Medicines Division report, it is questionable whether BPL could make a substantial increase in factor VIII output at present because of the fall-off in frozen fresh plasma supply during 1979. Financial restrictions at RTCs are only part of the problem."

Then it was this sentence, Dr Walford:

"Inability to co-ordinate the plasma programme is a central defect in NBTS organisation."

Then if we just look at the next page, we can

But what it was aiming for was to bring together Regional Transfusion Directors with the central blood laboratory directors and to try and get some degree of co-ordination.

Now, Dr Lane was entirely consistent throughout all the time I knew him: this is chaotic, it doesn't work, we absolutely have to co-ordinate the plasma with the BPL developments because, actually, without the plasma, we're nowhere. So he was always saying there needs to be a mechanism. He was proposing quite early on, as you see, a special health authority and, of course, ultimately a special health authority, the Central Blood Laboratory Authority was set up to actually co-ordinate the Central Blood Laboratories and their sources of plasma supply but I think what he's saying was fair comment.

Q. I think it's right, and we can look at the documents later if we need to but we may not need to, that the central committee, as you say, met in 1978 and then didn't meet again for two -- well, didn't meet again, disbanded in 1980 and the replacement advisory committee then was set up.

A. Yes.

Q. So for two years there wasn't even, at what might be thought to be a very critical time, there wasn't any

overarching committee in relation to NBTS?
A. No, that's right.
Q. So, if we now go to the memo that you produced on 19 September 1979, it's at DHSC0003618_023. It refers to an "attached scheme", so if we just look at the text, Soumik, thank you. So in the first paragraph it refers to an "attached scheme" and we will look at the scheme in a moment. You say:

"It represents my preliminary thoughts on a complex matter which has been preoccupying you for a considerably time and I do not doubt that this scheme, or something similar, is but one amongst the many options which you may have been considering."

You were fairly new to this job at the time. I think you had been in post probably for a matter of weeks at this point.
A. Three weeks.
Q. What was it that prompted you to come up with your own thinking and formulation of options?
A. Well, my supposition is that I knew I was coming into a new job. I knew a little bit about this from the Medicines Division angle. I had Sheila Waiter's very helpful paper, which obviously I used as a quarry for my further thinking, but it also seemed to me that there was an awful lot that needed to be done and,

therefore, I put forward some preliminary thoughts on what might be done. I actually thought I was putting them forward only up the medical hierarchy but when Dr Harris saw them he thought they ought to go further, so they went up to Mr Wormald and to Mr Harley as well.
Q. If we just look at the scheme and then come back to the text of the memo, so the scheme is at DHSC0003618_024. It's a useful way of looking at what you were putting forward. I wonder could you just talk us through, using this document, what it was you were suggesting?
A. Right, well I'll start from my left-hand side then onwards. Basically, what I saw was, as you see, I've got Scotland at the extreme left of my diagram where I foresaw that we would send more fresh frozen plasma to Liberton. In fact, I don't think we were sending any fresh frozen plasma to Liberton. We had in the past sent some outdated plasma for fractionation.

Then my view was that you would upgrade and modify Liberton to help to increase production but I also saw it as a kind of place where you could stockpile or keep an emergency supply of Factor VIII. In other words, it was, to a degree, a fallback but also to contribute to the national effort, if you

like, of England, Wales and Scotland all together.

So that was my initial thoughts about Scotland, and please remember these are initial thoughts and, obviously, I wasn't at all sure how they would land, apart from anything else.

Then I foresaw in England that actually we would do what the Trends Working Party, if 1977 -- that was the last time there was a working party looking at plasma supply and what products were needed and in 1977 the suggestion was that cryoprecipitate production should be phased out. That was of clear recommendation from the Trends Working Party. So I picked up on that and said, right, well, if you're not making cryoprecipitate at Regional Transfusion Centres that's all the more plasma for the Blood Products Laboratory, so we can increase the amount of intermediate Factor VIII, which was the product of choice at the time, that's the freeze-dried product, and that was the Trends Working Party product of choice and, subsequently, the Gunson Working Party in 1981. That was their product of choice as well.

I then have this dotted line. I think what I was trying to say here is that there had been a Royal Commission on the NHS. There were all sorts of plans afoot for restructuring the NHS and one

wanted to make sure that everything fitted in with the restructured NHS but I wasn't aware of what those plans would entail in detail.

So moving on to the heading "BPL", obviously we had the inspector's report. The inspector's report was damning. We needed to do something very quickly. So immediately I say implement stop-gap, please, which is why I think I was emphasising yesterday that I didn't think it was a good idea to stop stop-gap. Implement stop-gap and then also upgrade BPL to the extent that the Medicines Inspectorate required to make it safe.

I then took up from Sheila Waiter's suggestion. Because I knew we were dealing with an entity, the Blood Products Laboratory, that simply wasn't a pharmaceutical factory, it really wasn't fit to make pharmaceuticals on any scale, although it produced very good product and went, you know, in its low volume.

So I thought it would be helpful to have a commercial firm to fractionate for the NBTS for the UK under contract. That was my thought initially and that, actually, I think, coincided quite a lot with what Sheila Waiter was suggesting and Kabi, being a Swedish firm, seemed to be quite a good bet for

doing that, and it was her suggestion, which I was actually, if you like, piggy-backing on here to suggest that Kabi should maybe do that on our behalf.

Then there was the question of, well, could there be some different commercial involvement, not simply contract fractionation for us but if no firm was willing to just do that, maybe there could be some form of partnership with commerce, and so the thought was, well, immediately go into negotiations, see what Kabi could do or Immuno, which was an Austrian company, so European, if you will. Although at the time I didn't know that Immuno also fractionated American plasma. I just simply didn't know that. I thought it was purely European.

So I was suggesting that we ask Kabi to, as it were, keep running BPL, if you like, for two years and then, as BPL was upgraded, it would take over and run BPL and then build a new plant on the Lister site and supply to the NHS for us. So it would actually be almost a nationalised -- well, we would be using a commercial company to work for the State fractionating our plasma.

Then, for Immuno, I was suggesting again the same time-frame and here what I'm saying is probably controversial, but it was a suggestion because we knew

that most foreign firms wanted to import plasma for fractionation, but rather than do that, for them to set up a plasmapheresis centres using UK donors, which would actually -- probably, you would need to pay for the sort of plasmapheresis that was needed -- it was just a thought -- and that those UK plasmapheresis donors would supply the NHS.

If there were any UK-derived products which had been fractionated, which was surplus to NHS requirements, they could then be sold abroad. I thought the point of having two potential companies in there would be a way of not holding the NHS or the UK over a barrel, if you like, because if you didn't like one what one commercial company was doing you could actually threaten to take away what they were doing and give it to the other company.

So, as I say, I produced this three weeks into the job and I really didn't know how it was going to be received and I probably would not have put it up to others, because you know how irritating it can be if a new broom comes in and makes suggestions when people have been worrying about something for a long time. But those were my initial thoughts.

SIR BRIAN LANGSTAFF: May I just ask, before we move from this scheme, the one thing you didn't mention on the

far left-hand side, the very bottom, is the "plus R&D". That's research and development, I take it?

A. Yes.

SIR BRIAN LANGSTAFF: What did you have in mind for that?

A. Well, basically BPL needed -- any fractionator needs to keep doing R&D all the time to develop their product. It's not particularly basic R&D but they must keep developing and improving their product. BPL was doing some -- the plasma fractionation laboratory in Oxford was almost the main centre for the research that was being done into new product development. But there was absolutely no reason, in my view, why Scotland shouldn't be doing some R&D as well and, in fact, you will see from papers later on, they were always trying to change the composition of their products, to change the chemical constitution and so on. It's an absolutely essential part of being a fractionator. You just don't stand still; you keep looking to develop your products.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: If we then go to the accompanying memo again, DHSC0003618_023, just pick it up the paragraphs numbered 1 and 2. You say:

"If it is accepted that production at BPL should continue for the present, then stop-gap or an

appropriate modification of it should be implemented forthwith, both to satisfy the Medicines Inspectorate and to increase production."

Then 2:

"With agreement from Ministers as necessary [and you refer to Mr Harley's paper] we should enter into immediate and very searching negotiations with likely commercial contenders for UK fractionation. There may well be a sticking point about the margin of profit which the DHSS and the companies each consider acceptable! It may, therefore, become apparent at an early stage in these negotiations that the commercial option is less open or less attractive than it currently appears."

So it would appear that you were saying here: whatever was done needed to be done immediately?

A. If it were done, yes.

Q. Then we'll look at the extent to which that happened in practice.

But if we just then go further down the page, you then, at 3, talk about the modification of Liberton, and we'll come back to the issue of how -- or the extent to which that idea was taken forward.

Then you refer again to plasmapheresis. We may, if time permits, come back to the question of

plasmapheresis but in case we don't can I just ask you toll tell us in a sentence or two what plasmapheresis was and why it was being suggested?

A. Plasmapheresis is a way of getting more plasma from an individual donor than you could do without damaging the donor's health. So you take a unit of blood from a donor in the usual way, you centrifuge it -- you spin it -- you take off the plasma, you give back the red cells, which is really the cellular component of blood, which is really what people need to stop them becoming anaemic and to keep all their systems going, and you keep the plasma.

Now you can then do that a couple of times so that you could get, say, 500ml of plasma from a patient -- from a donor, sorry, at one siting, whereas normally speaking you wouldn't take more than one unit of blood, which may only yield less than 200ml of plasma.

So this is the system which was, of course, used extensively in America, but to an extreme degree, where they were plasmapheresing donors over and over again, I mean in a way which cannot have been healthy for the donors themselves, because they were taking off all this plasma which actually contained some useful nutrition, if you like, for the body.

But you could do a plasmapheresis either manually, which I've just described, or you could do it continuously in a machine. So machine plasmapheresis, manual plasmapheresis, either way you have got more plasma than you would get if you simply took a donation of blood from a donor.

Q. Then if we go over the page we can see, four lines down, the reference as we saw in the scheme, the diagrammatic scheme, a suggestion of ceasing the production of cryoprecipitate.

Now, did you at this point in time, as far as you can recall, give any consideration to what the consequences of ceasing production might be, at least in the short-term, which might be a greater reliance upon imported concentrates and a greater risk of viral transmission?

A. Well, you know, of course I can't think what I might have thought at that time but, I mean, one issue here was: don't make cryoprecipitate at the regional transfusion centres, send all the plasma to BPL. But cryoprecipitate is the starting material for intermediate Factor VIII, so if you wanted cryoprecipitate in any volume, you could actually make it at BPL, because they had to make cryoprecipitate, and then they went on to make intermediate concentrate

from it. So you wouldn't actually completely avoid making cryoprecipitate if you didn't want to, you just wouldn't be making it at the regional transfusion centres, which then meant that the plasma wouldn't be sent to BPL.

Q. Now, can I then -- we'll consider the extent to which these ideas were followed through when we look at some of the subsequent documents but can we then just look at a couple of meetings in the same month, September of 1979. The first is at DHSC0002195_044.

So this is a meeting on 26 September, "An *ad hoc* group of Regional Transfusion Directors", and we can see that you were in attendance, along with Dr Lane, Dr Gunson, Dr Tovey and others.

I just wanted to see whether you can assist us with the fourth paragraph, I think it is. It says:

"A tendency to revert to cryoprecipitate was discernible in some regions due, in part, to lack of money to buy commercial concentrate or to collect more plasma for fractionation at BPL. It was agreed that this was yet another example of the way in which the use of blood products and the development of blood product production was being distorted by the availability of products were apparently 'free'."

I wondered if you could assist us with, well,

two parts of this paragraph. The first suggests that some regions at least were going back to producing more cryoprecipitate. The second sentence, are you able to assist us with what that's referring to?

A. Well, I suppose Regional Health Authorities must have balked at buying commercial product if they thought that they could get BPL product free. Of course BPL product wasn't free. They were having -- the Regional Health Authorities needed to pay for the plasma from the Regional Transfusion Centres to go to BPL. There was never any proper costing of any of all this but this was not a cost-free option, if you like, having it made at BPL, but it didn't feel as painful as the Regional Health Authority having to put their metaphorical hand in their pocket to pay for the commercial stuff, which was very expensive.

Q. Then if we just go to the bottom of the page, just to pick up the theme that we explored by reference to Dr Lane's paper, we can see there is a discussion about the administration, the organisation of the Blood Transfusion Service, and it would appear that there's as lack of unanimity or consensus about Dr Lane's suggestion of having a "special health authority", and a suggestion that there should be directors co-ordinating the service professionally,

which I suppose is what was supposed to be happening but not quite happening in any event. Is that right?

A. Yes. It's interesting that Dr Jenkins referred to reluctance for the Government to, set up new quangos, and that was very true. There was a cull of quangos -- I mean, there was -- throughout my time in the Department there was a cull of quangos, but there was always a feeling that quangos were bad and basically they were uncontrollable so you didn't set them up.

I think there was some reluctance on the part of the Department for quite a long time to set up even the Special Health Authority, which was not a quango in the quasi-autonomous way. It was under the control, if you like, of the Health Service. But there was a reluctance to set up new bodies.

Q. Is that possibly one of the reasons why we see again and again around this time in the papers questions of new advisory groups, new working parties, new committees, et cetera, always had to go, it would appear, to the minister for a decision?

A. Yes.

Q. Then if we turn to a meeting I think on the same day -- at CBLA0001005 -- this is a meeting of that Scientific and Technical Committee for the Central

Blood Laboratories, and this would, I think, have been your first meeting as joint secretary?

A. Mm-hm.

Q. Then if we go to page 2 we can see, at paragraph 5, it refers to the report by the Medicines Inspectors, and there's a discussion about the issue both of short-term upgrading and longer term redevelopment.

If we look further down towards the bottom half of the page, the penultimate paragraph begins:

"Dr Dunnill said that he was disturbed by what he had read in the report and by the absence of any clear commitment by the Department to put matters right. The Committee now shared with the Director the responsibility for the safety of the products made at BPL. Both Dr Dunnill and Mr Smart expressed doubts about the advisability of proceeding with short-term measures without a commitment to the full-scale rebuilding of BPL."

Then Mr Smart's estimate of how long it would take to achieve that new building was three years.

Then we see:

"Mr Harley [asking] whether the Committee felt that they could confidently dismiss the other options set out in his paper for Ministers. Members doubted whether all the options were available in practice and

they agreed that the right course was to recommend that no time would be lost in planning a completely new plant, even if it was felt that other possibilities had to be examined concurrently."

Then if we just go to the next page, paragraph 6 refers to Mr Harley's paper. I'm not going to take time looking at that now but we can see in the second paragraph under that heading there's then a debate about commercial involvement, and I'm summarising but it would appear that the members of the committee are not supportive of the proposal for commercial involvement.

So it would appear that there was tension between what civil servants were proposing to investigate and explore with ministers, possibly because they thought that was what ministers might be most interested in -- I don't know -- and what those who were members of the committee saw as the right course. Is that fair?

A. I think that's fair. I think one of the things that bedevils these papers actually, when I came to look at them after all these years, was the difference between getting industry involved in fractionating our plasma, because that's what we needed, we needed that sort of industrial expertise, and actually some form of

takeover by industry which meant that, in fact, you had a wholly new company, a commercial company, which owned BPL and then, of course, it was out of everybody's control what would then happen.

So there's the difference between the two and I'm not ever quite sure what is being referred to in these various papers.

I think there's no question that from the word go the committee wanted to get on and rebuild BPL. I have to say they weren't alone in that view but there were obstacles because actually this was not a course of action that was immediately attractive to ministers.

Q. You say they're not alone in that view. I detect from your answers yesterday that you share that view?

A. I shared that view.

Q. The obstacles, if I can put it that way, were to some extent political because decisions had to be made about funding, bids had to be made to the Treasury and, as we'll see in some of the papers, but I know you have read them all, Dr Walford, there was also -- there's reference to the new Government being more in favour of the involvement of the private commercial sector than perhaps earlier governments had been.

A. Yes. I think that is obviously a factor but I think

if we're looking quite early on in the new Government, in the new administration, I'm not sure how well formulated that particular sort of ideological side of things was. I don't think I was necessarily particularly aware of that. I mean, there was -- my thought was that actually ministers couldn't think of where they were going to get the money from. Basically they were almost reluctant, if I can say that, reluctant to think about committing to rebuild BPL because they didn't know where the money was coming from.

Now, it couldn't come from the central budget because there simply wasn't enough. The Treasury had an absolutely iron grip on finances at the time and I think they were searching around for any other source of funding, and one of the potential sources was obviously to get commerce involved and to get them to do it.

Q. Then I think we can see, probably quite starkly, the difference of approach and the difference in terms of the sense of urgency between the Department and the committee if we look at two documents.

The first is a note from Mr Harley, copied to you, DHSC0002195_050. So it's Mr Harley to Mr Dutton. Can you just remind us who Mr Dutton was.

A. He was a principal in Mr Harley's division.

Q. So HS2?

A. Yes.

Q. Then we can see it refers to the meeting of the Scientific and Technical Committee, and then in the last main paragraph we can see reference to Professor Mollison as chair of the Scientific and Technical Committee being anxious to begin work on detailing what would be needed in a redeveloped facility.

"I tried without success to discourage him, and agreed that if non-departmental members wanted to do this I could hardly prevent them, but I thought officials should not be involved. We are not at the stage where planning can sensibly be started, and I made it clear that officials should not now be taking on additional work, particularly when it might prove nugatory."

Then he goes on to say:

"... whatever [is] done should not involve the expenditure of ... money."

And there's no budget "for the preparation of a development plan", and "I do not think [the] Committee is the right group" to do it anyway.

So that's Mr Harley essentially saying, is this

fair, "Put the brakes on because we're not at the stage of being able to start that work"?

A. I think, to be absolutely fair to Mr Harley, who was himself scrupulously fair and an excellent civil servant in my opinion, to be fair to him he knew that there wasn't ministerial approval, we hadn't obtained ministerial approval yet, we certainly would need to before going ahead and committing to rebuilding and, indeed, to any degree of additional expenditure. So although this looks very negative and a drag anchor, if you like, he probably had to do that because that was his job.

Q. Then if we look at what was produced by the chair, by Professor Mollison, at DHSC0002195_069, if we just zoom in a little closer, so we can see it's memorandum by the Chairman and then paragraph 2 refers to the medicines inspection report, and then says:

"Remedial action of two kinds is needed:

"(a) money is required immediately to upgrade the existing facilities;

"(b) a completely new plant must be planned and built with the greatest urgency.

"If the above two steps are taken there will be a reasonable defence against any possible accidents which may occur."

Then 3:

"The Committee has in fact been emphasising the need for new plant for some time. The Inspectors' report simply increases the urgency of this requirement."

Then there's reference to the economic justification, that was Mr Smart's paper, and then at paragraph 4, I'm not going to go through the detail of it, but he sets out his concerns about commercial involvement and describes it as a retrograde step at the end of the page.

Again, trying to take it fairly quickly but, I hope, fairly, he's saying --

A. Get on with it --

Q. -- put the accelerator on, drop the brakes?

A. Yes.

Q. Then there's a departmental meeting on 10 October, DHSC0002325_036. We can see it involved largely those working for the Department but also Dr Tovey, presumably in his capacity as consultant adviser to the CMO. It's 10 October 1979. We can see reference under paragraph 2 to your minute of the 19 September and the flow chart and then it talks about the principles of commercial involvement:

"... it was recognised that, in general,

Ministers favoured transfer of functions from the public sector to the private sector where this was likely to improve efficiency."

Then reference to Mr Smart's view to the contrary that this should be done by the NHS. Then the next paragraph:

"It was agreed that undertakings to move towards national of NHS self-sufficiency in blood products did not preclude industrial participation in the purely technical process of fractionating plasma."

Then we have Dr Tovey setting out his concerns and Mr Harley, bottom of the page, referring to possible union concerns.

If we then go over the page we can see what the upshot of the meeting is:

"It was agreed that Mr Harley should continue with his options paper but in practice there appeared to be only two courses to put to Ministers:

"(i) to spend the minimum necessary to upgrade BPL while at the same time rebuilding and expanding the laboratory within the NHS using NHS capital if available or significant alternative sources of funds if not.

"(ii) to spend the absolute minimum ... to satisfy to Medicines Inspectors and to seek

an agreement with industry to fraction NHS plasma [and so on].

"It was agreed that the first practical step was to find out as soon as possible what facilities industry was able to offer and on what terms."

So, is this right, there's an internal departmental decision to investigate further the contribution that could be made by commerce, by industry, before anything was going to be put to ministers?

A. Well, I think actually they had to approach ministers on the question of involving industry anyway.

Q. Yes. So it's a decision to find out more about the possibility of commercial involvement at that point in time.

A. Yes.

Q. Then if we pick that up in a memo from Mr Wormald at DHSC0003743_193, this is the following day. It refers to the meeting and, you're right, the meeting is -- it's now talking about what they are going to put to ministers. Paragraph 2, it suggests that:

"... we shall seek agreement to entering into discussions, via Supply Division, with the interested commercial firms ..."

Then paragraph 3 refers to the choice that will

have to be put to ministers.

Then, bottom of the page, we can see this. It refers to a draft, I think that was a draft of a proposed letter to the Medicines Inspectorate.

A. Yes.

Q. We don't need to worry about that. But if we pick it up halfway down that paragraph, Mr Wormald says:

"The availability of this money [so further expenditure for BPL] can by no means be assumed. Certainly there will be no extra in 1979/80. Until we have explored the financial position further we cannot put forward these proposals to Medicines Division except in very tentative and contingent terms ..."

Then, over the page, there's a reference in paragraph 7 to the possibility of sending a holding reply to the Medicines Division and then a reference in paragraph 8 to suggesting to Mr Nodder -- is that --

A. Mm-hm.

Q. -- that he should call an early meeting. Who was Mr Nodder?

A. He was Mr Wormald's boss, he was the deputy secretary.

Q. So, again, it would appear to be the proposal is to, as it were, tentatively approach ministers, is that fair?

A. Yes. I mean, the draft that I had written to respond to the Medicines Inspectorate, which of course I have reviewed because you sent it to me, actually I found it quite difficult to be critical of that draft.

