

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,

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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.

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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

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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

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1 overarching committee in relation to NBTS?
 2 **A.** No, that's right.
 3 **Q.** So, if we now go to the memo that you produced on
 4 19 September 1979, it's at DHSC0003618_023. It refers
 5 to an "attached scheme", so if we just look at the
 6 text, Soumik, thank you. So in the first paragraph it
 7 refers to an "attached scheme" and we will look at the
 8 scheme in a moment. You say:
 9 "It represents my preliminary thoughts on
 10 a complex matter which has been preoccupying you for
 11 a considerably time and I do not doubt that this
 12 scheme, or something similar, is but one amongst the
 13 many options which you may have been considering."
 14 You were fairly new to this job at the time.
 15 I think you had been in post probably for a matter of
 16 weeks at this point.
 17 **A.** Three weeks.
 18 **Q.** What was it that prompted you to come up with your own
 19 thinking and formulation of options?
 20 **A.** Well, my supposition is that I knew I was coming into
 21 a new job. I knew a little bit about this from the
 22 Medicines Division angle. I had Sheila Waiter's very
 23 helpful paper, which obviously I used as a quarry for
 24 my further thinking, but it also seemed to me that
 25 there was an awful lot that needed to be done and,

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1 like, of England, Wales and Scotland all together.
 2 So that was my initial thoughts about Scotland,
 3 and please remember these are initial thoughts and,
 4 obviously, I wasn't at all sure how they would land,
 5 apart from anything else.
 6 Then I foresaw in England that actually we would
 7 do what the Trends Working Party, if 1977 -- that was
 8 the last time there was a working party looking at
 9 plasma supply and what products were needed and in
 10 1977 the suggestion was that cryoprecipitate
 11 production should be phased out. That was of clear
 12 recommendation from the Trends Working Party. So
 13 I picked up on that and said, right, well, if you're
 14 not making cryoprecipitate at Regional Transfusion
 15 Centres that's all the more plasma for the Blood
 16 Products Laboratory, so we can increase the amount of
 17 intermediate Factor VIII, which was the product of
 18 choice at the time, that's the freeze-dried product,
 19 and that was the Trends Working Party product of
 20 choice and, subsequently, the Gunson Working Party in
 21 1981. That was their product of choice as well.
 22 I then have this dotted line. I think what
 23 I was trying to say here is that there had been
 24 a Royal Commission on the NHS. There were all sorts
 25 of plans afoot for restructuring the NHS and one

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1 therefore, I put forward some preliminary thoughts on
 2 what might be done. I actually thought I was putting
 3 them forward only up the medical hierarchy but when
 4 Dr Harris saw them he thought they ought to go
 5 further, so they went up to Mr Wormald and to
 6 Mr Harley as well.
 7 **Q.** If we just look at the scheme and then come back to
 8 the text of the memo, so the scheme is at
 9 DHSC0003618_024. It's a useful way of looking at what
 10 you were putting forward. I wonder could you just
 11 talk us through, using this document, what it was you
 12 were suggesting?
 13 **A.** Right, well I'll start from my left-hand side then
 14 onwards. Basically, what I saw was, as you see, I've
 15 got Scotland at the extreme left of my diagram where
 16 I foresaw that we would send more fresh frozen plasma
 17 to Liberton. In fact, I don't think we were sending
 18 any fresh frozen plasma to Liberton. We had in the
 19 past sent some outdated plasma for fractionation.
 20 Then my view was that you would upgrade and
 21 modify Liberton to help to increase production but
 22 I also saw it as a kind of place where you could
 23 stockpile or keep an emergency supply of Factor VIII.
 24 In other words, it was, to a degree, a fallback but
 25 also to contribute to the national effort, if you

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1 wanted to make sure that everything fitted in with the
 2 restructured NHS but I wasn't aware of what those
 3 plans would entail in detail.
 4 So moving on to the heading "BPL", obviously we
 5 had the inspector's report. The inspector's report
 6 was damning. We needed to do something very quickly.
 7 So immediately I say implement stop-gap, please, which
 8 is why I think I was emphasising yesterday that
 9 I didn't think it was a good idea to stop stop-gap.
 10 Implement stop-gap and then also upgrade BPL to the
 11 extent that the Medicines Inspectorate required to
 12 make it safe.
 13 I then took up from Sheila Waiter's suggestion.
 14 Because I knew we were dealing with an entity, the
 15 Blood Products Laboratory, that simply wasn't a
 16 pharmaceutical factory, it really wasn't fit to make
 17 pharmaceuticals on any scale, although it produced
 18 very good product and went, you know, in its low
 19 volume.
 20 So I thought it would be helpful to have
 21 a commercial firm to fractionate for the NBTS for the
 22 UK under contract. That was my thought initially and
 23 that, actually, I think, coincided quite a lot with
 24 what Sheila Waiter was suggesting and Kabi, being
 25 a Swedish firm, seemed to be quite a good bet for

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

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

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

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

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

3 **A.** Yes.

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

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

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

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

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

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

8 If there were any UK-derived products which had
9 been fractionated, which was surplus to NHS
10 requirements, they could then be sold abroad.

11 I thought the point of having two potential companies
12 in there would be a way of not holding the NHS or the
13 UK over a barrel, if you like, because if you didn't
14 like one what one commercial company was doing you
15 could actually threaten to take away what they were
16 doing and give it to the other company.

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

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

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

4 Then 2:

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

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

17 **A.** If it were done, yes.

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

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

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

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1 plasmapheresis but in case we don't can I just ask you
 2 toll tell us in a sentence or two what plasmapheresis
 3 was and why it was being suggested?
 4 **A.** Plasmapheresis is a way of getting more plasma from an
 5 individual donor than you could do without damaging
 6 the donor's health. So you take a unit of blood from
 7 a donor in the usual way, you centrifuge it -- you
 8 spin it -- you take off the plasma, you give back the
 9 red cells, which is really the cellular component of
 10 blood, which is really what people need to stop them
 11 becoming anaemic and to keep all their systems going,
 12 and you keep the plasma.
 13 Now you can then do that a couple of times so
 14 that you could get, say, 500ml of plasma from
 15 a patient -- from a donor, sorry, at one sitting,
 16 whereas normally speaking you wouldn't take more than
 17 one unit of blood, which may only yield less
 18 than 200ml of plasma.
 19 So this is the system which was, of course, used
 20 extensively in America, but to an extreme degree,
 21 where they were plasmapheresing donors over and over
 22 again, I mean in a way which cannot have been healthy
 23 for the donors themselves, because they were taking
 24 off all this plasma which actually contained some
 25 useful nutrition, if you like, for the body.

1 from it. So you wouldn't actually completely avoid
 2 making cryoprecipitate if you didn't want to, you just
 3 wouldn't be making it at the regional transfusion
 4 centres, which then meant that the plasma wouldn't be
 5 sent to BPL.
 6 **Q.** Now, can I then -- we'll consider the extent to which
 7 these ideas were followed through when we look at some
 8 of the subsequent documents but can we then just look
 9 at a couple of meetings in the same month, September
 10 of 1979. The first is at DHSC0002195_044.
 11 So this is a meeting on 26 September, "An *ad hoc*
 12 group of Regional Transfusion Directors", and we can
 13 see that you were in attendance, along with Dr Lane,
 14 Dr Gunson, Dr Tovey and others.
 15 I just wanted to see whether you can assist us
 16 with the fourth paragraph, I think it is. It says:
 17 "A tendency to revert to cryoprecipitate was
 18 discernible in some regions due, in part, to lack of
 19 money to buy commercial concentrate or to collect more
 20 plasma for fractionation at BPL. It was agreed that
 21 this was yet another example of the way in which the
 22 use of blood products and the development of blood
 23 product production was being distorted by the
 24 availability of products were apparently 'free'.
 25 I wondered if you could assist us with, well,

1 But you could do a plasmapheresis either
 2 manually, which I've just described, or you could do
 3 it continuously in a machine. So machine
 4 plasmapheresis, manual plasmapheresis, either way you
 5 have got more plasma than you would get if you simply
 6 took a donation of blood from a donor.
 7 **Q.** Then if we go over the page we can see, four lines
 8 down, the reference as we saw in the scheme, the
 9 diagrammatic scheme, a suggestion of ceasing the
 10 production of cryoprecipitate.
 11 Now, did you at this point in time, as far as
 12 you can recall, give any consideration to what the
 13 consequences of ceasing production might be, at least
 14 in the short-term, which might be a greater reliance
 15 upon imported concentrates and a greater risk of viral
 16 transmission?
 17 **A.** Well, you know, of course I can't think what I might
 18 have thought at that time but, I mean, one issue here
 19 was: don't make cryoprecipitate at the regional
 20 transfusion centres, send all the plasma to BPL. But
 21 cryoprecipitate is the starting material for
 22 intermediate Factor VIII, so if you wanted
 23 cryoprecipitate in any volume, you could actually make
 24 it at BPL, because they had to make cryoprecipitate,
 25 and then they went on to make intermediate concentrate

1 two parts of this paragraph. The first suggests that
 2 some regions at least were going back to producing
 3 more cryoprecipitate. The second sentence, are you
 4 able to assist us with what that's referring to?
 5 **A.** Well, I suppose Regional Health Authorities must have
 6 balked at buying commercial product if they thought
 7 that they could get BPL product free. Of course BPL
 8 product wasn't free. They were having -- the Regional
 9 Health Authorities needed to pay for the plasma from
 10 the Regional Transfusion Centres to go to BPL. There
 11 was never any proper costing of any of all this but
 12 this was not a cost-free option, if you like, having
 13 it made at BPL, but it didn't feel as painful as the
 14 Regional Health Authority having to put their
 15 metaphorical hand in their pocket to pay for the
 16 commercial stuff, which was very expensive.
 17 **Q.** Then if we just go to the bottom of the page, just to
 18 pick up the theme that we explored by reference to
 19 Dr Lane's paper, we can see there is a discussion
 20 about the administration, the organisation of the
 21 Blood Transfusion Service, and it would appear that
 22 there's as lack of unanimity or consensus about
 23 Dr Lane's suggestion of having a "special health
 24 authority", and a suggestion that there should be
 25 directors co-ordinating the service professionally,

1 which I suppose is what was supposed to be happening
 2 but not quite happening in any event. Is that right?
 3 **A.** Yes. It's interesting that Dr Jenkins referred to
 4 reluctance for the Government to, set up new quangos,
 5 and that was very true. There was a cull of
 6 quangos -- I mean, there was -- throughout my time in
 7 the Department there was a cull of quangos, but there
 8 was always a feeling that quangos were bad and
 9 basically they were uncontrollable so you didn't set
 10 them up.
 11 I think there was some reluctance on the part of
 12 the Department for quite a long time to set up even
 13 the Special Health Authority, which was not a quango
 14 in the quasi-autonomous way. It was under the
 15 control, if you like, of the Health Service. But
 16 there was a reluctance to set up new bodies.
 17 **Q.** Is that possibly one of the reasons why we see again
 18 and again around this time in the papers questions of
 19 new advisory groups, new working parties, new
 20 committees, et cetera, always had to go, it would
 21 appear, to the minister for a decision?
 22 **A.** Yes.
 23 **Q.** Then if we turn to a meeting I think on the same
 24 day -- at CBLA0001005 -- this is a meeting of that
 25 Scientific and Technical Committee for the Central

1 they agreed that the right course was to recommend
 2 that no time would be lost in planning a completely
 3 new plant, even if it was felt that other
 4 possibilities had to be examined concurrently."
 5 Then if we just go to the next page, paragraph 6
 6 refers to Mr Harley's paper. I'm not going to take
 7 time looking at that now but we can see in the second
 8 paragraph under that heading there's then a debate
 9 about commercial involvement, and I'm summarising but
 10 it would appear that the members of the committee are
 11 not supportive of the proposal for commercial
 12 involvement.
 13 So it would appear that there was tension
 14 between what civil servants were proposing to
 15 investigate and explore with ministers, possibly
 16 because they thought that was what ministers might be
 17 most interested in -- I don't know -- and what those
 18 who were members of the committee saw as the right
 19 course. Is that fair?
 20 **A.** I think that's fair. I think one of the things that
 21 bedevils these papers actually, when I came to look at
 22 them after all these years, was the difference between
 23 getting industry involved in fractionating our plasma,
 24 because that's what we needed, we needed that sort of
 25 industrial expertise, and actually some form of

1 Blood Laboratories, and this would, I think, have been
 2 your first meeting as joint secretary?
 3 **A.** Mm-hm.
 4 **Q.** Then if we go to page 2 we can see, at paragraph 5, it
 5 refers to the report by the Medicines Inspectors, and
 6 there's a discussion about the issue both of
 7 short-term upgrading and longer term redevelopment.
 8 If we look further down towards the bottom half
 9 of the page, the penultimate paragraph begins:
 10 "Dr Dunnill said that he was disturbed by what
 11 he had read in the report and by the absence of any
 12 clear commitment by the Department to put matters
 13 right. The Committee now shared with the Director the
 14 responsibility for the safety of the products made at
 15 BPL. Both Dr Dunnill and Mr Smart expressed doubts
 16 about the advisability of proceeding with short-term
 17 measures without a commitment to the full-scale
 18 rebuilding of BPL."
 19 Then Mr Smart's estimate of how long it would
 20 take to achieve that new building was three years.
 21 Then we see:
 22 "Mr Harley [asking] whether the Committee felt
 23 that they could confidently dismiss the other options
 24 set out in his paper for Ministers. Members doubted
 25 whether all the options were available in practice and

1 takeover by industry which meant that, in fact, you
 2 had a wholly new company, a commercial company, which
 3 owned BPL and then, of course, it was out of
 4 everybody's control what would then happen.
 5 So there's the difference between the two and
 6 I'm not ever quite sure what is being referred to in
 7 these various papers.
 8 I think there's no question that from the word
 9 go the committee wanted to get on and rebuild BPL.
 10 I have to say they weren't alone in that view but
 11 there were obstacles because actually this was not
 12 a course of action that was immediately attractive to
 13 ministers.
 14 **Q.** You say they're not alone in that view. I detect from
 15 your answers yesterday that you share that view?
 16 **A.** I shared that view.
 17 **Q.** The obstacles, if I can put it that way, were to some
 18 extent political because decisions had to be made
 19 about funding, bids had to be made to the Treasury
 20 and, as we'll see in some of the papers, but I know
 21 you have read them all, Dr Walford, there was also --
 22 there's reference to the new Government being more in
 23 favour of the involvement of the private commercial
 24 sector than perhaps earlier governments had been.
 25 **A.** Yes. I think that is obviously a factor but I think

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

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

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

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

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1 fair, "Put the brakes on because we're not at the
 2 stage of being able to start that work"?
 3 **A.** I think, to be absolutely fair to Mr Harley, who was
 4 himself scrupulously fair and an excellent civil
 5 servant in my opinion, to be fair to him he knew that
 6 there wasn't ministerial approval, we hadn't obtained
 7 ministerial approval yet, we certainly would need to
 8 before going ahead and committing to rebuilding and,
 9 indeed, to any degree of additional expenditure. So
 10 although this looks very negative and a drag anchor,
 11 if you like, he probably had to do that because that
 12 was his job.

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

18 "Remedial action of two kinds is needed:
 19 "(a) money is required immediately to upgrade
 20 the existing facilities;
 21 "(b) a completely new plant must be planned and
 22 built with the greatest urgency.

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

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

2 **Q.** So HS2?

3 **A.** Yes.

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

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

19 Then he goes on to say:

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

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

25 So that's Mr Harley essentially saying, is this

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1 Then 3:

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

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

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

14 **A.** Get on with it --

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

16 **A.** Yes.

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

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

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1 Ministers favoured transfer of functions from the
 2 public sector to the private sector where this was
 3 likely to improve efficiency."
 4 Then reference to Mr Smart's view to the
 5 contrary that this should be done by the NHS. Then
 6 the next paragraph:
 7 "It was agreed that undertakings to move towards
 8 national of NHS self-sufficiency in blood products did
 9 not preclude industrial participation in the purely
 10 technical process of fractionating plasma."
 11 Then we have Dr Tovey setting out his concerns
 12 and Mr Harley, bottom of the page, referring to
 13 possible union concerns.
 14 If we then go over the page we can see what the
 15 upshot of the meeting is:
 16 "It was agreed that Mr Harley should continue
 17 with his options paper but in practice there appeared
 18 to be only two courses to put to Ministers:
 19 "(i) to spend the minimum necessary to upgrade
 20 BPL while at the same time rebuilding and expanding
 21 the laboratory within the NHS using NHS capital if
 22 available or significant alternative sources of funds
 23 if not.
 24 "(ii) to spend the absolute minimum ... to
 25 satisfy to Medicines Inspectors and to seek

25

1 have to be put to ministers.
 2 Then, bottom of the page, we can see this. It
 3 refers to a draft, I think that was a draft of
 4 a proposed letter to the Medicines Inspectorate.
 5 **A.** Yes.
 6 **Q.** We don't need to worry about that. But if we pick it
 7 up halfway down that paragraph, Mr Wormald says:
 8 "The availability of this money [so further
 9 expenditure for BPL] can by no means be assumed.
 10 Certainly there will be no extra in 1979/80. Until we
 11 have explored the financial position further we cannot
 12 put forward these proposals to Medicines Division
 13 except in very tentative and contingent terms ..."
 14 Then, over the page, there's a reference in
 15 paragraph 7 to the possibility of sending a holding
 16 reply to the Medicines Division and then a reference
 17 in paragraph 8 to suggesting to Mr Nodder -- is
 18 that --
 19 **A.** Mm-hm.
 20 **Q.** -- that he should call an early meeting. Who was
 21 Mr Nodder?
 22 **A.** He was Mr Wormald's boss, he was the deputy secretary.
 23 **Q.** So, again, it would appear to be the proposal is to,
 24 as it were, tentatively approach ministers, is that
 25 fair?

