

Wednesday, 21 July 2021

(10.00 am)

DR DIANA MARION WALFORD (continued)

Questions by MS RICHARDS

MS RICHARDS: Good morning.

Yesterday when we were looking at the special meeting of Reference Centre Directors on 13 May, I think we explored the fact that the Galbraith letter and recommendation hadn't been circulated to those directors.

Can I then just ask you about its circulation more widely. It would appear from the documentation and evidence that the Inquiry has that Dr Galbraith's recommendation and report never reached ministers. First question: whose decision would it have been as to whether to provide that to ministers or not, both in terms of division and hierarchy?

A. Well, I'm not clear whether actually somebody would have taken a view that ministers needed to see that document until it had been discussed in the Committee on Safety of Medicines Biological Subcommittee because basically ministers would obviously have wanted to see what the experts were going to be saying about it.

It would have been for Med IMCD to make sure that the paper went to Medicines Division. Now, this

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was in a position to comment on the paper fully before the experts had had a look at it.

Q. Then, just going back to the question of whose role it might have been to alert ministers, if you can just help us understand what the process might have been. So Medicines Division you think would have been the part of the Department that would have been seized with thinking about that?

A. Well, not necessarily. I mean, I think that Med IMCD -- Dr Field at Med IMCD could well have decided that it would be a good thing to put it up. I guess one of the problems is that there's obviously a gap in the correspondence. I don't know about the discussions that Dr Field purported to have with doctors, the *ad hoc* discussions. I just have this lacuna in the evidence and I really can't help you very much more with that, I'm afraid.

Q. Can I then ask you to look at ARCH0002544.

Now, this is a document from Dr Peter Foster to Mr Watt dated 15 July 1983. There's no evidence to suggest that this is a document that would have crossed your desk in 1983 --

A. Right.

Q. -- or, indeed, I think the Department's desk at all, but I just wanted to draw your attention to it and

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thought had occurred to me as well when I was going through the papers, and I didn't see, in any of the correspondence from Mary Sibellas which reached me, that the paper had been copied, when Dr Galbraith sent it, to anyone in Medicines Division. So I don't know if Medicines Division was aware but I would certainly say that that would have been the place that it should have gone and that obviously, after discussion in the CSMB, ministers should have been told what the outcome was. I haven't found any papers which suggest that they were.

Q. That I think is certainly where our understanding is, Dr Walford.

Looking at it now, do you think that ministers should perhaps have been told what a leading public health doctor working within the Public Health Laboratory Service was saying to the Department?

A. I think it would be perfectly reasonable to have told them, yes.

Q. But actually, more than perfectly reasonable, the right thing to do to tell them?

A. I think it would have been difficult to tell them without some sort of forward advice, if you will, and basically I don't think any of us was in a position -- even had I been in charge of giving it to ministers,

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then ask you about it.

So we can see Dr Foster is seeking to summarise "key points concerning AIDS" from the meetings that had taken place in Stockholm -- so that's the World Federation of Haemophilia.

He refers to information presented by Dr Evatt of CDC. At paragraph 1 we can see he refers to the total number of confirmed cases in the States being "marginally higher than would be predicted from an exponential growth", so to be "consistent with the view that AIDS is a transmissible agent".

Point 2:

"Epidemiology strongly suggests a transmissible agent ..."

He refers to transmission between spouses, et cetera.

He then refers to there being evidence, epidemiological evidence, of "three stages to the disease". So essentially a long latency period.

If we go further down the page, we can see then, in paragraph 5:

"Predicted mortality is 100 per cent in 3-4 years for those with Kaposi's sarcoma and 100 per cent in 25 months for those with opportunistic infections.

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1 "6. Haemophiliacs are in the group which  
 2 develops opportunistic infections."  
 3 So a very bleak picture indeed in terms of  
 4 mortality.  
 5 Then he refers, at paragraph 7, to cases of  
 6 confirmed cases of haemophiliacs, said to be 16 in the  
 7 USA, half of whom are now dead. Then five in Europe,  
 8 although he seems to refer to Canada as part of  
 9 Europe, but in any event five cases, and he refers to  
 10 the three Spanish, the one Welsh. He refers to other  
 11 delegates, seeming to think there may be more cases  
 12 than this outside the USA.  
 13 Point 8 refers to, of the 16 cases in the  
 14 States, one being a mild haemophilia B case, and that  
 15 the haemophilia A cases encompass mild, moderate and  
 16 severe.  
 17 Then if we go over the page, he refers to AIDS  
 18 still being located mainly in key urban areas in the  
 19 USA but:  
 20 "... the haemophilia cases are generally located  
 21 in non-AIDS areas. This is strong evidence for  
 22 transmission by [Factor] VIII.  
 23 "10. Common lots of [Factor] VIII concentrate  
 24 seem to be 'rare or non-existent'.  
 25 Then he refers to the Welsh case having received

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1 a correct feeling.  
 2 First of all, would it have been helpful for  
 3 information of this kind to have been shared with the  
 4 Department, because this is an on-the-ground update of  
 5 what's being said, perhaps in a more informal setting,  
 6 by CDC?  
 7 **A.** Yes, obviously.  
 8 **Q.** Do you think if it had been made available to the  
 9 Department it might have shaped or influenced your  
 10 thinking to any different extent?  
 11 **A.** I honestly can't tell. Basically, it still remains  
 12 the case that the situation is, as it were, unproven,  
 13 but there's a strong epidemiological evidence that  
 14 AIDS is transmissible and I'm not sure, because we've  
 15 just gone through this again quickly, what it was  
 16 saying about Factor VIII concentrates. Is there some  
 17 sentence in there specifically?  
 18 **Q.** Well, I think if we just go further up the page --  
 19 sorry, I don't have my hard copy to hand --  
 20 **A.** Oh, yes.  
 21 "Common lots of [Factor] VIII concentrate seem  
 22 to be 'rare or non-existent'.  
 23 Yes.  
 24 **SIR BRIAN LANGSTAFF:** It's the last sentence of  
 25 paragraph 9, isn't it?

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1 products from Armour and Immuno as well as NHS. That  
 2 is paragraph 11:  
 3 "Other suspected European cases had  
 4 received products for Hyland ... and Hyland and  
 5 Immuno ..."  
 6 Then if we go to what he says after  
 7 paragraph 12, he says this:  
 8 "My general impression was that there was  
 9 a concentrated attempt from USA delegates to play down  
 10 the situation. The risk to haemophiliacs was said  
 11 (a number of times) to be one in a million (though  
 12 simple arithmetic suggests 1 in 1000). It was  
 13 stressed that the causes of death for  
 14 USA haemophiliacs is ..."  
 15 Then we can see the figures there set out.  
 16 "... ie. keep on taking concentrates.  
 17 "However this data is for 1982; data for 1983  
 18 could well be different."  
 19 Then if we look at the last paragraph:  
 20 "With the first haemophiliac case only 12 months  
 21 ago and a possible incubation period from 1-3 years  
 22 a number of delegates (mainly European) were clearly  
 23 uneasy and felt that we may still only be seeing the  
 24 tip of the iceberg."  
 25 Obviously, as things turned out, that was