I wasn't entirely sure what Mr Wormald was concerned about but, of course, it's perfectly obvious that I was -- in effect, it was implicit in my draft that rebuilding would be done, that we would one way or another rebuild BPL and, meanwhile, these were the proposals that we had to upgrade the BPL, insofar as we could to meet their requirements. You could never have met all of the Medicines Division requirements without a rebuild but you could get to the point where you hoped to satisfy them to a degree and, obviously, also perhaps then to be able to increase production.

The problem with my draft, as I see it, is that it was implicit that we were going to rebuild and we hadn't got ministerial permission so, obviously, Mr Wormald was right, if you like, to rein back and say I have problems with Dr Walford's draft, although he hasn't actually spelt that out, but that is clearly what he meant. At least I hope that's all he meant because otherwise I thought it was a jolly good draft.

Q. Then if we just go to DHSC0003813_052, we can see from this letter from Mr Dutton to Dr Lane,

6 December 1979, there's an agreement to proceed with some reasonably limited interim works and investigations on the basis it doesn't involve any further expenditure, it comes out of the existing allocation. We don't need to go through the details of the works but is it right to understand then that it's taken, by this time, well over six months to get from the damning inspection report, even to some limited interim works in response?

Now, you were only in post for the last period of that, so my question doesn't suggest that that's something for which you bear responsibility but do you have any observations on that timescale, on how long it took even to get to that?

A. Well, my observation about the whole thing and taking a sort of helicopter view over all the papers that you've sent me is that it took an unconscionable time to get submissions to ministers, to get responses from ministers, to move on. I mean, I think, just looking across all the ministerial submissions, it's a year from when I think I wrote my draft to the Medicines Inspectorate report, my draft to medicines inspectors to actually coming, at the end of the day, to the decision which was finally taken to rebuild BPL. So it was an extraordinarily lengthy business.

That isn't to say it wasn't complex. It was very complex and I don't want to underplay that. But everything did seem to take an unconscionable length of time and, in essence, one would like to have thought you could shave off some element of the time that it took.

Q. Then we can see a submission to ministers going in late December 1979 at DHSC0002307_049 to start with.

This just gives us the date, it is 20 December 1979, it's Mr Harley to Mr Nodder and it refers to the accompanying paper and it's a rewrite of that draft submission that we looked at yesterday that you prepared an initial draft of. Then if we go to the actual submission, DHSC0002307_050, just perhaps note whilst we're here paragraph 3, which says:

"Heavy reliance on commercial overseas supplies conflicts with a [World Health Organisation] resolution, to which the UK was party, that all countries should be self-sufficient in blood and blood products. It also increases greatly the risk of transmitting hepatitis."

So whether that's been spelt out to ministers before or not it's being spelt out to ministers here.

Then I won't go through the detail of it with you but if we go to page 5, I think, Soumik, we can

see what's being -- what ministers are being asked to decide, "Decisions required", paragraph 18:

"Ministers are asked:

"(a) to agree that [BPL] should continue to function, until it can be replaced, on the basis of a short-term upgrading, accepting that this will fall stored of the upgrading recommended by Medicines Division;

"(b) to decide, in principle, to rebuild the BPL but without any commitment as to the method or precise timing;

"(c) to agree to further exploration of the possibilities of rebuilding either within the NHS or in collaboration with industry."

So is it right to understand it's still very much a provisional situation. It gets some short-term works done, an in-principle agreement in relation to BPL, but whether it's going to be NHS, whether it's going to be a full redevelopment, whether it's going to involve commercial, how long it will take, all of that is still up in the air?

A. Yes, that's right.

Q. Then if we look at the ministerial responses, DHSC0002307_002, we have the response here from PS(H), so the Parliamentary Undersecretary of State, who was

George Young, I understand, who says:

"Perhaps a Minister should visit Elstree ... I think we should aim at cutting out imports ... I think the Private Sector could have a role to play in the new set-up."

Then we see the response of Gerald Vaughan, who was the Minister of State for Health at DHSC0002307_047. It says:

"MS(H) [so that's the Minister of State for Health] has seen your minute dated 21 December 1979. He has agreed to the recommendations (a) and (c) but not to 18(b). He has asked to be kept in close and regular touch on this."

So just to remind us, he has agreed, therefore, to some short-term upgrading, which was (a); he has agreed to exploratory discussions with industry or investigation with industry; he's not even agreed to an in-principle commitment to rebuild BPL.

A. That's right.

Q. Then if we just pick up the Scientific and Technical Committee then in January 1980, CBLA0001052, we can see the date there is 23 January and we can see that you're in attendance as joint secretary.

If we go to the second page, I think, if we just look at the top half of the page and we pick it up

about six lines in, it refers to Mr Smart thinking that:

"... the position which the Department appeared to be taking up was not an attractive one. Dr Dunnill remarked that it was not one which was in any way technically acceptable. The Committee agreed that, as presented to them, they could not endorse the views attributed to Ministers."

Then there's reference to the short-term upgrading, go a little further down. We can see Dr Lane saying he felt he was in an invidious position and then the next paragraph records:

"Mr Harley explained that Ministers had decided to defer the eventual decision on building a new laboratory within the NHS until the other possibilities had been investigated."

I'm not going to go through the rest of this or indeed the meeting of the Joint Management Committee which met the following month but it's right to say they weren't particularly happy with the Department's decision or the Minister's decision?

A. Absolutely.

Q. Now, you accompanied Dr Vaughan as Minister of State for Health on his visit to BPL on 21 March 1980 but I understand from your statement you don't have any

actual recollection of that?

A. None at all.

Q. So if we go to a document which records the visit, it's DHSC0002307_041. We can see it says "Note of a meeting at Elstree on 21 March 1980". MS(H) is, as I understand it, Dr Gerald Vaughan?

A. Yes.

Q. Then we can see who else was there including you and three other members, Dr Lane as director and then three other members of the Scientific and Technical Committee.

Then if we look at down the page, we can see -- just trying to find the reference I have. Yes, paragraph 3, "Expenditure on Up-grading", the last sentence:

"[The Minister of State] MS(H) said he was anxious that such short-term expenditure should be kept to the bare minimum."

Now, was that on financial grounds, funding restraints, as far as you know?

A. Well, I think it was a difficult thing for the Minister to have said in terms that he hadn't committed to a rebuild. I think had he committed to a rebuild and it could be started immediately, of course, it would still take a number of years but

actually then spending on a upgrade of the existing building might have been, to a certain extent, a nugatory expenditure, you might say. That is presumably his thinking.

I think the problem was that he hadn't committed to a rebuild and, therefore, there was a suggestion that we don't know if it's going to be rebuilt, we don't know how much is going to be allowed to be expended on upgrading and, actually, whatever might be thought to be appropriate for upgrading expenditure was to be kept now to a minimum.

Q. Then we can see that there then follows a detailed discussion about commercial involvement, and picking it up four lines down:

"At present, no British firm had the necessary expertise in the manufacture of blood products and only foreign firms had approached the Department, with a view to processing British plasma on the existing basis and, in addition, to processing and [reimporting] *(sic)* plasma from overseas."

Then we have Dr Lane saying that the American companies wanted to establish themselves and they liked the idea of the UK because of what was said to be a lack of controls over the collection of blood.

Then, at the bottom of the page, we can see the

Minister of State ruled out a partnership between the NHS and a foreign firm. So is it right to understand a decision was taken at this meeting by the Minister that, whilst commercial involvement would be explored, it had to be with a British and not a foreign firm?

A. Yes. I don't think he was taking that decision on the hoof. I think it was a decision he'd taken. I can't point you to the particular paper but I'm pretty sure that he had already decided, because of the representations that had been made -- I can't fix the dates in my mind now -- but, basically, there was a whole paper written for ministers about what firms might be available, what industry might be able to do and whether there were any commercial firms -- foreign commercial firms available, and I think that officials had concluded that, actually, it was going to be even more complex to involve a foreign firm than potentially involving a UK firm, though that was going to be difficult enough.

Q. Obviously, there are thousands of documents we could look and you would be here for a lot longer than three days if we did, Dr Walford, so I'm obviously taking you only to certain highlights.

I think it's right that there had been, in fact, even before Dr Waiter's memo in August 1979, there had

been some approaches from time to time and discussions with commercial companies and suspicion being expressed by some Departmental officials as to the motivation of commercial companies, essentially --

A. Yes.

Q. -- particularly the American pharmaceutical companies?

SIR BRIAN LANGSTAFF: Just before we move from this particular document, can you help me with what might have been meant by the relative lack of controls over the collection of blood in this country.

A. Well, it's quite extraordinary, actually. Compared with what was going on in the United States, for example, I just find it an extraordinary thing for anybody to have said. Somebody is alleging that the American companies thought that it would be good to set up in the UK because there were fewer controls, although the NBTS was not particularly well-managed, and to suggest that the ways in which they were actually securing their donations were less well controlled than the American products, it seems to me the American donations, given that what we know about plasmapheresis in America, I mean, that seems to me rather extraordinary.

I think, again to try to work out what might be meant, at the time the Inspectorate might not have --

the Medicines Inspectorate -- been inspecting Regional Transfusion Centres themselves. They were intending to and, certainly, I think that subsequently happened. So maybe it was said that the FDA inspected these premises in America, I don't know. But I don't think one could say for half a second that the plasma provided by the UK Blood Transfusion Service was any less safe than the plasma provided by the American voluntary donor service.

MS RICHARDS: We can see there the records, as I read out, of no British firm at present having the necessary expertise. If we go over the page, we can see paragraphs 5 and 6 record, in particular, Mr Smart -- and again I'm going to summarise rather than read it all out -- saying it's going to be difficult to devise a package that works for a British firm and we can try, and he records in paragraph 6 his initial contacts with pharmaceutical companies had not been promising. We can see he maintains his advice not to involve the private sector.

The decision that's recorded, as you say, may have been taken already but the decision that's then recorded at paragraph 7 is that:

"... [the] involvement of British firms should not be ruled out at this stage. He asked officials to

consider ... the possibility of devising a package of BTS and non-BTS items which might make the proposition commercially more attractive."

Then we can see the conclusions in paragraph 9:

"... agreed:

"i. that the voluntary blood-donor system should be maintained;

"ii. that co-ordination between BPL and the Regional Transfusion Centres should be improved;

"iii. that the existing laboratory should be kept going while its future was being considered; [and]

"iv. That BPL should be rebuilt either as an entirely NHS concern or in partnership with a British (and not a foreign) company and the possibility of making such a partnership attractive to the a British firm should be explored urgently ..."

Then, top of the next page:

"... expenditure on up-grading should be reviewed and minimised pending a decision on the laboratory's future.

So that's where we get to by the end of March of 1980.

SIR BRIAN LANGSTAFF: Could we just come back -- I'm sorry to ask you again about an expression in this letter to

see what you can help with, but if we go back to the page before, he describes BPL as a "money-spinner for [the] Government" -- further up the page.

MS RICHARDS: Paragraph 6, second paragraph.

SIR BRIAN LANGSTAFF: What did he mean by that?

A. Well, let me try. I would suppose that actually if BPL were allowed to manufacture to its utmost possibilities in a new factory, it would save vast sums of money because, if you accept Mr Smart's analysis, broadly speaking, it was absolutely going to save the Government across the board money because regions would not be spending on very expensive commercial products.

And the pay-back, it seemed, whether or not you accept the actual time-frame that Mr Smart proposed, which was a bit optimistic maybe, but nevertheless I think everybody in the Department, and the finance people as well, accepted that the pay-back would be quick and that we would then thereafter be actually making money from the -- or, rather, saving money from the expenditure that was being --

SIR BRIAN LANGSTAFF: Well, it's that difference between "making" and "saving" which is the implicit in the word "money-spinner". This is, on the face of it, not talking about saving money, which I can well

understand on the basis you have just set out, but it's making money, as if it were a commercial concern.

A. Well, yes, and there was a consideration at some stage that the BPL actually manufactured -- had spare material from its manufacture that was actually surplus to UK requirements and that they would then be throwing away, which is what they were doing. So if this material was actually something that other countries wanted or could form the basis of some of their own fractionation and they would pay for it, then potentially, since it was surplus to NHS requirements and it would otherwise be thrown away, and on no other basis, that could be used as a way of earning some money for UK Government.

SIR BRIAN LANGSTAFF: Yes, thank you.

MS RICHARDS: Then I'm not going to take time putting it on screen but there's also a note of a meeting between the minister and union representatives on the same occasion, on the same visit, at which the minister promised a final decision on the future of the laboratory would be taken as soon as possible.

I'll just give the reference for the record but I'm not going to go to it. It's CBLA0001085.

I then want to pick matters up, in May -- sorry, April of 1980, the next meeting of the Scientific and

Technical Committee.

CBLA0001093.

We can see the date of the meeting is 23 April 1980. If we go to the bottom of the second page, we see, picking up in the last paragraph, Mr Smart repeating his I think concern about how realistic it was to find a British company that could take on the task. He repeats that there's no British company with fractionating expertise and, at the top of the next page, he sets out a number of reasons why it might be difficult to find a British company willing to engage.

I'm not going to go through in detail but we can see just below that Mr Harley says that the minister will be advised of Mr Smart's views.

Then if we go to the next section, "Progress with the redevelopment of BPL", if we look at the second paragraph under that heading:

"Ministers recognised that there were difficulties at the BPL which needed to be resolved, and they and the Department would accept responsibility for these deficiencies. However, Medicines Division's requirements for improvements had to be considered in the light of the present financial situation, and the Department had accordingly agreed

a package of measures which had been approved by the STC. Ministers were now asking that these measures be re-examined to see if there might be scope for further savings."

So is it right to understand from this that that which had previously been agreed was now in doubt, simply in terms of some of the short-term interim measures?

A. Unfortunately, yes.

Q. You say in your statement, I think, that that would have been most unwelcome for Dr Lane to hear?

A. Yes.

Q. Then if we go to CBLA0003243, there's another internal meeting. This is 29 April 1980. Really just picking up on what we saw in the Scientific and Technical Committee, we can see here:

"Dr Harris [explaining] that although a programme of improvements have been agreed for BPL and budget provision made accordingly, Dr Vaughan had given specific instructions that the proposals should be completely reexamined with a view to cutting the cost very substantially."

So that's a direct ministerial decision rather than something that's been recommended by the civil servants; is that correct?

A. Yes.

Q. Then there's reference to what may have been, I think at this stage, supposition rather than a ministerial decision. The minister was clearly looking at the requirement against the background that there would be a totally new BPL, although this decision had not been formally promulgated, because I think there still was, as yet, no final decision on whether there would be a new BPL?

A. Yes.

Q. Then I wonder if you can help us with a minute that Dr Harris sent to you and Mr Wormald.

It's DHSC0002307_042, 8 May 1980, from Dr Harris to you and Mr Wormald. It refers to the meeting that we just looked at. Then he says, four lines down:

"... I am concerned that we should finalise our submission to Ministers as soon as possible."

And then this:

"If Ministers do not like the results of our reappraisal it is up to them to carry the responsibilities and the subsequent serious consequences."

Can you help us with understanding why you think Dr Harris might have written in those terms?

A. I think he was exasperated. I think we all were

exasperated.
Q. Because he thought ministers were taking the wrong course?
A. There was a clear course of action which was necessary at that time. It was barn-door obvious and yet, somehow or other, it wasn't possible to make progress, and so what Dr Harris was doing there was actually saying, "We must get on". He was encouraging that the final submissions should go to ministers and that decisions ministers should be encouraged to understand, but that at the end of the day they took responsibility if something went wrong.
Q. Is it right to understand we're still talking about what should be done in the short-term here?
A. Absolutely in terms of keeping things going for the short-term, but there had to be a commitment to rebuild because without that clearly the entire edifice was not going to be fit for purpose.
Q. Then I think, for the sake of completeness, we should look at DHSC0002313_046.
This is Dr Harris, 9 June 1980, again to you and to Mr Wormald, saying in that first paragraph: we've got the further information we needed from Dr Lane and -- and this is halfway down:
"... the critical factor is that close

examination of the proposed expenditure does not indicate any possible savings and, in fact, if we are going to ask Dr Lane to increase production there may be a slight increase in costs. These factors should not deter us from getting a submission to Ministers as soon as possible."
So is this right that the civil servants are going to be actually going back to ministers and saying, "We can't make you the savings you have asked us to make and, if anything, you're going to have to agree to spend more money just in the short-term"?
A. And, indeed, that's precisely what happened -- had to spend considerably more money than had initially been the intention -- and certainly there was no question of a reduction in the amount of money that was going to be spent in the short-term, which is of course what Dr Vaughan had hoped there would be.
Q. We can see in the same month you write memo to Dr Harris.
It's at DHSC0002307_008.
I'm not going to go through it in great detail. It's dated 12 June 1980, and again it's talking about a submission on short-term upgrading. Is it right, if we pick it up just halfway down to the page, you say:
"I think this will miss the central issue.

"In my view, the essence of the question is: is the up-graded BPL to be a fore-runner of a new laboratory, or not?"
Is this right, you were saying, "Rather than" -- and I'm paraphrasing so please say if I'm wrong -- "Rather than make an *ad hoc* decision about short-term improvements and don't take a decision about the longer term, you've got to do both and you've got to do now"?
A. Yes.
Q. "Because decision on the longer term will help you decide what you need to do in the shorter term"?
A. Exactly.
Q. Then we can see, if we just pick it up at DHSC0002315_007, we're now the second half of July, or 18 July, and we've got some discussions, it looks like on a fairly provisional basis, with some British firms have begun. So we have Beechams interested in taking discussions further, and there's going to be pre-meeting and then a meeting with Beechams to consider possible principles, so it's still quite a drawn out process that might be contemplated, and Mr Hart, who was in the Supply Division, remained sceptical, we can see from paragraph 2, but thinks it's worth trying, and there's also reference to

discussing possibilities with two other companies, Boots and Fisons.
If we then look at the ministerial submission, which is at SCGV0000127_046, we can see it's provided under -- it's a memo dated 24 July 1980 to Mr Knight.
Who was Mr Knight?
A. He was, I think it was, Dr Vaughan's private secretary, but I couldn't be absolutely certain.
Q. That sounds right. Then, again, I'm not going to go through the detail of the submission but we can pick it up, I think, just in two paragraphs, so paragraph 2 on page 2 it says:
"Officials have ... reviewed, with the Director [so with Dr Lane], the proposed short-term measures, taking account of the possibility of increased production ..."
And the recommendation is:
"... capital expenditure of £1.3 [million] over this year and next, and increased revenue expenditure of £0.1 [million] to come into effect over the same period."
If we go to page 5 -- I'm sorry, page 6, Soumik, paragraph 16 we can see the decision that the ministers are being asked to agree is whether a revised programme of improvements to BPL should be

put in hand.

So, again, important to understand we're in late July 1980 and this is now a decision about --

A. Interim.

Q. Interim measures still?

A. Yes.

Q. So over a year since the Medicines Inspection report?

A. Yes.

Q. I don't think we need to go to it but this proposal was agreed by a minister?

A. It was.

Q. Within a few days. If we then look at CBLA0001171, we're now in September of 1980. This is a further meeting of the Scientific and Technical Committee, and again you're in attendance as joint secretary, and if we go to the bottom of page 2 we can see from paragraph 8, no doubt pursuant to the ministerial approval from at the end of July, that the upgrading work has now started and is progressing.

And then the long-term redevelopment is discussed. We can see from paragraph 9:

"... officials have been instructed by Ministers to investigate the possibility of collaborating with private industry ... Initial discussions had taken place ... paper was to be submitted to Ministers

setting out advantages and disadvantages of such arrangement."

Then we can see, again, paragraph 10, the committee, or at least several members of the committee, expressing concern at the possibility of a commercial company taking over BPL.

So we are, in September, it would appear, still at the stage of initial discussions only with possible British firms?

A. Yes.

Q. Then I think it's within that context that we go back to your memo of 15 September 1980, which we looked at yesterday, when we were looking at hepatitis, and we'll just look at this before we break.

WITN0282008.

So this is your memo about the possible takeover by industry. You say:

"I think it is best if I confine my comments on the possible take-over of BPL by Beechams ..."

Which I think by now was the only possible contender?

A. That's right.

Q. "... to purely technical and medical comments, although I do have major worries about many other aspects of the proposals, as, I think, you yourself

have."

What were you referring to there in terms of your other worries?

A. Well, I think I was as concerned. I mean, everybody in the Department who was looking at this could see the enormous complexities of actually trying to involve a firm in doing this for the Blood Transfusion Service, if you like, and those were quite well set out in the submission, which went -- ultimately went to ministers about the involvement of industry. So whichever way you looked at it, it was going to be complex and negotiations were going to be difficult, and the question became: how confident would we have been that we could keep people to their agreement once setup had been handed over?

So I think everybody had a very big question mark over the whole feasibility of going with any firm, Beechams or any other firm, but I wasn't in this particular minute trying to comment on that because that was already understood and everybody was thinking about it and working out how to express those problems.

Q. Then we can see, paragraph 1, you say:

"The principal medical worry is presented by Beecham's intention to import plasma for

fractionation. Unless it were Beecham's intention to process such plasma in an entirely separate plant or with complete duplication of all facilities in a single plant, it would be impossible to prevent contamination of the UK material with imported hepatitis viruses."

Then we looked at what you set out below yesterday.

So you're raising a concern about imported plasma and risk of hepatitis?

A. Mm-hm.

Q. Then you say this:

"In my view, the Department has a moral obligation to ensure that any collaboration with industry does not increase the health hazards not only to recipients of blood products but to the community as a whole."

Can you just help us in understanding why you characterised it in those terms, what you meant by "moral obligation"?