27

1 an agreement with industry to fraction NHS plasma [and
 2 so on].
 3 "It was agreed that the first practical step was
 4 to find out as soon as possible what facilities
 5 industry was able to offer and on what terms."
 6 So, is this right, there's an internal
 7 departmental decision to investigate further the
 8 contribution that could be made by commerce, by
 9 industry, before anything was going to be put to
 10 ministers?
 11 **A.** Well, I think actually they had to approach ministers
 12 on the question of involving industry anyway.
 13 **Q.** Yes. So it's a decision to find out more about the
 14 possibility of commercial involvement at that point in
 15 time.
 16 **A.** Yes.
 17 **Q.** Then if we pick that up in a memo from Mr Wormald at
 18 DHSC0003743_193, this is the following day. It refers
 19 to the meeting and, you're right, the meeting is --
 20 it's now talking about what they are going to put to
 21 ministers. Paragraph 2, it suggests that:
 22 "... we shall seek agreement to entering into
 23 discussions, via Supply Division, with the interested
 24 commercial firms ..."
 25 Then paragraph 3 refers to the choice that will

26

1 **A.** Yes. I mean, the draft that I had written to respond
 2 to the Medicines Inspectorate, which of course I have
 3 reviewed because you sent it to me, actually I found
 4 it quite difficult to be critical of that draft.
 5 I wasn't entirely sure what Mr Wormald was concerned
 6 about but, of course, it's perfectly obvious that
 7 I was -- in effect, it was implicit in my draft that
 8 rebuilding would be done, that we would one way or
 9 another rebuild BPL and, meanwhile, these were the
 10 proposals that we had to upgrade the BPL, insofar as
 11 we could to meet their requirements. You could never
 12 have met all of the Medicines Division requirements
 13 without a rebuild but you could get to the point where
 14 you hoped to satisfy them to a degree and, obviously,
 15 also perhaps then to be able to increase production.
 16 The problem with my draft, as I see it, is that
 17 it was implicit that we were going to rebuild and we
 18 hadn't got ministerial permission so, obviously,
 19 Mr Wormald was right, if you like, to rein back and
 20 say I have problems with Dr Walford's draft, although
 21 he hasn't actually spelt that out, but that is clearly
 22 what he meant. At least I hope that's all he meant
 23 because otherwise I thought it was a jolly good draft.
 24 **Q.** Then if we just go to DHSC0003813_052, we can see from
 25 this letter from Mr Dutton to Dr Lane,

28

1 6 December 1979, there's an agreement to proceed with
 2 some reasonably limited interim works and
 3 investigations on the basis it doesn't involve any
 4 further expenditure, it comes out of the existing
 5 allocation. We don't need to go through the details
 6 of the works but is it right to understand then that
 7 it's taken, by this time, well over six months to get
 8 from the damning inspection report, even to some
 9 limited interim works in response?

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

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

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

3 "Ministers are asked:

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

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

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

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

22 **A.** Yes, that's right.

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

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

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

9 This just gives us the date, it is
 10 20 December 1979, it's Mr Harley to Mr Nodder and it
 11 refers to the accompanying paper and it's a rewrite of
 12 that draft submission that we looked at yesterday that
 13 you prepared an initial draft of. Then if we go to
 14 the actual submission, DHSC0002307_050, just perhaps
 15 note whilst we're here paragraph 3, which says:

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

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

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

1 George Young, I understand, who says:

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

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

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

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

19 **A.** That's right.

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

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

1 about six lines in, it refers to Mr Smart thinking
2 that:
3 "... the position which the Department appeared
4 to be taking up was not an attractive one. Dr Dunnill
5 remarked that it was not one which was in any way
6 technically acceptable. The Committee agreed that, as
7 presented to them, they could not endorse the views
8 attributed to Ministers."

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

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

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

22 **A.** Absolutely.

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

33

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

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

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

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

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

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

35

1 actual recollection of that?

2 **A.** None at all.

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

7 **A.** Yes.

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

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

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

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

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

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

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

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

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

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

5 **A.** Yes.

6 **Q.** -- particularly the American pharmaceutical companies?

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

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

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

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

4 Then we can see the conclusions in paragraph 9:

5 "... agreed:

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

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

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

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

18 Then, top of the next page:

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

22 So that's where we get to by the end of March of
 23 1980.

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

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

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

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

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

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

4 **MS RICHARDS:** Paragraph 6, second paragraph.

5 **SIR BRIAN LANGSTAFF:** What did he mean by that?

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

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

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

1 understand on the basis you have just set out, but
 2 it's making money, as if it were a commercial concern.
 3 **A.** Well, yes, and there was a consideration at some stage
 4 that the BPL actually manufactured -- had spare
 5 material from its manufacture that was actually
 6 surplus to UK requirements and that they would then be
 7 throwing away, which is what they were doing. So if
 8 this material was actually something that other
 9 countries wanted or could form the basis of some of
 10 their own fractionation and they would pay for it,
 11 then potentially, since it was surplus to NHS
 12 requirements and it would otherwise be thrown away,
 13 and on no other basis, that could be used as a way of
 14 earning some money for UK Government.

15 **SIR BRIAN LANGSTAFF:** Yes, thank you.

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

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

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

41

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

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

9 **A.** Unfortunately, yes.

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

12 **A.** Yes.

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

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

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

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1 Technical Committee.

2 CBLA0001093.

3 We can see the date of the meeting is
 4 23 April 1980. If we go to the bottom of the second
 5 page, we see, picking up in the last paragraph,
 6 Mr Smart repeating his I think concern about how
 7 realistic it was to find a British company that could
 8 take on the task. He repeats that there's no British
 9 company with fractionating expertise and, at the top
 10 of the next page, he sets out a number of reasons why
 11 it might be difficult to find a British company
 12 willing to engage.

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

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

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

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

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 20 given specific instructions that the proposals should
 21 be completely reexamined with a view to cutting the
 22 cost very substantially."

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

43

1 **A.** Yes.

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

10 **A.** Yes.

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

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

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

18 And then this:

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

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

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

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1 exasperated.

2 **Q.** Because he thought ministers were taking the wrong

3 course?

4 **A.** There was a clear course of action which was necessary

5 at that time. It was barn-door obvious and yet,

6 somehow or other, it wasn't possible to make progress,

7 and so what Dr Harris was doing there was actually

8 saying, "We must get on". He was encouraging that the

9 final submissions should go to ministers and that

10 decisions ministers should be encouraged to

11 understand, but that at the end of the day they took

12 responsibility if something went wrong.

13 **Q.** Is it right to understand we're still talking about

14 what should be done in the short-term here?

15 **A.** Absolutely in terms of keeping things going for the

16 short-term, but there had to be a commitment to

17 rebuild because without that clearly the entire

18 edifice was not going to be fit for purpose.

19 **Q.** Then I think, for the sake of completeness, we should

20 look at DHSC0002313_046.

21 This is Dr Harris, 9 June 1980, again to you and

22 to Mr Wormald, saying in that first paragraph: we've

23 got the further information we needed from Dr Lane

24 and -- and this is halfway down:

25 "... the critical factor is that close

45

1 "In my view, the essence of the question is: is

2 the up-graded BPL to be a fore-runner of a new

3 laboratory, or not?"

4 Is this right, you were saying, "Rather than" --

5 and I'm paraphrasing so please say if I'm wrong --

6 "Rather than make an *ad hoc* decision about short-term

7 improvements and don't take a decision about the

8 longer term, you've got to do both and you've got to

9 do now"?

10 **A.** Yes.

11 **Q.** "Because decision on the longer term will help you

12 decide what you need to do in the shorter term"?

13 **A.** Exactly.

14 **Q.** Then we can see, if we just pick it up at

15 DHSC0002315_007, we're now the second half of July, or

16 18 July, and we've got some discussions, it looks like

17 on a fairly provisional basis, with some British firms

18 have begun. So we have Beechams interested in taking

19 discussions further, and there's going to be

20 pre-meeting and then a meeting with Beechams to

21 consider possible principles, so it's still quite

22 a drawn out process that might be contemplated, and

23 Mr Hart, who was in the Supply Division, remained

24 sceptical, we can see from paragraph 2, but thinks

25 it's worth trying, and there's also reference to

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1 examination of the proposed expenditure does not

2 indicate any possible savings and, in fact, if we are

3 going to ask Dr Lane to increase production there may

4 be a slight increase in costs. These factors should

5 not deter us from getting a submission to Ministers as

6 soon as possible."

7 So is this right that the civil servants are

8 going to be actually going back to ministers and

9 saying, "We can't make you the savings you have asked

10 us to make and, if anything, you're going to have to

11 agree to spend more money just in the short-term"?

12 **A.** And, indeed, that's precisely what happened -- had to

13 spend considerably more money than had initially been

14 the intention -- and certainly there was no question

15 of a reduction in the amount of money that was going

16 to be spent in the short-term, which is of course what

17 Dr Vaughan had hoped there would be.

18 **Q.** We can see in the same month you write memo to

19 Dr Harris.

20 It's at DHSC0002307_008.

21 I'm not going to go through it in great detail.

22 It's dated 12 June 1980, and again it's talking about

23 a submission on short-term upgrading. Is it right, if

24 we pick it up just halfway down to the page, you say:

25 "I think this will miss the central issue.

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1 discussing possibilities with two other companies,

2 Boots and Fisons.

3 If we then look at the ministerial submission,

4 which is at SCGV0000127_046, we can see it's provided

5 under -- it's a memo dated 24 July 1980 to Mr Knight.

6 Who was Mr Knight?

7 **A.** He was, I think it was, Dr Vaughan's private

8 secretary, but I couldn't be absolutely certain.

9 **Q.** That sounds right. Then, again, I'm not going to go

10 through the detail of the submission but we can pick

11 it up, I think, just in two paragraphs, so paragraph 2

12 on page 2 it says:

13 "Officials have ... reviewed, with the Director

14 [so with Dr Lane], the proposed short-term measures,

15 taking account of the possibility of increased

16 production ..."

17 And the recommendation is:

18 "... capital expenditure of £1.3 [million] over

19 this year and next, and increased revenue expenditure

20 of £0.1 [million] to come into effect over the same

21 period."

22 If we go to page 5 -- I'm sorry, page 6, Soumik,

23 paragraph 16 we can see the decision that the

24 ministers are being asked to agree is whether

25 a revised programme of improvements to BPL should be

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1 put in hand.

2 So, again, important to understand we're in late

3 July 1980 and this is now a decision about --

4 **A.** Interim.

5 **Q.** Interim measures still?

6 **A.** Yes.

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

8 **A.** Yes.

9 **Q.** I don't think we need to go to it but this proposal

10 was agreed by a minister?

11 **A.** It was.

12 **Q.** Within a few days. If we then look at CBLA0001171,

13 we're now in September of 1980. This is a further

14 meeting of the Scientific and Technical Committee, and

15 again you're in attendance as joint secretary, and if

16 we go to the bottom of page 2 we can see from

17 paragraph 8, no doubt pursuant to the ministerial

18 approval from at the end of July, that the upgrading

19 work has now started and is progressing.

20 And then the long-term redevelopment is

21 discussed. We can see from paragraph 9:

22 "... officials have been instructed by Ministers

23 to investigate the possibility of collaborating with

24 private industry ... Initial discussions had taken

25 place ... paper was to be submitted to Ministers

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1 have."

2 What were you referring to there in terms of

3 your other worries?

4 **A.** Well, I think I was as concerned. I mean, everybody

5 in the Department who was looking at this could see

6 the enormous complexities of actually trying to

7 involve a firm in doing this for the Blood Transfusion

8 Service, if you like, and those were quite well set

9 out in the submission, which went -- ultimately went

10 to ministers about the involvement of industry. So

11 whichever way you looked at it, it was going to be

12 complex and negotiations were going to be difficult,

13 and the question became: how confident would we have

14 been that we could keep people to their agreement once

15 setup had been handed over?

16 So I think everybody had a very big question

17 mark over the whole feasibility of going with any

18 firm, Beechams or any other firm, but I wasn't in this

19 particular minute trying to comment on that because

20 that was already understood and everybody was thinking

21 about it and working out how to express those

22 problems.

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

24 "The principal medical worry is presented by

25 Beecham's intention to import plasma for

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1 setting out advantages and disadvantages of such

2 arrangement."

3 Then we can see, again, paragraph 10, the

4 committee, or at least several members of the

5 committee, expressing concern at the possibility of

6 a commercial company taking over BPL.

7 So we are, in September, it would appear, still

8 at the stage of initial discussions only with possible

9 British firms?

10 **A.** Yes.

11 **Q.** Then I think it's within that context that we go back

12 to your memo of 15 September 1980, which we looked at

13 yesterday, when we were looking at hepatitis, and

14 we'll just look at this before we break.

15 WITN0282008.

16 So this is your memo about the possible takeover

17 by industry. You say:

18 "I think it is best if I confine my comments on

19 the possible take-over of BPL by Beechams ..."

20 Which I think by now was the only possible

21 contender?

22 **A.** That's right.

23 **Q.** "... to purely technical and medical comments,

24 although I do have major worries about many other

25 aspects of the proposals, as, I think, you yourself

50

1 fractionation. Unless it were Beecham's intention to

2 process such plasma in an entirely separate plant or

3 with complete duplication of all facilities in

4 a single plant, it would be impossible to prevent

5 contamination of the UK material with imported

6 hepatitis viruses."

7 Then we looked at what you set out below

8 yesterday.

9 So you're raising a concern about imported

10 plasma and risk of hepatitis?

11 **A.** Mm-hm.

12 **Q.** Then you say this:

13 "In my view, the Department has a moral

14 obligation to ensure that any collaboration with

15 industry does not increase the health hazards not only

16 to recipients of blood products but to the community

17 as a whole."

18 Can you just help us in understanding why you

19 characterised it in those terms, what you meant by

20 "moral obligation"?

21 **A.** Moral obligation was -- it's not something that if

22 you -- I was trying to say don't actually proceed with

23 a plan that potentially could damage the health not

24 solely of the recipients of blood products but,

25 because this was a communicable disease, also the

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1 community as a whole. So I hope it sort of speaks for
 2 itself.
 3 I was concerned about the health impacts of
 4 potentially contaminating the UK plasma supply that
 5 was being used to fractionate and make Factor VIII and
 6 other products.
 7 **Q.** So would it be right to understand that essentially
 8 what you're saying it would be a morally wrong thing
 9 to do?
 10 **A.** That's what I think I was trying to say, yes.
 11 **Q.** So that's your first concern. Then your second
 12 concern, paragraph 2, was that if the Department
 13 didn't agree to imported plasma, Beechams would
 14 probably feel constrained to obtain the necessary
 15 extra volume of plasma by buying it in the UK, and you
 16 were concerned that that would lead to the
 17 establishment of plasmapheresis centres for paid
 18 donors and undermine the voluntary donor principle in
 19 the UK. That's probably fairly self-evident as to
 20 what you're saying there.
 21 You there refer to a visit to Liberton and the
 22 possibility of Liberton expanding production, which
 23 obviously your memo a year earlier had outlined, and
 24 I'll come back to the question of what happened in
 25 relation to Liberton in due course.