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1 **MS RICHARDS:** Yes, "strong evidence for transmission by  
 2 [Factor] VIII".  
 3 **A.** Right.  
 4 **Q.** We'll come later in the course of the morning to the  
 5 line that the Department used, the line to take the  
 6 "no conclusive proof".  
 7 **A.** Yes, indeed.  
 8 **Q.** This might, for example, have caused, earlier than in  
 9 fact happened, a shift in that thinking, did it not?  
 10 **A.** And the date of this Stockholm conference that was  
 11 reported here by Dr Watt?  
 12 **Q.** I can't remember the date off the top of my head  
 13 without looking. His memo is 15 July 1983. I think  
 14 the chair is going to be able to tell you momentarily  
 15 what the exact date of the World Federation of  
 16 Haemophilia conference was.  
 17 **SIR BRIAN LANGSTAFF:** I'm just looking to see. I'm not  
 18 sure I have it noted -- it's June '83. 30 June.  
 19 **A.** The reason I was asking about the date is because --  
 20 I mean, this was information which we didn't have but  
 21 there was information in an article in The Lancet, or  
 22 at least an editorial in The Lancet, about April 1983.  
 23 I've been provided with that by the Inquiry and  
 24 I think -- I don't have the reference immediately to  
 25 hand --

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- 1 **MS RICHARDS:** I can find it for you if you'll give me just  
2 a minute.
- 3 **A.** It's the words "tip of the iceberg" that reminded me  
4 that I've seen that Lancet article which actually  
5 refers to the "tip" of the "iceberg", but then goes on  
6 to cast quite significant doubt on how certain matters  
7 were in relation to transmission.
- 8 **Q.** It's PRSE0002723, and it's the column on the  
9 right-hand side. I think you might be referring --  
10 well, the last sentence of the first paragraph refers  
11 to:
- 12 "... the T cell population abnormalities  
13 commonly seen in haemophilia may be the submerged part  
14 of an iceberg of which AIDS ... is the clinically  
15 obvious 'tip'."
- 16 Then if we go to the last paragraph on that  
17 column there's reference to Desforges in the middle  
18 paragraph and then I think you may then be referring  
19 to the last four lines:
- 20 "The links suggested by the American workers  
21 must be regarded as not proven. Whilst careful  
22 surveillance must continue, the reported cases do not  
23 constitute a strong argument for a change in treatment  
24 policy."
- 25 **A.** Yes.

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- 1 Bristol case, which we'll come on to later. It  
2 pre-dates the World Federation of Haemophilia meeting  
3 that Dr Peter Foster was talking about.
- 4 **A.** Right. That was in Stockholm.
- 5 **Q.** In Stockholm. So if we just go back to Dr Foster's  
6 memo, ARCS0002544, if we go to the second page, three  
7 points I just wanted to emphasise from this. First of  
8 all, Dr Peter Foster's assertion this is strong  
9 evidence for transmission by Factor VIII; secondly,  
10 his impression that there's a concerted attempt by the  
11 American delegates to play down the situation; and  
12 then, thirdly, his sense, shared sense of some of the  
13 delegates, that this is the tip of the iceberg.
- 14 That, coupled with what is reported as being the  
15 very high mortality rate -- and we see the mortality  
16 rates, at that stage, in the cases of haemophilia  
17 patients -- might that not have led the Department to  
18 take a different view?
- 19 **A.** I can't say. I really can't say. But I wonder if  
20 I could actually draw your attention to a paper that  
21 the Inquiry gave me last night, amongst the papers  
22 that I sometimes get at the end of the day.
- 23 **Q.** Yes, I'm sorry about that.
- 24 **A.** I have it here because I think this is a very  
25 interesting paper. It's July 19, 1983, so almost

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- 1 **Q.** So that -- our understanding is that that's an  
2 editorial written by Dr Peter Jones in fact.
- 3 **A.** I didn't know that.
- 4 **Q.** I think that's what --
- 5 **SIR BRIAN LANGSTAFF:** There is, just if you remove the --  
6 that's it. Thank you. The actual phrase "tip of the  
7 iceberg" is used, isn't it, higher up? Yes.
- 8 **MS RICHARDS:** The end of the first paragraph.
- 9 **SIR BRIAN LANGSTAFF:** It's talking about -- can we just  
10 get rid of the -- thank you. It's:
- 11 "In the March issue of Annals of Internal  
12 Medicine three articles describe further cases ...  
13 An accompanying editorial by White and Lesesne  
14 suggests that the T cell population abnormalities  
15 commonly seen in haemophilia may be the submerged part  
16 of an iceberg of which AIDS (they mention 7 cases  
17 altogether) is the clinically obvious 'tip'."
- 18 So that may be where that editorial mentions  
19 "tip" of the "iceberg".
- 20 **A.** Thank you.
- 21 **MS RICHARDS:** This is, I think, early April; so  
22 2 April 1983.
- 23 **SIR BRIAN LANGSTAFF:** 2 April.
- 24 **A.** Yes.
- 25 **MS RICHARDS:** It obviously pre-dates any knowledge of the

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- 1 contemporaneous if you will, and it's a paper from --  
2 which was a meeting of the Blood Products Advisory  
3 Committee of the National Institutes of Health in  
4 America, a very prestigious organisation.
- 5 **Q.** Just pause there. I'm going to try to ascertain what  
6 the URL is. I don't recognise it ... oh, yes, I know  
7 what you're talking about, Dr Walford, my apologies.  
8 So it's a document, in fact, I think the Chair wants  
9 to ask you about. BAYP0004674.
- 10 **A.** I thought -- as I say, I read it for the first time  
11 last night -- I thought that this was quite  
12 a comprehensive exchange of views between relevant  
13 experts in America. It didn't certainly convey to me  
14 the impression that there was some sort of concerted  
15 attempt to play down the potential dangers, if you  
16 will, more the amount of uncertainty that existed  
17 between all these experts.
- 18 And I seem to recall in the summary -- yes, I've  
19 highlighted it for myself.
- 20 **Q.** Page 3.
- 21 **A.** Paragraph 9.
- 22 **Q.** Bottom of the page, Soumik.
- 23 **A.** Would you care to read that out?
- 24 **Q.** Yes.
- 25 "It was very clear that confronted with this

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1 complex problem the Committee felt that balance must  
 2 be struck between theoretical risk of the product to  
 3 recipients against the need for an uninterrupted  
 4 supply of a life-sustaining therapy. As several  
 5 members of the panel stressed, it would be undesirable  
 6 to distribute and use a lot of product which  
 7 incorporated plasma from a donor with a definite  
 8 diagnosis of AIDS. However, signs and symptoms  
 9 suggestive of AIDS (eg persistent lymphadenopathy,  
 10 night sweats, etc) would not be persuasive enough to  
 11 dictate a recall of product. Enough concern was  
 12 expressed about the question of supply that the  
 13 Committee was unwilling to advise the agency to take  
 14 an unalterable regulatory position calling for an  
 15 automatic recall which would likely jeopardise product  
 16 availability. Adding to the uncertainty with regard  
 17 to the decision of whether to quarantine or recall  
 18 a product lot, several Committee members and other  
 19 participants expressed the opinion that the risk of  
 20 AIDS from transfusion of plasma derivatives or use of  
 21 AHF concentrate has not been definitely established.  
 22 They cited the fact that nearly all the haemophiliacs  
 23 with AIDS had used material from differed lots, and  
 24 that many other haemophiliacs receiving these same  
 25 lots had not developed AIDS. They stressed the need