A. Moral obligation was -- it's not something that if you -- I was trying to say don't actually proceed with a plan that potentially could damage the health not solely of the recipients of blood products but, because this was a communicable disease, also the

community as a whole. So I hope it sort of speaks for itself.

I was concerned about the health impacts of potentially contaminating the UK plasma supply that was being used to fractionate and make Factor VIII and other products.

Q. So would it be right to understand that essentially what you're saying it would be a morally wrong thing to do?

A. That's what I think I was trying to say, yes.

Q. So that's your first concern. Then your second concern, paragraph 2, was that if the Department didn't agree to imported plasma, Beechams would probably feel constrained to obtain the necessary extra volume of plasma by buying it in the UK, and you were concerned that that would lead to the establishment of plasmapheresis centres for paid donors and undermine the voluntary donor principle in the UK. That's probably fairly self-evident as to what you're saying there.

You there refer to a visit to Liberton and the possibility of Liberton expanding production, which obviously your memo a year earlier had outlined, and I'll come back to the question of what happened in relation to Liberton in due course.

Then if you go over the page, you comment on certain figures in terms of demands for plasma. I'm not going to ask you about the detail of that but I just wanted to ask you about the last four lines. You say that:

"The projected requirements of Factor VIII, which were based on advice given to the Department earlier this year, may have to be reviewed in the face of very recent evidence which indicates that UK clinicians are coming under pressure from various quarters to step up the dosage regime for the home treatment of haemophilia."

Are you able to assist us with what that refers to? What was the pressure and who were the various quarters?

A. I don't know precisely who were the various quarters but basically there was pressure to do more by way of prophylaxis. I think that's presumably what I must have meant by that. Essentially, we knew that whatever amount of Factor VIII was currently being used, and the projections were that we were going to need more, the projections which were being considered were 90 million international units. Certainly Dr Lane's view was we needed to plan for 120 million international units based on what he could see was the

likely usage.

MS RICHARDS: Sir, that's probably the right point at which to take a break.

SIR BRIAN LANGSTAFF: Yes. Well, let's take a break now until 11.45.

(11.18 pm)

(A short break)

(11.46 am)

MS RICHARDS: Dr Walford, before we then look at the submission that went to ministers on the topic of commercial involvement, there's just, chronologically, one further document from this period I want to ask you to look at. It's DHSC0002199_055.

It's a minute from Dr Oliver to you, copied to Mr Wormald, date 30 September 1980. It says:

"On the question of self sufficiency of products for the treatment of haemophilia I had an informal talk with Dr Tovey. As I understand the position it is unlikely we could ever become self sufficient for Factor VIII to treat all haemophiliacs. However self sufficiency could be achieved if there were an accepted policy by those treating haemophilia to treat most haemophiliacs with cryoprecipitate and reserve purified Factor VIII for say 20 per cent of cases needing special treatment (eg for surgery

et cetera). Other countries apparently do this successfully.

"Though less easy to give than purified Factor VIII, cryoprecipitate is seemingly clinically acceptable. If all this is true and the policy were accepted it could have a significant impact on the need for imported plasma and the BPL development and could perhaps tide us over until Factor VIII was genetically engineered."

Then if we look at -- sorry:

"Or have I got it all wrong?"

Then if we look at the handwriting towards the bottom of the page, someone has put a note:

"(And how do we persuade clinicians to use cryoprecipitate?!)"

Then someone has said:

"Let us await Dr Walford's reply."

Then, bottom of the page:

"Checked with Dr Walford's PA. 13.10.80.

"Dr Walford has not yet replied to Dr Oliver's minute."

Dr Walford, we haven't, as yet at least, traced a reply. That doesn't mean there wasn't one because there are other documents we have been unable to trace from this time. Can you recall this exchange and your

reply?

A. No, I don't recall it at all but, probably, I spoke to Dr Oliver. He was my boss, we got on extremely well. I was often talking to him. I may well have replied to him.

This is interesting because Dr Tovey is there talking to Dr Oliver. Once again, he isn't talking to me. It's the way he operated within a hierarchy. But the interesting thing about it, I suppose, is actually Dr Tovey was part of the Gunson Working Party on plasma supplies, which were reported in 1981 and absolutely was talking about 80 per cent of intermediate Factor VIII being the product that was wanted. I think he had also advised on the earlier Trends Working Party. So this was, as it were, a new concept coming through from him. It's perfectly reasonable for him to have thought that. But, essentially, he doesn't seem to have said the same thing in any of the more formal working parties that -- he could have proposed that that was the thing to do.

Q. It might not have been a complete magic solution to self-sufficiency or BPL but would you agree that it was an idea worth considering further and perhaps worth talking to, say, haemophilia clinicians about?

A. I think we had to decide, or it had to be decided, if you made a lot more cryoprecipitate at Regional Transfusion Centres then, of course, there was very much less plasma. The problem was really there was not enough plasma to do whatever it was you wanted to do. So if you wanted to make more Factor VIII, there wasn't at the time enough plasma. If you made more cryoprecipitate, of course, that deprived BPL of the plasma.

There's another issue about making -- trying to get as close to self-sufficiency or at least making much more cryo than making concentrate, and this is a matter which is very clearly spelt out by Dr Lane. The cryoprecipitate supernatant needed -- was the material that was needed to then go on to fractionation for all the other products that BPL had to produce. So if, in fact, you ended up making an awful lot of cryoprecipitate in Regional Transfusion Centres, you had to devise a really quite complicated system of taking off the supernatant -- that is the fluid which is left after you have centrifuged the plasma, which is then taken, needs to go to BPL in order to make albumin, in order to make Factor IX, which is needed every bit as much for a severe Christmas disease or haemophilia B patient,

as is needed for Factor VIII, as is needed for severe haemophilia A.

So there were significant downsides to retaining plasma at the Regional Transfusion Centres in any large amounts because this starting material for all these other products, albumin, immunoglobulin, Factor IX had somehow to find its way to BPL, and the Regional Transfusion Centres were simply not set up to do some kind of sterile collection of this material in bulk to go to BPL.

I think making more cryoprecipitate for the treatment of mild haemophilia is a perfectly valid concept. So maybe increase the amount of cryoprecipitate at this point that you're thinking that you should do but, bearing in mind that for all the cryoprecipitate that you make and retain at the blood transfusion centres, you are reducing the amount of plasma that can go to BPL. And, at the time, the decision was taken by the various working parties that were involved in what was the product that was needed, and it was intermediate Factor VIII which had to be done at BPL.

Q. You've identified a potential disadvantage or disadvantages to increase the production of cryoprecipitate at Regional Transfusion Centres but

that would have to be balanced against a potential advantage, which is the advantage of viral safety.

A. Yes.

Q. So, I mean, would you agree that, although there might have been, further down the line, issues that would need to be explored if it was to be taken any further, it's somewhat surprising that it doesn't appear to have gone any further. There's no considered discussion of this particular proposal that seems to take place in any of the various working parties, committees, groups, and so on in the autumn of 1980, or later.

A. Well, it seems to me that, actually, Dr Tovey was in a prime position, he was in pole position to take it forward if he had chosen to. I haven't found anything in the papers in any of the Regional Transfusion Service or Haemophilia Centre Directors papers that Dr Tovey ever pronounced in this way. He could have done. It was certainly open to him to have actually suggested that, if he'd thought it was the appropriate thing to do.

Q. What would have been the ideal forum for that to be explored further? Regional Transfusion Directors together with the Haemophilia Centre Directors?

A. I think that would be a very good forum. Could we

just check the date of this one.
Q. It's 30 September 1980, if we just look -- that's it.
A. So it was Dr Gunson's worked party, I think, was set up in February 1981 to look at plasma supplies and Dr Tovey was one of the advisers to that working party. So that would have been exactly a prime forum, if you like, for him to make this suggestion.
I hadn't seen from the papers that he did.
Q. If we then, again, pick up the thread then of the issue about BPL's redevelopment and go to WITN -- no, sorry, that's the wrong reference. If we go to DHSC0002307_069, this is a minute from Mr Wormald to Mr Nodder and to Dr Harris and to Dr Knight, so it's going to the ministerial private offices and to the Deputy Chief Medical Officer, is that right?
A. That's right.
Q. It's dated 14 November 1980. We can see he refers in paragraph 1 to attaching a submission, long and complex, but the issue is a complex one, and then paragraph 2, he says:
"I should point out that the submission directs itself to the issue or 'whether or not Beecham'. It does not deal fully with other issues, which will need further consideration if the answer to Beecham is negative."

Then he sets out some weaknesses of the present arrangements, I'm not going to go through the detail of that. Under the heading "Plasma supply" in paragraph 6, he essentially, I think, says words to similar effect to what we saw in your memo of 15 September. Picking it up five lines down:
"All our advisers -- not only those from the NBTS itself, but those from industry and academia -- believe that commercialisation would make it difficult to increase our plasma supply from voluntary sources, or even to maintain it. I agree that this is a major risk."
He talks about the possibility of losing a substantial number of donors.
Then, if we go over the page, we can see there is a heading "Summary". He sets out the major advantages of an arrangement with Beecham: provision of commercial management expertise; transfer of technological risk; short-term expediency of their putting up the capital for redevelopment; and speed.
Then the main disadvantages.
"... the risk to the voluntary donor programme and implications if our plasma supply contracts or cannot be expanded
"the associated issue of commercialisation of

blood
"health and ethical problems relating to the import and export of plasma and products ..."
Would it be right to understand the health problems is referring to the increased risk of hepatitis?
A. Yes.
Q. Then:
"the possibility that the company could exploit their monopoly position to impose higher costs on the NHS."
There's reference then to strong opposition, which the proposal would undoubtedly arouse, and he refers to being:
"... particularly impressed by the fact that none even of our outside advisers -- including Dr Dunnill who has acted as consultant for many firms including Beecham -- favour the proposal on balance."
We know, of course, Mr Smart was strongly opposed to it.
Then, if we go further down the page, the heading "Recommendation", he says:
"I have involved myself closely in the discussions leading up to this submission both with Beecham and with our advisers -- and have given it

much thought over a prolonged period. The advantages and disadvantages are substantial, and I foresee continuing problems of both investment and management if we remain BPL within the NHS. The Beecham proposals are, at this stage, helpful and reasonable. From the point of view of fractionation pure and simple I would advocate Beecham. Nevertheless my conclusion is that wider disadvantages outweigh the advantages -- and in particular that the likely impact on the donor programme and possibly on the whole voluntary donor principle is too substantial to incur."
Then, paragraph 12, he says:
"I think it important we should reach a decision in principle now: that is we should either reject the commercial option or decide that we intend to implement it subject to satisfactory negotiations. A decision merely to continue negotiations, without commitment in principle, would prolong uncertainty, encourage continued argument and further damage morale at BPL. And it would not be fair to Beecham."
Then a number of decisions set out at the top of the next page: do we enter into detailed negotiations with Beecham and, if so, on what basis; do we abandon discussion and instead formulate plans to redevelop

BPL with public funds; and then (d) should we explore other possibilities, eg the Red Cross and NEB?

That's the National Enterprise Board, is it?

A. Yes.

Q. "... even though there is no present indication that they will be able to help us."

So then we can see reference in paragraph 14 to the forthcoming Granada programme, that's a Granada TV programme, I will come back to that.

So that's the memo which sets out Mr Wormald's views in summary form. We can take, I think, the submission, therefore, shortly but I will put it up on screen. It's DHSC0002307_070. We can pick it up in paragraph 2. It refers to the Minister of State having authorised the short-term upgrading of BPL and officials being asked to explore the possibility of a British pharmaceutical company, rebuilding of facilities, manufacturing of blood products. This paper reports on our discussions with industry and seeks decisions on the proposals made by Beecham Pharmaceuticals Limited.

Then, if we go over the page, paragraph 8 -- sorry, if we pick up the last sentence of paragraph 7:

"Beecham would have the option to terminate the contract and either get out of the business altogether

or set up in business as a commercial supplier of blood products.

"There is little doubt that the latter is their long term aim. It seemed clear in our discussions with them that their objective is similar to that of foreign companies which have approached the Department, namely to set up a factory in the South of England to import blood plasma and export blood products."

There's then a discussion about various considerations. If we go to the bottom of the next page, we see the risk of hepatitis there being spelt out in paragraph 13. Then if we go over to page 7, please, we can see it's set out in paragraph 20(a):

"... we do not know Beecham's objectives ... we believe their chief object is to get into the international blood product market."

Then if we look towards the bottom of the page it's said against Beecham:

"It is likely that they want the NHS primarily to [lean] on."

SIR BRIAN LANGSTAFF: "Learn on".

MS RICHARDS: "Learn on", sorry:

"They may not see it as the top priority [Freudian slip there] for their attention once they

develop a wider business."

Then:

"They have a reputation for being very 'hard-nosed'.

"Medicines Division have a low opinion of them, as meeting only minimum manufacturing standards."

Then over the page, it says:

"None of this amounts ... to good reasons for not using them -- subject to negotiating satisfactory terms ... they probably represent as good a commercial bet as we are likely to get."

Then the options as set out in the memo.

So this is November 1980. So, essentially, it's taken to the tail end of 1980 to get to the point where ministers are being asked just to make the in-principle decision: do we go further with Beecham or not? Do you have any observations about that timescale, Dr Walford?

A. My observation is the same as the observations about the entire timescale. It was very protracted, unnecessarily so in my view.

Q. Then we can see if we look at HCDO0000394_052, a press release which records the Minister's decision. There is also a written Parliamentary question and answer but this is 26 November 1980, "No commercial

management of Blood Products Laboratory, Modernisation programme already underway says Dr Vaughan". Then if we look towards the bottom of the page, we can see the penultimate paragraph:

"There have been rumours we intend to hand the laboratory over to a commercial company to run. This is not so. We thought it only right to examine a number of different ways of developing the laboratory, including possibly bringing in commercial management. But we have decided against this."

So two points, Dr Walford: first of all, this is a public communication of the Minister's decision, essentially in answer to Mr Wormald's question, don't take discussions right further with Beecham; is that right?

A. Yes.

Q. But, secondly, is it right to understand or is it right to say that it was not the case that the Department was exploring handing over the laboratory to a commercial company to run?

A. As one reads this, which was obviously written by the press office but with ministerial sanction, that's what they are saying. I think we've seen otherwise looking at the papers.

Q. So it's not an entirely accurate characterisation of

what's been looked at?
A. It's decidedly not accurate.
Q. I don't know whether you would know the answer to this but it's a question I've been asked by some to raise with you. Do you know whether, and we've seen reference to it, the forthcoming Granada TV World in Action programme was what caused the Minister to take a different view?
A. The issue for me is that I don't know what that programme was. I don't even know if I saw it or whether I may have seen it subsequently. I simply don't know what that programme was. But it might have been something which accelerated a ministerial decision, if you like, but I don't know what the programme actually was about.
Q. Don't worry. We'll be looking at that programme again in later hearings.

Would you -- just standing back now, as it were, with the helicopter overview that you referred to earlier, Dr Walford, was it a mistake for the Department to embark upon what turned out to be a fairly prolonged investigation of this commercial option, in circumstances where Mr Smart, Dr Dunnill, Dr Lane, others were firmly of the view that it's unrealistic and that the right way to proceed was

through redevelopment as an NHS facility?
A. I think the only reason, really, in my view, of involving any form of commercial enterprise was to see if they would run it under contract or provide the commercial management nous, if you like, to run it and then potentially help to put in place plans for a whole new build. But essentially to keep it within the NHS but with a much bigger infusion of commercial expertise, if you will, because that's what it absolutely desperately needed.

So for my -- in my view, that's really the only commercial side of things that one really needed to consider. I think that there was -- your question was, was it the wrong thing to have -- could you just rephrase the question?
Q. Was it a mistake, given everything that was being said by Smart, Lane, Dunnill, et cetera, to embark upon this particular prolonged investigation?
A. Personally I think it was a mistake.
Q. It's right to note, is it not, and relevant to note in that regard, Mr Smart had made it clear from the outset that there were no British companies with fractionation experience?
A. Yes. Well, Beechams wasn't a fractionator, so it was going to bring in commercial pharmaceutical expertise

but I think it was going to be relying on BPL to provide the fractionation expertise.
Q. And on any view would you agree, in light of your earlier answers, that it took too long to get to this point?
A. It took too long.
Q. If we then look at [WITN4461046], this is really just to complete the picture for 1980.

Yes, [WITN4461046] is the reference I've got but that might be a different one. No? Let me just see whether there's another reference. No, I'm just going to turn to ... *(Pause)*

What I might do -- it's very short -- is read it out, because it's really just -- it's one paragraph. I'll tell you what it is and then if we get it on screen under a different reference we'll do so.

So it's a memo -- a minute from Mr Knight, so the minister's private office, to Mr Harley, dated 8 January 1981, and it says:

"This minute confirms that when you and Messrs Wormald, Hart and Bolitho met MSH [so the Minister] and PSH [Parliamentary Undersecretary] on 17 September, ministers asked that planning and design should begin at the redevelopment scheme on the Blood Products Laboratory."

A. Yes.
Q. So the purpose in reading that out, and I know it's one of the documents you refer to in your statement, is just to show that -- the point in time at which we reach, the end of 1980, is -- is a decision now well over 18 months after the Medicines Inspection report to begin the process of planning?
A. Yes.
Q. And that is, I think to use a word that you've used on more than one occasion in your evidence already, an unconscionable period of time?
A. Yes.
Q. Can I then pick matters up in April of 1981.

DHSC0002315_049.

So this is again Mr Wormald to Mr Knight, 10 April 1981, and paragraph 2:

"It is widely known, following the very unfavourable Medicines Division report, that the Government intend to redevelop BPL. The Minister made this clear in his 'World in Action' interview earlier in the year. We have never, however, committed ourselves to a particular timetable, nor decided how much of the laboratory will be rebuilt."

Then he goes on to set out various considerations that need to be considered. So is it

right to understand, Dr Walford, that now, two years on from the Medicines Inspection report, there's still no timetable and no decision, is it going to be a completely new building, is it going to be using part of the existing building and developing that?

A. Yes.

Q. Then if we go to DHSC0002309_004.

This is now 18 June 1981, with dates at the bottom of the page. It's from Mr Wormald to Mr Knight again, and I just want to ask if you can assist us with understanding the first paragraph:

"Secretary of State has now agreed that RHA capital allocations will, if necessary, be 'top-sliced' to pay for redevelopment of BPL. This enables us to proceed with detailed planning."

Then it talks about some of the aspects of planning that will need to be considered. What's the reference to top-slicing the RHA allocations?

A. Well, the RHA allocations, that was sort of programmatic allocations. So each Regional Health Authority had its allocation. It was really up to Government, it's up to the ministers, to decide whether or not they decided to cut the allocations across the board to regions or in some differential fashion, depending on their view, in order to pay for

the redevelopment.

So essentially it's wrong to say "robbing Peter to pay Paul" but essentially not putting so much money out into the NHS but actually keeping some back to redevelop BPL.

Q. So I would be right to understand this as having this consequence, that ministers were not at this point envisaging finding more money or new money --

A. No.

Q. -- they were going to take the existing allocations to Regional Health Authorities and essentially keep back some of that?

A. Yes.

Q. Do you know why, given -- if that was an obvious solution, it wasn't considered at any earlier stage? I know that wasn't part of your main remit.

A. I think it was a very unpopular thing for ministers to do. They never really wanted to do that because obviously what the regions would then say is: well, we've planned, you aren't giving us enough money, you are really going to have to increase the amount of money. But I think it fair, in all fairness, to say this was probably the hardest time financially that you can conceivably imagine for the NHS. It was in the sort of teeth of having been a recession very --

you know, very recent recession. The amount of money that was available in terms of percentage of GDP, as I've spelt out in my statement, was tiny and essentially, really and truly, there was not enough money to go around, and the Treasury was very strict in controlling the purse strings.

So ministers might have tried, for all I know, to approach their Treasury colleagues, but essentially it was -- looks as if it didn't work anyway, even if they did try, and that's what they found the solution was: to actually reduce the money going to the NHS.

Q. Now, if we look at WITN4461048, what we can see here is a submission to ministers asking for them to agree to the setting up of what became, I think, the policy steering group for the redevelopment of BPL.

A. Mmm.

Q. Why was ministerial approval required for what would -- not even now the establishment of a new group but just the formation of a subcommittee?

A. I don't really know actually, because that shouldn't, I don't think, normally have required ministerial approval. No, I really don't know.

Q. If we look then at page 11, I think it is, of this document, we can see a letter -- this is from the previous year, May of 1980, from Mr Dunnill, but

I just want to draw attention to one bit of it that you refer to in your statement.

If we go further down the page, it's paragraph 3:

"The Medicines Division's recommendations follow a series of recommended short-term expedients designed to boost production by tinkering with the present inadequate plant. This has created a trail of overlapping and confused initiatives which are made more difficult to implement by the inevitably slow process of funding in the ministry."

Do you disagree with the observation Dr Dunnill was making there?

A. Well, as I said -- I spelt out in my statement, I was in agreement fully with what Dr Dunnill was saying. It had been a totally chaotic, protracted and difficult process, and needlessly so in my view.

Q. In your statement, you -- it's just one sentence, so I'll just read it out. You refer to that. You say:

"... it seems to me to be a good summation of the situation ... I do remember, too, my own frustration about innumerable and repetitive meetings which generally ended without moving matters forward to any appreciable extent."

A. Yes.

Q. It's right to say I'm really taking you to the documents to -- where -- the points in time where things do move forward.
A. Mm.
Q. You've reviewed a much larger number of documents, many of which are referred to in your statement, which were we're not looking at --
A. Yes.
Q. -- which show meeting after meeting after meeting?
A. Exactly so.
Q. Now, the policy steering group I don't need to go to it, just to give us a date, though, met for the first time on 24 August 1981, and you were part of that group?
A. Yes.
Q. But if we then pick the picture up in a document at DHSC0020710_056, we can see a minute from Dr Harris to Mr Harley. I just wanted to ask you about the last paragraph. He refers to the policy steering group commissioning a feasibility study, and then he says this:

"As I have already mentioned in an earlier note after my discussion with Lord Elton, the Group must give consideration to the use of an existing factory which could be adapted at relatively low cost to the

requirements of a new BPL rather than devote a lot of time to designing a new building from the outset."