1 likely usage.
 2 **MS RICHARDS:** Sir, that's probably the right point at
 3 which to take a break.
 4 **SIR BRIAN LANGSTAFF:** Yes. Well, let's take a break now
 5 until 11.45.
 6 **(11.18 pm)**
 7 **(A short break)**
 8 **(11.46 am)**
 9 **MS RICHARDS:** Dr Walford, before we then look at the
 10 submission that went to ministers on the topic of
 11 commercial involvement, there's just, chronologically,
 12 one further document from this period I want to ask
 13 you to look at. It's DHSC0002199_055.
 14 It's a minute from Dr Oliver to you, copied to
 15 Mr Wormald, date 30 September 1980. It says:
 16 "On the question of self sufficiency of products
 17 for the treatment of haemophilia I had an informal
 18 talk with Dr Tovey. As I understand the position it
 19 is unlikely we could ever become self sufficient for
 20 Factor VIII to treat all haemophiliacs. However self
 21 sufficiency could be achieved if there were
 22 an accepted policy by those treating haemophilia to
 23 treat most haemophiliacs with cryoprecipitate and
 24 reserve purified Factor VIII for say 20 per cent of
 25 cases needing special treatment (eg for surgery

1 Then if you go over the page, you comment on
 2 certain figures in terms of demands for plasma. I'm
 3 not going to ask you about the detail of that but
 4 I just wanted to ask you about the last four lines.
 5 You say that:
 6 "The projected requirements of Factor VIII,
 7 which were based on advice given to the Department
 8 earlier this year, may have to be reviewed in the face
 9 of very recent evidence which indicates that UK
 10 clinicians are coming under pressure from various
 11 quarters to step up the dosage regime for the home
 12 treatment of haemophilia."
 13 Are you able to assist us with what that refers
 14 to? What was the pressure and who were the various
 15 quarters?
 16 **A.** I don't know precisely who were the various quarters
 17 but basically there was pressure to do more by way of
 18 prophylaxis. I think that's presumably what I must
 19 have meant by that. Essentially, we knew that
 20 whatever amount of Factor VIII was currently being
 21 used, and the projections were that we were going to
 22 need more, the projections which were being considered
 23 were 90 million international units. Certainly
 24 Dr Lane's view was we needed to plan for 120 million
 25 international units based on what he could see was the

1 et cetera). Other countries apparently do this
 2 successfully.
 3 "Though less easy to give than purified
 4 Factor VIII, cryoprecipitate is seemingly clinically
 5 acceptable. If all this is true and the policy were
 6 accepted it could have a significant impact on the
 7 need for imported plasma and the BPL development and
 8 could perhaps tide us over until Factor VIII was
 9 genetically engineered."
 10 Then if we look at -- sorry:
 11 "Or have I got it all wrong?"
 12 Then if we look at the handwriting towards the
 13 bottom of the page, someone has put a note:
 14 "(And how do we persuade clinicians to use
 15 cryoprecipitate?!)"
 16 Then someone has said:
 17 "Let us await Dr Walford's reply."
 18 Then, bottom of the page:
 19 "Checked with Dr Walford's PA. 13.10.80.
 20 "Dr Walford has not yet replied to Dr Oliver's
 21 minute."
 22 Dr Walford, we haven't, as yet at least, traced
 23 a reply. That doesn't mean there wasn't one because
 24 there are other documents we have been unable to trace
 25 from this time. Can you recall this exchange and your

1 reply?

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

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

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

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

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

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

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

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

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

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

3 **A.** Yes.

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

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

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

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

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1 just check the date of this one.

2 **Q.** It's 30 September 1980, if we just look -- that's it.

3 **A.** So it was Dr Gunson's worked party, I think, was set

4 up in February 1981 to look at plasma supplies and

5 Dr Tovey was one of the advisers to that working

6 party. So that would have been exactly a prime forum,

7 if you like, for him to make this suggestion.

8 I hadn't seen from the papers that he did.

9 **Q.** If we then, again, pick up the thread then of the

10 issue about BPL's redevelopment and go to WITN -- no,

11 sorry, that's the wrong reference. If we go to

12 DHSC0002307_069, this is a minute from Mr Wormald to

13 Mr Nodder and to Dr Harris and to Dr Knight, so it's

14 going to the ministerial private offices and to the

15 Deputy Chief Medical Officer, is that right?

16 **A.** That's right.

17 **Q.** It's dated 14 November 1980. We can see he refers in

18 paragraph 1 to attaching a submission, long and

19 complex, but the issue is a complex one, and then

20 paragraph 2, he says:

21 "I should point out that the submission directs

22 itself to the issue of 'whether or not Beecham'. It

23 does not deal fully with other issues, which will need

24 further consideration if the answer to Beecham is

25 negative."

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1 blood

2 "health and ethical problems relating to the

3 import and export of plasma and products ..."

4 Would it be right to understand the health

5 problems is referring to the increased risk of

6 hepatitis?

7 **A.** Yes.

8 **Q.** Then:

9 "the possibility that the company could exploit

10 their monopoly position to impose higher costs on the

11 NHS."

12 There's reference then to strong opposition,

13 which the proposal would undoubtedly arouse, and he

14 refers to being:

15 "... particularly impressed by the fact that

16 none even of our outside advisers -- including

17 Dr Dunnill who has acted as consultant for many firms

18 including Beecham -- favour the proposal on balance."

19 We know, of course, Mr Smart was strongly

20 opposed to it.

21 Then, if we go further down the page, the

22 heading "Recommendation", he says:

23 "I have involved myself closely in the

24 discussions leading up to this submission both with

25 Beecham and with our advisers -- and have given it

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1 Then he sets out some weaknesses of the present

2 arrangements, I'm not going to go through the detail

3 of that. Under the heading "Plasma supply" in

4 paragraph 6, he essentially, I think, says words to

5 similar effect to what we saw in your memo of

6 15 September. Picking it up five lines down:

7 "All our advisers -- not only those from the

8 NBTS itself, but those from industry and academia --

9 believe that commercialisation would make it difficult

10 to increase our plasma supply from voluntary sources,

11 or even to maintain it. I agree that this is a major

12 risk."

13 He talks about the possibility of losing

14 a substantial number of donors.

15 Then, if we go over the page, we can see there

16 is a heading "Summary". He sets out the major

17 advantages of an arrangement with Beecham: provision

18 of commercial management expertise; transfer of

19 technological risk; short-term expediency of their

20 putting up the capital for redevelopment; and speed.

21 Then the main disadvantages.

22 "... the risk to the voluntary donor programme

23 and implications if our plasma supply contracts or

24 cannot be expanded

25 "the associated issue of commercialisation of

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1 much thought over a prolonged period. The advantages

2 and disadvantages are substantial, and I foresee

3 continuing problems of both investment and management

4 if we remain BPL within the NHS. The Beecham

5 proposals are, at this stage, helpful and reasonable.

6 From the point of view of fractionation pure and

7 simple I would advocate Beecham. Nevertheless my

8 conclusion is that wider disadvantages outweigh the

9 advantages -- and in particular that the likely impact

10 on the donor programme and possibly on the whole

11 voluntary donor principle is too substantial to

12 incur."

13 Then, paragraph 12, he says:

14 "I think it important we should reach a decision

15 in principle now: that is we should either reject the

16 commercial option or decide that we intend to

17 implement it subject to satisfactory negotiations.

18 A decision merely to continue negotiations, without

19 commitment in principle, would prolong uncertainty,

20 encourage continued argument and further damage morale

21 at BPL. And it would not be fair to Beecham."

22 Then a number of decisions set out at the top of

23 the next page: do we enter into detailed negotiations

24 with Beecham and, if so, on what basis; do we abandon

25 discussion and instead formulate plans to redevelop

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1 BPL with public funds; and then (d) should we explore
 2 other possibilities, eg the Red Cross and NEB?
 3 That's the National Enterprise Board, is it?
 4 **A.** Yes.
 5 **Q.** "... even though there is no present indication that
 6 they will be able to help us."
 7 So then we can see reference in paragraph 14 to
 8 the forthcoming Granada programme, that's a Granada TV
 9 programme, I will come back to that.
 10 So that's the memo which sets out Mr Wormald's
 11 views in summary form. We can take, I think, the
 12 submission, therefore, shortly but I will put it up on
 13 screen. It's DHSC0002307_070. We can pick it up in
 14 paragraph 2. It refers to the Minister of State
 15 having authorised the short-term upgrading of BPL and
 16 officials being asked to explore the possibility of
 17 a British pharmaceutical company, rebuilding of
 18 facilities, manufacturing of blood products. This
 19 paper reports on our discussions with industry and
 20 seeks decisions on the proposals made by Beecham
 21 Pharmaceuticals Limited.
 22 Then, if we go over the page, paragraph 8 --
 23 sorry, if we pick up the last sentence of paragraph 7:
 24 "Beecham would have the option to terminate the
 25 contract and either get out of the business altogether

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1 develop a wider business."
 2 Then:
 3 "They have a reputation for being very
 4 'hard-nosed'.
 5 "Medicines Division have a low opinion of them,
 6 as meeting only minimum manufacturing standards."
 7 Then over the page, it says:
 8 "None of this amounts ... to good reasons for
 9 not using them -- subject to negotiating satisfactory
 10 terms ... they probably represent as good a commercial
 11 bet as we are likely to get."
 12 Then the options as set out in the memo.
 13 So this is November 1980. So, essentially, it's
 14 taken to the tail end of 1980 to get to the point
 15 where ministers are being asked just to make the
 16 in-principle decision: do we go further with Beecham
 17 or not? Do you have any observations about that
 18 timescale, Dr Walford?
 19 **A.** My observation is the same as the observations about
 20 the entire timescale. It was very protracted,
 21 unnecessarily so in my view.
 22 **Q.** Then we can see if we look at HCDO0000394_052, a press
 23 release which records the Minister's decision. There
 24 is also a written Parliamentary question and answer
 25 but this is 26 November 1980, "No commercial

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1 or set up in business as a commercial supplier of
 2 blood products.
 3 "There is little doubt that the latter is their
 4 long term aim. It seemed clear in our discussions
 5 with them that their objective is similar to that of
 6 foreign companies which have approached the
 7 Department, namely to set up a factory in the South of
 8 England to import blood plasma and export blood
 9 products."
 10 There's then a discussion about various
 11 considerations. If we go to the bottom of the next
 12 page, we see the risk of hepatitis there being spelt
 13 out in paragraph 13. Then if we go over to page 7,
 14 please, we can see it's set out in paragraph 20(a):
 15 "... we do not know Beecham's objectives ... we
 16 believe their chief object is to get into the
 17 international blood product market."
 18 Then if we look towards the bottom of the page
 19 it's said against Beecham:
 20 "It is likely that they want the NHS primarily
 21 to [lean] on."
 22 **SIR BRIAN LANGSTAFF:** "Learn on".
 23 **MS RICHARDS:** "Learn on", sorry:
 24 "They may not see it as the top priority
 25 [Freudian slip there] for their attention once they

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1 management of Blood Products Laboratory, Modernisation
 2 programme already underway says Dr Vaughan". Then if
 3 we look towards the bottom of the page, we can see the
 4 penultimate paragraph:
 5 "There have been rumours we intend to hand the
 6 laboratory over to a commercial company to run. This
 7 is not so. We thought it only right to examine
 8 a number of different ways of developing the
 9 laboratory, including possibly bringing in commercial
 10 management. But we have decided against this."
 11 So two points, Dr Walford: first of all, this is
 12 a public communication of the Minister's decision,
 13 essentially in answer to Mr Wormald's question, don't
 14 take discussions right further with Beecham; is that
 15 right?
 16 **A.** Yes.
 17 **Q.** But, secondly, is it right to understand or is it
 18 right to say that it was not the case that the
 19 Department was exploring handing over the laboratory
 20 to a commercial company to run?
 21 **A.** As one reads this, which was obviously written by the
 22 press office but with ministerial sanction, that's
 23 what they are saying. I think we've seen otherwise
 24 looking at the papers.
 25 **Q.** So it's not an entirely accurate characterisation of

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1 what's been looked at?

2 **A.** It's decidedly not accurate.

3 **Q.** I don't know whether you would know the answer to this

4 but it's a question I've been asked by some to raise

5 with you. Do you know whether, and we've seen

6 reference to it, the forthcoming Granada TV World in

7 Action programme was what caused the Minister to take

8 a different view?

9 **A.** The issue for me is that I don't know what that

10 programme was. I don't even know if I saw it or

11 whether I may have seen it subsequently. I simply

12 don't know what that programme was. But it might have

13 been something which accelerated a ministerial

14 decision, if you like, but I don't know what the

15 programme actually was about.

16 **Q.** Don't worry. We'll be looking at that programme again

17 in later hearings.

18 Would you -- just standing back now, as it were,

19 with the helicopter overview that you referred to

20 earlier, Dr Walford, was it a mistake for the

21 Department to embark upon what turned out to be

22 a fairly prolonged investigation of this commercial

23 option, in circumstances where Mr Smart, Dr Dunnill,

24 Dr Lane, others were firmly of the view that it's

25 unrealistic and that the right way to proceed was

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1 but I think it was going to be relying on BPL to

2 provide the fractionation expertise.

3 **Q.** And on any view would you agree, in light of your

4 earlier answers, that it took too long to get to this

5 point?

6 **A.** It took too long.

7 **Q.** If we then look at [WITN4461046], this is really just

8 to complete the picture for 1980.

9 Yes, [WITN4461046] is the reference I've got but

10 that might be a different one. No? Let me just see

11 whether there's another reference. No, I'm just going

12 to turn to ... *(Pause)*

13 What I might do -- it's very short -- is read it

14 out, because it's really just -- it's one paragraph.

15 I'll tell you what it is and then if we get it on

16 screen under a different reference we'll do so.

17 So it's a memo -- a minute from Mr Knight, so

18 the minister's private office, to Mr Harley, dated

19 8 January 1981, and it says:

20 "This minute confirms that when you and

21 Messrs Wormald, Hart and Bolitho met MSH [so the

22 Minister] and PSH [Parliamentary Undersecretary] on

23 17 September, ministers asked that planning and design

24 should begin at the redevelopment scheme on the Blood

25 Products Laboratory."

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1 through redevelopment as an NHS facility?

2 **A.** I think the only reason, really, in my view, of

3 involving any form of commercial enterprise was to see

4 if they would run it under contract or provide the

5 commercial management nous, if you like, to run it and

6 then potentially help to put in place plans for

7 a whole new build. But essentially to keep it within

8 the NHS but with a much bigger infusion of commercial

9 expertise, if you will, because that's what it

10 absolutely desperately needed.

11 So for my -- in my view, that's really the only

12 commercial side of things that one really needed to

13 consider. I think that there was -- your question

14 was, was it the wrong thing to have -- could you just

15 rephrase the question?

16 **Q.** Was it a mistake, given everything that was being said

17 by Smart, Lane, Dunnill, et cetera, to embark upon

18 this particular prolonged investigation?

19 **A.** Personally I think it was a mistake.

20 **Q.** It's right to note, is it not, and relevant to note in

21 that regard, Mr Smart had made it clear from the

22 outset that there were no British companies with

23 fractionation experience?

24 **A.** Yes. Well, Beechams wasn't a fractionator, so it was

25 going to bring in commercial pharmaceutical expertise

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1 **A.** Yes.

2 **Q.** So the purpose in reading that out, and I know it's

3 one of the documents you refer to in your statement,

4 is just to show that -- the point in time at which we

5 reach, the end of 1980, is -- is a decision now well

6 over 18 months after the Medicines Inspection report

7 to begin the process of planning?

8 **A.** Yes.

9 **Q.** And that is, I think to use a word that you've used on

10 more than one occasion in your evidence already, an

11 unconscionable period of time?

12 **A.** Yes.

13 **Q.** Can I then pick matters up in April of 1981.

14 DHSC0002315_049.

15 So this is again Mr Wormald to Mr Knight,

16 10 April 1981, and paragraph 2:

17 "It is widely known, following the very

18 unfavourable Medicines Division report, that the

19 Government intend to redevelop BPL. The Minister made

20 this clear in his 'World in Action' interview earlier

21 in the year. We have never, however, committed

22 ourselves to a particular timetable, nor decided how

23 much of the laboratory will be rebuilt."

24 Then he goes on to set out various

25 considerations that need to be considered. So is it

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

6 **A.** Yes.

7 **Q.** Then if we go to DHSC0002309_004.

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

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

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

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

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

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

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

16 **A.** Mmm.

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

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

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

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1 the redevelopment.

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

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

9 **A.** No.

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

13 **A.** Yes.

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

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

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

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

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

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

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

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

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

25 **A.** Yes.

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1 Q. It's right to say I'm really taking you to the
 2 documents to -- where -- the points in time where
 3 things do move forward.
 4 A. Mm.
 5 Q. You've reviewed a much larger number of documents,
 6 many of which are referred to in your statement, which
 7 were we're not looking at --
 8 A. Yes.
 9 Q. -- which show meeting after meeting after meeting?
 10 A. Exactly so.
 11 Q. Now, the policy steering group I don't need to go to
 12 it, just to give us a date, though, met for the first
 13 time on 24 August 1981, and you were part of
 14 that group?
 15 A. Yes.
 16 Q. But if we then pick the picture up in a document at
 17 DHSC0020710_056, we can see a minute from Dr Harris to
 18 Mr Harley. I just wanted to ask you about the last
 19 paragraph. He refers to the policy steering group
 20 commissioning a feasibility study, and then he says
 21 this:
 22 "As I have already mentioned in an earlier note
 23 after my discussion with Lord Elton, the Group must
 24 give consideration to the use of an existing factory
 25 which could be adapted at relatively low cost to the

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1 But, well, as I had a different boss in
 2 a different life who used to say "Order, counterorder,
 3 disorder", and that's effectively what we were
 4 getting.
 5 Q. Because by this time what we've got is a -- leaving
 6 aside the short-term measures, the interim measures
 7 that are being funded, we've got decisions about what
 8 not to do but we still haven't got a decision as to
 9 what is going to be done longer term?
 10 A. Yes.
 11 Q. If we then, in that same month, October 1981, then go
 12 to DHSC0002211_063.
 13 This is a meeting of the Joint Management
 14 Committee for the Central Blood Laboratories. We've
 15 been looking mostly at the Scientific and Technical
 16 Committee meetings, but this is the JMC.
 17 23 October 1981.
 18 If we go to the second page I think we get
 19 a sense of the committee's frustrations. So if we
 20 look at paragraph 9 under the heading "Long-Term
 21 Management Arrangements":
 22 "Mr Godfrey reported that Ministers were still
 23 considering the management structure for the Central
 24 Blood Laboratories. The importance of an early
 25 decision had been emphasised by officials. The

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

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1 Committee stressed the difficulties that would occur
 2 if the matter were not decided before the completion
 3 of the proposed feasibility study on redevelopment."
 4 Management in the long-term is a slightly
 5 different issue from the redevelopment of the
 6 facility, but we can see there that what is being
 7 suggested by the committee is that you can't do one
 8 without the other; is that right?
 9 A. It certainly needed some way of managing this very
 10 major project.
 11 Q. This isn't, I think, just management of the project,
 12 is it, it's management of the Central Blood
 13 Laboratories themselves?
 14 A. Yes, but actually also the co-ordination, if you like,
 15 with the NBTS.
 16 Q. Then if we go to the next page, we can see, at the
 17 top, the heading "Policy steering group for the
 18 redevelopment of BPL", a report by Mr Smart:
 19 "Mr Smart reported that the group had agreed to
 20 meet as and when necessary ... had done so three times
 21 to date. Its work was hampered to an extent by the
 22 lack of ministerial decision on long-term management
 23 arrangements."
 24 So it would appear that is holding up the
 25 planning that the policy steering group can do; is

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1 that right?