1 the international implication of that, I suppose,  
 2 would be any product made before 24 May should be  
 3 recalled, one would have thought.  
 4 **A.** Any product made before --  
 5 **SIR BRIAN LANGSTAFF:** 24 May -- March.  
 6 **A.** March.  
 7 **SIR BRIAN LANGSTAFF:** Because --  
 8 **A.** One assumes much of it would actually have been, by  
 9 then, in patients rather than be available. I think  
 10 the sort of gravamen of what they were wanting to say  
 11 in relation to those new regulations was we have  
 12 instructed the fractionators to do this far more  
 13 testing sort of surveillance of their donors making  
 14 sure that the donors that belonged to high risk  
 15 groups, and so on, are excluded and -- so that they  
 16 hoped that their product would thereby be safer after  
 17 24 March than it had been before then.  
 18 But there wasn't a suggestion here that  
 19 necessarily a particular batch might be withdrawn.  
 20 I have found this really quite interesting because,  
 21 I don't know if I can refer to -- I did refer to the  
 22 NIBSC report of February 1984, where they were still  
 23 considering whether a batch, which was thought to have  
 24 had product -- a donor in it who had either developed  
 25 AIDS or had possibly developed AIDS should be

1 for studies to followup recipients of blood products  
 2 derived from AIDS patients. The consensus of the  
 3 Committee was that the action to be taken for each  
 4 incident of inclusion of plasma from a donor who might  
 5 have AIDS into a product pool should be decided on  
 6 a case-by-case basis."

7 **A.** So I merely recall this because I read it so recently  
 8 and there is quite a dense discussion between the  
 9 various participants. There's a participant from the  
 10 National Haemophilia Federation, there are some  
 11 fractionators, there is Dr Bruce Evatt of CDC, a very  
 12 influential character and I think that this certainly  
 13 doesn't suggest that there was a well-formed view that  
 14 the personnel in America knew what they should be  
 15 doing about it and they have a degree of uncertainty  
 16 that we ourselves were under at that time.

17 **SIR BRIAN LANGSTAFF:** Certainly, as I read the paper, the  
 18 issue there was whether or not there should be  
 19 a requirement for any product made from plasma, to  
 20 which someone suspected of AIDS had contributed,  
 21 should be recalled, and it might be thought, mightn't  
 22 it, that the earlier decision taken in March, when  
 23 the FDA recommended to pharmaceutical companies that  
 24 they did not distribute any product which had been  
 25 made from plasma collected before 24 March in the USA,

1 withdrawn.

2 I mean, it seemed to me absolutely axiomatic, if  
 3 you had the slightest suspicion that a product might  
 4 have had in it a donor who had either developed AIDS  
 5 or might well be suspected of having AIDS, that you  
 6 would absolutely withdraw that batch wholesale.  
 7 I think there could be no -- really, I don't think  
 8 there was a discussion about that.

9 It was a bit surprising to see in America that  
 10 they suggested that patients who had quite suggestive  
 11 indicators that they might be incubating AIDS, if you  
 12 like, they didn't think that was sufficient grounds  
 13 for withdrawing a batch. I personally think that  
 14 seems to be a mistake but it's interesting that the  
 15 matter was still being debated by NIBSC in 1984.

16 **SIR BRIAN LANGSTAFF:** The question which I was going to  
 17 ask you, let me ask you it now, as we're talking about  
 18 this document, was really the basis upon which -- or  
 19 part of the basis on which the committee reached its  
 20 conclusion because this, of course, was reflected in  
 21 the Congress decision which you knew about by the --  
 22 Congress didn't go down the road of saying you've got  
 23 to withdraw all product --

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

25 **SIR BRIAN LANGSTAFF:** -- or you have got to ban, and the

1 reason for not automatically requiring recall, in  
2 part, may have been, perhaps, the contribution made at  
3 paragraph 6.

4 **MS RICHARDS:** Bottom of page 2 please, Soumik.

5 **SIR BRIAN LANGSTAFF:** That's bottom of page 2. There's  
6 a contribution from someone who represents the  
7 Pharmaceutical Manufacturers Association and the  
8 summary of this -- it's a bit dense in this text. We  
9 can look, please, Soumik, at the start of the next  
10 page, top of the next page. Thank you.

11 What he -- the point he was making in arguing  
12 against, as I understand it, the idea that should be  
13 a recall of product was set out there. The best way  
14 perhaps to summarise it is to draw from the work of  
15 Mr Justice Krever in his report on the Canadian blood  
16 product situation.

17 What he said about this was in July 1983,  
18 Dr Michael Rodell, the Vice President Regulatory and  
19 Technical Affairs of the Armour Pharmaceutical  
20 Company, Armour, one of the four US fractionators,  
21 described the possibility of large scale contamination  
22 at a meeting of the Blood Products Advisory Committee  
23 of the Center for Biologics Evaluation and Research,  
24 a standing committee that advised the US Secretary of  
25 State for Health, the Assistant Secretary of Health

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1 pool sizes were so big that you couldn't let the  
2 system fail?

3 **A.** Undoubtedly, the pool sizes were massive and they were  
4 far bigger than the pool sizes in the UK.

5 **SIR BRIAN LANGSTAFF:** But it would -- it's a stunning --  
6 it may be a stunning comment for him, stunning  
7 argument for him to put forward, mightn't it, that  
8 essentially the pharmaceutical companies' method of  
9 production had become so efficient in the commercial  
10 sense they couldn't be allowed to fail because they  
11 might be contaminated with something that could kill.

12 **A.** Well, that's absolutely true, sir, but on the other  
13 hand, if you think about a pool size of whatever size,  
14 one infected donor which -- a donor unknown to the  
15 manufacturers, unknown to themselves because they're  
16 incubating in an asymptomatic fashion, one infected  
17 donor in a pool of any size will contaminate the pool,  
18 and, of course, in one blood transfusion can  
19 contaminate the pool.

20 If you have an organism which you cannot detect,  
21 which is potentially in blood and plasma, then  
22 potentially it will contaminate whatever size pool you  
23 put it in.

24 **SIR BRIAN LANGSTAFF:** So the task is really minimising  
25 that risk, isn't it?

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1 and the Commissioner of the FDA. Dr Rodell said that,  
2 on average, persons who were paid for their plasma had  
3 it collected 40 to 60 times per year. I think you  
4 mentioned this yesterday and made a slightly  
5 disparaging comment about that practice.

6 **A.** Absolutely.

7 **SIR BRIAN LANGSTAFF:** He then estimated that, at that  
8 rate, and, given the pool sizes used in the  
9 United States, four infected persons could contaminate  
10 the entire world supply of Factor VIII concentrate.  
11 I think this is the Americans thinking that they were  
12 the sole source of Factor VIII in the world. That's  
13 what comes out there but, be that as it may, certainly  
14 they were the major commercial providers.

15 His conclusion was based on analysis that were  
16 confined to concentrates made from USA plasma but they  
17 were exported to many countries, including Canada.

18 So, really, the implications of what he was  
19 saying, that if you have -- if you are going to go  
20 down to the road of saying because someone's got AIDS  
21 you've got to bin the batch which is formed from it,  
22 you would inevitably be binning a quarter of the  
23 production if you found one of these regular donors  
24 who suffered. That would follow and one way of  
25 looking at that might be, mightn't it, that simply the

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1 **A.** It is minimising that risk and finding a way in which  
2 you can inactivate the virus if there is a virus.

3 **SIR BRIAN LANGSTAFF:** Yes, thank you for that.

4 **MS RICHARDS:** Dr Walford, can I now ask you about  
5 something you say in your witness statement. It's  
6 paragraph 80.4, I think.