Now, this is 13 October 1981, so we're now a good ten months or so further on from -- 11 months further on from the minister's decision not to go with the Beecham proposal.
A. Yes.
Q. At this point in time it would appear there's still no decision, even in principle, to rebuilding a new facility, and your group -- or, sorry, the policy steering group, of which you are a member, is being asked to explore the possibility of adapting the existing buildings; is that right?
A. Yes. I had to look up who Lord Elton was, I'm afraid, when I was coming to look at the various papers. I think he came before Lord Glenarthur as the parliamentary secretary in the Lords, who presumably therefore had the blood transfusion brief. I'm not entirely sure. But he was, I think, only in the Department for about six months, and yet somehow, after everything that had happened, there was a need then to consider and spend time considering could we find some other building instead of rebuilding, and in point of fact officials did spend time looking at that and there were no such buildings.

But, well, as I had a different boss in a different life who used to say "Order, counterorder, disorder", and that's effectively what we were getting.
Q. Because by this time what we've got is a -- leaving aside the short-term measures, the interim measures that are being funded, we've got decisions about what not to do but we still haven't got a decision as to what is going to be done longer term?
A. Yes.
Q. If we then, in that same month, October 1981, then go to DHSC0002211_063.

This is a meeting of the Joint Management Committee for the Central Blood Laboratories. We've been looking mostly at the Scientific and Technical Committee meetings, but this is the JMC.
23 October 1981.

If we go to the second page I think we get a sense of the committee's frustrations. So if we look at paragraph 9 under the heading "Long-Term Management Arrangements":

"Mr Godfrey reported that Ministers were still considering the management structure for the Central Blood Laboratories. The importance of an early decision had been emphasised by officials. The

Committee stressed the difficulties that would occur if the matter were not decided before the completion of the proposed feasibility study on redevelopment."

Management in the long-term is a slightly different issue from the redevelopment of the facility, but we can see there that what is being suggested by the committee is that you can't do one without the other; is that right?
A. It certainly needed some way of managing this very major project.
Q. This isn't, I think, just management of the project, is it, it's management of the Central Blood Laboratories themselves?
A. Yes, but actually also the co-ordination, if you like, with the NBTS.
Q. Then if we go to the next page, we can see, at the top, the heading "Policy steering group for the redevelopment of BPL", a report by Mr Smart:

"Mr Smart reported that the group had agreed to meet as and when necessary ... had done so three times to date. Its work was hampered to an extent by the lack of ministerial decision on long-term management arrangements."

So it would appear that is holding up the planning that the policy steering group can do; is

that right?
A. Yes.
Q. There was a further ministerial visit to BPL in January of 1982. I can't remember without checking which minister it was, but do you recall whether you went on that?
A. I don't remember. I might have done, but I don't -- I was in and out of BPL, so the trouble is I just don't remember particular visits.
Q. Then if we look at DHSC0002215_087, this is a meeting of the policy steering group 1 March 1982.

Now, you weren't, in fact, in attendance at this meeting, but it's just to note, if we go to page 2, paragraph 6, there's reference there to a report from Liberton, and I'm gong to come on to the Liberton issue and the shift working trial. But we can see the last two sentences of that paragraph:

"Mr Harley was asked to seek JMC [that's the] Joint Management Committee] approval for planning to proceed on the assumption that BPL would process all plasma for England and Wales. The estimated production capacity of the new Laboratory could be revised if necessary at a later date if there were a substantial change in Liberton's position."

So the point we've reached by March of 1982

is: we're going to plan on an assumption that we can't use the Scottish fractionation services?
A. Yes.
Q. You were then on maternity leave April to October 1982, I think --
A. Yes.
Q. -- so I'm not going to ask you about what or was not happening in that period of time, but I am going to ask you to look at a submission to ministers which went in September of 1982 which was copied to you, possibly in anticipation of your return from maternity leave. So it's DHSC0002309_017.

If we look at the bottom of the page, we can see it's from Mr Godfrey. It's 22 September 1982. And we can see it's copied to a number of people, including you. Then if we go to the top of the page, paragraph 1, it says:

"In April 1981 Ministers agreed that a Policy Steering Group should begin planning the redevelopment of the Blood Products Laboratory (BPL) ... and that health authorities' allocation should be reduced ..."

So that's the top slicing:

"Redevelopment has been approved in principle by the Treasury who have also agreed that the project should be 'fast-tracked'."

SIR BRIAN LANGSTAFF: Ahem.
MS RICHARDS: Yes, I was going to make no comment on that.

"2. The Steering Group have now reached the stage at which Ministerial decisions are required on ... size ... scale of production; and ... cost."

And then there's reference to an attached paper. As I say, because you weren't involved in putting that together, I'm not going to ask you about that, but if we then look at paragraph 5 it says:

"The paper concludes ... by seeking Ministers' approval to submit a Stage Two submission to the Treasury."

Then there's reference to the matter being "put forward for information to Scottish Ministers".

So it's really just to complete the timetable, as it were, on this issue. September 1982, bearing in mind we really started, for present purposes, with the Medicines Inspection report in April of 1979.
A. Mm-hm.
Q. We have taken until now to get the stage where decisions, actual concrete decisions, on size, scale and costs are even being sought from ministers.
A. Yes. I think, though, it's probably fair to say that there had been some involvement of a commercial company, Norcain Hall*(sic)* or -- I forget its name

precisely -- to do a feasibility study to look at more detail. I don't think it was total stasis. I think that there was work going on which the Joint Management Committee had actually commissioned, or the steering group had commissioned, to get some design input or --
Q. Yes, yes -- no, you are absolutely right. There were things happening to get to that stage but, again, it's the overall period of time, again, would you accept, using your own word earlier, unconscionable?
A. Yes.
Q. Then we can see DHSC0002309_019. This is meeting on 7 October 1982. Again, you're not present although you are copied into it, but we can see reference to Mr Finsberg, so that's the minister, agreeing that the investment appraisal should go forward to the Treasury. So that's, as it were, the next stage.

We then, in terms of your own involvement, have -- and I'm not going put it on screen because there's nothing in the detailed content of it I want to ask you about, but there's a meeting of the Joint Management Committee attended by you on 5 October 1982, so you're now back from maternity leave?
A. Yes.

Q. Your recollection set out in your statement is that you then didn't have any significant ongoing involvement in relation to the redevelopment of BPL; is that right?

A. That's right, because the Central Blood Laboratories Authority then took over from the Joint Management Committee and, as you will have seen from the various papers, basically I was not entitled to attend those meetings, although it was said that I might be given permission if necessary to attend. But I was not involved at all in their meetings.

Q. So that leads me on to the next, as it were, subtopic, which was about the establishment of the Central Blood Laboratories Authority. We know, and your statement sets it out for us, that that was established on 1 December 1982 as a Special Health Authority, so as a specific legal entity.

A. Yes.

Q. With responsibility for the management of BPL, the PFL in Oxford and the Blood Reference Group --

A. Blood Group Reference Laboratory, yes.

Q. I think, again, your statement says you weren't closely involved with its establishment but there are just two or three documents I would like to look at with you to see whether you can cast any light on

them.

The first is DHSC0002307_034.

This is a minute from Mr Wormald to Mr Nodder, dated 6 April 1981, and it deals in part with BPL but I'm not going to ask you about that.

If we go to the second page, we can see there's a heading "Future management of Central Blood Laboratories":

"7. The present arrangements were set up for the short term and pose many problems. All concerned are agreed that they cannot continue.

"8. For simplicity this minute assumes that BPL/PFL and BCRL will continue under the same management ...

"9. We have considered many possibilities, but really there are only three runners - management by a Health Authority; management by an enlarged and reconstituted [Public Health Laboratory Service]; and a Special Health Authority."

It referred to a discussion at a meeting.

"Our conclusion was that a Special Health Authority was the clear first choice."

Then, if we look at -- it's paragraph 10:

"The first point to make is that the Laboratories, or at any rate the BPL, could not be run

properly by the ordinary [Regional Health Authority] and RTO ..."

What's that acronym for? "RTO structure"?

A. I'm trying to find the bit --

Q. I'm so sorry, it's the second line of paragraph 10. My apologies.

A. Oh, right. Regional treasurers, I'd imagine. I'm not sure. Not quite sure.

Q. "BPL is a large, complex and highly specialised factory operation which needs much special expertise, in our view at 'Board' as well as management level."

Then that's further discussed. Then paragraph 12 it says:

"We envisage that the members, or at any rate the 'Chairman' would exercise considerable oversight over the management ..."

And I understand that to be referring to the management of BPL:

"... which does not and cannot possess all the necessary skills and is, to boot, a little idiosyncratic."

Do you know who or what there was being described as idiosyncratic?

A. I'm just trying to follow. I've got it now on paragraph 12 but this was -- was this a meeting that

I was at?

Q. You're copied into the minutes. So this is April 1981. I don't know whether you had been at any meetings relating to it but it's a minute that's cc'd to you.

A. No, I've no idea which bit of the existing management was being deemed idiosyncratic.

Q. Don't worry then. But we can see, in any event, April 1981, the clear steer is in support of a special health authority. And just so that we can understand some of the difficulties of the temporary arrangements that had been put in place following Lister disappearing out of the picture, if we look at WITN4461063.

This is a paper -- I don't think -- in fact, it's a ministerial submission. I don't have a precise date for it but I'm sure we can check that. Bottom of the page.

So it sets out the history in terms of how it's being managed over the recent years, and then paragraph 5, bottom of the page:

"The chief difficulties over these temporary arrangements are that management is too diffuse, with too many people exercising a fragmented responsibility; management is insufficiently and not

continuously co-ordinated; at RHA level [so that's the North West Thames Regional Health Authority] particularly the task of management is largely an addition to the normal work of those who are carrying it out ..."

Next page:

"... few of those responsible have any experience in the management of facilities such as the BPL, which is mainly a large scale manufacturing plant; and responsibilities are vested in the Department for which it is not equipped, and which should, in principle, be elsewhere. The Directors of the laboratories are not subject to the expert direction and monitoring which should apply. It is often difficult to reach fairly elementary policy decisions quickly and to ensure that they are implemented ..."

Pausing there, it might be said an element of the pot calling the kettle black, but in any event:

"... partly but not only because attention to the management of the laboratories has to be dropped from time to time in order to deal with other pressing matters. These problems will be even more acute now that we have to plan new facility at Elstree."

So is that a fair summary of what the concerns

were about these -- what were only ever intended to be a temporary management system?

A. Yes. I mean, either the Department of Health -- DHSS's was or the North West Thames Regional Health Authority was suitable as the definitive management structure, and the sooner it could be replaced the better, really.

Q. That submission, I said it wasn't dated but it's probably the submission which accompanies the memo we looked at from April 1981.

In any event, if we go to DHSC0002309_095. DHSC000 -- that's it. Thank you.

So this is dated 29 May 1981 from Mr Nodder. We can see, bottom, it's copied to you, and then it sets out in the first paragraph:

"... [reluctance] to support a proposal for creation of a Special Health Authority, not simply because this is a new 'quango' ... but because it will [inevitably] mean increased overheads, and ... hassle over composition ... uncertainty about getting the right type of person ... But careful consideration leads me to conclusion that we had better advise Ministers to go down this road than any other."

So the bottom of that page, paragraph 4 says:

"Subject to these observations, I support the

submission."

So I don't think we got to hand the final ministerial decision but we can see, in any event, the private office in May 1981 supporting it?

A. Yes.

Q. Now, it's not until 1 December 1982 that the special health authority, the Central Blood Laboratories Authority, was established to take over management?

A. Yes.

Q. Do you have any idea as to why it took so long?

A. No.

Q. Were you directly involved in the process?

A. No.

Q. Just, again, really looking at it from the perspective of -- with a degree of overview, do you think that period of what was *ad hoc* management, effectively, from 1978 through to December 1982, had any impact or effect on either the way in which BPL operated or the process of planning for the future of BPL?

A. It was clearly not independent of Government and therefore had to have very much due regard to what was happening within the Department. So I suspect, had there been -- I don't know, of course, but had there been a more independent management structure, which had then the ability to make its representations very

firmly to Government, to the Department's ministers, that might have moved things on faster. But I don't think, as constituted, the Joint Management Committee was really in any position to make very strong representations to ministers that they were going to need to take very, very careful consideration of.

Q. If we can then come on to the issue that I have referred to a couple of times already and we've seen referred to in the documents, that the use of Scotland, the Liberton plant, and whether plasma for England and Wales could be fractionated in Scotland.

If we could look, first of all, at DHSC0003715. It's a very faint document. Could we zoom in?

It's just about legible. It's from you and it's November of 1979, and it's to Mr Harley:

"Note of a meeting held to discuss English plasma fractionated by PFC, Edinburgh."

Now, this is a specific issue about what to do with a volume of product. So it says:

"I met I with Dr Lane ... on 14 November 1979 to discuss what was to be done with the 27,000 bottles of PPF fractionated by PFC from English plasma, which were currently being stored at PFC."

Then to summarise, I think, the next long paragraph, Dr Lane said this product was below BPL

standards and, essentially, contained impurities that could be a hazard to patients, so he didn't want to use it; is that right?

A. Yes, that's right.

Q. If we look at the last sentence of that paragraph, he talks about:

"... his position at present in relation to the Medicines Inspectorate's report is so vulnerable that he cannot afford to issue to clinicians a product about which he has grounds for concern in relation to patient safety."

Just in terms of what the product was that this is discussing, it's described as PPF. What was that?

A. Presumably being plasma protein fraction. But BPL made plasma protein fraction. Liberton made something which was called SPPS, I think, stable plasma protein solution. These products were slightly different and the question was I think, in this case, Dr Lane concerned that the constitution of the Scottish fractionated product was not one that he was comfortable with.

My recollection is, I think, later on in this document, that the Scottish National Blood Transfusion Service and Dr Cash, who was its medical director, was perfectly happy with the product, and was perfectly

happy to use it in the Scotland. So we had a difference of view. On the one hand Dr Lane feeling vulnerable because the Medicines Inspectorate and so on, feeling that potentially this product had within it an allergen or something which actually might cause adverse reactions in patients. He didn't want to take responsibility for this. It wasn't, as it were, his product because it had been manufactured in Scotland. The Scots saying: well, there's nothing wrong with this product actually. We're happy with it, we'll use it.

This email -- it's not an email, of course! It's a minute that I wrote, was trying to say: look, the Scots are happy, the English not happy, why don't we just let the Scots have this product? Okay, we're foregoing a certain amount of product for our own use but essentially let them have it if they're prepared to use it. Because basically we didn't want it to go to waste.

Q. Is it right to understand we're not talking about a Factor VIII concentrate?

A. No, no, this is -- yes, it's a plasma protein-type product. It's a sort of precursor of albumin.

Q. If we just look further down the page, under the heading "Opinion", it says:

"This has been a rather unhappy experiment in which there have clearly been technical problems experienced in Scotland. The 20,000 litres of plasma were sent to Scotland in the first instance, not because of they were surplus to BPL's fractionating capacity but because BPL was having problems with its cold storage."

In the last few lines of that paragraph you say:

"Various technical lessons have been learnt from this venture but it remains to be determined whether PFC could, by their different method of fractionation, produce a product comparable to that produced by BPL."

Then you say this, so this is the broader significance:

"This has fundamental implications for any future coordinated UK fractionation effort."

A. Yes.

Q. Then as you say, I think if we look at the last few lines, the suggestion is to allow the Scots to use the product in Scotland, which they are apparently willing to do.

One of the questions I've been asked to raise with you, and it's perhaps a very understandable one, given what is set out there, is why would it be regarded as acceptable for a product described as

potentially hazardous for use in England and Wales to be administered or used for patients in Scotland?

A. I really don't know. I don't think there was -- I don't know what Dr Lane was really concerned about. It was clearly not a product he felt comfortable with. He was the responsible officer, if I can put it that way. Essentially, if something was wrong with the product, if anybody had an adverse reaction it was then down to him, at least initially, even if in some way he could say, well, it wasn't me, it was Scotland. But he was uneasy about it. Clearly, the Scots were not uneasy about it and I thought that the best way to resolve this was to actually let the Scots use a product that they were comfortable with, and that indeed is what happened.

I can't speak for Dr Lane and it's any amount of pity, as I have been thinking all the way along this Inquiry, that Dr Lane is not able to represent himself here.

Q. If we then move to the question -- the bigger question that had been floated in Dr Waiter's memo of August 1979 and in your own scheme in September 1979 of using Liberton to fractionate plasma for the purpose of producing Factor VIII concentrate.

A. Yes.

Q. If we go to DHSC0000064, and we go to the second page, we can see these are the minutes of a meeting on 1 December with the Scottish Home and Health Department, the Department of Health and Social Services, Northern Ireland, and the Welsh Office to discuss UK self-sufficiency in blood and blood products, and then there are a number of attendees from the Department, including you and Mr Harley, we've got representatives from Scottish Home and Health Department, we've got Dr Cash and representatives from Northern Ireland and from Wales.

If we go to the bottom of the page, and we pick it up -- well, paragraph 3 records Dr Cash talking about the possibility of a plasmapheresis programme and, again, we may come back to the question of plasmapheresis.

Then paragraph 4 talks about Dr Cash and Mr MacPherson saying PFC could fractionate an extra 500 litres of fresh frozen plasma to produce Factor VIII and albumin, ancillary staff needed to take on this extra work were available.

Then 5:

"In the longer term it was considered that PFC could cope with up to 1,500 litres per week, and perhaps more provided funds were made available and

provided agreement could be reached on shift working. SHHD intended to give the go ahead early in the new year to an experimental 3-4 week shift run to assess how the PFC would cope with the system. DHSS agreed that such an experiment would prove most useful."

A. Yes.

Q. So first question, Dr Walford, is: are you able to assist us in understanding why, given the idea had certainly been mooted at least by August and September 1979. We're now in December 1980, when it really only appeared to be concrete discussions to take it further forward?

A. I can't say precisely why but I think that it's fair to say -- and again just trying to fix the dates here, but Dr Dunnill of the Scientific and Technical Committee was very keen that Scotland's facilities should be exploited to the maximum of their ability. I think it's also true to say, actually, that there was a period in which we thought in that committee that the experiment for the shift working was imminent and it kept being put back and back and back and I don't think -- but please correct me if I'm wrong, I'm doing this from memory -- that, actually, the shift working didn't get going until about the end of -- was it about November 1981?

Q. That's absolutely right. Another year.

A. Yes. Well, people wouldn't understand that. Why was it taking so long? It was always on offer but it never seemed to occur.

Q. Leaving aside the shift-work experiment, which we will come on to in a moment, was there ever any kind of assessment undertaken by the Department, as far as you are aware, of the capacity of the Liberton plant to fractionate for England and Wales?

A. No, the Department wouldn't have been in any position to formulate that view. The whole point was that we needed to understand what was possible. I mean, the beauty of the Liberton plant was that it was purpose-built to do the continuous processing over a 24-hour period. It was a much more state of the art facility than the BPL. Obviously, it had been built very much later and we had -- England contributed £400,000 to its building, so there was always the intention that it should be used, absolutely, and essentially, in order to work out what could be done, you did need to do this shift-working experiment. It wasn't being used in a continuous manner, which is what the facility had been built for. It was being used discontinuously. We can see from subsequent papers that a discontinuous process in a plant built

for continuous process was inefficient and actually ended up with loss of product, and so on.

So the issue was well, let's have a look, see what -- you had to do this experiment without which you really couldn't take a view as to what Scotland could do.

Q. Now, it's right to note I'm not going to go through all of the documents but we see in November 1981, the shift-work experiment having finally taken place, Dr Lane appears to have had significant reservations about its success.

A. Mm-hm.

Q. Then if we can then pick the position up in December 1981 with CBLA0001517. This is -- again, it's slightly faint in places but it is a meeting of the policy steering group of which you were a member on 18 December 1981 or you were part of the secretariat, I should say?

A. Yes.

Q. If we go to the second page, we can see the heading towards the top of the page "Shift-working Experiment at PFC, Liberton", and then we have Mr Hibbert reporting:

"... he had attended PFC as an observer during the shift-work experiment. His general impressions

were that PFC was capable of improvement. Its layout was not ideal and its output might be increased if the present system were changed. It seemed less cost-effective than BPL but it was planning to introduce a costing system ... PFC hoped eventually to service the Northern English Regions. While Mr Hibbert did not expect the findings of the exercise to prove conclusively that continuous working would overcome the short-comings of the existing system, the experiment had shown that the equipment could function on such a basis. Dr Lane expressed some reservations about the experiment. He was particularly concerned that there appeared to be several inconsistencies in the information provided and that the study had examined only one aspect of the production process. It was dread that the BPL representatives' report should be circulated to PSG members."

Then we can see the next paragraph:

"The Group [so it's the Policy Steering Group] recognised the importance of a full exchange of information between PFC and BPL. A small working party might be required in order to ensure that the new BPL embodied the best aspects of both laboratories. In the meantime it was essential to obtain a firm commitment from the Scottish Home and

Health Department of the amount of plasma from England which PFC, Liberton could fractionate. The Group asked Mr Harley to press SHHD for this information as a matter of urgency."

So we've got there, to some extent, a slightly mixed report. Mr Hibbert thinking it was reasonably successful, Dr Lane expressing some reservations but the group want to know what really how it could be taken forward, is that right?

A. I think Mr Hibbert was part of the BPL setup, rather than -- I have seen subsequent papers, so -- which the Inquiry has given me, so I can give more rounded explanation if you would like me to do that.

Q. Please do, because we'll look at what Mr -- some of that correspondence between Mr Harley and the Scottish Home and Health Department but we've also provided you with some notes by Mr Watt about his perception of how the shift-work experiment worked and also a rather later letter from Dr Cash, saying he thought it was something that was perfectly achievable.