2 **A.** Yes.

3 **Q.** There was a further ministerial visit to BPL in

4 January of 1982. I can't remember without checking

5 which minister it was, but do you recall whether you

6 went on that?

7 **A.** I don't remember. I might have done, but I don't --

8 I was in and out of BPL, so the trouble is I just

9 don't remember particular visits.

10 **Q.** Then if we look at DHSC0002215_087, this is a meeting

11 of the policy steering group 1 March 1982.

12 Now, you weren't, in fact, in attendance at this

13 meeting, but it's just to note, if we go to page 2,

14 paragraph 6, there's reference there to a report from

15 Liberton, and I'm going to come on to the Liberton

16 issue and the shift working trial. But we can see the

17 last two sentences of that paragraph:

18 "Mr Harley was asked to seek JMC [that's the

19 Joint Management Committee] approval for planning to

20 proceed on the assumption that BPL would process all

21 plasma for England and Wales. The estimated

22 production capacity of the new Laboratory could be

23 revised if necessary at a later date if there were

24 a substantial change in Liberton's position."

25 So the point we've reached by March of 1982

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1 **SIR BRIAN LANGSTAFF:** Ahem.

2 **MS RICHARDS:** Yes, I was going to make no comment on that.

3 "2. The Steering Group have now reached the

4 stage at which Ministerial decisions are required on

5 ... size ... scale of production; and ... cost."

6 And then there's reference to an attached paper.

7 As I say, because you weren't involved in putting that

8 together, I'm not going to ask you about that, but if

9 we then look at paragraph 5 it says:

10 "The paper concludes ... by seeking Ministers'

11 approval to submit a Stage Two submission to the

12 Treasury."

13 Then there's reference to the matter being "put

14 forward for information to Scottish Ministers".

15 So it's really just to complete the timetable,

16 as it were, on this issue. September 1982, bearing in

17 mind we really started, for present purposes, with the

18 Medicines Inspection report in April of 1979.

19 **A.** Mm-hm.

20 **Q.** We have taken until now to get the stage where

21 decisions, actual concrete decisions, on size, scale

22 and costs are even being sought from ministers.

23 **A.** Yes. I think, though, it's probably fair to say that

24 there had been some involvement of a commercial

25 company, Norcain Hall(sic) or -- I forget its name

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1 is: we're going to plan on an assumption that we can't

2 use the Scottish fractionation services?

3 **A.** Yes.

4 **Q.** You were then on maternity leave April to

5 October 1982, I think --

6 **A.** Yes.

7 **Q.** -- so I'm not going to ask you about what or was not

8 happening in that period of time, but I am going to

9 ask you to look at a submission to ministers which

10 went in September of 1982 which was copied to you,

11 possibly in anticipation of your return from maternity

12 leave. So it's DHSC0002309_017.

13 If we look at the bottom of the page, we can see

14 it's from Mr Godfrey. It's 22 September 1982. And we

15 can see it's copied to a number of people, including

16 you. Then if we go to the top of the page,

17 paragraph 1, it says:

18 "In April 1981 Ministers agreed that a Policy

19 Steering Group should begin planning the redevelopment

20 of the Blood Products Laboratory (BPL) ... and that

21 health authorities' allocation should be reduced ..."

22 So that's the top slicing:

23 "Redevelopment has been approved in principle by

24 the Treasury who have also agreed that the project

25 should be 'fast-tracked'."

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1 precisely -- to do a feasibility study to look at more

2 detail. I don't think it was total stasis. I think

3 that there was work going on which the Joint

4 Management Committee had actually commissioned, or the

5 steering group had commissioned, to get some design

6 input or --

7 **Q.** Yes, yes -- no, you are absolutely right. There were

8 things happening to get to that stage but, again, it's

9 the overall period of time, again, would you accept,

10 using your own word earlier, unconscionable?

11 **A.** Yes.

12 **Q.** Then we can see DHSC0002309_019. This is meeting on

13 7 October 1982. Again, you're not present although

14 you are copied into it, but we can see reference to

15 Mr Finsberg, so that's the minister, agreeing that the

16 investment appraisal should go forward to the

17 Treasury. So that's, as it were, the next stage.

18 We then, in terms of your own involvement,

19 have -- and I'm not going to put it on screen because

20 there's nothing in the detailed content of it I want

21 to ask you about, but there's a meeting of the Joint

22 Management Committee attended by you on

23 5 October 1982, so you're now back from maternity

24 leave?

25 **A.** Yes.

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1 Q. Your recollection set out in your statement is that
 2 you then didn't have any significant ongoing
 3 involvement in relation to the redevelopment of BPL;
 4 is that right?
 5 A. That's right, because the Central Blood Laboratories
 6 Authority then took over from the Joint Management
 7 Committee and, as you will have seen from the various
 8 papers, basically I was not entitled to attend those
 9 meetings, although it was said that I might be given
 10 permission if necessary to attend. But I was not
 11 involved at all in their meetings.
 12 Q. So that leads me on to the next, as it were, subtopic,
 13 which was about the establishment of the Central Blood
 14 Laboratories Authority. We know, and your statement
 15 sets it out for us, that that was established on
 16 1 December 1982 as a Special Health Authority, so as
 17 a specific legal entity.
 18 A. Yes.
 19 Q. With responsibility for the management of BPL, the PFL
 20 in Oxford and the Blood Reference Group --
 21 A. Blood Group Reference Laboratory, yes.
 22 Q. I think, again, your statement says you weren't
 23 closely involved with its establishment but there are
 24 just two or three documents I would like to look at
 25 with you to see whether you can cast any light on

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1 properly by the ordinary [Regional Health Authority]
 2 and RTO ..."
 3 What's that acronym for? "RTO structure"?
 4 A. I'm trying to find the bit --
 5 Q. I'm so sorry, it's the second line of paragraph 10.
 6 My apologies.
 7 A. Oh, right. Regional treasurers, I'd imagine. I'm not
 8 sure. Not quite sure.
 9 Q. "BPL is a large, complex and highly specialised
 10 factory operation which needs much special expertise,
 11 in our view at 'Board' as well as management level."
 12 Then that's further discussed. Then
 13 paragraph 12 it says:
 14 "We envisage that the members, or at any rate
 15 the 'Chairman' would exercise considerable oversight
 16 over the management ..."
 17 And I understand that to be referring to the
 18 management of BPL:
 19 "... which does not and cannot possess all the
 20 necessary skills and is, to boot, a little
 21 idiosyncratic."
 22 Do you know who or what there was being
 23 described as idiosyncratic?
 24 A. I'm just trying to follow. I've got it now on
 25 paragraph 12 but this was -- was this a meeting that

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1 them.
 2 The first is DHSC0002307_034.
 3 This is a minute from Mr Wormald to Mr Nodder,
 4 dated 6 April 1981, and it deals in part with BPL but
 5 I'm not going to ask you about that.
 6 If we go to the second page, we can see there's
 7 a heading "Future management of Central Blood
 8 Laboratories":
 9 "7. The present arrangements were set up for
 10 the short term and pose many problems. All concerned
 11 are agreed that they cannot continue.
 12 "8. For simplicity this minute assumes that
 13 BPL/PFL and BCRL will continue under the same
 14 management ...
 15 "9. We have considered many possibilities, but
 16 really there are only three runners - management by
 17 a Health Authority; management by an enlarged and
 18 reconstituted [Public Health Laboratory Service]; and
 19 a Special Health Authority."
 20 It referred to a discussion at a meeting.
 21 "Our conclusion was that a Special Health
 22 Authority was the clear first choice."
 23 Then, if we look at -- it's paragraph 10:
 24 "The first point to make is that the
 25 Laboratories, or at any rate the BPL, could not be run

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1 I was at?
 2 Q. You're copied into the minutes. So this is
 3 April 1981. I don't know whether you had been at any
 4 meetings relating to it but it's a minute that's cc'd
 5 to you.
 6 A. No, I've no idea which bit of the existing management
 7 was being deemed idiosyncratic.
 8 Q. Don't worry then. But we can see, in any event,
 9 April 1981, the clear steer is in support of a special
 10 health authority. And just so that we can understand
 11 some of the difficulties of the temporary arrangements
 12 that had been put in place following Lister
 13 disappearing out of the picture, if we look at
 14 WITN4461063.
 15 This is a paper -- I don't think -- in fact,
 16 it's a ministerial submission. I don't have a precise
 17 date for it but I'm sure we can check that. Bottom of
 18 the page.
 19 So it sets out the history in terms of how it's
 20 being managed over the recent years, and then
 21 paragraph 5, bottom of the page:
 22 "The chief difficulties over these temporary
 23 arrangements are that management is too diffuse, with
 24 too many people exercising a fragmented
 25 responsibility; management is insufficiently and not

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

6 Next page:

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

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

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

25 So is that a fair summary of what the concerns

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1 submission."

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

5 **A.** Yes.

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

9 **A.** Yes.

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

11 **A.** No.

12 **Q.** Were you directly involved in the process?

13 **A.** No.

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

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

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

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

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

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

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

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

24 So the bottom of that page, paragraph 4 says:

25 "Subject to these observations, I support the

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

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

12 If we could look, first of all, at DHSC0003715.

13 It's a very faint document. Could we zoom in?

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

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

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

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

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

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

4 **A.** Yes, that's right.

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

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

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

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

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

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

8 In the last few lines of that paragraph you say:

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

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

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

17 **A.** Yes.

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

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

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

12 This email -- it's not an email, of course!

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

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

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

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

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

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

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

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

25 **A.** Yes.

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1 Q. If we go to DHSC0000064, and we go to the second page,
2 we can see these are the minutes of a meeting on
3 1 December with the Scottish Home and Health
4 Department, the Department of Health and Social
5 Services, Northern Ireland, and the Welsh Office to
6 discuss UK self-sufficiency in blood and blood
7 products, and then there are a number of attendees
8 from the Department, including you and Mr Harley,
9 we've got representatives from Scottish Home and
10 Health Department, we've got Dr Cash and
11 representatives from Northern Ireland and from Wales.

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

17 Then paragraph 4 talks about Dr Cash and
18 Mr MacPherson saying PFC could fractionate an extra
19 500 litres of fresh frozen plasma to produce
20 Factor VIII and albumin, ancillary staff needed to
21 take on this extra work were available.

22 Then 5:

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

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1 Q. That's absolutely right. Another year.

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

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

10 A. No, the Department wouldn't have been in any position
11 to formulate that view. The whole point was that we
12 needed to understand what was possible. I mean, the
13 beauty of the Liberton plant was that it was
14 purpose-built to do the continuous processing over
15 a 24-hour period. It was a much more state of the art
16 facility than the BPL. Obviously, it had been built
17 very much later and we had -- England contributed
18 £400,000 to its building, so there was always the
19 intention that it should be used, absolutely, and
20 essentially, in order to work out what could be done,
21 you did need to do this shift-working experiment. It
22 wasn't being used in a continuous manner, which is
23 what the facility had been built for. It was being
24 used discontinuously. We can see from subsequent
25 papers that a discontinuous process in a plant built

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

6 A. Yes.

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

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

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

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

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

12 A. Mm-hm.

13 Q. Then if we can then pick the position up in December
14 1981 with CBLA0001517. This is -- again, it's
15 slightly faint in places but it is a meeting of the
16 policy steering group of which you were a member on
17 18 December 1981 or you were part of the secretariat,
18 I should say?

19 A. Yes.

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

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

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

18 Then we can see the next paragraph:

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

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1 the Policy Steering Group receive those Scottish
2 internal materials at the time?
3 **A.** No, no.
4 **Q.** Then if you can give that perhaps fuller explanation
5 of what your understanding is.
6 **A.** Yes. Well, to finish just on this particular
7 document, I notice that the Policy Steering Group was
8 absolutely clear, look, to sort this all out we have
9 to ask SHHD what's doable. I mean, it was well known
10 that there was a difference of view between Dr Lane
11 and Dr Watt -- in fact, I should say differences of
12 view between Dr Lane and Dr Watt on just about
13 everything.

14 Therefore, I think it was felt that the best way
15 of finding out what was doable and on what basis was
16 to ask for a formal letter from SHHD and that I've
17 also seen and, undoubtedly, of course, it went to this
18 committee, and I can short circuit things by saying
19 what that letter from the Scottish Home and Health
20 Department said was, well, we can obviously do quite
21 a lot in terms of the amount of fractionation we can
22 do for the UK but, actually, it's going to take
23 £6 to 7 million because we need to do extra building
24 in order to be able to accommodate all this
25 requirement and it's going to take about two and a

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

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

- 10 **A.** I think Mr Hibbert was part of the BPL setup, rather
11 than -- I have seen subsequent papers, so -- which the
12 Inquiry has given me, so I can give more rounded
13 explanation if you would like me to do that.
14 **Q.** Please do, because we'll look at what Mr -- some of
15 that correspondence between Mr Harley and the Scottish
16 Home and Health Department but we've also provided you
17 with some notes by Mr Watt about his perception of how
18 the shift-work experiment worked and also a rather
19 later letter from Dr Cash, saying he thought it was
20 something that was perfectly achievable.
21 **A.** Yes.
22 **Q.** We don't, I think, necessarily need to put those on
23 screen you have read them.
24 **A.** Yes.
25 **Q.** First of all, as far as you can recall, did you or did

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1 half years.

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

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

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

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

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

10 So the experiment, from that point of view,
11 didn't really help take matters forward. But what
12 actually then probably put a stop to any further
13 discussions was that there was going to be a cost of
14 £6 to 7 million, avowedly so, because that's what SHHD
15 said, and it was going to take about two and a half
16 years.

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

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

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1 **Q.** So it was about negotiating --

2 **A.** Terms.

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

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

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

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

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

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

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

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

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

4 **A.** Yes.

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

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

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

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

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

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

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

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

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

24 **A.** That's right.

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

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

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

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

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1 division towards the end of 1983.

2 **A.** Yes.

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

5 **A.** Yes.

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

9 **A.** Yes.

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

13 **A.** Thank you.

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

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

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

23 **A.** That's right.

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

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

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

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

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

17 **A.** Yes, in a word.

18 **SIR BRIAN LANGSTAFF:** Thank you. 2.00.
 19 (1.03 pm)
 20 (Luncheon Adjournment)
 21 (2.00 pm)
 22 **MS RICHARDS:** Dr Walford, I'm going to move now to the
 23 question of AIDS and the Department's knowledge, your
 24 own knowledge and decisions that were taken largely in
 25 the course of 1983 because obviously you then left the

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1 in the Department, someone in Med IMCD --

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

4 **A.** I'm sorry, sir.

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

7 **A.** Very good. Absolutely.

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

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

18 **A.** That's right.

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

22 **A.** Yes, yes.

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

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

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1 certain.

2 **Q.** No, understood.

3 So if we look at the material that you just

4 referred to -- Soumik, it's DHSC0002219_009.

5 And so if we look at the bottom of the page we

6 can see it's from Mr Godfrey dated 16 July 1982.

7 First of all, can you just remind us who Mr Godfrey

8 was?

9 **A.** Mr Godfrey was the principal in HS1A division and

10 I think he reported to Mr John Parker at that time.

11 **Q.** Then it says "cc Dr Clarke". Do you know who that was

12 referring to?

13 **A.** That was the doctor in Med SEB who was, as it were,

14 standing in for me while I was on maternity leave.

15 **Q.** Was that Dr Petronella Clarke?

16 **A.** Dr Petronella Clarke.

17 **Q.** Then if we look at the top of the page we can see it

18 was addressed to Dr Holgate and Dr Holgate was which

19 division?

20 **A.** He was the principle medical officer in Medicines

21 Division who dealt with biological products.

22 **Q.** So we can see it reports this:

23 "You will wish to know that Dr Harold Gunson,

24 our Consultant Adviser in Blood Transfusion, has

25 received information from the American Bureau of

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1 "From the DHSS point of view, we can defend the

2 National Blood Transfusion Service's own record.

3 Someone taking drugs (gay or not) would not be bled

4 provided that the injection marks showed. In any case

5 with our voluntary unpaid donor system we do not have

6 the same problem as in the States where drug addicts

7 are tempted to give blood simply for the money.

8 However, about half of the Factor VIII bought from

9 commercial companies is imported from the USA. Your

10 Division, when the published study is available --

11 I understand that one of your Sections scans the

12 technical literature for such material -- may have to

13 consider revoking licences of certain manufacturers.