7 So, Soumik, WITN4461001 and it's page 182.

8 Now, you were, at this point in your witness  
9 statement, talking about that note from Dr Sweeney to  
10 Ms Fraenkel that we discussed yesterday. I'm not  
11 going to ask you to go back to the note but it is your  
12 understanding of what the consequences would be for  
13 those with haemophilia if there was a reversion to  
14 cryoprecipitate and reduced usage of Factor VIII  
15 concentrates that I wanted to ask you about.

16 You say this:

17 "My view ..."

18 That's the view about the value of the clotting  
19 concentrates far outweighing the possible transmission  
20 of AIDS:

21 "My view will have then been based on the fact  
22 that, whilst the introduction of cryoprecipitate in  
23 the 1960s had been highly beneficial for severe  
24 haemophiliacs and significantly improved their life  
25 expectancy, they still suffered a life constrained by

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1 pain, disability and the need for frequent hospital  
2 admissions and, in many cases, premature death. With  
3 the advent of Factor VIII concentrates both life  
4 expectancy and quality of life were greatly improved."

5 You also, I think -- just for the sake of  
6 completeness, if we look at paragraph 86.34, page 198,  
7 and we look at the last sentence of that paragraph,  
8 and again the context here is you expressing your  
9 views to Dr Field about Dr Galbraith's call for action  
10 on AIDS. You say here:

11 "The lack of information [that's the lack of  
12 information about AIDS] needed to be set against the  
13 very well-known and severe harms that would be caused  
14 to haemophiliacs if American Factor VIII concentrates  
15 were withdrawn or curtailed without any realistic  
16 replacements."

17 If we just go back to the paragraph 80.5 on  
18 page 182, you yourself hadn't been involved as  
19 a clinician in haemophilia care, other than the period  
20 of time you told us about when you were a Senior House  
21 Officer earlier in the 1970s?

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

23 **Q.** So your view about the impact of concentrates or not  
24 having concentrates, as opposed to cryoprecipitate, on  
25 patients would not have been based upon your own

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1 corrected by people who treat haemophilia if they were  
2 to say, well, this is actually overblown. I would not  
3 myself think it was.

4 **Q.** Paragraph 80.4. My apologies.

5 What you appear to be saying was that, even with  
6 cryoprecipitate, there would be many cases of  
7 premature death. What was the factual basis for that  
8 understanding?

9 **A.** Well, I think basically before cryoprecipitate the  
10 life expectancy for haemophiliacs was -- I think the  
11 median was about 37 years before cryoprecipitate.  
12 I think was about 1964, Judith Pool produced  
13 cryoprecipitate or showed the method for producing  
14 cryoprecipitate.

15 After that, obviously there were clear  
16 improvements but the main cause of death remained, and  
17 everything that I've read suggests that this is true,  
18 that the main cause of death, premature death, in  
19 haemophiliacs was bleeding.

20 **Q.** The vast majority of haemophiliacs receiving treatment  
21 with Factor VIII concentrates on a day-to-day basis,  
22 and I'm just talking for the moment about severe  
23 haemophiliacs but, of course, there are haemophiliacs  
24 with mild and moderate haemophilia --

25 **A.** Yes.

23

1 clinical experience?

2 **A.** Of my limited experience, which was not actually to be  
3 the person who was treating the patients, but I did  
4 see patients quite a lot, simply because I was going  
5 there with the thawed cryo and helping maybe to put up  
6 the drip, for example. So, basically, I didn't  
7 actually treat the patients but clearly some of the  
8 patients were wheelchair-bound, some of the patients  
9 were obviously -- had obvious manifestations, if you  
10 will, of having had bleeds.

11 Now, of course, I don't know first hand but  
12 I had read quite extensively about haemophilia and  
13 I would suggest that what I'm describing there is  
14 probably realistic. Certainly it was so much more  
15 difficult if a patient was receiving cryo and couldn't  
16 rapidly get to a hospital. The bleed would be  
17 continuing, obviously, damage would be being done,  
18 damage which was sometimes irreversible. Certainly  
19 the major cause of death in patients with haemophilia  
20 at the time we're writing about was bleeding and  
21 usually a cerebral bleed, but not exclusively -- it  
22 could be a bleed into the gastrointestinal tract or  
23 other organs.

24 So I don't think what I'm describing is  
25 incorrect but, of course, I would stand to be

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1 **Q.** -- as far as the evidence the Inquiry's heard seems to  
2 establish, they are receiving treatment for -- largely  
3 because of their joints --

4 **A.** Yes.

5 **Q.** -- an ankle bleed, elbow problems and the like.  
6 That's not life-threatening. It can, if untreated, of  
7 course, have significant adverse consequences for the  
8 patients. But it might be said that what's being  
9 painted here in paragraph 80.4 is a picture that if  
10 you remove cryoprecipitate -- if you remove  
11 Factor VIII concentrates, and use cryoprecipitate,  
12 even for six months, a year, 18 months, two years, for  
13 a temporary period, there's going to be multiple cases  
14 of disability and death. Was that not  
15 an overstatement?

16 **A.** You've just mentioned potentially removing Factor VIII  
17 concentrate for a period of, I don't know, six months  
18 or -- I don't think six months would obviously have --  
19 not going to do the trick here but maybe two years.  
20 That's removing concentrate.

21 The problem was that we didn't have enough  
22 cryoprecipitate. If there had been copious supplies  
23 of cryoprecipitate readily available, then you would  
24 have reverted to the *status quo ante* before  
25 concentrates came into manufacture and that would have

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1 not been ideal for patients with haemophilia, but it  
2 would have obviously been better than if there had  
3 been a very clear view that everybody was going to get  
4 AIDS if you didn't do that. I mean, that would have  
5 been a quite clear and dichotomous decision and you  
6 could see what the way forward was.

7 But there wasn't anything like enough  
8 cryoprecipitate and it could not have been made  
9 quickly. It would have had to restart over time. You  
10 then have the problem of making sure that you've got  
11 enough cryoprecipitate supernatant to BPL to make the  
12 Factor IX that patients with haemophilia B needed so  
13 that they didn't suffer as a result of what you had  
14 done in relation to haemophilia A patients.

15 So my sort of question would be: how could some  
16 40 million international units of Factor VIII be rapid  
17 replaced by cryo? Now, you said to me yesterday, and  
18 I think it's a very valid point, you wouldn't  
19 necessarily replace it all, you'd stop home treatment,  
20 you would stop prophylaxis, you'd stop elective  
21 surgery. I have to say, if one had -- I think if the  
22 Haemophilia Society at the time had been told that  
23 that was what was going to happen there would have  
24 been huge concern and complaints from patients that  
25 their entire lives were going to be turned upside

25

1 So it was an awful conundrum to be faced with  
2 and I don't think there was any particular right  
3 answer. But to suppose that you could absolutely rely  
4 on cryo to replace the needed amount, not the desired  
5 amount or the demand, it wasn't feasible at that time.  
6 **Q.** We'll come on to the Committee on the Safety of  
7 Medicines Subcommittee meeting later in the course of  
8 the morning but it's right, isn't it, that none of  
9 either the measures that I mentioned yesterday, and  
10 you've summarised a number of them, neither those nor  
11 what would need to be done, what could be done within  
12 RTCs was ever actively explored at the time by the  
13 Department?

14 **A.** At the time to revert to cryo?

15 **Q.** Yes.

16 **A.** Well, it was actively explored not within Regional  
17 Transfusion Centres but Dr Gunson, who was the chair  
18 of the Regional Transfusion Centre Directors, said it  
19 was not feasible, Dr Lane said he could not produce  
20 small pool cryoprecipitate freeze-dried. I wrote  
21 a paper for the CBLA specifically asking whether we  
22 could do something about that, whether we -- BPL could  
23 produce small pool products to replace the larger pool  
24 intermediate concentrate, and the answer was he  
25 couldn't do it on logistic grounds.