A. Yes.

Q. We don't, I think, necessarily need to put those on screen you have read them.

A. Yes.

Q. First of all, as far as you can recall, did you or did

the Policy Steering Group receive those Scottish internal materials at the time?

A. No, no.

Q. Then if you can give that perhaps fuller explanation of what your understanding is.

A. Yes. Well, to finish just on this particular document, I notice that the Policy Steering Group was absolutely clear, look, to sort this all out we have to ask SHHD what's doable. I mean, it was well known that there was a difference of view between Dr Lane and Dr Watt -- in fact, I should say differences of view between Dr Lane and Dr Watt on just about everything.

Therefore, I think it was felt that the best way of finding out what was doable and on what basis was to ask for a formal letter from SHHD and that I've also seen and, undoubtedly, of course, it went to this committee, and I can short circuit things by saying what that letter from the Scottish Home and Health Department said was, well, we can obviously do quite a lot in terms of the amount of fractionation we can do for the UK but, actually, it's going to take £6 to 7 million because we need to do extra building in order to be able to accommodate all this requirement and it's going to take about two and a

half years.

So that was obviously a sort of bitter blow, if you like, to think that you could reasonably easily use PFC. It clearly wasn't the case and this was the formal letter from SHHD to the Department of Health saying this is the basis on which we can do it, never mind any additional cost to the DHSS of actually running a system through in PFC.

That was that but I have also seen Mr Wesley's report, which was -- Mr Wesley was a senior scientist in BPL who has described in very -- very moderate and perfectly reasonable terms and I thought it seemed to me entirely a reasonable report, explaining what the successes were of the shift working system and what the downsides were.

Now, the big problem with the downsides was that actually, although they found they could make a product which would satisfy Dr Lane in terms of the amount of albumin that was in it -- so they were able to sort the chemical constitution out all right -- the way in which the experiment had been run had three major flaws. One is that you couldn't make immunoglobulin running it in that way, you couldn't actually make salt poor albumin, which was another important product, but there was no experiment to see

how much Factor VIII you could produce. So the main thrust of what we wanted to do was to produce Factor VIII concentrate at Liberton.

Albumin was never really the big problem here and, actually, the Scottish experiment had not even started to tackle the potential to produce Factor VIII in any amount. They were just producing the normal amount of Factor VIII that they usually would produce for the needs of Scotland.

So the experiment, from that point of view, didn't really help take matters forward. But what actually then probably put a stop to any further discussions was that there was going to be a cost of £6 to 7 million, avowedly so, because that's what SHHD said, and it was going to take about two and a half years.

Q. I'm just going to read out, for the sake of the transcript, the document references for Mr Watt's notes, Dr Cash's letter and Mr Wesley's account but I'm not going to ask for any of them to go up on screen. So we have SBTS0000612_026, SBTS0000187_047 and CBLA0001528. So anyone who wishes to investigate that, as well as the legal representatives, can do so.

I just want to, before we finish on this topic, just to deal with the exchange of correspondence, if

we may, between Mr Harley and the Scottish Home and Health Department. If we look at CBLA0001532, is this the letter to which you were referring?

A. Yes.

Q. It's 11 January 1982. It refers in the first paragraph to there having been a telephone discussion and Mr Harley wanting an early response because he was due to be seeing Mr Finsberg, the Minister. Then he says in paragraph 2:

"I prefaced my remarks by mentioning two conditions which would have to be met before any progress can be made. First of all, I stressed that although the shift-working trial round the clock at PFC had been concluded satisfactorily, the staff cannot be expected to work in shifts regularly until an agreement on shift-working has been concluded through the usual Whitley Council machinery. That is, as you recognised when we spoke, very much a matter for your colleagues on the Whitley Council side of DHSS to pursue, and you indicated that the necessary action would be taken."

Can you just assist us with understanding what that's referring to?

A. Well, the Whitley Council was the negotiating body between NHS staff and management.

Q. So it was about negotiating --

A. Terms.

Q. -- the contractual terms upon which staff would be employed --

A. To work shifts, which was, of course, an unusual employment method, if you like.

SIR BRIAN LANGSTAFF: It's a pretty common employment method in factories at the time but I think it might have commanded a shift premium, presumably.

A. Oh, absolutely would have commanded a shift premium, and I think that was one of the problems.

MS RICHARDS: Then if we look at the second paragraph -- sorry, the third paragraph the second pre-condition, as it were:

"... I pointed out that the PFC, Liberton could process substantial quantities of English plasma only if further ancillary facilities can be provided, and that more land will be needed for the building required."

Then further explanation given in relation to that. Paragraph 4:

"Given that the obstacles referred to in the two previous paragraphs can be overcome, I do not think that the Common Services Agency Management Committee, who are responsible for the PFC, would raise any

difficulties; and as we have indicated all along we ourselves would be quite willing to have English plasma processed at Liberton."

Then paragraph 5 gives some further information about the potential as to what could be processed in terms of plasma. Over the page, again I think we get the figure that you referred to. So paragraph 6 gives more details about expanding the ancillary facilities and the last sentence, in what appears to be a darker print, says:

"We estimate that the total expenditure called for would be of the order of £6-7 million, but we cannot give you a detailed breakdown of this at present."

Then if we skip down to paragraph 8, I think we see the assessment of the necessarily building work being two and a half years, the last sentence of paragraph 8. Then there's a reference to providing more detailed information about the shift-working trials.

We haven't given you every document relating to this because I think your involvement in it was -- you were not a central part of the process.

A. That's right.

Q. But do you know what happened after this because we

see that in later meetings -- we saw a reference to it earlier -- Liberton is discounted for the purposes of planning for the redevelopment of BPL. Did this letter essentially bring the issue to an end, as far as you can recall?

A. I think it must have done because the steering group for the redevelopment of BPL had said the only way we can resolve this in terms is to ask SHHD what is doable. The letter is very clear from SHHD. They say what they can do but they also indicate the constraints under which that might be done and to wait two and a half years to see if this would work out fine, you can imagine, given the delays that we've already seen happen within, you know, bureaucracies, this might have been longer than two and a half years, to spend £6 to 7 million on getting the Scottish plant up to speed, if you will, when you could be getting on with spending the money on a new plant for BPL, obviously can't have made very much sense to them and I think this was probably deemed to be the definitive answer to whether or not we could make extensive use of the Scottish plant.

MS RICHARDS: Sir, we may be able to pick that up with further witnesses who were more closely involved than Dr Walford with that decision-making. I note the time

and I'm going to be moving on to a new topic after lunch, so a good point for a break, I think.

SIR BRIAN LANGSTAFF: Yes. Just one question, if I may, since we're on this topic at the moment. You have mentioned how Mr Lane and Mr Watt didn't see eye to eye on more or less anything. What were relationships like between Mr Lane and Dr Cash?

A. Specifically Dr Cash. I don't think -- I think they were not good. Really, we're in -- it's a sort of privileged environment we're in. Dr Cash had a rather confrontational approach to almost everything and, therefore, it doesn't particularly surprise me that Dr Lane, who was himself not the calmest of individuals, and Dr Cash didn't necessarily get on.

SIR BRIAN LANGSTAFF: So they hit sparks off each other, did they?

A. Yes, in a word.

SIR BRIAN LANGSTAFF: Thank you. 2.00.

(1.03 pm)

(Luncheon Adjournment)

(2.00 pm)

MS RICHARDS: Dr Walford, I'm going to move now to the question of AIDS and the Department's knowledge, your own knowledge and decisions that were taken largely in the course of 1983 because obviously you then left the

division towards the end of 1983.

A. Yes.

Q. Can I start by exploring with you your developing knowledge of the issues?

A. Yes.

Q. So you have told us in your witness statement that you became aware sometime in 1981 of reports of cases of this syndrome --

A. Yes.

Q. -- in the States, and your recollection -- it's paragraph 70.5, I think, of your statement if you want to look at it --

A. Thank you.

Q. -- was that you think you might have seen MMWR reports, perhaps in the second half of 1981.

A. Yes, probably. I don't know whether I saw those first reports. Those were reports of AIDS in homosexual men, yes.

Q. Then you say you were not aware of the MMWR report from July 1982, which identified three cases of AIDS in people with haemophilia in the States because you were on maternity leave at that point in time.

A. That's right.

Q. Would that, nonetheless, or would you expect that, nonetheless, to have come to the attention of someone

in the Department, someone in Med IMCD --

SIR BRIAN LANGSTAFF: I was going to say you are nodding, which is fine for us but --

A. I'm sorry, sir.

SIR BRIAN LANGSTAFF: -- it's not very good for the transcript.

A. Very good. Absolutely.

So it will have come and precisely the format in which it came I don't know but one of the papers that I have seen, which did come when I was on maternity leave, was a note from the principal -- the then principal in HS2 or 1, who -- Stan Godfrey, who had received report from Dr Gunson --

MS RICHARDS: We're going to look at that. We'll do that straight away. Just before I turn to it, the MMWR would have been received at some point in the division that we know, for example, Dr Sibellas worked in.

A. That's right.

Q. Then ordinarily would you expect it to have been, because it concerned blood, blood products potentially --

A. Yes, yes.

Q. -- haemophilia, blood products, being referred to someone in Med SEB?

A. You would have thought so but I don't know for

certain.
Q. No, understood.
So if we look at the material that you just referred to -- Soumik, it's DHSC0002219_009.
And so if we look at the bottom of the page we can see it's from Mr Godfrey dated 16 July 1982. First of all, can you just remind us who Mr Godfrey was?
A. Mr Godfrey was the principal in HS1A division and I think he reported to Mr John Parker at that time.
Q. Then it says "cc Dr Clarke". Do you know who that was referring to?
A. That was the doctor in Med SEB who was, as it were, standing in for me while I was on maternity leave.
Q. Was that Dr Petronella Clarke?
A. Dr Petronella Clarke.
Q. Then if we look at the top of the page we can see it was addressed to Dr Holgate and Dr Holgate was which division?
A. He was the principle medical officer in Medicines Division who dealt with biological products.
Q. So we can see it reports this:
"You will wish to know that Dr Harold Gunson, our Consultant Adviser in Blood Transfusion, has received information from the American Bureau of

Biologics via Dr Joe Smith at NIBSC that there may be considerable publicity in the next couple of weeks concerning the safety of American Factor VIII.
"Please forgive the layman's explanation below -- I hope it makes some sense. Apparently some research is about to be published showing fairly conclusively that plasma taken from homosexual drug-takers contains a sort of virus which goes undetected when the plasma is tested but it is suppressed by the drugs. However, when used for Factor VIII, it becomes active again. It seems that 400 haemophiliacs in the USA have exhibited signs of the virus. The report is expected to be picked up by the lay press and may cause a furore. I do not know which brands of Factor VIII are involved."
Obviously, that's not likely to be an entirely accurate account but, nonetheless --
A. No, it wasn't.
Q. But, clearly, the chain appears to be the American Bureau of Biologics providing information to Dr Joseph Smith, who has provided information to Dr Gunson --
A. Yes.
Q. -- who was providing information to the Department?
A. Yes.
Q. Then the next paragraph:

"From the DHSS point of view, we can defend the National Blood Transfusion Service's own record. Someone taking drugs (gay or not) would not be bled provided that the injection marks showed. In any case with our voluntary unpaid donor system we do not have the same problem as in the States where drug addicts are tempted to give blood simply for the money. However, about half of the Factor VIII bought from commercial companies is imported from the USA. Your Division, when the published study is available -- I understand that one of your Sections scans the technical literature for such material -- may have to consider revoking licences of certain manufacturers. Of course it may turn out that none of the Factor VIII involved is supplied to this country."
Then he says if you want to talk to Dr Gunson, if only to clarify my explanation of the virus he can be reached at the Manchester Transfusion Centre.
If we look at Dr Holgate's reply to Mr Godfrey at DHSC0002219_012, it's dated 20 July 1982. If we look at the bottom of the page, we can see again it's copied to Dr Clarke, who was filling in for you whilst on maternity leave, and then we can see if we look at the text of it:
"I was aware of the potential adverse publicity

concerning the safety of Factor VIII in the USA (and certain other blood products, in my opinion) where the original donation was obtained from the homosexual community. I suspect our press will pick this up in view of the recent events at Buckingham Palace."
I do not know what that's a reference to.
A. I don't either.
Q. "I do not entirely agree with your account of the technicalities [so perhaps a polite way of explaining that some of the description is inaccurate] but that makes no difference to the eventual outcome. Although I know Dr Griffin is aware of this ..."
Who was Dr Griffin?
A. He was head of Medicines Division, the medical head of Medicines Division.
Q. "... I am copying the correspondence to him and to Dr Fowler ..."
Dr Fowler was also in the Medicines Division?
A. He was senior medical officer.
Q. "... who will have to take any action that proves necessary.
"The element of doubt I have in your thesis is that the drug taking may not be an essential feature of the affair -- but I am open to correction on this; if it is solely the curious activities of the

homosexual male which lead to the infection, without superadded drugs, then our own blood production system may not be exempt.

"Either I or Dr Fowler will keep in touch with you over developments."

So we have that exchange in July 1982. So somehow or other information about -- in terms of what is coming out of the States has made its way to the Department?

A. That's right.

Q. Obviously you are on maternity leave at this point in time but would you expect that this would have come to your notice in some shape or other when you returned?

A. I would have supposed so, yes. I mean, I would have expected Dr Clarke to brief me because she was standing in for me, so she will have briefed me on anything that might have arisen. Mr Godfrey, with whom I had a very good working relationship, might well have briefed me and Dr Oliver also. So I probably heard about it when I got back but of course I've got no papers to guide me on that.

Q. Then again, just taking things chronologically, we know from other material, and I think you alluded to this yesterday morning, that CDSC began its surveillance in September 1982 --

A. Yes.

Q. -- although you have explained you weren't aware of that at the time.

A. Yes.

Q. Can I ask you to look next at some documents from Dr Craske. Soumik, if we start with HCDO0000557. Now, just to give a date and context to it, this is a letter from Dr Craske, 11 November 1982, to Ms Spooner at the Oxford Haemophilia Centre and she says:

"For your information I enclose a copy of a paper I have prepared for the meeting of the MRC Hepatitis Vaccine Working Group which describes the most recent information available about this new syndrome."

He refers to having liaised with CDC in Atlanta, having been given information about five haemophiliacs identified with the syndrome, two of whom recently died:

"All these cases are without the usual association of homosexual practices, drug addiction or treatment with immunosuppressive drugs ..."

Then he talks about, if we look at the next paragraph:

"The hypothesis at present being used to explain

the acquisition of these cases ... is that one or two patients in the incubation period of the disease donated plasma which has since been used to prepare Factor VIII or IX concentrates. All the haemophiliacs who have had the disease have had severe coagulation defects requiring regular treatment with factor VIII. The likelihood is, therefore, that other cases will be identified amongst severe haemophiliacs, though probably at a low prevalence."

Then the paper, before I ask you a question about it, the paper is at CBLA0001653_003. I don't need to go through, I think, the detail of it. If we go to the bottom of the second page and the Inquiry looked at this and various papers of Dr Craske on a number of occasions, Dr Walford, but we see under the heading "Aetiology" he sets out theories, (1) and effectively discounts them, (2) says seems unlikely, over the page identifies there as (3) the possibility of an infectious agent with a similar epidemiology to that of hepatitis B.

Now, I just wanted to establish whether you think you might have seen this at the time. You weren't on the MRC Hepatitis Vaccine Working Group, I think?

A. No.

Q. We've seen that got sent by Dr Craske to some other haemophilia clinicians at around the same time, no particular evidence of him sending it to you, but do you recall whether you saw a report from Dr Craske at around this time?

A. I couldn't say at around this time. It depends if he then had put that same report to the UKHCDO because, whatever was the relevant meeting, if I had been at it and he would have presumably put this report forward, then I would have seen it then.

Q. My recollection, Dr Walford, although I'll need to check, is that this report or something very like it was discussed by the Hepatitis Working Party in January but you weren't --

A. I wasn't at that.

Q. -- involved with that.

A. That, again, you know, one meeting, after another, after another, but basically that working party report would then subsequently be reported to a UKHCDO meeting, so it was altogether possible that I will have seen it then.

Q. Well, we certainly know, and your statement tells us, that you saw his updated version of this report --

A. Oh, I see.

Q. -- which was dated March, was sent to you directly in

April 1983 --
A. Fine, fine.
Q. Now, just then, again, as I say, taking it chronologically, you say in your statement you recall reading about the San Francisco baby case in late 1982 or early 1983?
A. Yes.
Q. If we go to your witness statement, Soumik, WITN -- you are ahead of me, thank you, it's paragraph 71.2. So it's page 169, please, Soumik. It's the bottom of the page, you say this:

"Apart from the fact AIDS was occurring in haemophiliacs in the USA who had received coagulation factor concentrates, I believe it will have been at the end of 1982 or early in 1983 that I read about the presumed case of AIDS in a baby who had required blood and platelet transfusions at birth and had later developed an AIDS-like illness. One of the platelet donors had subsequently been diagnosed with AIDS. This was the 'San Francisco' baby that has previously been described to the Inquiry. It is fair to say that this case, added to the mounting reports of cases in haemophiliacs in the USA, was instrumental in my feeling that it was likely that AIDS was transmissible through blood, as well as through sex."

Then you explain how you remained perplexed as to why Haitian immigrants seemed to be another significant risk group.

Then you say in the next paragraph, and I want to explore this in a moment in a little more detail, that:

"... from January 1983 the Department's awareness of the potential for transmission of AIDS through blood and blood products grew incrementally."

Just leaving it there for the moment, is it right to understand from your statement that, by the beginning or at the beginning of 1983, your sense was that it was likely that this was transmissible through blood and blood products?
A. Yes, it was.
Q. Was that the prevailing view amongst your colleagues, as far as you can recall?
A. Well, as I say, a little bit later on, that I think that view developed incrementally. Certainly that baby, poor little thing, was a sort of watershed, as far as I was concerned. It rang all sorts of alarm bells.

Of course you could not actually conclude from the one case -- for which other explanations were being given, I may say, rather than that it was

a transmission of AIDS. That was still controversial, even amongst those who knew about that case, in the medical press. But I think that gradually the feeling in the wider department, if you like, was that: actually, this is looking more and more likely that blood and blood products are certainly capable of transmitting this agent. Not necessarily we conclude that they have but they are capable of doing it.
Q. We'll look in due course, when we get to the July meeting of the biological subcommittee on the Committee on Safety of Medicine at a paper written by Dr Fowler.
A. Yes.
Q. But leaving aside Dr Fowler's views, were you aware in the early part of 1983 of anyone within the Department voicing a markedly different view, doubting or being sceptical about there being a link between blood, blood products and AIDS?
A. I don't remember really anybody in the Department voicing such a view. I think there was a degree of not necessarily scepticism but reticence amongst UK Haemophilia Centre Directors that this was potentially transmissible, but actually in the Department I don't recall anybody saying, "No, no, it's absolutely obvious that it isn't."

The exception was, if you like, Dr Fowler, whose paper I only saw when it came to the Committee on Safety of Medicines -- and to be fair, again, although he was putting forward a theory that had been put forward by Sonnabend in the outside world, he's -- nevertheless the rest of his paper went on to say, "but we have to take all these necessary precautions". So although he was not sure whether a transmissible agent was actually the main cause, if you like, of AIDS, he was -- nevertheless thought that we should treat it as if it was.
Q. We will almost certainly look at his paper in a little more detail later, but just sticking with around January/February 1983, in Med SEB and in Med IMCD, which would have had AIDS one of its primary concerns presumably at this point in time --
A. Yes.
Q. -- you can't recall anyone voicing a significantly different view from the one --
A. No.
Q. If we then look at DHSC0002353_021, we can see this is a letter from Dr Craske to you, dated 10 January 1983. He refers in the first paragraph to a letter that it's planned will be submitted to The Lancet, which gives the current situation with regard to the risk of

non-A, non-B hepatitis.

And the "we", I should say, is a reference to Dr Craske, Dr Rizza, Mary Fletcher and Dr Joan Trowell.

I don't think we need to go to the letter itself, but it was the issue about hepatitis-reduced products that had triggered that?

A. Yes.

Q. Then the second paragraph says this:

"The problem related to the investigation of factor VIII-related Acquired Immune Deficiency Syndrome (AIDS) has been satisfactorily resolved. We will report any patient detected in the UK who has received UK commercial factor VIII direct to CDC and will at the same time notify CDSC at Colindale. I have obtained Dr Galbraith's consent to this arrangement, and I intend to produce a short note in the communicable disease report describing the present situation."

Now, it sounds from that letter as though there might have been some earlier communication between you and him, because saying something's been satisfactorily resolved might suggest that he had previously raised it with you or discussed it with you, although there's no documentary trail to that

effect.

A. I actually don't think that's probably what happened. Looking -- it seems to me it was discussed at a UKHCDO meeting and there was an issue of who was going to report to whom. Dr Craske I think raised in the meeting a need that -- that he had been approached by Dr Dale, I think it was, of CDC Atlanta, and that basically the Americans really wanted the UK Haemophilia Centre Directors to report any case that they knew, because, of course, it was American Factor VIII that was being incriminated at the time.

So I believe it was discussed at a meeting, and basically he's trying to tell me -- well, there must have been quite a bit of toing and froing, as there often was at those meetings, as to, "Well, do we do it both ways? How do we do it?" And he says, "Well, I've resolved that and I'm going to send the reports through to Dr Dale and also at the same time I'll send them to CDSC, so everything is going to be all right in respect of reporting."

Q. Then if we move to DHSC0002223_085.

This is an article in The Observer on 6 January 1983, and we can see it is entitled "Mystery disease threat", by Christine Doyle:

"A commercial blood product imported into

Britain from the United States may pose a grave threat to the health of haemophiliacs who inject it to encourage clotting."