14 Of course it may turn out that none of the Factor VIII

15 involved is supplied to this country."

16 Then he says if you want to talk to Dr Gunson,

17 if only to clarify my explanation of the virus he can

18 be reached at the Manchester Transfusion Centre.

19 If we look at Dr Holgate's reply to Mr Godfrey

20 at DHSC0002219_012, it's dated 20 July 1982. If we

21 look at the bottom of the page, we can see again it's

22 copied to Dr Clarke, who was filling in for you whilst

23 on maternity leave, and then we can see if we look at

24 the text of it:

25 "I was aware of the potential adverse publicity

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1 Biologics via Dr Joe Smith at NIBSC that there may be

2 considerable publicity in the next couple of weeks

3 concerning the safety of American Factor VIII.

4 "Please forgive the layman's explanation

5 below -- I hope it makes some sense. Apparently some

6 research is about to be published showing fairly

7 conclusively that plasma taken from homosexual

8 drug-takers contains a sort of virus which goes

9 undetected when the plasma is tested but it is

10 suppressed by the drugs. However, when used for

11 Factor VIII, it becomes active again. It seems that

12 400 haemophiliacs in the USA have exhibited signs of

13 the virus. The report is expected to be picked up by

14 the lay press and may cause a furore. I do not know

15 which brands of Factor VIII are involved."

16 Obviously, that's not likely to be an entirely

17 accurate account but, nonetheless --

18 **A.** No, it wasn't.

19 **Q.** But, clearly, the chain appears to be the American

20 Bureau of Biologics providing information to Dr Joseph

21 Smith, who has provided information to Dr Gunson --

22 **A.** Yes.

23 **Q.** -- who was providing information to the Department?

24 **A.** Yes.

25 **Q.** Then the next paragraph:

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1 concerning the safety of Factor VIII in the USA (and

2 certain other blood products, in my opinion) where the

3 original donation was obtained from the homosexual

4 community. I suspect our press will pick this up in

5 view of the recent events at Buckingham Palace."

6 I do not know what that's a reference to.

7 **A.** I don't either.

8 **Q.** "I do not entirely agree with your account of the

9 technicalities [so perhaps a polite way of explaining

10 that some of the description is inaccurate] but that

11 makes no difference to the eventual outcome. Although

12 I know Dr Griffin is aware of this ..."

13 Who was Dr Griffin?

14 **A.** He was head of Medicines Division, the medical head of

15 Medicines Division.

16 **Q.** "... I am copying the correspondence to him and to

17 Dr Fowler ..."

18 Dr Fowler was also in the Medicines Division?

19 **A.** He was senior medical officer.

20 **Q.** "... who will have to take any action that proves

21 necessary.

22 "The element of doubt I have in your thesis is

23 that the drug taking may not be an essential feature

24 of the affair -- but I am open to correction on this;

25 if it is solely the curious activities of the

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

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

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

10 **A.** That's right.

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

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

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

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

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

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

25 **A.** No.

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1 **A.** Yes.

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

4 **A.** Yes.

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

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

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

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

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

25 "The hypothesis at present being used to explain

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

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

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

15 **A.** I wasn't at that.

16 **Q.** -- involved with that.

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

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

24 **A.** Oh, I see.

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

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1 April 1983 --

2 **A.** Fine, fine.

3 **Q.** Now, just then, again, as I say, taking it

4 chronologically, you say in your statement you recall

5 reading about the San Francisco baby case in late 1982

6 or early 1983?

7 **A.** Yes.

8 **Q.** If we go to your witness statement, Soumik, WITN --

9 you are ahead of me, thank you, it's paragraph 71.2.

10 So it's page 169, please, Soumik. It's the bottom of

11 the page, you say this:

12 "Apart from the fact AIDS was occurring in

13 haemophiliacs in the USA who had received coagulation

14 factor concentrates, I believe it will have been at

15 the end of 1982 or early in 1983 that I read about the

16 presumed case of AIDS in a baby who had required blood

17 and platelet transfusions at birth and had later

18 developed an AIDS-like illness. One of the platelet

19 donors had subsequently been diagnosed with AIDS.

20 This was the 'San Francisco' baby that has previously

21 been described to the Inquiry. It is fair to say that

22 this case, added to the mounting reports of cases in

23 haemophiliacs in the USA, was instrumental in my

24 feeling that it was likely that AIDS was transmissible

25 through blood, as well as through sex."

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1 a transmission of AIDS. That was still controversial,

2 even amongst those who knew about that case, in the

3 medical press. But I think that gradually the

4 feeling in the wider department, if you like, was

5 that: actually, this is looking more and more likely

6 that blood and blood products are certainly capable of

7 transmitting this agent. Not necessarily we conclude

8 that they have but they are capable of doing it.

9 **Q.** We'll look in due course, when we get to the July

10 meeting of the biological subcommittee on the

11 Committee on Safety of Medicine at a paper written by

12 Dr Fowler.

13 **A.** Yes.

14 **Q.** But leaving aside Dr Fowler's views, were you aware in

15 the early part of 1983 of anyone within the Department

16 voicing a markedly different view, doubting or being

17 sceptical about there being a link between blood,

18 blood products and AIDS?

19 **A.** I don't remember really anybody in the Department

20 voicing such a view. I think there was a degree of

21 not necessarily scepticism but reticence amongst UK

22 Haemophilia Centre Directors that this was potentially

23 transmissible, but actually in the Department I don't

24 recall anybody saying, "No, no, it's absolutely

25 obvious that it isn't."

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1 Then you explain how you remained perplexed as

2 to why Haitian immigrants seemed to be another

3 significant risk group.

4 Then you say in the next paragraph, and I want

5 to explore this in a moment in a little more detail,

6 that:

7 "... from January 1983 the Department's

8 awareness of the potential for transmission of AIDS

9 through blood and blood products grew incrementally."

10 Just leaving it there for the moment, is it

11 right to understand from your statement that, by the

12 beginning or at the beginning of 1983, your sense was

13 that it was likely that this was transmissible through

14 blood and blood products?

15 **A.** Yes, it was.

16 **Q.** Was that the prevailing view amongst your colleagues,

17 as far as you can recall?

18 **A.** Well, as I say, a little bit later on, that I think

19 that view developed incrementally. Certainly that

20 baby, poor little thing, was a sort of watershed, as

21 far as I was concerned. It rang all sorts of

22 alarm bells.

23 Of course you could not actually conclude from

24 the one case -- for which other explanations were

25 being given, I may say, rather than that it was

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1 The exception was, if you like, Dr Fowler, whose

2 paper I only saw when it came to the Committee on

3 Safety of Medicines -- and to be fair, again, although

4 he was putting forward a theory that had been put

5 forward by Sonnabend in the outside world, he's --

6 nevertheless the rest of his paper went on to say,

7 "but we have to take all these necessary precautions".

8 So although he was not sure whether a transmissible

9 agent was actually the main cause, if you like, of

10 AIDS, he was -- nevertheless thought that we should

11 treat it as if it was.

12 **Q.** We will almost certainly look at his paper in a little

13 more detail later, but just sticking with around

14 January/February 1983, in Med SEB and in Med IMCD,

15 which would have had AIDS one of its primary concerns

16 presumably at this point in time --

17 **A.** Yes.

18 **Q.** -- you can't recall anyone voicing a significantly

19 different view from the one --

20 **A.** No.

21 **Q.** If we then look at DHSC0002353_021, we can see this is

22 a letter from Dr Craske to you, dated 10 January 1983.

23 He refers in the first paragraph to a letter that it's

24 planned will be submitted to The Lancet, which gives

25 the current situation with regard to the risk of

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1 non-A, non-B hepatitis.
 2 And the "we", I should say, is a reference to
 3 Dr Craske, Dr Rizza, Mary Fletcher and
 4 Dr Joan Trowell.
 5 I don't think we need to go to the letter
 6 itself, but it was the issue about hepatitis-reduced
 7 products that had triggered that?
 8 **A.** Yes.
 9 **Q.** Then the second paragraph says this:
 10 "The problem related to the investigation of
 11 factor VIII-related Acquired Immune Deficiency
 12 Syndrome (AIDS) has been satisfactorily resolved. We
 13 will report any patient detected in the UK who has
 14 received UK commercial factor VIII direct to CDC and
 15 will at the same time notify CDSC at Colindale.
 16 I have obtained Dr Galbraith's consent to this
 17 arrangement, and I intend to produce a short note in
 18 the communicable disease report describing the present
 19 situation."
 20 Now, it sounds from that letter as though there
 21 might have been some earlier communication between you
 22 and him, because saying something's been
 23 satisfactorily resolved might suggest that he had
 24 previously raised it with you or discussed it with
 25 you, although there's no documentary trail to that

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1 Britain from the United States may pose a grave threat
 2 to the health of haemophiliacs who inject it to
 3 encourage clotting."
 4 Then it goes on to give more detail. I don't
 5 think I need to ask you about the detail, save perhaps
 6 to note actually, if we look at the right-hand column,
 7 about halfway down, it talks about:
 8 "... the deaths of at least 10 American
 9 haemophiliacs are now known to [have been] caused by
 10 the disease ..."
 11 If we just go to the handwriting at the top of
 12 the page, we can see someone has written a note to you
 13 saying:
 14 "It would be useful to know the outcome of
 15 Haemophilia Centre Directors' meeting. Perhaps we can
 16 discuss at an opportune moment."
 17 That's, I think, your handwriting, where you
 18 say:
 19 "I have written to Prof Bloom for details of the
 20 meeting."
 21 **A.** Yes, it is.
 22 **Q.** Then if we look at your letter to Professor Bloom,
 23 which is at BPLL0001351_047, this is a letter from
 24 you, 19 January 1983:
 25 "Dear Arthur

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1 effect.
 2 **A.** I actually don't think that's probably what happened.
 3 Looking -- it seems to me it was discussed at a UKHCDO
 4 meeting and there was an issue of who was going to
 5 report to whom. Dr Craske I think raised in the
 6 meeting a need that -- that he had been approached by
 7 Dr Dale, I think it was, of CDC Atlanta, and that
 8 basically the Americans really wanted the
 9 UK Haemophilia Centre Directors to report any case
 10 that they knew, because, of course, it was American
 11 Factor VIII that was being incriminated at the time.
 12 So I believe it was discussed at a meeting, and
 13 basically he's trying to tell me -- well, there must
 14 have been quite a bit of toing and froing, as there
 15 often was at those meetings, as to, "Well, do we do it
 16 both ways? How do we do it?" And he says, "Well,
 17 I've resolved that and I'm going to send the reports
 18 through to Dr Dale and also at the same time I'll send
 19 them to CDSC, so everything is going to be all right
 20 in respect of reporting."
 21 **Q.** Then if we move to DHSC0002223_085.
 22 This is an article in The Observer on
 23 6 January 1983, and we can see it is entitled "Mystery
 24 disease threat", by Christine Doyle:
 25 "A commercial blood product imported into

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1 "As you can imagine, recent publicity about
 2 cases of acquired immune deficiency syndrome in
 3 haemophiliacs in the USA has generated quite a bit of
 4 interest in the Department.
 5 "I believe that the topic was to be discussed at
 6 a recent meeting of Haemophilia Centre Directors and
 7 I should be most grateful if you could possibly let me
 8 know what conclusions were reach at the meeting.
 9 Perhaps it would be simplest if you could telephone me
 10 whenever convenient rather than bothering with
 11 a letter."
 12 We haven't traced a letter. Do you recall what
 13 conversation or discussion or response you had from
 14 Professor Bloom?
 15 **A.** No, I don't recall at all but I will have asked for
 16 a telephone conversation so that I could find out
 17 quickly. One just simply didn't know how long it was
 18 going to take for him to write a letter to me and
 19 obviously this was concerning and I basically wanted
 20 to hear from him as soon as possible.
 21 **Q.** Based on what you recall of Professor Bloom, and you
 22 had many interactions with him --
 23 **A.** Yes.
 24 **Q.** -- at this point in time, do you think it's more
 25 likely than not that he would have responded to your

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1 letter?
 2 **A.** To a letter?
 3 **Q.** No, responded to your letter whether by picking up the
 4 phone and speaking --
 5 **A.** Oh, absolutely. Absolutely he would, yes.
 6 **Q.** So either he will have written back to you or, perhaps
 7 more likely, there will have been a telephone
 8 conversation --
 9 **A.** I would have hoped there would have been a telephone
 10 conversation because that's what I was really aiming
 11 to get.
 12 **Q.** But you've no recollection now --
 13 **A.** No.
 14 **Q.** -- as to whether that happened?
 15 Then if we go to DHSC0002223_088, this is
 16 a minute dated 18 January 1983. It's copied to you.
 17 It's from TK Sweeney to Ms Fraenkel.
 18 Can you just, again, assist us with
 19 understanding whose they are?
 20 **A.** Can you just move it up a bit -- I want to see if
 21 I can -- "Med HPS", okay, he was a medic. I'm having
 22 to interpret the hieroglyphics here. He was a medic.
 23 And it looks as if -- I don't actually know what HPS
 24 was, for medic, so I'm afraid I'm not terribly sure
 25 about that.

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1 this, isn't it, that there has been a communication,
 2 possibly oral --
 3 **A.** Yes.
 4 **Q.** -- between you and probably Dr Sweeney. Is it right
 5 to understand you've got no independent recollection
 6 of that?
 7 **A.** None at all.
 8 **Q.** What this records you as saying is, in fairly powerful
 9 terms --
 10 **A.** Yes.
 11 **Q.** -- the value of factor concentrates to severe
 12 haemophiliacs "far outweigh the possible, and as yet
 13 unproven hazards of transmission of [AIDS]".
 14 Doing the best you can, given that you, several
 15 decades removed, don't have an actual memory of the
 16 conversation, what would have been, do you think, the
 17 factual basis for saying that the balance is such that
 18 the value far outweighs the risk of transmission of
 19 this disease?
 20 **A.** I think my -- what I would have thought was: we have
 21 no evidence -- this hasn't happened in the UK, we have
 22 no cases that we are aware of, it's happening to
 23 a small extent in America. There's significant
 24 controversy as to what's causing it and -- relatively
 25 of course -- few people with haemophilia in America

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1 But clearly this was copied to me, an
 2 interaction between two people that I did not actually
 3 know, reporting something that I had said to one or
 4 other of them and to Mr Sweeney -- or Dr Sweeney, if
 5 it was Dr Sweeney, and I must have been asked to
 6 simply comment on this press article, and you have my
 7 comments there.
 8 **Q.** You are right, the heading refers to The Observer
 9 article we looked at, and then:
 10 "Dr Walford has confirmed that the value to
 11 severe haemophiliacs of clotting factors 8 and 9 far
 12 outweigh the possible, and as yet unproven hazards of
 13 the transmission of acquired immune deficiency
 14 syndrome. The NHS is about to commit about
 15 £20 million to building a new blood laboratory to
 16 manufacture (among other products) factor 8 with
 17 a target of 100 million [international units]
 18 factor 8. This is well known in the haematology
 19 world. I do not think you need worry about the draft
 20 which can stand as written."
 21 Now, I'm afraid we don't know what that draft
 22 refers to, and we haven't found further communications
 23 between these two individuals which casts any light on
 24 it, but just go back to what is said in the opening
 25 sentence of the paragraph. It's fair to infer from

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1 had actually developed the disease.
 2 So that was, on the one hand, what I did know
 3 about AIDS. What I did know about severe haemophilia
 4 was that the main cause of death from haemophilia was
 5 still bleeding. Haemophiliacs were still bleeding.
 6 Severe haemophiliacs had a really dreadful time if
 7 they were not treated appropriately. And so, from the
 8 perspective of not having any cases in the UK, not
 9 understanding the genesis of the illness truly, a lot
 10 of controversy -- I mean, it may seem terribly evident
 11 now that everybody thought that this was
 12 a transmissible agent in blood; that was not --
 13 absolutely was not -- a consensus that was available
 14 at the time. And the notion that, on the other hand,
 15 severe haemophilia was a dreadful disease and
 16 basically they needed their Factor VIII.
 17 So that was my thought. I still think now -- of
 18 course I now know about AIDS and its terrible
 19 consequences -- but I still believe that, at that
 20 time, the hazards were unproven of transmission and
 21 basically what one knew was that the severe
 22 haemophiliacs desperately needed Factor VIII or
 23 Factor IX. That was the basis of my thinking.
 24 **Q.** This is the day before your letter to Professor Bloom,
 25 so it doesn't sound as though the conclusion that

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

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

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

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

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

23 **A.** Yes, yes.

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

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1 sentiment at all.

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

10 **A.** He said that --

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

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

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

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

18 **Q.** Yes.

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

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

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

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

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

11 **A.** Yes.

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

13 **A.** Yes.

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

17 **A.** Not at all.

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

21 **A.** Yes.

22 **Q.** Can we just look at that DHSC0002223_065.

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

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1 A. Yes.

2 Q. It says:

3 "Factor VIII concentrate with reduced hepatitis

4 risk.