27

1 down. That was on the basis of the fact that, by May,  
2 we had one patient who had developed AIDS in the UK  
3 and it is the case -- and we possibly come to it  
4 later, I hope we do -- but I see that the CMO letter,  
5 which was ultimately written in 1985, refers to the  
6 fact that there had been three cases in the UK, three  
7 cases of AIDS in haemophiliacs.

8 So you would have made a massive transfer of, as  
9 it were, risk of bleeds, and so on, however severe --  
10 and actually one ought not to minimise the awful  
11 bleeding into joints, really painful, really sometimes  
12 irreversible, and if you can't then do surgery because  
13 you haven't got the concentrate to do the surgery --  
14 I feel I shouldn't, in a sense, be advocating for  
15 patients with haemophilia, they can speak absolutely  
16 for themselves, and if it's felt that I am  
17 exaggerating the problems that they might have  
18 experienced from a sudden massive shortage of  
19 Factor VIII in one form or another, then I obviously  
20 stand corrected. I just don't think I am  
21 exaggerating, and it's interesting that the Committee  
22 on Safety of Medicines, when it came to look at -- in  
23 the Biological Subcommittee, was referring to these  
24 Factor VIII as being life-preserving, if you will.  
25 I forget the exact words they used.

26

1 So it was not *not* thought of, it just seemed  
2 totally impractical and impossible.

3 **Q.** In terms of what Dr Lane was saying about BPL's  
4 ability -- you have referred to that in your statement  
5 and you have accurately summarised it, I'm not  
6 proposing to go to it -- what is the material that  
7 you're relying on and, if you can't find it now, by  
8 all means come back after one of the breaks and let me  
9 know what it is, because I'm not trying to put you on  
10 the spot. But when you're talking about Dr Gunson, as  
11 it were, representing the position of RTCs, what  
12 particular interactions or reports or views of his do  
13 you have in mind?

14 **A.** The one I can sort of immediately call to mind now is  
15 that he wrote to the Chief Medical Officer because he  
16 was the consultant adviser and he had heard that there  
17 was going to be a meeting of all the relevant  
18 consultant advisers, there was only one in blood  
19 transfusion and that was him, that there was going to  
20 be a meeting and he thought that all these consultant  
21 advisers needed to be aware of the problem, which had  
22 arisen and he'd just come back from the Council of  
23 Europe meeting, I think, at that time, where he had  
24 pointed out that it was obvious that Council of Europe  
25 was beginning to talk about moving to cryoprecipitate.

28

1 This is what they were thinking was a good thing to  
 2 do. He also pointed out that that was actually the  
 3 main product used in quite a number of countries and  
 4 he talked about the downsides of some of those  
 5 products but, nevertheless, he pointed out that it  
 6 looked as if there was going to be a push towards  
 7 using cryoprecipitate.

8 He didn't think that that was something that  
 9 could be done at the moment. He didn't think that  
 10 that was going to be practical and he wrote  
 11 accordingly to the CMO.

12 So that was a reliance on Dr Gunson there, who  
 13 would have taken the temperature, if you will, of  
 14 regional transfusion directors.

15 **Q.** I know the document you are referring to. I haven't  
 16 got the reference to hand but it is in here somewhere.

17 **A.** It's in here.

18 **Q.** We may come back to that, in that case, perhaps after  
 19 the break.

20 Can I then just come on to the issue to which  
 21 the chair was alluding when we looked at the Rodell  
 22 observations. The concern about the dumping --

23 **A.** Yes.

24 **Q.** -- of pre-March 1983 plasma in the UK.

25 **A.** Yes.

1 HCDO0000003\_122, and we can see this is now in  
 2 May 1983. It's following the meeting of Reference  
 3 Centre Directors on 13 May, and he says:

4 "... there is one outstanding point which I do  
 5 not think was finally [closed]. This refers to the  
 6 possibility that some of the American factor VIII  
 7 manufacturers may consider it advantageous to export  
 8 products which were made from plasma collected before  
 9 March 24th rather than retain them for domestic use."

10 Then he refers to the FDA guidelines, and says:

11 "I have some misgivings concerning the  
 12 possibility that stocks held by the manufacturers and  
 13 source plasma collected before that date will be  
 14 preferentially exported. Whilst I do not wish to  
 15 overstate the risk from imported American factor VIII  
 16 concentrates, nevertheless I think that Haemophilia  
 17 Centre Directors would wish to be reassured that  
 18 factor VIII concentrates imported are at least up to  
 19 the standards recommended for use in the USA. I was  
 20 glad to learn ... that you intend to take this up with  
 21 the Medicines Division ... I hope that is will be  
 22 possible rapidly to vary the Product Licence for  
 23 relevant imported products to take account of these  
 24 recent developments."

25 So Professor Bloom is sufficiently concerned to

1 **Q.** So if we just pick it up, first of all, at  
 2 DHSC0001204. So this is and one of the communications  
 3 from the States, the Department of Health and Human  
 4 Services, Public Health Service Food and Drug  
 5 Administration, 24 March 1983, and it sets out --  
 6 I won't go through the detail of it -- but it sets out  
 7 the steps that were advised should be taken by all  
 8 establishments collecting blood for transfusion or for  
 9 use in plasma pools.

10 Do you recall whether this document or a summary  
 11 of it came to your attention at this stage, in  
 12 March 1983?

13 **A.** No, it didn't, and what I have seen from looking at  
 14 the papers is that Dr Joe Smith of the -- Director of  
 15 NIBSC, sent it through to Medicines Division, I think  
 16 to Dr Fowler, and I was not aware of this, of this  
 17 paper. Of course, I knew that regulations had been  
 18 introduced. I can't remember exactly when I learnt --  
 19 I think in April, something like that -- but I didn't  
 20 see the detail.

21 I subsequently, when I had been shown the  
 22 detail, reported that in one of my briefings and spelt  
 23 out what the details were.

24 **Q.** If we then go to an exchange of correspondence you had  
 25 on the subject with Professor Bloom, it's

1 write in these terms. If we look at your reply  
 2 DHSC0001206, 16 May, you have obviously had  
 3 a telephone conversation with Professor Bloom and then  
 4 you say:

5 "I have today both spoken to and minuted  
 6 Dr Keith Fowler of Medicines Division to draw his  
 7 attention to the possible need to institute new  
 8 labelling requirements for [Factor]VIII concentrates  
 9 derived from plasma taken before the new FDA  
 10 regulations came into force.

11 "I have also asked him whether, for products  
 12 currently available in the UK, it would be possible to  
 13 find out the period in which the donors were bled and  
 14 whereabouts in the USA the donor centres supplying  
 15 each manufacturer is situated.

16 "I have asked if he will treat this as a matter  
 17 of the utmost priority."

18 We'll come on to your exchange of minutes with  
 19 Dr Fowler. Did you understand Professor Bloom to be  
 20 advocating, actually, some form of ban, stop order,  
 21 whatever the mechanism might be, on pre-March  
 22 products, because your response appears to be about  
 23 the possibility of addressing the concern in a rather  
 24 less radical way by labelling?