Then it goes on to give more detail. I don't think I need to ask you about the detail, save perhaps to note actually, if we look at the right-hand column, about halfway down, it talks about:

"... the deaths of at least 10 American haemophiliacs are now known to [have been] caused by the disease ..."

If we just go to the handwriting at the top of the page, we can see someone has written a note to you saying:

"It would be useful to know the outcome of Haemophilia Centre Directors' meeting. Perhaps we can discuss at an opportune moment."

That's, I think, your handwriting, where you say:

"I have written to Prof Bloom for details of the meeting."

A. Yes, it is.

Q. Then if we look at your letter to Professor Bloom, which is at BPLL0001351_047, this is a letter from you, 19 January 1983:

"Dear Arthur

"As you can imagine, recent publicity about cases of acquired immune deficiency syndrome in haemophiliacs in the USA has generated quite a bit of interest in the Department.

"I believe that the topic was to be discussed at a recent meeting of Haemophilia Centre Directors and I should be most grateful if you could possibly let me know what conclusions were reach at the meeting. Perhaps it would be simplest if you could telephone me whenever convenient rather than bothering with a letter."

We haven't traced a letter. Do you recall what conversation or discussion or response you had from Professor Bloom?

A. No, I don't recall at all but I will have asked for a telephone conversation so that I could find out quickly. One just simply didn't know how long it was going to take for him to write a letter to me and obviously this was concerning and I basically wanted to hear from him as soon as possible.

Q. Based on what you recall of Professor Bloom, and you had many interactions with him --

A. Yes.

Q. -- at this point in time, do you think it's more likely than not that he would have responded to your

letter?
A. To a letter?
Q. No, responded to your letter whether by picking up the phone and speaking --
A. Oh, absolutely. Absolutely he would, yes.
Q. So either he will have written back to you or, perhaps more likely, there will have been a telephone conversation --
A. I would have hoped there would have been a telephone conversation because that's what I was really aiming to get.
Q. But you've no recollection now --
A. No.
Q. -- as to whether that happened?

Then if we go to DHSC0002223_088, this is a minute dated 18 January 1983. It's copied to you. It's from TK Sweeney to Ms Fraenkel.

Can you just, again, assist us with understanding whose they are?
A. Can you just move it up a bit -- I want to see if I can -- "Med HPS", okay, he was a medic. I'm having to interpret the hieroglyphics here. He was a medic. And it looks as if -- I don't actually know what HPS was, for medic, so I'm afraid I'm not terribly sure about that.

But clearly this was copied to me, an interaction between two people that I did not actually know, reporting something that I had said to one or other of them and to Mr Sweeney -- or Dr Sweeney, if it was Dr Sweeney, and I must have been asked to simply comment on this press article, and you have my comments there.
Q. You are right, the heading refers to The Observer article we looked at, and then:

"Dr Walford has confirmed that the value to severe haemophiliacs of clotting factors 8 and 9 far outweigh the possible, and as yet unproven hazards of the transmission of acquired immune deficiency syndrome. The NHS is about to commit about £20 million to building a new blood laboratory to manufacture (among other products) factor 8 with a target of 100 million [international units] factor 8. This is well known in the haematology world. I do not think you need worry about the draft which can stand as written."

Now, I'm afraid we don't know what that draft refers to, and we haven't found further communications between these two individuals which casts any light on it, but just go back to what is said in the opening sentence of the paragraph. It's fair to infer from

this, isn't it, that there has been a communication, possibly oral --
A. Yes.
Q. -- between you and probably Dr Sweeney. Is it right to understand you've got no independent recollection of that?
A. None at all.
Q. What this records you as saying is, in fairly powerful terms --
A. Yes.
Q. -- the value of factor concentrates to severe haemophiliacs "far outweigh the possible, and as yet unproven hazards of transmission of [AIDS]".

Doing the best you can, given that you, several decades removed, don't have an actual memory of the conversation, what would have been, do you think, the factual basis for saying that the balance is such that the value far outweighs the risk of transmission of this disease?
A. I think my -- what I would have thought was: we have no evidence -- this hasn't happened in the UK, we have no cases that we are aware of, it's happening to a small extent in America. There's significant controversy as to what's causing it and -- relatively of course -- few people with haemophilia in America

had actually developed the disease.

So that was, on the one hand, what I did know about AIDS. What I did know about severe haemophilia was that the main cause of death from haemophilia was still bleeding. Haemophiliacs were still bleeding. Severe haemophiliacs had a really dreadful time if they were not treated appropriately. And so, from the perspective of not having any cases in the UK, not understanding the genesis of the illness truly, a lot of controversy -- I mean, it may seem terribly evident now that everybody thought that this was a transmissible agent in blood; that was not -- absolutely was not -- a consensus that was available at the time. And the notion that, on the other hand, severe haemophilia was a dreadful disease and basically they needed their Factor VIII.

So that was my thought. I still think now -- of course I now know about AIDS and its terrible consequences -- but I still believe that, at that time, the hazards were unproven of transmission and basically what one knew was that the severe haemophiliacs desperately needed Factor VIII or Factor IX. That was the basis of my thinking.
Q. This is the day before your letter to Professor Bloom, so it doesn't sound as though the conclusion that

you're reported to have expressed here had been based upon something that Professor Bloom was saying to you, because if there had been a recent conversation between you and Professor Bloom, one might have thought your letter of 19 January would be differently expressed.

Do you think this is you coming up with your own view, not --

A. Yes, yes. I absolutely do not resile from the thought that I had at the time, which was: oh my goodness, be careful what you are potentially going for here, potentially, as it were, in some way cutting off the Factor VIII from -- and IX, of course -- from severe haemophiliacs.

So I think it was really trying to say: on the one hand we know the serious damage that can be done if they don't have the factors; on the other hand, we really don't know enough about AIDS to consider it a balanced proposition.

Q. But it's right to observe, isn't it, that it's around this time that you have formed the view that it's likely that AIDS is a transmissible agent?

A. Yes, yes.

Q. Although, correctly observed, there haven't been very many cases, in terms of absolute numbers, and none yet

in the UK, what was known already was that this was a disease with a high mortality rate. Do you think, on reflection, it was wise to express yourself in such strong terms, given what you say in part is a state of uncertain knowledge?

A. Well, I was commenting -- you know, I didn't actually expect necessarily that my colleague was going to report back what I said. I don't at all resile from the fact that I will have said that or something very like it but basically we had this mystery disease, The Observer headlines, which were giving a very -- obviously a very scary account of what was, in terms, a very scary disease actually, and he must have asked my opinion because it looks like we -- I have "confirmed", and I think it must have been -- he must have rung me up or something of that kind because I haven't seen any papers.

Q. Yes.

A. So he must have spoken to me and I must have spoken in quite definite terms that actually this disease is awful, haemophilia -- so is AIDS, of course, but haemophilia is a dreadful disease and they desperately need their Factor VIII and Factor IX. I will obviously have said that. He is reporting it in his words not necessarily mine but I don't resile from the

sentiment at all.

SIR BRIAN LANGSTAFF: Can I just explore that last comment with you, that this is expressing his view, albeit attributing it to you, because the words which he uses, the value outweighs the possible hazards -- in fact, "far outweigh the possible ... hazards", how can you say that without knowing more about what those hazards are? Why are you limiting the possibilities? It's his writing his words.

A. He said that --

SIR BRIAN LANGSTAFF: It is a very, very -- it has all the feeling, to me, of a communication which is designed to procure a desired result rather than necessarily reflecting what might have been said to him.

A. Well, I honestly can't say, sir. Basically I'm needing to interpret this. I can't remember a phone call. I don't actually know who this person was that I was speaking to. So I have to take it as read. I believe I will have felt quite strongly at the time that -- a good deal of worry that what was being attacked there, if you like, was the Factor VIII which was sustaining the lives and lifestyles of haemophiliacs in this country, and my concern was that this story -- which was not actually supported by sufficient evidence, let me put it that way,

sufficient evidence. As we found, the Committee on Safety of Medicines didn't think there was sufficient evidence on which to actually withdraw this product.

So this was really my thoughts there, however reported, and, as I say, I believe I will have thought that.

SIR BRIAN LANGSTAFF: Thank you.

MS RICHARDS: Now, the Inquiry's looked on a number of occasions at notes of a meeting on 24 January 1983 at a Heathrow Airport hotel --

A. Yes.

Q. -- involving Immuno and then a number of clinicians.

A. Yes.

Q. You have explained in your statement that you weren't present at that. We know your name is not in the list of attendees and you weren't aware of it?

A. Not at all.

Q. But you have drawn attention to a minute from Dr Fowler which suggests that there might have been an earlier meeting?

A. Yes.

Q. Can we just look at that DHSC0002223_065.

This is Dr Fowler to you 31 December 1982 and Dr Fowler's Medicines Division, as we have already established?

A. Yes.
Q. It says:
"Factor VIII concentrate with reduced hepatitis risk.
"Although we have had discussions with Travenol about their product, we have so far had no application of any kind for a reduced hepatitis risk [Factor] VIII. It is our understanding that Travenol propose to apply for a CTX some time around March 1983. This, however, is pre-empted by Immuno's recent meeting with the haemophilia centre directors and the directors of BPL and PFC, the outcome of which is, we are led to believe, a multi-centre clinical trial of the product in named patients. I had not heard that Travenol proposed to hold a symposium, although it would be very much in character were they to do so. The Immuno meeting is said to have been quite an expensive exercise at Heathrow. I was not invited, but my information comes indirectly via John Holgate from one of the participants. We also hear that overseas experts from Travenol have had a meeting with Duncan Thomas and his people at NIBSC and furthermore that there may be other companies interested in this field apart from those who have already made or hope to make hepatitis-free FVIII

biosynthetically. It is possible that Richard Lane may be able to give you more information on this subject."
Now, the significance of this is the date, 31 December 1982, and it's very clearly talking about a meeting that has already happened --
A. Yes.
Q. -- involving Immuno, Haemophilia Centre Directors and, it's said here also, directors of BPL and PFC, who were not, I think, as far as we know, at the meeting on 24 January, but I may need to check that.
Do you know any more than what is set out here?
A. No. This came as -- when I saw the papers, this came as a complete surprise to me, because I thought there was a meeting in January, the following year from this, which is the one that we heard about, although the minutes or notes of the meeting seemed to be a long time coming, I think they came several months later.
Then, to my surprise, I came across this particular minute, which seemed to imply that there had been either another meeting at Heathrow or somebody had got their dates mixed. I don't know the answer.
Q. Now, given -- we can take that down, thank you.

Given your own sense, in early 1983, that it was likely that AIDS was transmitted through blood and blood products, the lack of any vocal view to the contrary in the Department --
A. Yes.
Q. -- and what you have described as effectively something that became mainstream acceptance within the Department that that was likely, were there, as far as you're aware, any particular steps taken by the Department between January and April of 1983 in response to or in relation to the risk of AIDS in relation to blood products?
A. I don't -- I'm not aware. I couldn't find anything in the papers which said that. In March, a communication occurred between Dr Joseph Smith of -- the director of NIBSC, and Medicines Division --
Q. We'll come on to that.
A. And I don't think I heard about that until April. But of course I should point out again that Med SEB was not in the lead for infections from blood, so whatever was going on in Med IMCD, apart from the surveillance that CDSC was obviously doing, I'm not aware.
Q. So we then, I think, in terms of the next discussion involving those within the Department that I'm aware of to a CBLA meeting, so the Central Blood

Laboratories Authority meeting, 27 April 1983 you weren't actually present and you told us you didn't generally attend but, just for the sake of completeness, I'd like to briefly look at it. It's BPLL0003987_002. We can see it's a meeting of 27 April and, although you were not there, Mr Godfrey was and Mr Winstanley was.
A. Right.
Q. So there were two fairly senior members of the administrative hierarchy of the Department in attendance.
If we go to the bottom of page 3, you see the heading "AIDS", there's reference to a report from Dr Lane. I'm not going to go to that for present purposes. Then there's a report from Dr Gunson. It's said that RTDs, so Regional Transfusion Directors, had:
"... considered all the American literature on the subject and at the next meeting of their Committee it would be recommended that no further measures be taken apart from those already being carried out."
Just pausing there, we'll come on to the question of a leaflet from the Blood Transfusion Service at a later point in the chronology but that's not yet, as it were, actively on the cards, I think,

by this point in time.
A. Right.
Q. Do you know from your own knowledge or from your reading of the papers what measures were already being carried out that Dr Gunson could have been referring to?
A. No, I don't, unless you can point me -- I think there was a meeting that he had had. I recall there was a meeting that he had been at where the whole subject had been explored. It wasn't a meeting that I was at and I think I've referred to it in my statement but --
Q. I'll check and if necessary take you back to it.
A. Thank you.
Q. Then, over the page, we see Professor Bloom reporting that:

"... he had given a talk on AIDS to the AGM of the Haemophilia Society. His impression was that haemophiliacs were not greatly concerned about AIDS."

Then it's said:

"It was agreed that Mr Winstanley should try to ascertain how many telephone calls had been made to the number given at the end of the television programme on AIDS."

Now, are you able to assist us with the last of those points?

A. Not really. As I understand it, in reporting back at a subsequent meeting -- I mean, I'm doing this now from memory, I'm not referring back to my statement, because it would help if I did, I guess -- but, essentially, I think there been -- there had been obviously a telephoned programme. I don't know what the television programme was.
Q. There was one called Killer in the Village, or something along those lines, as I recall from April 1983.
A. So a nice restrained programme. Basically, I think what had happened was the CBLA had wanted to find out had there been much public interest in it and how many phone calls, therefore, were being made to the television channel, to find out really how it had been perceived, I guess, and apparently Mr Winstanley had contacted the channel, had actually ascertained that there had been quite a lot of phone calls but that was as quantified as I believe it got.
Q. We have got the documentation in relation to Mr Winstanley reporting back somewhere. Do you recall there being any discussion within the Department on that issue?
A. No, I don't remember anything.
Q. Then just whilst we're still in the spring of 1983,

can we go to PRSE0006049. This is an extract from the evidence given by Professor Richard Tedder to the Penrose Inquiry, so we can see that from the bottom of the first page and then if we go over the page, if we pick it up at line 13, the question is posed:

"You knew both Dr Smithies and Dr Walford. Is that correct?"

Then the answer from Professor Tedder is:

"... I mean, obviously, I was more in contact with Alison ..."

That's Dr Smithies, who was your successor.
A. That's right.
Q. "... because of her position, once we were actually hands-on involved with HIV testing. But I had met Dr Walford on one or two occasions prior to that.

"Q. Had you met her in connection with the whole AIDS problem?

"A. Yes, I had. I had been -- I think I mentioned the NIH meeting in Washington, which there was discussion of the aetiology of the infection and the disease which was presented in the MMWR first paper. After that and after the meeting, the NIH meeting, discussing this, it must have been early 1983, Philip and I went to DHSS to ask what the plans were for -- what was ready -- what was going to be the

plans for readiness to deal with what, I think I alluded to earlier this morning, was a disease or infection which sounded awfully like Hepatitis B in terms of affecting the same group, having the same sort of transmissions. And the moment we heard, in early 1983, end of 1982, about haemophiliacs also being involved, that gave one -- there were two reasons people put forward for the involvement of the haemophiliacs: either David Parillo, the American physician immunologist, was saying it was antigen overload which was damaging the immune system, or there was the virology camp, in which Philip and I were deeply embedded, saying, 'This sounds awfully like a transmissible virus infection. It's going in blood products, it's going in gay men, it's going in people who we know get Hepatitis B."

So that's just by way of background. Then Professor Tedder says:

"So we felt empowered to go and ask the DHSS what we could do to explore this, and it was as cold a meeting inside the room as it was outside. It was a sort of cold spring morning up in one of the DHSS towers and we were told this was really not any of our business and it was not going to be a problem and go away and stop rocking the boat."

Then, top of the next page, he says:

"... I can't speak for Philip. You would need to ask him. But I was somewhat taken aback and pretty irritated."

Now, that appears to be his recollection of a meeting with you because it's introduced by talking about having met you on one or two occasions. I'll ask you in a moment to look at a letter from Dr Tedder to you in May 1983 but do you have any recollection of the meeting he might be referring to and any comment upon his account that the DHSS response was "Go away and stop rocking the boat"?

A. I didn't remember the meeting. I knew it had happened. I didn't remember what it had been about. I kind of assumed, and this was borne out, as we will see, that it was to do with can we have some funding for research. I believe that's probably fundamentally what it was all about, though I have to say that the irony of having me in a cold room seems -- you know, it's not lost on me. It's most -- it sounds most unlike me. I don't know what I can have said that could have possibly given him the feeling that I was asking him to go away and stop rocking the boat. This is not really characteristic, is all I can say.

Q. If we look at the letter that we have from the time

from Dr Tedder to you, it's at DHSC0003824_164. It's 20 May 1983, addressed to you:

"Dear Dr Walford,

"Thank you for seeing Dr Mortimer and myself last week."

Dr Mortimer is Philip Mortimer, the "Philip" referred to in the evidence to Penrose.

A. That's right.

Q. "I gather Dr Catterall has already written to Dr Graveney, I expect [I think it might be the wrong way round, perhaps] like you I have seen a copy of his letter. It is, I believe a reasonable statement of intent."

Then he goes to make various comments as a virologist on the problem of AIDS, starting off in the next paragraph:

"This condition is likely to be caused by an infectious agent or agents. Its epidemiology bears a striking similarity to hepatitis B."

Then he goes on to set out some suggested approach to research and, over the page, to discuss funding for research.

As far as you can recall, did you have any other meetings with Dr Tedder and Dr Mortimer at this time?

A. No, I can't recall.

Q. Given what you have told us, that Med IMCD was the lead branch dealing with communicable diseases, why was it that you were having this meeting with Dr Mortimer and Dr Tedder?

A. I have absolutely no idea.

Q. Do you know whether the Department did provide funding?

A. Well, I'm then reading the papers, I mean, essentially I had presumably said, just reading the first paragraph, look, if it's funding that you need, the way to do it is to apply to the Office of the Chief Scientist. I obviously seemed to have given him that signposting, if you like, and he's then writing to me to elaborate on the research that they are wanting to do but he says that actually Dr Catterall who was involved, I believe, with the research had already written to Dr Graveney, I think it's Dr Graveney, of the Office of the Chief Scientist.

Then we do know there was a discussion at the June referred meeting of officials, where we were looking at the issues to do with AIDS in the round, absolutely everything, and I think it was Dr Graveney who said that they had received a letter from Dr Catterall and then I think I saw, following it up in an MRC meeting, that in fact Dr Tedder and

Dr Adler's submission, I think, had been funded. Dr Adler was a GUM physician.

So I believe the money will have been found to support this research but I have to get at it indirectly through the various papers.

Q. As far as you're able to recall, would you have been involved in that funding process or the decision-making process?

A. Well, no, I mean, I was not involved in actual taking decision. I might have been asked whether it was a good thing to fund or not. I don't know whether I was but he was funded so I'm assuming that somebody at least had endorsed that. But, I mean, it seems to me it would have been a perfectly proper thing for the Department to fund.

Q. Now, I want to move then to a number of communications events in May 1983 and we start with DHSC0001651. Now, this is from -- if we just go further down the page this is from Mr Parker HS1. It's dated 3 May. It's copied to a number of recipients, including you, and if we go further up we can see it's addressed to Mrs Walden. Are you able to assist with who Mrs Walden --

A. Private office, yes.

Q. Private office of who?

A. I think that would probably have been Mr Finsberg.
Q. Then it says this:
"You will recall that we were asked to provide briefing for Prime Minister's Questions on the stories which appeared over the weekend about AIDS."
That is a reference -- I'm not going to go to the newspaper articles but it was a reference to certainly one particular article, possibly more.
"I attach a copy of the 'line to take' which went to Number 10 together with a background note written in supplementary question and answer form, both of which I am circulating more widely within the office.
"Officials are in touch with representatives of the Directors of Haemophilia Centres and the Blood Transfusion Service as well as the Haemophilia Society. During these discussions, the Haemophilia Society indicated that they would welcome an opportunity to discuss AIDS with Ministers by the end of this week. Whilst one of the main purposes of background briefing is to put the problem of AIDS into proper perspective -- a view shared by the Society -- we think it would be helpful if Mr Finsberg were to offer to meet representatives of the Society. Meanwhile, there appears to be little to be gained

from Ministers issuing statements about a matter which has been sensationalised and, in some cases, distorted by the media and on which, with the present state of knowledge, there is no immediate action which Ministers could be advised to take. We should, however, review this line after officials' discussions are complete and the proposed meeting with Mr Finsberg has taken place."
Then there's a question of whether Mr Finsberg agrees to a meeting with the Haemophilia Society.
Now, if we just follow the paper thread through, the "line to take" is over the page:
"I was very concerned to read this weekend's Press Reports and can well understand the anxiety which some sensational reports may have caused. It is important to put this in perspective: there is as yet no conclusive proof that AIDS has been transmitted from American blood products. The risk that these products may transmit the disease must be balanced against the obvious risks to haemophiliacs of withdrawing a major source of supplies. Already, in this country, there is a special surveillance system, established by the Communicable Disease Surveillance Centre, to monitor the occurrence of AIDS, in collaboration with the Centers for Disease Control in

the USA. Every opportunity is being taken from this country to learn from the experience of this disease in the USA."
That's the "line to take". We'll look at the background paper, the question and answer paper, in a moment.
This may be the origin of the line of no conclusive proof or no conclusive evidence and I'm going to come back to that and your own involvement with that issue at a later stage of my questioning.
A. Right.
Q. Do you know if you had any involvement in the formulation of this line to take at this point in time?
A. I believe I didn't. In fact, I think I have no recollection of how this briefing was produced. I have no recollection of knowing that something was coming up at Prime Minister's Questions and, basically, Mr Parker is responding, as administrative staff would do, but I would say that it must really have been on advice of Med IMCD.
The reason that I say that is that -- well, we come to the Q&A briefing that was associated with this line or was certainly associated with the paper that went to Mr Finsberg, because it referred to three

Spanish haemophiliacs who had developed AIDS, and I think it also referred to one patient in the UK, and which was obviously Professor Bloom's patient in Cardiff.
I didn't know about any of those cases until Dr Galbraith's paper was sent to Med IMCD on 6 -- well, it was sent on 9 May, I think, but 6 May was when Dr Sibellas told me about it. So, essentially, I didn't know about those cases and, therefore, I can't see how is could have provided that statement.
Q. It's right, you observe in your witness statement, in fact that line was not used by the Prime Minister on that occasion --
A. So it appears.
Q. -- as a matter of fact. She said something else.
Just so that we can also look at the Q&A briefing which accompanies Mr Parker's minute, it's at WITN -- no, DHSC0003824_173, please, Soumik. We've got the "line to take" there and then, if we go over the page, we've got the question and answer paper. So we've got the question: "What is AIDS?"; "Symptoms"; "Who is at risk from AIDS?" If we just look there, it says:
"The disease occurred predominantly in homosexual males but other groups such as mainline

drug abusers, Haitian immigrants and haemophiliacs requiring treatment with antihaemophilic factor concentrates ... have also been identified as being at increased risk."