5 "Although we have had discussions with Travenol

6 about their product, we have so far had no application

7 of any kind for a reduced hepatitis risk

8 [Factor] VIII. It is our understanding that Travenol

9 propose to apply for a CTX some time around

10 March 1983. This, however, is pre-empted by Immuno's

11 recent meeting with the haemophilia centre directors

12 and the directors of BPL and PFC, the outcome of which

13 is, we are led to believe, a multi-centre clinical

14 trial of the product in named patients. I had not

15 heard that Travenol proposed to hold a symposium,

16 although it would be very much in character were they

17 to do so. The Immuno meeting is said to have been

18 quite an expensive exercise at Heathrow. I was not

19 invited, but my information comes indirectly via

20 John Holgate from one of the participants. We also

21 hear that overseas experts from Travenol have had a

22 meeting with Duncan Thomas and his people at NIBSC and

23 furthermore that there may be other companies

24 interested in this field apart from those who have

25 already made or hope to make hepatitis-free FVIII

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1 Given your own sense, in early 1983, that it was

2 likely that AIDS was transmitted through blood and

3 blood products, the lack of any vocal view to the

4 contrary in the Department --

5 A. Yes.

6 Q. -- and what you have described as effectively

7 something that became mainstream acceptance within the

8 Department that that was likely, were there, as far as

9 you're aware, any particular steps taken by the

10 Department between January and April of 1983 in

11 response to or in relation to the risk of AIDS in

12 relation to blood products?

13 A. I don't -- I'm not aware. I couldn't find anything in

14 the papers which said that. In March, a communication

15 occurred between Dr Joseph Smith of -- the director of

16 NIBSC, and Medicines Division --

17 Q. We'll come on to that.

18 A. And I don't think I heard about that until April. But

19 of course I should point out again that Med SEB was

20 not in the lead for infections from blood, so whatever

21 was going on in Med IMCD, apart from the surveillance

22 that CDSC was obviously doing, I'm not aware.

23 Q. So we then, I think, in terms of the next discussion

24 involving those within the Department that I'm aware

25 of to a CBLA meeting, so the Central Blood

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1 biosynthetically. It is possible that Richard Lane

2 may be able to give you more information on this

3 subject."

4 Now, the significance of this is the date,

5 31 December 1982, and it's very clearly talking about

6 a meeting that has already happened --

7 A. Yes.

8 Q. -- involving Immuno, Haemophilia Centre Directors and,

9 it's said here also, directors of BPL and PFC, who

10 were not, I think, as far as we know, at the meeting

11 on 24 January, but I may need to check that.

12 Do you know any more than what is set out here?

13 A. No. This came as -- when I saw the papers, this came

14 as a complete surprise to me, because I thought there

15 was a meeting in January, the following year from

16 this, which is the one that we heard about, although

17 the minutes or notes of the meeting seemed to be

18 a long time coming, I think they came several months

19 later.

20 Then, to my surprise, I came across this

21 particular minute, which seemed to imply that there

22 had been either another meeting at Heathrow or

23 somebody had got their dates mixed. I don't know the

24 answer.

25 Q. Now, given -- we can take that down, thank you.

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1 Laboratories Authority meeting, 27 April 1983 you

2 weren't actually present and you told us you didn't

3 generally attend but, just for the sake of

4 completeness, I'd like to briefly look at it. It's

5 BPLL0003987_002. We can see it's a meeting of

6 27 April and, although you were not there, Mr Godfrey

7 was and Mr Winstanley was.

8 A. Right.

9 Q. So there were two fairly senior members of the

10 administrative hierarchy of the Department in

11 attendance.

12 If we go to the bottom of page 3, you see the

13 heading "AIDS", there's reference to a report from

14 Dr Lane. I'm not going to go to that for present

15 purposes. Then there's a report from Dr Gunson. It's

16 said that RTDs, so Regional Transfusion Directors,

17 had:

18 "... considered all the American literature on

19 the subject and at the next meeting of their Committee

20 it would be recommended that no further measures be

21 taken apart from those already being carried out."

22 Just pausing there, we'll come on to the

23 question of a leaflet from the Blood Transfusion

24 Service at a later point in the chronology but that's

25 not yet, as it were, actively on the cards, I think,

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1 by this point in time.
 2 **A.** Right.
 3 **Q.** Do you know from your own knowledge or from your
 4 reading of the papers what measures were already being
 5 carried out that Dr Gunson could have been referring
 6 to?
 7 **A.** No, I don't, unless you can point me -- I think there
 8 was a meeting that he had had. I recall there was
 9 a meeting that he had been at where the whole subject
 10 had been explored. It wasn't a meeting that I was at
 11 and I think I've referred to it in my statement but --
 12 **Q.** I'll check and if necessary take you back to it.
 13 **A.** Thank you.
 14 **Q.** Then, over the page, we see Professor Bloom reporting
 15 that:
 16 "... he had given a talk on AIDS to the AGM of
 17 the Haemophilia Society. His impression was that
 18 haemophiliacs were not greatly concerned about AIDS."
 19 Then it's said:
 20 "It was agreed that Mr Winstanley should try to
 21 ascertain how many telephone calls had been made to
 22 the number given at the end of the television
 23 programme on AIDS."
 24 Now, are you able to assist us with the last of
 25 those points?

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1 can we go to PRSE0006049. This is an extract from the
 2 evidence given by Professor Richard Tedder to the
 3 Penrose Inquiry, so we can see that from the bottom of
 4 the first page and then if we go over the page, if we
 5 pick it up at line 13, the question is posed:
 6 "You knew both Dr Smithies and Dr Walford. Is
 7 that correct?"
 8 Then the answer from Professor Tedder is:
 9 "... I mean, obviously, I was more in contact
 10 with Alison ..."
 11 That's Dr Smithies, who was your successor.
 12 **A.** That's right.
 13 **Q.** "... because of her position, once we were actually
 14 hands-on involved with HIV testing. But I had met
 15 Dr Walford on one or two occasions prior to that.
 16 "Q. Had you met her in connection with the
 17 whole AIDS problem?
 18 "A. Yes, I had. I had been -- I think
 19 I mentioned the NIH meeting in Washington, which there
 20 was discussion of the aetiology of the infection and
 21 the disease which was presented in the MMWR first
 22 paper. After that and after the meeting, the NIH
 23 meeting, discussing this, it must have been early
 24 1983, Philip and I went to DHSS to ask what the plans
 25 were for -- what was ready -- what was going to be the

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

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1 plans for readiness to deal with what, I think
 2 I alluded to earlier this morning, was a disease or
 3 infection which sounded awfully like Hepatitis B in
 4 terms of affecting the same group, having the same
 5 sort of transmissions. And the moment we heard, in
 6 early 1983, end of 1982, about haemophiliacs also
 7 being involved, that gave one -- there were two
 8 reasons people put forward for the involvement of the
 9 haemophiliacs: either David Parillo, the American
 10 physician immunologist, was saying it was antigen
 11 overload which was damaging the immune system, or
 12 there was the virology camp, in which Philip and I
 13 were deeply embedded, saying, 'This sounds awfully
 14 like a transmissible virus infection. It's going in
 15 blood products, it's going in gay men, it's going in
 16 people who we know get Hepatitis B.'
 17 So that's just by way of background. Then
 18 Professor Tedder says:
 19 "So we felt empowered to go and ask the DHSS
 20 what we could do to explore this, and it was as cold
 21 a meeting inside the room as it was outside. It was
 22 a sort of cold spring morning up in one of the DHSS
 23 towers and we were told this was really not any of our
 24 business and it was not going to be a problem and go
 25 away and stop rocking the boat."

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1 Then, top of the next page, he says:
 2 "... I can't speak for Philip. You would need
 3 to ask him. But I was somewhat taken aback and pretty
 4 irritated."
 5 Now, that appears to be his recollection of
 6 a meeting with you because it's introduced by talking
 7 about having met you on one or two occasions. I'll
 8 ask you in a moment to look at a letter from Dr Tedder
 9 to you in May 1983 but do you have any recollection of
 10 the meeting he might be referring to and any comment
 11 upon his account that the DHSS response was "Go away
 12 and stop rocking the boat"?
 13 **A.** I didn't remember the meeting. I knew it had
 14 happened. I didn't remember what it had been about.
 15 I kind of assumed, and this was borne out, as we will
 16 see, that it was to do with can we have some funding
 17 for research. I believe that's probably fundamentally
 18 what it was all about, though I have to say that the
 19 irony of having me in a cold room seems -- you know,
 20 it's not lost on me. It's most -- it sounds most
 21 unlike me. I don't know what I can have said that
 22 could have possibly given him the feeling that I was
 23 asking him to go away and stop rocking the boat. This
 24 is not really characteristic, is all I can say.
 25 **Q.** If we look at the letter that we have from the time

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1 **Q.** Given what you have told us, that Med IMCD was the
 2 lead branch dealing with communicable diseases, why
 3 was it that you were having this meeting with
 4 Dr Mortimer and Dr Tedder?
 5 **A.** I have absolutely no idea.
 6 **Q.** Do you know whether the Department did provide
 7 funding?
 8 **A.** Well, I'm then reading the papers, I mean, essentially
 9 I had presumably said, just reading the first
 10 paragraph, look, if it's funding that you need, the
 11 way to do it is to apply to the Office of the Chief
 12 Scientist. I obviously seemed to have given him that
 13 signposting, if you like, and he's then writing to me
 14 to elaborate on the research that they are wanting to
 15 do but he says that actually Dr Catterall who was
 16 involved, I believe, with the research had already
 17 written to Dr Graveney, I think it's Dr Graveney, of
 18 the Office of the Chief Scientist.
 19 Then we do know there was a discussion at the
 20 June referred meeting of officials, where we were
 21 looking at the issues to do with AIDS in the round,
 22 absolutely everything, and I think it was Dr Graveney
 23 who said that they had received a letter from
 24 Dr Catterall and then I think I saw, following it up
 25 in an MRC meeting, that in fact Dr Tedder and

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1 from Dr Tedder to you, it's at DHSC0003824_164. It's
 2 20 May 1983, addressed to you:
 3 "Dear Dr Walford,
 4 "Thank you for seeing Dr Mortimer and myself
 5 last week."
 6 Dr Mortimer is Philip Mortimer, the "Philip"
 7 referred to in the evidence to Penrose.
 8 **A.** That's right.
 9 **Q.** "I gather Dr Catterall has already written to
 10 Dr Graveney, I expect [I think it might be the wrong
 11 way round, perhaps] like you I have seen a copy of his
 12 letter. It is, I believe a reasonable statement of
 13 intent."
 14 Then he goes to make various comments as
 15 a virologist on the problem of AIDS, starting off in
 16 the next paragraph:
 17 "This condition is likely to be caused by an
 18 infectious agent or agents. Its epidemiology bears
 19 a striking similarity to hepatitis B."
 20 Then he goes on to set out some suggested
 21 approach to research and, over the page, to discuss
 22 funding for research.
 23 As far as you can recall, did you have any other
 24 meetings with Dr Tedder and Dr Mortimer at this time?
 25 **A.** No, I can't recall.

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1 Dr Adler's submission, I think, had been funded.
 2 Dr Adler was a GUM physician.
 3 So I believe the money will have been found to
 4 support this research but I have to get at it
 5 indirectly through the various papers.
 6 **Q.** As far as you're able to recall, would you have been
 7 involved in that funding process or the
 8 decision-making process?
 9 **A.** Well, no, I mean, I was not involved in actual taking
 10 decision. I might have been asked whether it was
 11 a good thing to fund or not. I don't know whether
 12 I was but he was funded so I'm assuming that somebody
 13 at least had endorsed that. But, I mean, it seems to
 14 me it would have been a perfectly proper thing for the
 15 Department to fund.
 16 **Q.** Now, I want to move then to a number of communications
 17 events in May 1983 and we start with DHSC0001651.
 18 Now, this is from -- if we just go further down the
 19 page this is from Mr Parker HS1. It's dated 3 May.
 20 It's copied to a number of recipients, including you,
 21 and if we go further up we can see it's addressed to
 22 Mrs Walden. Are you able to assist with who Mrs
 23 Walden --
 24 **A.** Private office, yes.
 25 **Q.** Private office of who?

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1 A. I think that would probably have been Mr Finsberg.

2 Q. Then it says this:

3 "You will recall that we were asked to provide
4 briefing for Prime Minister's Questions on the stories
5 which appeared over the weekend about AIDS."

6 That is a reference -- I'm not going to go to
7 the newspaper articles but it was a reference to
8 certainly one particular article, possibly more.

9 "I attach a copy of the 'line to take' which
10 went to Number 10 together with a background note
11 written in supplementary question and answer form,
12 both of which I am circulating more widely within the
13 office.

14 "Officials are in touch with representatives of
15 the Directors of Haemophilia Centres and the Blood
16 Transfusion Service as well as the Haemophilia
17 Society. During these discussions, the Haemophilia
18 Society indicated that they would welcome
19 an opportunity to discuss AIDS with Ministers by the
20 end of this week. Whilst one of the main purposes of
21 background briefing is to put the problem of AIDS into
22 proper perspective -- a view shared by the Society --
23 we think it would be helpful if Mr Finsberg were to
24 offer to meet representatives of the Society.
25 Meanwhile, there appears to be little to be gained

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1 the USA. Every opportunity is being taken from this
2 country to learn from the experience of this disease
3 in the USA."

4 That's the "line to take". We'll look at the
5 background paper, the question and answer paper, in
6 a moment.

7 This may be the origin of the line of no
8 conclusive proof or no conclusive evidence and I'm
9 going to come back to that and your own involvement
10 with that issue at a later stage of my questioning.

11 A. Right.

12 Q. Do you know if you had any involvement in the
13 formulation of this line to take at this point in
14 time?

15 A. I believe I didn't. In fact, I think I have no
16 recollection of how this briefing was produced.
17 I have no recollection of knowing that something was
18 coming up at Prime Minister's Questions and,
19 basically, Mr Parker is responding, as administrative
20 staff would do, but I would say that it must really
21 have been on advice of Med IMCD.

22 The reason that I say that is that -- well, we
23 come to the Q&A briefing that was associated with this
24 line or was certainly associated with the paper that
25 went to Mr Finsberg, because it referred to three

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1 from Ministers issuing statements about a matter which
2 has been sensationalised and, in some cases, distorted
3 by the media and on which, with the present state of
4 knowledge, there is no immediate action which
5 Ministers could be advised to take. We should,
6 however, review this line after officials' discussions
7 are complete and the proposed meeting with Mr Finsberg
8 has taken place."

9 Then there's a question of whether Mr Finsberg
10 agrees to a meeting with the Haemophilia Society.

11 Now, if we just follow the paper thread through,
12 the "line to take" is over the page:

13 "I was very concerned to read this weekend's
14 Press Reports and can well understand the anxiety
15 which some sensational reports may have caused. It is
16 important to put this in perspective: there is as yet
17 no conclusive proof that AIDS has been transmitted
18 from American blood products. The risk that these
19 products may transmit the disease must be balanced
20 against the obvious risks to haemophiliacs of
21 withdrawing a major source of supplies. Already, in
22 this country, there is a special surveillance system,
23 established by the Communicable Disease Surveillance
24 Centre, to monitor the occurrence of AIDS, in
25 collaboration with the Centers for Disease Control in

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1 Spanish haemophiliacs who had developed AIDS, and
2 I think it also referred to one patient in the UK, and
3 which was obviously Professor Bloom's patient in
4 Cardiff.

5 I didn't know about any of those cases until
6 Dr Galbraith's paper was sent to Med IMCD on 6 --
7 well, it was sent on 9 May, I think, but 6 May was
8 when Dr Sibellas told me about it. So, essentially,
9 I didn't know about those cases and, therefore,
10 I can't see how it could have provided that statement.