25 **A.** Of course, we wouldn't have known about when the



1 plasma was taken from the donors without labelling,  
 2 without being able to identify. Sort of *a priori* we  
 3 needed to know how we could identify such material.  
 4 So the first thing was -- I mean, I totally agreed  
 5 with Professor Bloom that we might be faced with  
 6 a dumping situation, so obviously wanted to avoid  
 7 that, but how do you avoid that if you don't know when  
 8 the plasma was taken? And we didn't know, as it  
 9 turned out. We didn't have any way of identifying the  
 10 date on which the plasma was taken for the product.  
 11 Obviously, you knew the date that the product was  
 12 actually manufactured but not when the plasma was  
 13 withdrawn from the donors.

14 So my first concern was, well, you know,  
 15 a diagnostic, if you like, how would we know when the  
 16 plasma was taken? He then came back to me, and I'm  
 17 sure you will probably take me to this, to say that  
 18 actually we don't know when it was taken but we could  
 19 make it a condition.

20 **Q.** So if we go then to your communications with  
 21 Dr Fowler, DHSC0001394, this is 16 May 1983.  
 22 "We spoke", and then you refer to the FDA new  
 23 requirements, and then you say, this four lines down:  
 24 "However, the UK product licences do not contain  
 25 this requirement [that's the labelling requirement]

1 CDSC, and to be investigated as a matter of the utmost  
 2 priority.

3 If we look at, first of all, a comment from  
 4 Dr Oliver, DHSC0002227\_052. So he circulates your  
 5 minute more widely, says the questions you have posed  
 6 are:

7 "... clearly of considerable importance and have  
 8 wide implications for the Licensing Authority, Supply  
 9 Division and of course for HS. It seems to me  
 10 important that our activities are fully co-ordinated  
 11 so that we safeguard our own supply position and if  
 12 possible obtain Factor VIII from the safest available  
 13 sources. Ideally I suppose we would like to see any  
 14 imported Factor VIII which is derived from American  
 15 material to be manufactured after 24 March ..."

16 Then there's a suggestion of a meeting. Then he  
 17 says:

18 "Whatever we do we must not take any precipitate  
 19 action which might affect the supply of necessary  
 20 Factor VIII."

21 Then just so that we see the full exchange of  
 22 correspondence, we get to Dr Fowler's replies at  
 23 DHSC0002229\_006. This is the first of two minutes  
 24 from Dr Fowler, dated 23 May. In the first paragraph  
 25 he says:

1 and there are fears among haemophilia centre directors  
 2 that the more 'dangerous' material may be dumped in  
 3 the UK. You may like to consider whether there is  
 4 a need to make a similar labelling requirement for  
 5 material imported into the UK?

6 "In relation to the whole issue of the  
 7 transmission of AIDS in blood products, several  
 8 questions have been put to me ..."

9 Then you raise four matters:

10 "Is it possible to obtain concentrates made from  
 11 plasma which does not come from [the] centres ... with  
 12 the highest numbers of AIDS cases?"

13 "2. Is it possible to accept only concentrates  
 14 made from plasma taken after 24 March regulations were  
 15 published? If so, would sufficient finished product  
 16 be immediately available?"

17 "3. Can we find out, for each manufacturer, the  
 18 date of plasma collection in relation to each batch of  
 19 concentrate in current use in the UK?"

20 Then 4 was whether Immuno or other European  
 21 manufacturers could produce sufficient material  
 22 derived from European plasma.

23 You say that these matters have been raised with  
 24 you essentially by both Professor Bloom, as chair of  
 25 the Haemophilia Centre Directors, and the Director of

1 "... manufacturers are certainly able to  
 2 identify ... batches of plasma collected after 24 May  
 3 (*sic*)."

4 So manufacturers should be able to identify pre-  
 5 and post 24 March -- sorry, I think I said May --

6 **A.** Yes.

7 **Q.** -- plasma. Whether or not they would be prepared to  
 8 release this information is another matter.

9 Then he talks about the stop order procedure  
 10 which requires:

11 "... manufacturers to submit protocols and  
 12 samples from every batch they propose to sell in the  
 13 UK, to Dr Duncan Thomas's department at NIBSC. The  
 14 content of an individual manufacturer's protocol is  
 15 very much a matter for agreement between Dr Thomas and  
 16 the company. I do not think that date of plasma  
 17 collection is a requirement at present, but I see no  
 18 reason why it should not become so if it were thought  
 19 desirable. The Licensing Authority would then, on the  
 20 advice of Dr Thomas, be able to reject those batches  
 21 which did not comply.

22 "The practical and legal aspects of this  
 23 suggestion would, of course, have to be checked  
 24 beforehand, but even the threat of such action might  
 25 be sufficient to persuade to manufacturers to comply

1 voluntarily."  
 2 So is this right or is this what you understood  
 3 from Dr Fowler's first minute, he is essentially  
 4 saying there is potentially a way of dealing with  
 5 this --  
 6 **A.** Yes.  
 7 **Q.** -- the USA manufacturers can identify the difference,  
 8 as it were, and there is a mechanism, the stop order  
 9 mechanism, which could be introduced by the Licensing  
 10 Authority?  
 11 **A.** That's right.  
 12 **Q.** Then if we go to the second page, we see his second  
 13 minute. In his second paragraph, he says:  
 14 "Your suggestion that USA manufacturers ..."  
 15 Sorry, can we go slightly up the page:  
 16 "... may try to 'dump' pre-24 March 1983  
 17 material on the UK market has to be taken seriously."  
 18 Then he refers to the stop order process and  
 19 says if that's a non-runner then we'll be wholly  
 20 dependent on the manufacturers. Then he answers your  
 21 other questions. Point 1, he doesn't know whether it  
 22 was possible to obtain concentrates made from plasma  
 23 which doesn't come from the highest risk areas. He  
 24 doesn't know the position about adequacy of post  
 25 24 March 1983 supplies -- that's paragraph 2. But he

1 of material made beforehand but no suggestion that  
 2 this any stock of post 23 March regulation. That's  
 3 hardly surprising when you consider, you know, the  
 4 length of time it was taking to make a batch of  
 5 product but, essentially, within the country, there  
 6 were some tens of millions of international units of  
 7 Factor VIII made from before those regulations came  
 8 into force, though I should actually caveat that by  
 9 saying a number of the manufacturers, and in fact,  
 10 sir, Ms Richards, you gave me a paper last night from  
 11 Alpha Therapeutics, who had introduced their own and  
 12 actually possibly even, if not more stringent, as  
 13 stringent, controls on their donor selection before  
 14 the 23 March FDA regulation came into force.  
 15 So there was some material within the stocks in  
 16 the UK that was potentially usable, if you like, if  
 17 you only wanted to use material that was made in  
 18 conformity or approximately in conformity with the  
 19 23 March regulation, and we did get a list of that and  
 20 Medicines Division provided me with a list of the  
 21 material that was available.  
 22 So you had the stocks where actually plasma had  
 23 been obviously just taken before the regulations came  
 24 in, and then the manufacturers who had introduced  
 25 their own and quite stringent requirements before the