Question:

"Is it caused by a virus?

"The cause of AIDS is unknown. Although medical opinion is tending to favour a virus as the agent responsible, there is no proof that this is the case. There is no means of testing ..."

Then there's a reference to laboratory tests. Bottom of the page, "Mortality":

"The mortality from the established disease is high: at least 40 per cent of cases die after a variable period of months or years after contracting the disease."

Next page, "Is it transmitted in blood or blood products?":

"As yet there is no conclusive proof that AIDS is transmitted by blood as well as by homosexual contact but the evidence is suggestive that this is likely to be the case. The evidence relates to some 11 haemophiliacs in the USA and 3 in Spain in whom the most likely explanation for the development of AIDS was their exposure to American [Factor]VIII

concentrates. There is also some evidence that AIDS has been transmitted to babies in blood transfusions."

Then if we look at the next question, "Are there any cases of AIDS in UK haemophiliacs?":

"As far as can be established, there are no proven cases of AIDS in UK haemophiliacs. There is a suspect case in Cardiff of whom we have details but the reported (in the Sunday Mail) case in London has not yet been traced. The case in Cardiff has not received any American [Factor]VIII concentrate since 1980. This would not exonerate America [Factor]VIII because of the long incubation period which there may be between exposure to the agent and the manifestation of the disease. On the other hand, the patient, who is a severe haemophiliac, has received since 1980 a great deal of British made [Factor]VIII concentrate and it is not possible to know whether British concentrate may contain the AIDS agent.

"Should a ban be placed on imports of US Factor VIII concentrate?

"At present, haemophilia experts in this country take the view that to ban imports US [Factor]VIII would be to place haemophiliacs at greater risk from bleeding than they would be acquiring AIDS.

Then there's a question about switching to

European concentrates and then a question about what action we're taking: Reference to blood transfusion directors:

"It is considered impossible to ask donors if they are homosexual. However, they will avoid wherever possible bleeding donors who are known to be homosexual ..."

Then 2:

"All haemophilia centre directors have received instructions to report any suspect cases of AIDS ... to the Oxford Haemophilia Centre to the Communicable Disease Surveillance Centre."

Then there's reference to the Blood Transfusion Research Committee of the Central Blood Laboratories.

I won't read the rest of the answers but if we just go back to -- yes, that's the one.

So as I understand your earlier answer, it's in particular the reference to the three cases in Spain --

A. Yes.

Q. -- that makes you think you wouldn't have been involved in drafting this at this point in time, the beginning of May, because you weren't aware on 3 May of those cases?

A. No, I had no idea. I didn't also know about the

suspect case in Cardiff.

Q. That would tend to suggest then that whoever did draft this must have had some communication with Dr Craske or Professor Bloom -- to know about the case in Cardiff there must have been some contact. You were the primary UKHCDO conduit, as it were, in the Department. Do you know whether Med IMCD had direct dealings with Professor Bloom or --

A. I don't know but what I noticed was that slightly earlier on, in April I think it was, Dr Sibellas was reporting some surveillance that CDSC had been doing. As I said, I didn't know that then but I've seen the papers subsequently and I noticed that there was a report from her about the CDSC surveillance in late April, I think it was, something like that, and it wasn't copied to me. In fact, there were a couple of documents not copied to me which showed that Med IMCD was pretty active in discussions with CDSC.

So whether actually Med IMCD in discussion with CDSC, which was then going to re-report in this Cardiff case in the CDR -- Communicable Disease Review -- on 6 May, this is only a few days beforehand, it's possible that that's -- they got their information from CDSC, as opposed to necessarily directly with Bloom.

But I also noticed that Dr Sibellas referred to talking to Dr Gunson about these matters. Now, of course she was entirely at liberty to talk to Dr Gunson. I certainly -- it wasn't just that he related to me, he was a consultant advisor in blood transfusion to the CMO, and if there had been a worry about something in terms of blood and blood products, Mary, or anybody else for that matter, could have consulted Dr Gunson. But it was clear that she had been in discussion with Dr Gunson, because what was reported in one of those minutes was not me saying, "We've been in discussion with Dr Gunson and he says X, Y and Z, we're looking for other sources of blood", essentially it was obviously Mary had. And so I would have supposed that this is entirely consistent with Med IMCD being on the ball, being in touch with the people they needed to be in touch with, and actually providing the briefing for the Prime Minister and for Mr Finsberg.

Q. So is this correct: first of all, as far as you can recall, you were not the originator of the "no conclusive proof" line to take that we see referred to in Mr Parker's minute?

A. Absolutely.

Q. And then, in terms of the Q&A briefing, would you

accept it looks like it's had some medical input?

A. Definitely.

Q. It's not simply the work of an administrative civil servant.

A. Right.

Q. Your hypothesis would be it's most likely to be Med IMCD who would have the data from CDSC?

A. Yes.

Q. I will come back to the question of "no conclusive proof" in detail at a later stage --

A. Sure.

Q. -- and your subsequent involvement in the issue of continuing to use that line.

If we then go to DHSC0002227_021, this potentially throws some of the timings into a degree of confusion because of the date of it but we will see what we can try and work out.

This is from Dr Sibellas in Med IMCD to Dr Oliver. It's dated 6 May 1983. We can see that you were copied into this.

If we look at higher up the page, it says:

"Dr Spence Galbraith telephone from CDSC this morning with the following information:-

"The male patient ... in Cardiff who is a known haemophiliac now appears to have the right symptoms

and signs for a diagnosis of AIDS."

There is reference to him having an opportunistic infection, been ill for a month, been treated with American Factor VIII.

"We have no further news of the haemophiliac patient in London (as mentioned in the press on Sunday 1 May 1983).

"Dr Galbraith last night received information from Spain that three haemophiliac patients there are thought to have AIDS and have also been treated with American [Factor] VIII."

Then it says in the next paragraph:

"Dr Galbraith asks that the Department should consider the matter as a priority - and asks that any top level meeting should include CDSC (who are collecting all data on AIDS cases for us). I assured him we would liaise with CDSC and also told him that we had already met Dr Gunson (CA in blood transfusion) [consultant adviser] and he was in touch with Regional Transfusion Directors - and that alternative supplies of [Factor] VIII are being considered but are not going to be easy to come by - the matter is under active consideration. (Swiss supplies are considered doubtful - is Germany a possibility)?"

Then there's a reference to you being in

Newcastle.

Now this would suggest that Dr Galbraith himself only received the information from Spain on 5 May, so it doesn't quite fit with what seems to be the timing of the question and answer briefing, but I don't think from what you've told us you can cast any further light on that.

A. No.

Q. Is this the document by which you became aware both of the Spanish cases and of the Cardiff case, as far as you can recall?

A. This particular document I suspect, but I did receive a few days later Dr Galbraith's report, which was the really key report that you know I was obviously paying huge attention to.

I'm just wondering in relation -- because, I mean, the point that you raise is absolutely pertinent. You're saying Dr Galbraith apparently didn't know until the night before this -- 6 May, about the Spanish cases, so is the Q&A brief the Q&A brief that went to Mr Finsberg?

Q. Or to the Prime Minister?

A. Or to the Prime Minister.

Q. You are right to pose the question, Dr Walford. I think the answer is at the moment we don't know.

I'm sorry, I should have said you were, of course, copied into Mr Finsberg's -- the memo to Mr Finsberg on 3 May, which attached both a copy of the line to take and a background note in question and answer form, whether it's that precise one or another one, so you may have received information on 3 May or you may have received information on 6 May but, in any event, it's in early May that you have learnt about the Spanish cases and the Cardiff case?

A. Yes.

Q. Now, bearing in mind that you knew Professor Bloom fairly well, you had had a number of interactions with Professor Bloom, do you think you would have contacted Professor Bloom and asked for more information about the Cardiff case?

A. Well, did I? I don't know whether I did or I didn't because, again, that would depend on having something which showed me that I did.

Obviously I went to the subsequent meeting on 13 May with the UK Haemophilia Centre Directors where this very matter was discussed. So I don't know -- I certainly don't recall but I don't think, from the papers that I have seen or not seen, that I particularly got in touch with Dr Bloom about that case.

Q. Then we know following 6 May we have Dr Galbraith's letter to Dr Field on 9 May. I'm going to come back to that as a separate topic?

A. Of course.

Q. If we then just carry on with the thread chronologically in the course of May of 1983 and go to DHSC0002227_038.

This is a minute from Dr Sibellas so Med IMCD, 12 May 1983, copied to you. We can see it's addressed to Dr Field and it's on the topic of having a working party on AIDS. It says:

"I understand Dr Galbraith has already written to you suggesting that we should have a Working Party on AIDS.

"The preferable chairman would probably be from the Department (? yourself - your recent knowledge on this topic on the international front is a help) with suggested representatives from:

"(i) the blood products field (to be suggested by Dr Oliver/Dr Walford ? the CA in Blood Transfusion - Dr Harold Gunson)

"(ii) CDSC - Dr Galbraith and/or Dr McEvoy

"(iii) PHLS - a virologist (Dr Joan Davies has already suggested Dr John Craske)

"(iv) The STD field (? The CA in Genito Urinary

Medicine or his nominee)"

Then last paragraph says:

"I would appreciate your comments on these (very preliminary) suggestions. I imagine we could ask for short papers from Dr Walford and/or Dr Gunson ..."

Et cetera, et cetera.

So it seems from this minute that what was being mooted was the formation of, as it were, a cross-disciplinary working party on AIDS set up by the Department drawing on a range of different disciplines.

A. Yes.

Q. If we look at the top of the page, the handwriting, it says, right on the left-hand side:

"... this idea has now been abandoned. Drs will now have *ad hoc* discussions."

Is what I think it says.

A. That's what's I thought it said.

Q. I think you rightly in your statement pointed out that there's a memo from you a little later -- we'll look at it for a different purpose -- where you make some suggestion of who could be on a working party, so I think you have said in your statement you weren't fundamentally opposed to the idea of a working party?

A. Not at all. Not at all.

Q. Do you know why the idea was abandoned?

A. No, I don't know. I have no idea. And I don't know what was -- I think this must be Dr Field writing. Dr Field was head of Med IMCD. I don't know what he meant by *"ad hoc* discussions" or -- I don't think this is Dr Mary Sibellas' writing, which I think I've seen elsewhere. So if it was Dr Field then he was suggesting there was another way of dealing with this.

But I had assumed that there would be a working party and that probably -- or at least I would be contributing some papers to it, if not being actually on it, and Mr Parker would also be involved.

Q. Now, we know that at some point in 1983 -- I can't remember the precise date off the top of my head -- that a Medical Research Council working party on AIDS was formed. Obviously, its priority, its focus, was research because it was under the auspices of the MRC. It could be said that, looking at both the MRC and the Department, the priority then appears to have been on research rather than on seeking the best and widest possible advice on how to prevent or minimise infection, by not establishing this working party. Do you have any observations on that?

A. No. I mean, I think a working party would have been a perfectly sensible useful thing to do, always

helpful to have multiple inputs from experts.
Q. We can see if we look at WITN4461127, this is a letter -- it's from Dr Craske to Dr Whitehead at the Public Health Laboratory Service in London, so it's an internal PHLS document, 10 May.
We can see in the first paragraph he is referring to discussions with Peggy Pereira. Do you know who that was?
A. She was a really very senior doctor at the PHLS.
Q. Then Philip Mortimer, who we have seen reference to in the context of meeting with Dr Tedder.
Dr Craske at least is adding support for the proposal that a working party should be set up to co-ordinate the investigation of cases and the prevalence of the disease.
Just by way of completing this issue, if we go to DHSC0002229_004, this is a minute from you dated 23 May 1983. You're responding to Dr Field. "Action on AIDS" is the heading of Dr Galbraith's report -- and we'll come back to that -- but it says:
"I agree entirely with your suggestion for handling this issue ..."
I think we'd need to obviously check what Dr Field was saying to know what the suggestion was, but you say:

"They certainly would not wish to press for a formal working party at this stage."
So you didn't push the issue. Any particular reason for that?
A. Well, I only wish I knew what his suggestions were. I can't find any piece of paper which tells me what he said to me or how he explained why he didn't want a working party or what ideas he had in mind to do something different. That would be good to know. But basically whatever it was he said, I then thought, well, I can't really press for a working party.
The working party hadn't, of course, been my idea at the beginning, so it was -- I was very happy that there should be a working party, and in many respects I wish there had been, but basically he had obviously got some other idea and I wasn't going to particularly press for a working party in the light of whatever it was he told me.
Q. I don't know whether you can then answer the next question but it's really one that invites your reflection or comment, rather than your factual knowledge at the time. We know that something called EAGA (the Expert Advisory Group on AIDS) was set up --
A. Yes.
Q. -- and met in early 1985. You subsequently in a later

role with the Department became involved with the work of EAGA?
A. Yes.
Q. But of course by the time it was set up, you'd moved to an unrelated job and Dr Smithies was performing the role you'd performed.
With everything that you know now, the subsequent involvement you had with EAGA, do you think it would have been a good idea to have something like EAGA set up rather earlier, perhaps in 1983?
A. I absolutely think that it would have been wonderful for all of us if we had had an expert group reporting to the Chief Medical Officer and taking the best possible view of the assembled multidisciplinary doctors and scientists to give us the best view of this. I think it's, in retrospect, a terrible shame that we didn't have but we didn't.
MS RICHARDS: Sir, I note the time. Perhaps a good point for an afternoon break.
SIR BRIAN LANGSTAFF: Yes. We'll take a break until 3.45. 3.45.
(3.17 pm)
(A short break)
(3.46 pm)
MS RICHARDS: Dr Walford, still in May 1983, I want to

turn next to the Reference Centre Directors' special meeting on 13 May, which you attended.
A. Yes.
Q. Soumik it's HCDO0000003_008, please. So we can see there "Special Meeting of Haemophilia Reference Centre Directors", St Thomas' Hospital 13 May 1983. Dr Bloom is there, Dr Craske, various other Reference Centre Directors and then we can see you attending as a DHSS observer.
Had you invited yourself to that meeting or been invited to it, can you recall?
A. I think I had invited myself. I know I invited myself to a subsequent meeting. I'm pretty sure I must have done because it was a reference centre meeting. So I think I did.
Q. Then we can see, if we just look at the text, and I know you have read it, so I won't go through all of it, but there's reference to publicity, anxiety, a need for Haemophilia Centre Directors to discuss what should be done. There's reference to one haemophiliac suspected of suffering from AIDS, which is presumably a reference to Professor Bloom's own case.
Then, if we go over the page, we can see, towards the end of that first paragraph, reference to

the reporting system and then it says:

"The steps to be taken should a patient develop the features of the full-blown condition were then discussed. It was agreed there was insufficient information available from the US experience to warrant changing the type of concentrate used in any particular patient."

Then, in terms of general policy, in the following paragraph, it notes:

"... that many directors have up until now reserved a supply of [NHS] concentrates for children and mildly affected haemophiliacs ... it was considered ... circumspect to continue with that policy. It was ... agreed that there was, as yet, insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy."

That's then said to be a situation that will be kept under constant review.

Do you have any recollection of that meeting?

A. Yes, I can remember being at it, yes.

Q. Do you have any recollection about the discussions, beyond that which we see summarised with minutes?

A. No. I mean, I think it went on for much longer than the minutes appear to imply. These are really,

I think, fairly condensed notes of the meeting.

Q. Certainly, it's described as a meeting that was held at 11.00 am and it says the meeting closed at 2.15 pm?

A. So it was quite long.

Q. Do you recall whether there was any discussion of any other possible changes of general policy or changes to treatment approaches other than what we see here?

A. No, I don't remember the discussion really at all. I obviously took note of the conclusions because I then went straight back to the Department and, as it were, quoted them back to Dr Field. So I was obviously taking notes myself at the time but I took notes of the conclusions and then came back and reported the meeting to Dr Field.

Q. I do not know whether you can answer this, Dr Walford, but is your best recollection that there wasn't a discussion of other strategies or are you simply unable to say one way or another?

A. I am simply unable to say one way or another. I simply don't recall the totality of the discussion. I mean, clearly I've been reminded and reminded several times of what the conclusions were but, more than that, I don't remember.

Q. There's no reference in here to what we know was, by now, the proposal from Dr Galbraith. There's no

reference in terms, at least?

A. That's right.

Q. There's a suggestion that there was insufficient evidence to warrant restriction of the use of imported concentrates but no more than that and certainly the Inquiry's heard some evidence to suggest that the content of Dr Galbraith's letter wasn't widely known amongst clinicians.

Did it occur to you to share the content of Dr Galbraith's proposal with the Reference Centre Directors?

A. Well, I don't think it can have done if it doesn't appear and, essentially, it is a bit surprising, you might think. The question is whether or not they knew about that proposal. That suggestion came in on 9 May and this meeting was on the 13th. I simply don't know actually. But I think it would have been a good idea if they'd had that paper but there's no reference to that and I don't know that they ever did have.

Q. Then, in terms of the Cardiff case, again, there's really very -- a passing reference to it almost in the minutes.

A. Yes.

Q. Do you recall whether there was any more detailed discussion about it because you were here face-to-face

with Professor Bloom. It was potentially an obvious opportunity to ask more about it.

A. Well, I think the thing is that these notes are so truncated I can't -- I obviously am not recorded as having intervened, so I either was sitting there saying nothing or they simply haven't recorded what I said, nor is there really any, as it were, verbatim record, "Dr This said this and Dr That said that", because you did find that in other meetings. So these notes were really notes. I don't think it could be described as a minute of the meeting.

Q. So if we then turn to Dr Galbraith's letter and then your response setting out your views about it, the letter from Dr Galbraith is CBLA0000043_040.

We've got the letter there, 9 May, addressed to Dr Field and then we can see headed "Action on AIDS", which is then the heading we see, I think, in some later minutes.

Just maybe worth noting he records The Lancet of 30 April, this is in the first paragraph, referring to the three cases in haemophiliacs in Spain. So it may be that that was a mechanism as to how that information got to the Department or into the public domain.

But, in any event, we then go over -- actually,

sorry, can I pick it up, the last paragraph of that letter. He says:

"... I am most surprised that the USA manufacturers of the implicated blood products have not informed their customers of this new hazard. I assume no official warning has been received in the United Kingdom?"

Then over the page we have his paper and his reasons for withdrawal of USA blood products. Now, I'll come to your observations about it in your memo and in your statement but, essentially, what you say this doesn't reflect is the consequences to haemophiliacs of not having the treatment.

A. Yes.

Q. Before we get to that side of the coin, as it were, is there anything particular in what Dr Galbraith sets out here that you disagreed with at the time?

A. Apart from obviously the corollary, which is basically "so withdraw the products", in terms of whether the evidence seemed to be strong enough, clearly there was epidemiological evidence and it was a strong epidemiological association that he was talking about. We were in the situation in which we really didn't know how much of an issue this was going to be in the UK. I mean, he's talking about implicated products in

the USA. Was he talking about specific products or was he talking about the generality of Factor VIII?

We really had insufficient -- really had insufficient evidence that what was being suggested here was the right course of action at this time and, of course, against the fact that, actually, you were going to cause real damage potentially to patients with haemophilia who couldn't get -- who wouldn't be able to get their Factor VIII. The Factor VIII would be cut by about a half, in effect, and so there would be massive rationing because the implication -- he was actually saying withdraw now on a temporary basis. But, on a temporary basis, you would have 50 per cent less Factor VIII in the country to treat haemophiliacs.

So it was a very, very draconian proposal on the basic of one case, and I totally accept that the case in Cardiff was a case, and CDSC had defined it as a case, but we had one case in this country and about 10 or 11 cases in the United States.

So, was the evidence sufficient? Certainly epidemiologically the evidence was strong -- epidemiologically -- but we had no other evidence to support that. We had no transmissible agent, for example, that we could actually identify at that time.

So I was, of course, far from being alone in this thought because Dr Craske, whose letter to Dr Whitehead, who was the director then of the PHLS, said that he personally didn't think the evidence was strong enough at the moment and he thought that there was going to be a need to wait and see what might eventuate. But we had to prepare ourselves potentially for taking more draconian action. So he didn't think the evidence was there yet. And quite clearly, of course, when ultimately it came to be looked at by the Committee on Safety of Medicines biological subcommittee, they didn't think it was sufficient either, or at least they thought -- they concluded that the risk to haemophiliacs at the time was low. And I'm sure you are going to want to talk to me about that.

Q. I will, absolutely, and we will come to that probably tomorrow. But just before we get to that, and we will also look at the remaining bit of Dr Craske's letter that you drew attention to, but if we just -- I just want to get a sense of whether there was any issue, as it were, between you, the Department, on the one hand, and Dr Galbraith about his reasons, as opposed to the corollary.

So, 1, "probably due to a transmissible agent".

Well, that was already your own view and had been for some months.