11 Q. It's right, you observe in your witness statement, in
12 fact that line was not used by the Prime Minister on
13 that occasion --

14 A. So it appears.

15 Q. -- as a matter of fact. She said something else.

16 Just so that we can also look at the Q&A
17 briefing which accompanies Mr Parker's minute, it's at
18 WITN -- no, DHSC0003824_173, please, Soumik. We've
19 got the "line to take" there and then, if we go over
20 the page, we've got the question and answer paper. So
21 we've got the question: "What is AIDS?"; "Symptoms";
22 "Who is at risk from AIDS?" If we just look there, it
23 says:

24 "The disease occurred predominantly in
25 homosexual males but other groups such as mainline

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1 drug abusers, Haitian immigrants and haemophiliacs
 2 requiring treatment with antihaemophilic factor
 3 concentrates ... have also been identified as being at
 4 increased risk."
 5 Question:
 6 "Is it caused by a virus?
 7 "The cause of AIDS is unknown. Although medical
 8 opinion is tending to favour a virus as the agent
 9 responsible, there is no proof that this is the case.
 10 There is no means of testing ..."
 11 Then there's a reference to laboratory tests.
 12 Bottom of the page, "Mortality":
 13 "The mortality from the established disease is
 14 high: at least 40 per cent of cases die after
 15 a variable period of months or years after contracting
 16 the disease."
 17 Next page, "Is it transmitted in blood or blood
 18 products?":
 19 "As yet there is no conclusive proof that AIDS
 20 is transmitted by blood as well as by homosexual
 21 contact but the evidence is suggestive that this is
 22 likely to be the case. The evidence relates to some
 23 11 haemophiliacs in the USA and 3 in Spain in whom the
 24 most likely explanation for the development of AIDS
 25 was their exposure to American [Factor]VIII

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1 European concentrates and then a question about what
 2 action we're taking: Reference to blood transfusion
 3 directors:
 4 "It is considered impossible to ask donors if
 5 they are homosexual. However, they will avoid
 6 wherever possible bleeding donors who are known to be
 7 homosexual ..."
 8 Then 2:
 9 "All haemophilia centre directors have received
 10 instructions to report any suspect cases of AIDS ...
 11 to the Oxford Haemophilia Centre to the Communicable
 12 Disease Surveillance Centre."
 13 Then there's reference to the Blood Transfusion
 14 Research Committee of the Central Blood Laboratories.
 15 I won't read the rest of the answers but if we
 16 just go back to -- yes, that's the one.
 17 So as I understand your earlier answer, it's in
 18 particular the reference to the three cases in
 19 Spain --
 20 **A.** Yes.
 21 **Q.** -- that makes you think you wouldn't have been
 22 involved in drafting this at this point in time, the
 23 beginning of May, because you weren't aware on 3 May
 24 of those cases?
 25 **A.** No, I had no idea. I didn't also know about the

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1 concentrates. There is also some evidence that AIDS
 2 has been transmitted to babies in blood transfusions."
 3 Then if we look at the next question, "Are there
 4 any cases of AIDS in UK haemophiliacs?":
 5 "As far as can be established, there are no
 6 proven cases of AIDS in UK haemophiliacs. There is
 7 a suspect case in Cardiff of whom we have details but
 8 the reported (in the Sunday Mail) case in London has
 9 not yet been traced. The case in Cardiff has not
 10 received any American [Factor]VIII concentrate since
 11 1980. This would not exonerate America [Factor]VIII
 12 because of the long incubation period which there may
 13 be between exposure to the agent and the manifestation
 14 of the disease. On the other hand, the patient, who
 15 is a severe haemophiliac, has received since 1980
 16 a great deal of British made [Factor]VIII concentrate
 17 and it is not possible to know whether British
 18 concentrate may contain the AIDS agent.
 19 "Should a ban be placed on imports of US
 20 Factor VIII concentrate?
 21 "At present, haemophilia experts in this country
 22 take the view that to ban imports US [Factor]VIII
 23 would be to place haemophiliacs at greater risk from
 24 bleeding than they would be acquiring AIDS.
 25 Then there's a question about switching to

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1 suspect case in Cardiff.
 2 **Q.** That would tend to suggest then that whoever did draft
 3 this must have had some communication with Dr Craske
 4 or Professor Bloom -- to know about the case in
 5 Cardiff there must have been some contact. You were
 6 the primary UKHCDO conduit, as it were, in the
 7 Department. Do you know whether Med IMCD had direct
 8 dealings with Professor Bloom or --
 9 **A.** I don't know but what I noticed was that slightly
 10 earlier on, in April I think it was, Dr Sibellas was
 11 reporting some surveillance that CDSC had been doing.
 12 As I said, I didn't know that then but I've seen the
 13 papers subsequently and I noticed that there was
 14 a report from her about the CDSC surveillance in
 15 late April, I think it was, something like that, and
 16 it wasn't copied to me. In fact, there were a couple
 17 of documents not copied to me which showed that
 18 Med IMCD was pretty active in discussions with CDSC.
 19 So whether actually Med IMCD in discussion with
 20 CDSC, which was then going to re-report in this
 21 Cardiff case in the CDR -- Communicable Disease
 22 Review -- on 6 May, this is only a few days
 23 beforehand, it's possible that that's -- they got
 24 their information from CDSC, as opposed to necessarily
 25 directly with Bloom.

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

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

24 **A.** Absolutely.

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

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1 and signs for a diagnosis of AIDS."

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

5 "We have no further news of the haemophiliac
6 patient in London (as mentioned in the press on Sunday
7 1 May 1983).

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

12 Then it says in the next paragraph:

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

25 Then there's a reference to you being in

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

2 **A.** Definitely.

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

5 **A.** Right.

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

8 **A.** Yes.

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

11 **A.** Sure.

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

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

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

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

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

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

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1 Newcastle.

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

8 **A.** No.

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

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

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

22 **Q.** Or to the Prime Minister?

23 **A.** Or to the Prime Minister.

24 **Q.** You are right to pose the question, Dr Walford.

25 I think the answer is at the moment we don't know.

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

10 A. Yes.

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

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

19 Obviously I went to the subsequent meeting on
20 13 May with the UK Haemophilia Centre Directors where
21 this very matter was discussed. So I don't know --
22 I certainly don't recall but I don't think, from the
23 papers that I have seen or not seen, that
24 I particularly got in touch with Dr Bloom about that
25 case.

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1 Medicine or his nominee)"

2 Then last paragraph says:
3 "I would appreciate your comments on these (very
4 preliminary) suggestions. I imagine we could ask for
5 short papers from Dr Walford and/or Dr Gunson ..."

6 Et cetera, et cetera.

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

12 A. Yes.

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

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

17 Is what I think it says.

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

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

25 A. Not at all. Not at all.

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

4 A. Of course.

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

8 This is a minute from Dr Sibellas so Med IMCD,
9 12 May 1983, copied to you. We can see it's addressed
10 to Dr Field and it's on the topic of having a working
11 party on AIDS. It says:

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

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

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

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

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

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

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1 Q. Do you know why the idea was abandoned?

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

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

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

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

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1 helpful to have multiple inputs from experts.

2 **Q.** We can see if we look at WITN4461127, this is

3 a letter -- it's from Dr Craske to Dr Whitehead at the

4 Public Health Laboratory Service in London, so it's an

5 internal PHLS document, 10 May.

6 We can see in the first paragraph he is

7 referring to discussions with Peggy Pereira. Do you

8 know who that was?

9 **A.** She was a really very senior doctor at the PHLS.

10 **Q.** Then Philip Mortimer, who we have seen reference to in

11 the context of meeting with Dr Tedder.

12 Dr Craske at least is adding support for the

13 proposal that a working party should be set up to

14 co-ordinate the investigation of cases and the

15 prevalence of the disease.

16 Just by way of completing this issue, if we go

17 to DHSC0002229_004, this is a minute from you dated

18 23 May 1983. You're responding to Dr Field. "Action

19 on AIDS" is the heading of Dr Galbraith's report --

20 and we'll come back to that -- but it says:

21 "I agree entirely with your suggestion for

22 handling this issue ..."

23 I think we'd need to obviously check what

24 Dr Field was saying to know what the suggestion was,

25 but you say:

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1 role with the Department became involved with the work

2 of EAGA?

3 **A.** Yes.

4 **Q.** But of course by the time it was set up, you'd moved

5 to an unrelated job and Dr Smithies was performing the

6 role you'd performed.

7 With everything that you know now, the

8 subsequent involvement you had with EAGA, do you think

9 it would have been a good idea to have something like

10 EAGA set up rather earlier, perhaps in 1983?

11 **A.** I absolutely think that it would have been wonderful

12 for all of us if we had had an expert group reporting

13 to the Chief Medical Officer and taking the best

14 possible view of the assembled multidisciplinary

15 doctors and scientists to give us the best view of

16 this. I think it's, in retrospect, a terrible shame

17 that we didn't have but we didn't.

18 **MS RICHARDS:** Sir, I note the time. Perhaps a good point

19 for an afternoon break.

20 **SIR BRIAN LANGSTAFF:** Yes. We'll take a break until 3.45.

21 3.45.

22 **(3.17 pm)**

23 **(A short break)**

24 **(3.46 pm)**

25 **MS RICHARDS:** Dr Walford, still in May 1983, I want to

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1 "They certainly would not wish to press for

2 a formal working party at this stage."

3 So you didn't push the issue. Any particular

4 reason for that?

5 **A.** Well, I only wish I knew what his suggestions were.

6 I can't find any piece of paper which tells me what he

7 said to me or how he explained why he didn't want

8 a working party or what ideas he had in mind to do

9 something different. That would be good to know. But

10 basically whatever it was he said, I then thought,

11 well, I can't really press for a working party.

12 The working party hadn't, of course, been my

13 idea at the beginning, so it was -- I was very happy

14 that there should be a working party, and in many

15 respects I wish there had been, but basically he had

16 obviously got some other idea and I wasn't going to

17 particularly press for a working party in the light of

18 whatever it was he told me.

19 **Q.** I don't know whether you can then answer the next

20 question but it's really one that invites your

21 reflection or comment, rather than your factual

22 knowledge at the time. We know that something called

23 EAGA (the Expert Advisory Group on AIDS) was set up --

24 **A.** Yes.

25 **Q.** -- and met in early 1985. You subsequently in a later

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1 turn next to the Reference Centre Directors' special

2 meeting on 13 May, which you attended.

3 **A.** Yes.

4 **Q.** Soumik it's HCDO0000003_008, please. So we can see

5 there "Special Meeting of Haemophilia Reference Centre

6 Directors", St Thomas' Hospital 13 May 1983. Dr Bloom

7 is there, Dr Craske, various other Reference Centre

8 Directors and then we can see you attending as a DHSS

9 observer.

10 Had you invited yourself to that meeting or been

11 invited to it, can you recall?

12 **A.** I think I had invited myself. I know I invited myself

13 to a subsequent meeting. I'm pretty sure I must have

14 done because it was a reference centre meeting. So

15 I think I did.

16 **Q.** Then we can see, if we just look at the text, and

17 I know you have read it, so I won't go through all of

18 it, but there's reference to publicity, anxiety,

19 a need for Haemophilia Centre Directors to discuss

20 what should be done. There's reference to one

21 haemophiliac suspected of suffering from AIDS, which

22 is presumably a reference to Professor Bloom's own

23 case.

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

25 towards the end of that first paragraph, reference to

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1 the reporting system and then it says:
2 "The steps to be taken should a patient develop
3 the features of the full-blown condition were then
4 discussed. It was agreed there was insufficient
5 information available from the US experience to
6 warrant changing the type of concentrate used in any
7 particular patient."

8 Then, in terms of general policy, in the
9 following paragraph, it notes:
10 "... that many directors have up until now
11 reserved a supply of [NHS] concentrates for children
12 and mildly affected haemophiliacs ... it was
13 considered ... circumspect to continue with that
14 policy. It was ... agreed that there was, as yet,
15 insufficient evidence to warrant restriction of the
16 use of imported concentrates in other patients in view
17 of the immense benefits of therapy."

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

20 Do you have any recollection of that meeting?

- 21 **A.** Yes, I can remember being at it, yes.
22 **Q.** Do you have any recollection about the discussions,
23 beyond that which we see summarised with minutes?
24 **A.** No. I mean, I think it went on for much longer than
25 the minutes appear to imply. These are really,

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1 reference in terms, at least?

- 2 **A.** That's right.
3 **Q.** There's a suggestion that there was insufficient
4 evidence to warrant restriction of the use of imported
5 concentrates but no more than that and certainly the
6 Inquiry's heard some evidence to suggest that the
7 content of Dr Galbraith's letter wasn't widely known
8 amongst clinicians.
9 Did it occur to you to share the content of
10 Dr Galbraith's proposal with the Reference Centre
11 Directors?
12 **A.** Well, I don't think it can have done if it doesn't
13 appear and, essentially, it is a bit surprising, you
14 might think. The question is whether or not they knew
15 about that proposal. That suggestion came in on 9 May
16 and this meeting was on the 13th. I simply don't know
17 actually. But I think it would have been a good idea
18 if they'd had that paper but there's no reference to
19 that and I don't know that they ever did have.
20 **Q.** Then, in terms of the Cardiff case, again, there's
21 really very -- a passing reference to it almost in the
22 minutes.
23 **A.** Yes.
24 **Q.** Do you recall whether there was any more detailed
25 discussion about it because you were here face-to-face

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1 I think, fairly condensed notes of the meeting.

- 2 **Q.** Certainly, it's described as a meeting that was held
3 at 11.00 am and it says the meeting closed at 2.15 pm?
4 **A.** So it was quite long.
5 **Q.** Do you recall whether there was any discussion of any
6 other possible changes of general policy or changes to
7 treatment approaches other than what we see here?
8 **A.** No, I don't remember the discussion really at all.
9 I obviously took note of the conclusions because
10 I then went straight back to the Department and, as it
11 were, quoted them back to Dr Field. So I was
12 obviously taking notes myself at the time but I took
13 notes of the conclusions and then came back and
14 reported the meeting to Dr Field.
15 **Q.** I do not know whether you can answer this, Dr Walford,
16 but is your best recollection that there wasn't
17 a discussion of other strategies or are you simply
18 unable to say one way or another?
19 **A.** I am simply unable to say one way or another.
20 I simply don't recall the totality of the discussion.
21 I mean, clearly I've been reminded and reminded
22 several times of what the conclusions were but, more
23 than that, I don't remember.
24 **Q.** There's no reference in here to what we know was, by
25 now, the proposal from Dr Galbraith. There's no

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

- 3 **A.** Well, I think the thing is that these notes are so
4 truncated I can't -- I obviously am not recorded as
5 having intervened, so I either was sitting there
6 saying nothing or they simply haven't recorded what
7 I said, nor is there really any, as it were, verbatim
8 record, "Dr This said this and Dr That said that",
9 because you did find that in other meetings. So these
10 notes were really notes. I don't think it could be
11 described as a minute of the meeting.
12 **Q.** So if we then turn to Dr Galbraith's letter and then
13 your response setting out your views about it, the
14 letter from Dr Galbraith is CBLA000043_040.
15 We've got the letter there, 9 May, addressed to
16 Dr Field and then we can see headed "Action on AIDS",
17 which is then the heading we see, I think, in some
18 later minutes.
19 Just maybe worth noting he records The Lancet of
20 30 April, this is in the first paragraph, referring to
21 the three cases in haemophiliacs in Spain. So it may
22 be that that was a mechanism as to how that
23 information got to the Department or into the public
24 domain.
25 But, in any event, we then go over -- actually,

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1 sorry, can I pick it up, the last paragraph of that
2 letter. He says:
3 "... I am most surprised that the USA
4 manufacturers of the implicated blood products have
5 not informed their customers of this new hazard.
6 I assume no official warning has been received in the
7 United Kingdom?"

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

14 **A.** Yes.

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

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

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

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

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

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

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

16 So it was a very, very draconian proposal on the
17 basic of one case, and I totally accept that the case
18 in Cardiff was a case, and CDSC had defined it as
19 a case, but we had one case in this country and about
20 10 or 11 cases in the United States.

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

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

3 **A.** Yes.

4 **Q.** "... probably transmitted by blood and blood
5 products."

6 Again, you were already of that view --

7 **A.** Yes.

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

10 **A.** Yes.

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

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

16 **A.** Mm-hm.

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

19 **A.** Yes.

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

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

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

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

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

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

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

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

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

25 **A.** Yes.

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

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

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

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

3 **A.** Yes.

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

6 **A.** Absolutely.

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

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

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1 UKHCDO.

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

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

11 Now, absolutely, some regions were making more
12 cryoprecipitate than others but, basically, if you
13 look at the chart that I've put into my evidence,
14 I think that the country as a whole was making about
15 5 million units of cryoprecipitate, and Dr Lane, in
16 one of his papers, said that actually some of the
17 Regional Transfusion Centres had simply stopped making
18 it altogether and had re-purposed some of their
19 accommodation and would have to set the whole thing up
20 again.

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

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

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

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

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

24 **A.** Yes.

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

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

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

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

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

7 **A.** I would say that's fair.

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

11 **A.** Can I --

12 **Q.** Yes --

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

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

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1 over to cryoprecipitate, consideration was given to
 2 whether BPL could produce small pool products and for
 3 each matter the view was no, we can't on logistic
 4 grounds.
 5 **Q.** When you say consideration was given to switch over to
 6 cryo, are you talking the Committee on the Safety of
 7 Medicines decision there?
 8 **A.** No, I mean, Dr Gunson considered it, Dr Lane
 9 considered it, I think people were aware that there
 10 might be a call for more cryo and considerably more
 11 cryo, and the question was: could that actually be
 12 done? Given the state of play with the production of
 13 cryo in the RTDs at the time, with about maybe
 14 5 million international units, it takes quite a lot of
 15 gearing up for them to be able to make -- not
 16 a sufficient amount, they'd never have made
 17 a sufficient amount, but to make quite a lot more
 18 cryoprecipitate than was being made at the time and,
 19 of course, as soon as you don't make
 20 cryoprecipitate -- you make cryoprecipitate you're not
 21 sending plasma to BPL and they you have got the
 22 problem of, well, how are you going to make your
 23 Factor IX because you need the cryo supernatant to go
 24 to BPL to make Factor IX for the haemophilia B
 25 patients, you need to make immunoglobulin and

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1 looking at it, and please correct me if I'm wrong, but
 2 I don't think we see it being looked at in that light
 3 in the materials?
 4 **A.** No, I think that's totally fair.
 5 **Q.** So then if we just -- just to complete this document,
 6 we can see there's reference at the top of that second
 7 page to the incubation period several months, two
 8 years, maybe as long as four years. Then he talks
 9 about what the consequence might be in terms of the
 10 number of cases seen:
 11 "Factor VIII concentrate ... would appear to
 12 have a high risk of being contaminated with AIDS agent
 13 because homosexuals and drug abusers are known to be
 14 frequent blood donors and each plasma pool from which
 15 it is manufactured is collected from as many as 1,000
 16 donors."
 17 In fact, I think the number is probably
 18 considerably in excess of that but, again, there's
 19 nothing controversial, is there, in terms of what Dr
 20 Galbraith was saying there, that was well known to the
 21 Department?
 22 **A.** Yes.
 23 **Q.** Point 5 I think again is, again, uncontroversial:
 24 "... no known means of ensuring ... blood or
 25 blood products are free of the AIDS agent."