1 does say, essentially, there probably is an issue in  
 2 relation to there being pre-March 1983 concentrates  
 3 effectively already in the UK awaiting clearance by  
 4 NIBSC, and then he doesn't think that the European  
 5 option is a runner essentially.  
 6 **A.** No.  
 7 **Q.** Now, I'll look in a moment with you at 3 June 1983  
 8 interdepartmental meeting.  
 9 **A.** Yes.  
 10 **Q.** But, broadly speaking, as far as you're aware, was any  
 11 particular action taken in relation to pre-24 March  
 12 concentrates?  
 13 **A.** Well, I sent another minute which I hope somebody can  
 14 lay their hands on to Dr Fowler, asking even more  
 15 questions to be put to manufacturers, and so there was  
 16 a list of long questions that I thought that they  
 17 should be asked and, of course, the question that  
 18 I was also asking, and again I can't remember whether  
 19 it was in the same minute or another minute, was tell  
 20 me about the stocks. What have we got? You know,  
 21 what is available? Could we have material only made  
 22 from post 23 March plasma, as it were, made in  
 23 conformity with the regulations of 23 March.  
 24 He then describes the stocks in one of my -- one  
 25 of the minutes to me, where there is substantial stock

1 23 March regulations.  
 2 So we had that information and there was some  
 3 material which could be used if all you were concerned  
 4 about was that it needed to have been after the  
 5 23 March regulations came in.  
 6 But the question, I suppose -- and this was  
 7 again something the Committee on Medicines dealt with,  
 8 at least not at length but a little -- was how  
 9 effective the 23 March regulations were likely to be  
 10 because they did rely quite considerably on a degree  
 11 of donor honesty in terms of their health. They  
 12 relied also on some kind of actual physical  
 13 examination by personnel in the plasmapheresis  
 14 centres, which sounded interesting but kind of, you  
 15 know, how realistic was it?  
 16 So I think the question was how much difference  
 17 it was likely to make to the safety of any Factor VIII  
 18 and, obviously, any improvement is better than no  
 19 improvement but it was not necessarily going to be,  
 20 well, if we simply take the post 23 March regulation  
 21 material, that material is likely to be substantially  
 22 safer than material taken beforehand. I don't think  
 23 you could conclude that but, obviously, it would have  
 24 been good to have been able to use that material in  
 25 preference. But this wasn't a question of we're

1 stopping all American Factor VIII, it's just you  
 2 wanted -- if you were going to get American  
 3 Factor VIII, it needed to have been in conformity with  
 4 the FDA regulations.  
 5 **Q.** I mean, you're rightly explaining that there are  
 6 a number of considerations, and absolutely there's  
 7 further exchanges of minutes and we'll look at some of  
 8 them, I think. My question is: ultimately, was  
 9 anything done, whether by NIBSC in terms of labelling,  
 10 or by providing information about what batches were  
 11 known to have been produced in conformity with the  
 12 manufacturers' own internally imposed standard,  
 13 sharing that information to Haemophilia Centre  
 14 Directors so that they could say, "Well, I'm not going  
 15 to use those but I will use those"; was anything  
 16 actually done in the end?  
 17 **A.** Yes, I looked at all the papers that I was provided  
 18 with and I couldn't see that.  
 19 One of the things that I saw was, in the June 3  
 20 meeting of officials, there was a Miss Spencer from  
 21 Medicines Division and there was a question asked  
 22 about the issue of could we stop this material made  
 23 from before the March 23 regulations, and she seemed  
 24 to think that legally it was going to be difficult.  
 25 **Q.** We'll come to that in just a moment. But is this

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1 "1. To consider whether there is any further  
 2 action the [National Blood Transfusion Service] or  
 3 Haemophilia Reference Centres can take, and whether  
 4 any further assistance or complementary action by the  
 5 Department is appropriate ...  
 6 "2. To consider what action can be taken by  
 7 Medicines Division and Supply Division to minimise  
 8 risks in the light of the new FDA requirements ...  
 9 "3. To consider what action is appropriate with  
 10 regard to the implications of the introduction of  
 11 heat-treated [Factor] VIII concentrates ...  
 12 "4. To consider what should be done further to  
 13 encourage research into AIDS."  
 14 Just go further down:  
 15 "5. To consider the implications for NBTS of  
 16 the line taken by the Council of Europe.  
 17 "6. To consider the implications for CBLA ..."  
 18 So that that's Central Blood Laboratories  
 19 Authority.  
 20 "... and the plans for the redevelopment of BPL.  
 21 "7. To consider what action is needed by DHSS  
 22 in respect of homosexual rights groups."  
 23 And:  
 24 "8. What further action should be taken with  
 25 the Haemophilia Society?"

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1 right then, that as far as you know from your own  
 2 knowledge and from the documentation that you have  
 3 seen --  
 4 **A.** I haven't seen it --  
 5 **Q.** -- there's nothing to suggest that ultimately any  
 6 steps were taken in relation to limiting or providing  
 7 information or imposing requirements on pre-March 1983  
 8 plasma?  
 9 **A.** I haven't seen that but obviously if you are going to  
 10 speak to anyone from NIBSC they may be able to provide  
 11 much more information.  
 12 **Q.** Yes, absolutely. Yes, indeed, it may be that  
 13 Dr Thomas will be able to assist in that regard.  
 14 Let's come then to 3 June meeting.  
 15 So if we start with the agenda, which is  
 16 DHSC0002353\_038.  
 17 So on 1 June -- is it Dr Green?  
 18 **A.** No.  
 19 **Q.** Mr Green?  
 20 **A.** No.  
 21 **Q.** Ms Green?  
 22 **A.** Mr.  
 23 **Q.** Mr Green circulates an agenda and papers for the  
 24 meeting and, if we go to the next page, we can see  
 25 what the agenda was for that meeting:

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1 So there's the agenda. Now there were a number  
 2 of papers prepared for this meeting, I think most of  
 3 which were prepared by you?  
 4 **A.** Yes.  
 5 **Q.** So if we just look and see what those are, they are at  
 6 DHSC0002229\_019 to start.  
 7 So we've got paper 1, which is a background  
 8 paper. I'm not going to ask you to go through the  
 9 detail of it but we can see, bottom of the page, we've  
 10 got the question:  
 11 "Is it transmitted in blood or blood products?  
 12 "As yet there is no conclusive proof that AIDS  
 13 is transmitted by blood as well as by homosexual  
 14 contact but the evidence is suggestive that this is  
 15 likely to be the case."  
 16 Then you refer to the cases in the States and in  
 17 Spain and the transfusion cases.  
 18 **A.** Yes.  
 19 **Q.** Which no doubt includes implicitly a reference to the  
 20 San Francisco baby case.  
 21 **A.** Yes.  
 22 **Q.** Then, over the page, we can see the second heading is  
 23 "AIDS in haemophiliacs in the UK". You say:  
 24 "There is one suspect case in Cardiff. Although  
 25 CDSC states that this case meets the USA criteria for

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1 AIDS, the clinician in charge does not consider that  
2 either should be regarded as a confirmed case."  
3 Just pausing there, you must presumably have got  
4 that from Professor Bloom?  
5 **A.** I don't know about getting it from Professor Bloom but  
6 he seemed to consistently -- he seemed to consistently  
7 say that this may be a case that he had in Cardiff but  
8 was -- although CDSC very clearly stated that it was  
9 a case according to the criteria that they used, and  
10 I was in no doubt whatsoever that it was a case, it  
11 was -- I simply maintain that the clinician in charge  
12 didn't consider it to be regarded as a confirmed case.  
13 That was the fact of the matter.  
14 **Q.** You presumably were not aware that Professor Bloom had  
15 described it as a probable case in his notification to  
16 CDSC?  
17 **A.** No.  
18 **Q.** Does it --  
19 **A.** I didn't know he'd notified CDSC actually.  
20 **Q.** Does it cause you concern, thinking about it now, that  
21 he was -- seems, on a number of occasions,  
22 essentially -- arguably, it might be said,  
23 underplaying whether this was a true case of AIDS?  
24 **A.** It seems to be the case that he was very reluctant to  
25 actually confirm that he agreed it was a case.