A. Yes.

Q. "... probably transmitted by blood and blood products."

Again, you were already of that view --

A. Yes.

Q. -- and you said by this time it was a mainstream view within the Department?

A. Yes.

Q. 3 is a recognition that the number of cases at present is very small, but this is a rather important point he makes, isn't it:

"... this may NOT indicate that the risk is small" -- "not" in capitals.

A. Mm-hm.

Q. And then he talks about the period of time that might elapse.

A. Yes.

Q. So that was not news to you, presumably, in May of 1983?

A. No. I think that what I was -- I don't think I had ever been aware of the actual potential range of the incubation period, and in point of fact I think that range, which I think he put from six months to two and

a half years or something like that, was probably, if you like, an underestimate. I mean, certainly the incubation period appeared to be long. I'm not sure how much information we had at the time about the length of the incubation period. I think -- coming back to this of course, as naturally I have come back this and I have looked and I thought: well, there's some inconsistency, to a degree, in what he is saying, though I don't know that I identified it at that time, because he's saying withdraw all the product from 1978. And we chose 1978 because he said that AIDS had first appeared in America in 1978. Well, the implication was that actually product made in maybe 1976 was potentially infected. If we've actually got AIDS appearing by 1978 then, with a long incubation period, actually there were infections in the donor population before 1978.

I think possibly 1978 was a strange number to -- or strange date to suggest that material was withdrawn from, because basically there would have been no such material left in the country. But he was obviously saying, in terms: withdraw whatever you've got. If you will. Which meant actually not only not using the stocks that were in the country but not using any stocks that might be in hospitals around the country

and that might but in people's fridges. You would have had to have called in everything. So you would have immediately needed to say to patients who were having home treatment with freeze-dried Factor VIII, "Sorry, you no longer can have that, hand in all your freeze-dried Factor VIII, and basically we're going to try and see if we can give you some other substitute."

Now, what the other substitute would have been -- as much NHS Factor VIII as was available, of course you didn't know that NHS Factor VIII was going to be free of AIDS. So you might assume that potentially, even if it were in the UK blood supply, and of course we ultimately knew that it was, that it would be much less prevalent in UK donors than appeared to have been the case in American donors, or alternatively cryoprecipitate for a bad bleed, and there was virtually no cryoprecipitate being made in the country at the time. Something like 5 million international units.

So suddenly, as it were, on a sixpence, the country would have had to cut out 50 per cent of the Factor VIII that was being used in the country at the time, certainly all the home treatment and any elective surgery and so on. There would be a question mark over the NHS Factor VIII, but you might still

think that was likely to be safer -- likely to be safer -- and then there was not enough cryoprecipitate to really go around.

So it was the most, as it were, draconian course of action that could be proposed, and the question was could one -- if you acted to do that on, if you like, the precautionary principle, that would be to try to prevent people having American Factor VIII.

On the other hand, you potentially were going to do more harm to haemophiliacs by withdrawing their source of Factor VIII and doing it in a way that would cause chaos and a totally chaotic rationing system. So it was absolutely between a rock and a hard place, if you like. There was no good option available.

Q. I'll come back to some of what you have said at a later stage, in particular what the consequences in terms of harm to haemophiliacs might have been or not been.

Just in terms of the practicalities, this is a defined and known cohort of patients, so severe haemophiliacs at least, by their very nature of receiving treatment as severe haemophiliacs, will each have been registered at a haemophilia centre. So they will be known.

A. Yes.

Q. If they are on a home treatment programme, that will be known.

A. Yes.

Q. If they've got supplies in their fridge, that's either known or not difficult to ascertain?

A. Absolutely.

Q. The Inquiry certainly has received evidence to suggest that some areas had decent supplies of cryoprecipitate. It's obviously a matter that the Inquiry will have to investigate further. It wouldn't have to have been, would it, a question of turning off the type immediately, necessarily? So there could have been a period of working up to the production of increasing the production of cryoprecipitate in Regional Transfusion Centres; non-elective surgery postponed on a temporary basis; treatment -- the amount of treatment used could have been reduced; the amount of concentrates used, so a conservative approach; batch dedication or concentrate dedication, instead of patients receiving multiple different batches from multiple different concentrates.

So there's a whole range of possible strategies that could have been considered but there doesn't appear to be any evidence to suggest that they were considered, either by the Department or indeed by

UKHCDO.

Are you aware of any of those matters being given consideration?

A. In terms of a strategy to try to see what you could do by way of rationing and to minimise the effects of rationing, I am not aware that there was any formal consideration of that. I think the issue, really, is if there's a problem then you need to address it pretty well straight away. That means that you turn the tap off straight away.

Now, absolutely, some regions were making more cryoprecipitate than others but, basically, if you look at the chart that I've put into my evidence, I think that the country as a whole was making about 5 million units of cryoprecipitate, and Dr Lane, in one of his papers, said that actually some of the Regional Transfusion Centres had simply stopped making it altogether and had re-purposed some of their accommodation and would have to set the whole thing up again.

Of course, there was the tension between wanting to be able to provide NHS Factor VIII for those haemophiliacs who really needed it, severe haemophiliacs who might have bled because of surgery or trauma or they had a significant amount of

inhibitors, which meant they were not going to respond properly to cryoprecipitate. So I'm completely sold on the notion that you could have devised a strategy which would have minimised the really significant disruption but what was not there was the time in which to do it. In other words, to get that as right as you could possibly get it, given that you were going to cut the amount of commercial Factor VIII in the country by a half, when you still had a question mark over UK Factor VIII concentrate, but even setting that to one side, you were short about 30/40 million international units of Factor VIII, which could not be readily made up and it would have taken a lot of time, a lot of effort, but potentially you could ultimately have increased significantly the production of cryo in Regional Transfusion Centres but over time.

Q. I think it's right that there wasn't, as it happened, an assessment or exploration of that as an option, as far as we can see, so there isn't anything which says, well, we've assessed it and this is how long it will take because, effectively, it was seen, was it not, as a yes or no, all or nothing question?

A. Yes, I think that's absolutely right. It appeared to be you need to do this straight away, Dr Galbraith's proposition, and I think it was seen as, well,

either/or. There was also the situation that was happening in America, which we got to know about fairly soon after this, which was the whole same considerations were being applied in America and America, the FDA, also took the view that supplies should not be curtailed -- well, because of their concern about the effects on haemophiliacs.

So they weren't withdrawing product in America and, essentially, given that they had more haemophilia sufferers who had actually developed AIDS in America, that wasn't the line that they were taking. They even had a discussion in Congress in America to decide whether or not that should be done, and decided on the basis of supply, reasoning perhaps exactly the way that was being done in the UK, that it just was an impossibility, given the likely effects on haemophiliacs.

Q. I'll come on to some of those matters, in particular, in relation to what was being said in the States and the Department's response to that in due course.

Just sticking with Dr Galbraith, if I may, you may be right that what Dr Galbraith was essentially proposing was turning off the tap --

A. Yes.

Q. -- you have explained why you didn't think you could

immediately turn off the tap but, just because that was what he was proposing, doesn't mean the Department couldn't have come up with a more nuanced slightly longer to implement programme, but there appears to be nothing to suggest anyone applied their mind to that. Is that fair?

A. I would say that's fair.

Q. Just to go back to the same document -- sorry, Soumik if we could have it back on screen -- and if we go to the next page.

A. Can I --

Q. Yes --

A. It was absolutely fair that, actually, nobody was taking the view that we should try to pivot to cryoprecipitate straight away but there were -- thought had been given to turning over to cryoprecipitate and, in fact, to seeing if there was some way for BPL to make small pool products which might potentially be less dangerous, if you like, than the large pool products, and all the thoughts that there were, were discounted on grounds of logistics and practicality.

So I suppose, in a sense, I'm not being fair to the collective view around the time, which was consideration was given to whether we could change

over to cryoprecipitate, consideration was given to whether BPL could produce small pool products and for each matter the view was no, we can't on logistic grounds.

Q. When you say consideration was given to switch over to cryo, are you talking the Committee on the Safety of Medicines decision there?

A. No, I mean, Dr Gunson considered it, Dr Lane considered it, I think people were aware that there might be a call for more cryo and considerably more cryo, and the question was: could that actually be done? Given the state of play with the production of cryo in the RTDs at the time, with about maybe 5 million international units, it takes quite a lot of gearing up for them to be able to make -- not a sufficient amount, they'd never have made a sufficient amount, but to make quite a lot more cryoprecipitate than was being made at the time and, of course, as soon as you don't make cryoprecipitate -- you make cryoprecipitate you're not sending plasma to BPL and they you have got the problem of, well, how are you going to make your Factor IX because you need the cryo supernatant to go to BPL to make Factor IX for the haemophilia B patients, you need to make immunoglobulin and

albumin -- you can make that from time-expired plasma but, basically, you needed the Factor VIII, the cryoprecipitate supernatant to go to BPL.

So you had not just to make cryo at the local RTDs, you had to have a system -- and Dr Lane describes it very well, I think, in his draft evidence for the HIV litigation -- in which Regional Transfusion Centres, totally unused to doing this, would have needed to find a method sterilely to collect the cryoprecipitate supernatant to get it to BPL so that Factor IX could be produced because you did not want to disadvantage patients with haemophilia B while you were trying to advantage patients with haemophilia A.

Q. As far as you can recall, was the assumption on which these matters were being considered an assumption that you'd need to somehow find a way of replicating the amount of concentrate through cryoprecipitate; in other words, the assumption was we've got to continue treatment at the same level, we've got to continue home treatment, because part of an answer to what you're describing might have been a cessation of home treatment, a restriction of concentrates for the truly life-threatening or the necessary surgery, so there were potentially more imaginative adaptive ways of

looking at it, and please correct me if I'm wrong, but I don't think we see it being looked at in that light in the materials?

A. No, I think that's totally fair.

Q. So then if we just -- just to complete this document, we can see there's reference at the top of that second page to the incubation period several months, two years, maybe as long as four years. Then he talks about what the consequence might be in terms of the number of cases seen:

"Factor VIII concentrate ... would appear to have a high risk of being contaminated with AIDS agent because homosexuals and drug abusers are known to be frequent blood donors and each plasma pool from which it is manufactured is collected from as many as 1,000 donors."

In fact, I think the number is probably considerably in excess of that but, again, there's nothing controversial, is there, in terms of what Dr Galbraith was saying there, that was well known to the Department?

A. Yes.

Q. Point 5 I think again is, again, uncontroversial:

"... no known means of ensuring ... blood or blood products are free of the AIDS agent."

At that point in time.

A. Yes.

Q. Reference to the multi-transfused infant. And then, again, a significant fact, a mortality rate, a very high mortality rate articulated in 6. And although there might be different percentages given in different documents, there was no dispute, was there, the mortality rate was a very high mortality rate?

A. It was.

Q. So if we then look at your views at the time as recorded in your memo, or your minute to Dr Field, it's DHSC0002227_047.

So it's 13 May 1983, and you have clearly, from the text, written it after you had attended the meeting at St Thomas'?

A. Yes.

Q. Its addressed to Dr Field, top of the page. So it refers to the letter from Dr Galbraith. You say:

"In my view this suggestion is premature in relation to the evidence and unbalanced in that it does not take into account the risks to haemophiliacs of withdrawing a major source of their [Factor] VIII supplies.

"Perhaps the situation is best put in perspective by a statement which was drafted to appear

in the minutes of the meeting of the Directors of Haemophilia Reference Centres which I attended today ..."

Then we see your note of what was agreed, which I don't think is materially different from what we've seen in the minutes. So "circumspect" to continue the policy in relation to children and mild haemophiliacs to NHS material, "not sufficient evidence to restrict the use", and a suggestion of Regional Transfusion Directors meeting.

If we just go back to your observation in the second paragraph, I think it's -- I understand from your evidence as to why you say Dr Galbraith's suggestion was "unbalanced". Again, please correct me if I'm wrong, I don't read that as you saying unbalanced as in unhinged?

A. No.

Q. You are saying it hasn't put the implications for haemophiliacs into the balance?

A. It was not weighing the -- you know, in public health terms, actually, first do no harm. So you take a public health action, you expect to improve matters and not actually to do harm. Potentially -- potentially -- the action he proposed would cause harm, and his document didn't refer to that at all.

He didn't, apparently, go on to say, "I recognise that this may cause severe and major problems in the treatment of patients with haemophilia". Understandably, because that wasn't his particular discipline, but it wasn't mentioned in his document at all.

Q. As a matter of fact -- that's obviously correct that it wasn't mentioned -- conversely one could say, in terms of the no harm, that where the Department, UKHCDO, the others, ended up was exposing patients to a risk -- we obviously know the full extent of that risk now, but a known risk of a fatal disease?

A. Yes.

Q. So the "do no harm" could apply equally the other way, couldn't it?

A. It could but what we didn't know then -- I mean, there was a huge amount we didn't know then, and I think that is an important consideration, is essentially we were working in nearly total ignorance of almost anything, but what we didn't know then was that subsequently emerged really very good evidence from the use of stored samples, which I know is controversial but nevertheless stored samples were used from the Royal Free, for example, where it was shown that well before the date of this meeting

haemophiliacs at the Royal Free, in fact 100 per cent of the haemophiliacs being treated at the Royal Free, were actually in -- seroconverted, so that they had actually already been infected.

Q. I don't think that's quite right, Dr Walford, but -- because the Inquiry's looked at that data and, indeed, seroconversion data about others, and it's actually a much wider spread, so there is certainly seroconversion --

A. Before.

Q. Before this date.

A. Yes.

Q. But there are also significant numbers of seroconversions after.

A. Of course. I'm not for one moment denying that seroconversions would have occurred afterwards, but there was the issue that a certain number of infections had already occurred. There was nothing you could do about it in fact because it was in the rear view mirror, so to speak, they had actually occurred. And it was a not insignificant number.

So we didn't know that. I am now talking with the retrospectoscope, if you like, the benefit of total hindsight, we didn't know that and I couldn't possibly have concluded it.

What we didn't know was whether this material, this infection, was in the UK blood supply at all, for a start. So that would make UK plasma not safe. But also, had you taken the action proposed here and had a certain number of haemophiliacs been damaged as a result of it, had bled, had had a cerebral bleed, had had a major internal bleed, had had a crippling bleed into joints as a result of that action, and they may have in any case have been infected already, unbeknownst to us, that would have been yet a double blow.

So I would really propose to you that there was no good solution here. There was no good solution. On the one hand we potentially were going to harm haemophiliacs by withdrawing this material, because you couldn't readily actually replace it, and, on the other hand, of course, we were potentially going to do harm by not withdrawing the material because of the transmission of an infectious agent which had, by that stage, hardly put in an appearance in the UK.

Q. I want to come back tomorrow to the question of what the severity of the consequences might have been for haemophiliacs of either a reduction or cessation or change in treatment, so I'll leave that to tomorrow, if I may.

Can I just ask this: you refer to the Royal Free data, you refer to the fact that some people had already been infected, numbers obviously not yet known. But was there an assumption, in your mind or in the minds, as far as you're aware, of any of those who were involved in the decision-making, was there an assumption that played a part: well, if people have been infected, they have already been infected, so there's no point in taking any action? Did that come into the decision-making process?

A. It appears to have come into the decision-making process in the HCDO, because they actually mention that.

I am not aware that that was, in any sense, in my thoughts of the time, nor, I think, did I see it referred to at all in the CSM consideration.

SIR BRIAN LANGSTAFF: It is referred to in HCDO0000003_008, the minutes you have just mentioned.

A. Yes.

SIR BRIAN LANGSTAFF: They were the short notes that you have given. I noticed in passing there seemed to be something of what I thought was an illogicality in it. Can we just go back to that?

MS RICHARDS: Second page.

SIR BRIAN LANGSTAFF: We started just after the break.

MS RICHARDS: HCDO0000003_008.

A. The 13 May one, I think.

SIR BRIAN LANGSTAFF: That's right.

MS RICHARDS: HCDO0000003_008, it's the second page, bottom half of the page. That's it.

SIR BRIAN LANGSTAFF: Can we go up the page, thank you.

It was this, the contrast between these two sentences which caught my eye when we were looking at it:

"It was agreed there was insufficient information available from the US experience to warrant changing the type of concentrate used in any particular patient."

In other words, there's not enough evidence, that people are at risk. But it then goes on to say:

"... once the condition is fully developed it seems to be irreversible so that there would seem to be no clinical benefit to be gained by changing to another type of factor VIII."

So, on the one hand, there's no evidence that anyone has it; on the other hand, it's assuming that everyone has it?

A. On the other hand -- I'm sorry?

SIR BRIAN LANGSTAFF: There is no clinical benefit to be gained by changing to another type of Factor VIII

supposes that the only product available is causing and has already caused the illness which is yet to materialise, isn't that what it's saying?

A. I think what it was saying here, though actually I would almost take issue with the notion that just because somebody has developed "full-blown AIDS" that actually giving them some more virus was necessarily totally harmless. I just -- that struck me as being a very strange way of saying things.

SIR BRIAN LANGSTAFF: You just don't know, do you?

A. You certainly don't know, but what I think they seem to be saying is that if you can possibly -- if this is transmitting, then we have to be very careful with making sure that the right concentrate is used with the right patient, or the right factor, Factor VIII, be it cryo, or DDAVP, or whatever is used with the right patients, so that if they are not already infected there isn't so much of a possibility they will become infected. I think what they are saying here is that once full-blown AIDS is manifest in a patient -- and it had to be said that, apart from Dr Bloom's patient, nobody seen such a case in the UK, but in America if they still needed product because they were bleeding because they were haemophiliacs, then it wasn't going to do yet more harm, is what they

are alleging, to give them the Factor VIII concentrate again, because they were already irreversibly affected and were likely, unfortunately, to die of AIDS.

SIR BRIAN LANGSTAFF: It just seemed to being put forward an argument that even though you did not know whether someone was infected or not, there would be no point in changing because they might already be.

A. Well, I didn't -- I confess I didn't read it that way. My quibble, if you like, was -- when I saw this was with that second sentence, the:

"Moreover once the condition is fully developed ..."

In other words, the patient is known to have AIDS. AIDS with its very significant mortality rate. They are saying that change of product is immaterial because even if changing the product would prevent transmission to patients who hadn't got AIDS, once they already had got AIDS there was -- it was immaterial what product you gave them because they already had the condition and it was irreversible. That was my reading.

SIR BRIAN LANGSTAFF: I follow that. The problem perhaps is the word "moreover".

A. Ah. Well, I'm happy to say it wasn't my word.

SIR BRIAN LANGSTAFF: No, of course, it's not your word,

and it is admittedly, as you would have it, a very truncated summary of what was being said.

A. Yes.

SIR BRIAN LANGSTAFF: But it appears to be using, as a justification for continuing as they were, that if the condition --

A. Oh, I see. Yes, no, sorry, I had misunderstood.

SIR BRIAN LANGSTAFF: That's the significance of the word, "moreover", I think.

A. Yes, I totally misunderstood. And if you took the "moreover" out, it makes more sense, yes, because it was apparently a corollary to -- following on from the sentence before, but it isn't, in effect.

SIR BRIAN LANGSTAFF: Well, it can't be, can it?

A. No.

SIR BRIAN LANGSTAFF: It's either a separate point which has nothing to do with what treatment you give to people who you do not know to have the condition.

A. No, I understand, yes.

SIR BRIAN LANGSTAFF: It can't be a reason for going on as you are doing.

A. No.

SIR BRIAN LANGSTAFF: That was all -- that's what struck me.

Thank you.

MS RICHARDS: Then, just before we finish for today and for the sake of completeness, I just wanted to go back to Dr Craske's letter, because you made reference to his views.

It's WITN4461127, Soumik. We looked at it earlier in the context of the proposal for there to be a working party.

If we go to the third paragraph, there's reference to the meeting on 13 May. It refers to him attending and you'll be attending. It would appear that there's been a discussion between Dr Galbraith and Dr Craske, and reference to him writing to the Department, and, of course, we know that on the day of that telephone conversation Dr Galbraith did write to the Department. Dr Craske's views are expressed in these terms:

"I am not sure myself that we are at the stage when there is enough evidence to justify this step, but I think both the Department of Health and the Haemophilia Centre Directors will have to face this problem in the near future, and the earlier it is seriously considered the easier it will be make a rational decision. I think that the outcome of the meeting will be that we will await the appearance of further evidence, but that if any more cases appear

then this may very well precipitate suspension of the use of this product in the UK."

So Dr Craske's position may have been a little more nuanced, which was: not today but any more cases and it may well be a different outcome.

A. Yes, I hadn't seen this letter until I saw the papers that you sent me. I wasn't aware of his view.

MS RICHARDS: Sir, that's probably a good point at which to finish for today.

SIR BRIAN LANGSTAFF: Just on that last point, you described in your minute that it would be premature to do what Dr Galbraith was proposing.

A. Mm-hm.

SIR BRIAN LANGSTAFF: What would have been sufficient, as you can remember seeing it at the time -- and I appreciate it's difficult to put yourself back into a position which you weren't actually in -- but what did you consider might have been what would have ceased it being premature and made it now the time?

A. Well, I mean, for sure if there had been firm microbiological or virological evidence that this was happening. I think it needs to be understood that, for example, in America there was still a lot of controversy as to what was causing AIDS. So it wasn't a sort of a done deal, if I can put it that way,

anywhere. There was controversy. There was controversy in America, particularly controversy to a degree in this country.

Basically, people were looking at an epidemiological association. An epidemiological association, as I certainly learnt in subsequent years when I did my MSc in epidemiology, is not actually evidence of causation and at the time this was a debatable proposition. Frankly, my own view was that in fact it was transmitting but not everybody felt that.

I'm pretty sure if there had been virological evidence that this was happening and there was some way of actually detecting it through virology, I think that action would have probably been forthcoming much faster than it ultimately was.

SIR BRIAN LANGSTAFF: Thank you very much. We'll take a break there until 10.00 tomorrow. So 10.00 tomorrow. Thank you very much.

(4.33 pm)

(Adjourned until 10.00 am the following day)

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