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1 albumin -- you can make that from time-expired plasma
 2 but, basically, you needed the Factor VIII, the
 3 cryoprecipitate supernatant to go to BPL.
 4 So you had not just to make cryo at the local
 5 RTDs, you had to have a system -- and Dr Lane
 6 describes it very well, I think, in his draft evidence
 7 for the HIV litigation -- in which Regional
 8 Transfusion Centres, totally unused to doing this,
 9 would have needed to find a method sterily to
 10 collect the cryoprecipitate supernatant to get it to
 11 BPL so that Factor IX could be produced because you
 12 did not want to disadvantage patients with
 13 haemophilia B while you were trying to advantage
 14 patients with haemophilia A.
 15 **Q.** As far as you can recall, was the assumption on which
 16 these matters were being considered an assumption that
 17 you'd need to somehow find a way of replicating the
 18 amount of concentrate through cryoprecipitate; in
 19 other words, the assumption was we've got to continue
 20 treatment at the same level, we've got to continue
 21 home treatment, because part of an answer to what
 22 you're describing might have been a cessation of home
 23 treatment, a restriction of concentrates for the truly
 24 life-threatening or the necessary surgery, so there
 25 were potentially more imaginative adaptive ways of

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1 At that point in time.
 2 **A.** Yes.
 3 **Q.** Reference to the multi-transfused infant. And then,
 4 again, a significant fact, a mortality rate, a very
 5 high mortality rate articulated in 6. And although
 6 there might be different percentages given in
 7 different documents, there was no dispute, was there,
 8 the mortality rate was a very high mortality rate?
 9 **A.** It was.
 10 **Q.** So if we then look at your views at the time as
 11 recorded in your memo, or your minute to Dr Field,
 12 it's DHSC0002227_047.
 13 So it's 13 May 1983, and you have clearly, from
 14 the text, written it after you had attended the
 15 meeting at St Thomas'?
 16 **A.** Yes.
 17 **Q.** Its addressed to Dr Field, top of the page. So it
 18 refers to the letter from Dr Galbraith. You say:
 19 "In my view this suggestion is premature in
 20 relation to the evidence and unbalanced in that it
 21 does not take into account the risks to haemophiliacs
 22 of withdrawing a major source of their [Factor] VIII
 23 supplies.
 24 "Perhaps the situation is best put in
 25 perspective by a statement which was drafted to appear

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1 in the minutes of the meeting of the Directors of
2 Haemophilia Reference Centres which I attended
3 today ..."

4 Then we see your note of what was agreed, which
5 I don't think is materially different from what we've
6 seen in the minutes. So "circumspect" to continue the
7 policy in relation to children and mild haemophiliacs
8 to NHS material, "not sufficient evidence to restrict
9 the use", and a suggestion of Regional Transfusion
10 Directors meeting.

11 If we just go back to your observation in the
12 second paragraph, I think it's -- I understand from
13 your evidence as to why you say Dr Galbraith's
14 suggestion was "unbalanced". Again, please correct me
15 if I'm wrong, I don't read that as you saying
16 unbalanced as in unhinged?

17 **A.** No.

18 **Q.** You are saying it hasn't put the implications for
19 haemophiliacs into the balance?

20 **A.** It was not weighing the -- you know, in public health
21 terms, actually, first do no harm. So you take
22 a public health action, you expect to improve matters
23 and not actually to do harm. Potentially --
24 potentially -- the action he proposed would cause
25 harm, and his document didn't refer to that at all.

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1 haemophiliacs at the Royal Free, in fact 100 per cent
2 of the haemophiliacs being treated at the Royal Free,
3 were actually in -- seroconverted, so that they had
4 actually already been infected.

5 **Q.** I don't think that's quite right, Dr Walford, but --
6 because the Inquiry's looked at that data and, indeed,
7 seroconversion data about others, and it's actually
8 a much wider spread, so there is certainly
9 seroconversion --

10 **A.** Before.

11 **Q.** Before this date.

12 **A.** Yes.

13 **Q.** But there are also significant numbers of
14 seroconversions after.

15 **A.** Of course. I'm not for one moment denying that
16 seroconversions would have occurred afterwards, but
17 there was the issue that a certain number of
18 infections had already occurred. There was nothing
19 you could do about it in fact because it was in the
20 rear view mirror, so to speak, they had actually
21 occurred. And it was a not insignificant number.

22 So we didn't know that. I am now talking with
23 the retrospectoscope, if you like, the benefit of
24 total hindsight, we didn't know that and I couldn't
25 possibly have concluded it.

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1 He didn't, apparently, go on to say, "I recognise that
2 this may cause severe and major problems in the
3 treatment of patients with haemophilia".

4 Understandably, because that wasn't his particular
5 discipline, but it wasn't mentioned in his document at
6 all.

7 **Q.** As a matter of fact -- that's obviously correct that
8 it wasn't mentioned -- conversely one could say, in
9 terms of the no harm, that where the Department,
10 UKHCDO, the others, ended up was exposing patients to
11 a risk -- we obviously know the full extent of that
12 risk now, but a known risk of a fatal disease?

13 **A.** Yes.

14 **Q.** So the "do no harm" could apply equally the other way,
15 couldn't it?

16 **A.** It could but what we didn't know then -- I mean, there
17 was a huge amount we didn't know then, and I think
18 that is an important consideration, is essentially we
19 were working in nearly total ignorance of almost
20 anything, but what we didn't know then was that
21 subsequently emerged really very good evidence from
22 the use of stored samples, which I know is
23 controversial but nevertheless stored samples were
24 used from the Royal Free, for example, where it was
25 shown that well before the date of this meeting

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1 What we didn't know was whether this material,
2 this infection, was in the UK blood supply at all, for
3 a start. So that would make UK plasma not safe. But
4 also, had you taken the action proposed here and had
5 a certain number of haemophiliacs been damaged as
6 a result of it, had bled, had had a cerebral bleed,
7 had had a major internal bleed, had had a crippling
8 bleed into joints as a result of that action, and they
9 may have in any case have been infected already,
10 unbeknownst to us, that would have been yet a double
11 blow.

12 So I would really propose to you that there was
13 no good solution here. There was no good solution.
14 On the one hand we potentially were going to harm
15 haemophiliacs by withdrawing this material, because
16 you couldn't readily actually replace it, and, on the
17 other hand, of course, we were potentially going to do
18 harm by not withdrawing the material because of the
19 transmission of an infectious agent which had, by that
20 stage, hardly put in an appearance in the UK.

21 **Q.** I want to come back tomorrow to the question of what
22 the severity of the consequences might have been for
23 haemophiliacs of either a reduction or cessation or
24 change in treatment, so I'll leave that to tomorrow,
25 if I may.

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1 Can I just ask this: you refer to the Royal Free
2 data, you refer to the fact that some people had
3 already been infected, numbers obviously not yet
4 known. But was there an assumption, in your mind or
5 in the minds, as far as you're aware, of any of those
6 who were involved in the decision-making, was there an
7 assumption that played a part: well, if people have
8 been infected, they have already been infected, so
9 there's no point in taking any action? Did that come
10 into the decision-making process?

11 **A.** It appears to have come into the decision-making
12 process in the HCDO, because they actually mention
13 that.

14 I am not aware that that was, in any sense, in
15 my thoughts of the time, nor, I think, did I see it
16 referred to at all in the CSM consideration.

17 **SIR BRIAN LANGSTAFF:** It is referred to in
18 HCDO0000003_008, the minutes you have just mentioned.

19 **A.** Yes.

20 **SIR BRIAN LANGSTAFF:** They were the short notes that you
21 have given. I noticed in passing there seemed to be
22 something of what I thought was an illogicality in it.

23 Can we just go back to that?

24 **MS RICHARDS:** Second page.

25 **SIR BRIAN LANGSTAFF:** We started just after the break.

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1 supposes that the only product available is causing
2 and has already caused the illness which is yet to
3 materialise, isn't that what it's saying?

4 **A.** I think what it was saying here, though actually
5 I would almost take issue with the notion that just
6 because somebody has developed "full-blown AIDS" that
7 actually giving them some more virus was necessarily
8 totally harmless. I just -- that struck me as being
9 a very strange way of saying things.

10 **SIR BRIAN LANGSTAFF:** You just don't know, do you?

11 **A.** You certainly don't know, but what I think they seem
12 to be saying is that if you can possibly -- if this is
13 transmitting, then we have to be very careful with
14 making sure that the right concentrate is used with
15 the right patient, or the right factor, Factor VIII,
16 be it cryo, or DDAVP, or whatever is used with the
17 right patients, so that if they are not already
18 infected there isn't so much of a possibility they
19 will become infected. I think what they are saying
20 here is that once full-blown AIDS is manifest in
21 a patient -- and it had to be said that, apart from
22 Dr Bloom's patient, nobody seen such a case in the UK,
23 but in America if they still needed product because
24 they were bleeding because they were haemophiliacs,
25 then it wasn't going to do yet more harm, is what they

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1 **MS RICHARDS:** HCDO0000003_008.

2 **A.** The 13 May one, I think.

3 **SIR BRIAN LANGSTAFF:** That's right.

4 **MS RICHARDS:** HCDO0000003_008, it's the second page,
5 bottom half of the page. That's it.

6 **SIR BRIAN LANGSTAFF:** Can we go up the page, thank you.
7 It was this, the contrast between these two
8 sentences which caught my eye when we were looking at
9 it:

10 "It was agreed there was insufficient
11 information available from the US experience to
12 warrant changing the type of concentrate used in any
13 particular patient."

14 In other words, there's not enough evidence,
15 that people are at risk. But it then goes on to say:

16 "... once the condition is fully developed it
17 seems to be irreversible so that there would seem to
18 be no clinical benefit to be gained by changing to
19 another type of factor VIII."

20 So, on the one hand, there's no evidence that
21 anyone has it; on the other hand, it's assuming that
22 everyone has it?

23 **A.** On the other hand -- I'm sorry?

24 **SIR BRIAN LANGSTAFF:** There is no clinical benefit to be
25 gained by changing to another type of Factor VIII

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1 are alleging, to give them the Factor VIII concentrate
2 again, because they were already irreversibly affected
3 and were likely, unfortunately, to die of AIDS.

4 **SIR BRIAN LANGSTAFF:** It just seemed to be put forward
5 an argument that even though you did not know whether
6 someone was infected or not, there would be no point
7 in changing because they might already be.

8 **A.** Well, I didn't -- I confess I didn't read it that way.
9 My quibble, if you like, was -- when I saw this was
10 with that second sentence, the:

11 "Moreover once the condition is fully
12 developed ..."

13 In other words, the patient is known to
14 have AIDS. AIDS with its very significant mortality
15 rate. They are saying that change of product is
16 immaterial because even if changing the product would
17 prevent transmission to patients who hadn't got AIDS,
18 once they already had got AIDS there was -- it was
19 immaterial what product you gave them because they
20 already had the condition and it was irreversible.

21 That was my reading.

22 **SIR BRIAN LANGSTAFF:** I follow that. The problem perhaps
23 is the word "moreover".

24 **A.** Ah. Well, I'm happy to say it wasn't my word.

25 **SIR BRIAN LANGSTAFF:** No, of course, it's not your word,

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1 and it is admittedly, as you would have it, a very
 2 truncated summary of what was being said.
 3 **A.** Yes.
 4 **SIR BRIAN LANGSTAFF:** But it appears to be using, as
 5 a justification for continuing as they were, that if
 6 the condition --
 7 **A.** Oh, I see. Yes, no, sorry, I had misunderstood.
 8 **SIR BRIAN LANGSTAFF:** That's the significance of the word,
 9 "moreover", I think.
 10 **A.** Yes, I totally misunderstood. And if you took the
 11 "moreover" out, it makes more sense, yes, because it
 12 was apparently a corollary to -- following on from the
 13 sentence before, but it isn't, in effect.
 14 **SIR BRIAN LANGSTAFF:** Well, it can't be, can it?
 15 **A.** No.
 16 **SIR BRIAN LANGSTAFF:** It's either a separate point which
 17 has nothing to do with what treatment you give to
 18 people who you do not know to have the condition.
 19 **A.** No, I understand, yes.
 20 **SIR BRIAN LANGSTAFF:** It can't be a reason for going on as
 21 you are doing.
 22 **A.** No.
 23 **SIR BRIAN LANGSTAFF:** That was all -- that's what struck
 24 me.
 25 Thank you.

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1 then this may very well precipitate suspension of the
 2 use of this product in the UK."
 3 So Dr Craske's position may have been a little
 4 more nuanced, which was: not today but any more cases
 5 and it may well be a different outcome.
 6 **A.** Yes, I hadn't seen this letter until I saw the papers
 7 that you sent me. I wasn't aware of his view.
 8 **MS RICHARDS:** Sir, that's probably a good point at which
 9 to finish for today.
 10 **SIR BRIAN LANGSTAFF:** Just on that last point, you
 11 described in your minute that it would be premature to
 12 do what Dr Galbraith was proposing.
 13 **A.** Mm-hm.
 14 **SIR BRIAN LANGSTAFF:** What would have been sufficient, as
 15 you can remember seeing it at the time -- and
 16 I appreciate it's difficult to put yourself back into
 17 a position which you weren't actually in -- but what
 18 did you consider might have been what would have
 19 ceased it being premature and made it now the time?
 20 **A.** Well, I mean, for sure if there had been firm
 21 microbiological or virological evidence that this was
 22 happening. I think it needs to be understood that,
 23 for example, in America there was still a lot of
 24 controversy as to what was causing AIDS. So it wasn't
 25 a sort of a done deal, if I can put it that way,

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1 **MS RICHARDS:** Then, just before we finish for today and
 2 for the sake of completeness, I just wanted to go back
 3 to Dr Craske's letter, because you made reference to
 4 his views.
 5 It's WITN4461127, Soumik. We looked at it
 6 earlier in the context of the proposal for there to be
 7 a working party.
 8 If we go to the third paragraph, there's
 9 reference to the meeting on 13 May. It refers to him
 10 attending and you'll be attending. It would appear
 11 that there's been a discussion between Dr Galbraith
 12 and Dr Craske, and reference to him writing to the
 13 Department, and, of course, we know that on the day of
 14 that telephone conversation Dr Galbraith did write to
 15 the Department. Dr Craske's views are expressed in
 16 these terms:
 17 "I am not sure myself that we are at the stage
 18 when there is enough evidence to justify this step,
 19 but I think both the Department of Health and the
 20 Haemophilia Centre Directors will have to face this
 21 problem in the near future, and the earlier it is
 22 seriously considered the easier it will be make
 23 a rational decision. I think that the outcome of the
 24 meeting will be that we will await the appearance of
 25 further evidence, but that if any more cases appear

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1 anywhere. There was controversy. There was
 2 controversy in America, particularly controversy to
 3 a degree in this country.
 4 Basically, people were looking at an
 5 epidemiological association. An epidemiological
 6 association, as I certainly learnt in subsequent years
 7 when I did my MSc in epidemiology, is not actually
 8 evidence of causation and at the time this was
 9 a debatable proposition. Frankly, my own view was
 10 that in fact it was transmitting but not everybody
 11 felt that.
 12 I'm pretty sure if there had been virological
 13 evidence that this was happening and there was some
 14 way of actually detecting it through virology, I think
 15 that action would have probably been forthcoming much
 16 faster than it ultimately was.
 17 **SIR BRIAN LANGSTAFF:** Thank you very much. We'll take
 18 a break there until 10.00 tomorrow. So 10.00
 19 tomorrow. Thank you very much.

20 (4.33 pm)

21 (Adjourned until 10.00 am the following day)

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<p>MS RICHARDS: [21] 1/5 11/21 38/10 40/4 41/16 55/2 55/9 66/23 83/2 107/12 109/23 110/22 112/14 136/8 167/18 167/25 193/24 194/1 194/4 198/1 199/8</p> <p>SIR BRIAN LANGSTAFF: [40] 10/24 11/4 11/20 37/7 39/24 40/5 40/22 41/15 55/4 66/22 83/1 107/7 110/3 110/15 110/18 112/2 112/5 135/2 135/11 136/7 167/20 193/17 193/20 193/25 194/3 194/6 194/24 195/10 196/4 196/22 196/25 197/4 197/8 197/14 197/16 197/20 197/23 199/10 199/14 200/17</p> <p>'Board' [1] 87/11 'Chairman' [1] 87/15 'fast' [1] 82/25 'fast-tracked' [1] 82/25 'free' [1] 15/24 'hard' [1] 67/4 'hard-nosed' [1] 67/4 'line' [1] 149/9 'quango' [1] 90/18 'San' [1] 121/20 'This' [1] 144/13 'top' [1] 73/14 'top-sliced' [1] 73/14 'whether' [1] 61/22 'World' [1] 72/20</p> <p>... [5] 101/5 169/10 169/12 169/13 173/3 ... 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