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1 orders and labelling and so on.  
2 So you pose essentially the same questions or  
3 similar questions to those you had posed to Dr Fowler?  
4 **A.** Yes.  
5 **Q.** Paper 4, which is the next page, we can simply note  
6 it's looking at the possibility of heat-treated  
7 Factor VIII concentrates. I'm not going to ask you  
8 about the detail.  
9 Paper 5 I won't trouble you with. You didn't  
10 write, I think, paper 5, and it was concerned with  
11 research, in any event?  
12 **A.** That's right.  
13 **Q.** Then paper 6 is at DHSC0002229\_020.  
14 Now, this was about the "Implications of AIDS  
15 for production of [Factor] VIII at BPL". You refer  
16 to -- point 4:  
17 "The more [cryo] a Region produces, the less  
18 plasma it can send to BPL ..."  
19 You talk about the advantages of cryoprecipitate  
20 in paragraph 5.  
21 Then, if we go down to paragraph 7, you talk  
22 about disadvantages to cryoprecipitate: convenience,  
23 possible allergic reactions, et cetera.  
24 Then over the page, at paragraph 9, you say:  
25 "... haemophilia centre directors in the UK are

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1 **Q.** And we can see now there's reference to a possible  
2 case in Bristol. So you've become aware of that. So  
3 that's paper 1.  
4 Paper 2, which is the next page:  
5 "Action already taken by relevant authorities  
6 outside the Department."  
7 Again, I'm not going to go through the detail of  
8 it but we can see you identify the leaflet proposal by  
9 Regional Transfusion Directors, and we'll look at that  
10 later, at paragraph 1.  
11 At paragraph 2 you refer to the Haemophilia  
12 Reference Centre Directors' recommendation. Again,  
13 I'm going to come back to that in a little while.  
14 At 3 you refer to the FDA regulations.  
15 Over the page, at 4, you refer to the Council of  
16 Europe and its draft recommendations, and again I'm  
17 going to come back to that.  
18 So that's paper 2. Paper 3 is the next page.  
19 Just so that we can see what material was at the  
20 meeting. So this is looking specifically at the  
21 dumping issue, and you pose a number of questions such  
22 as that at paragraph 2 on that page:  
23 "Should we accept only 'post 24 March' products?  
24 Would there be adequate supplies?"  
25 You refer to the possibility of using stop

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1 not advocating a change in the pattern of treatment of  
2 haemophiliacs which would require increased production  
3 of cryoprecipitates."  
4 That, presumably, is a reflection of the 13 May  
5 Reference Centre Directors' meeting?  
6 **A.** I'm assuming so, yes.  
7 **Q.** Then paragraph 10:  
8 "If there were to be a significantly increased  
9 demand for cryoprecipitate, this would pose major  
10 operational and financial problems for RTCs and would  
11 reduce significantly - or even totally - the amount of  
12 plasma sent to BPL."  
13 That's based, is it, essentially, on your  
14 understanding from Dr Gunson that would be the  
15 problem?  
16 **A.** Dr Gunson and Dr Lane I think, both together.  
17 **Q.** Yes, sorry. In relation to BPL, absolutely Dr Lane.  
18 In relation to RTCs, Dr Gunson's essentially your  
19 source of information?  
20 **A.** Yes, although there were various meetings of regional  
21 transfusion directors and I can't tell whether or not  
22 they came, you know, before all this or not, but  
23 Dr Gunson was a very good source of information which,  
24 I believe, he'd fully reflected the views of his  
25 fellow transfusion directors, in most cases.

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1 Q. Then you explain in paragraph 11 that:  
 2 "The preceding paragraph describes a worst-case  
 3 situation."  
 4 So effectively an all or nothing situation.  
 5 "Nevertheless, the demand for cryoprecipitate  
 6 could well increase to a certain extent and we need to  
 7 know what contingency plans the CBLA has - or is in  
 8 the process of developing ..."  
 9 So those are the papers. Then if we can just  
 10 look at the minutes --  
 11 **SIR BRIAN LANGSTAFF:** Just before you do that, can I go  
 12 back up the page? Thank you.  
 13 It's paragraph 9. I'm just a little puzzled by  
 14 the last sentence there. Referring to what the  
 15 Haemophilia Centre Directors were deciding, it  
 16 suggests that the decision "could well change if  
 17 a haemophiliac who had received only BPL concentrate  
 18 were found to have developed AIDS".  
 19 So I can understand that that might make them  
 20 reluctant to use BPL concentrate but why not -- or did  
 21 the logic apply to commercial concentrate?  
 22 **A.** Basically I suppose that the thinking would be that if  
 23 a BPL concentrate was found to have transmitted AIDS,  
 24 then there was AIDS in the UK donor blood population.  
 25 That would mean that, obviously, large pool products,

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1 asking the question is the first sentence is talking  
 2 about whether to increase the use of cryoprecipitate  
 3 or not. Now, at that time there was roughly twice as  
 4 much commercial concentrate being used as domestically  
 5 produced concentrates, was there not?  
 6 **A.** About half and half, I think. No, you're right about  
 7 concentrate, but we had about half and half in terms  
 8 of cryo plus concentrate. You're right.  
 9 **SIR BRIAN LANGSTAFF:** So the question might be thought, if  
 10 commercial concentrate was shown to have produced --  
 11 **A.** AIDS.  
 12 **SIR BRIAN LANGSTAFF:** -- AIDS, that might have  
 13 implications for the continued use of commercial  
 14 concentrate?  
 15 **A.** Absolutely.  
 16 **SIR BRIAN LANGSTAFF:** So I would understand the last  
 17 sentence if it said "this could well change of  
 18 a haemophiliac who had received concentrate -- or  
 19 commercial concentrate -- were found to have developed  
 20 AIDS, even more so if only BPL concentrate". But what  
 21 the -- it's the combination of the two, that's why I'm  
 22 asking you.  
 23 **A.** It's another *non sequitur* here presumably, sir.  
 24 **SIR BRIAN LANGSTAFF:** It is.  
 25 **A.** Yes. Well, I accept that.

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1 such as concentrate, would be capable of transmitting  
 2 if a single donor was infected.  
 3 At that point a reversion to cryoprecipitate,  
 4 which -- if you could do it -- where you are really  
 5 only using a far smaller number of donations -- you  
 6 may be using 20 or 30 bags of cryoprecipitate at  
 7 a time but nevertheless it's much smaller than the  
 8 pools that were being used in BPL to make intermediate  
 9 concentrates -- it might have been felt to be safer.  
 10 But it wouldn't have been entirely safe.  
 11 But clearly at the time I think that -- I can't  
 12 totally answer your question because it's absolutely  
 13 fundamental to what does this sentence mean.  
 14 At the minute they were not satisfied,  
 15 I suppose, that there was a significant risk to the  
 16 haemophiliacs from American Factor VIII. They needed  
 17 to go on using American Factor VIII. But the whole  
 18 scene would have been transformed if there could have  
 19 been proof, if you will, that a patient who'd only  
 20 ever had UK Factor VIII at that point in time had  
 21 developed AIDS, because -- I mean, it would have  
 22 thrown us all into the most terrible confusion because  
 23 it would suggest that AIDS was in the UK blood supply,  
 24 and at the time that wasn't thought to be the case.  
 25 **SIR BRIAN LANGSTAFF:** I follow that, but the reason for

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1 **SIR BRIAN LANGSTAFF:** I appreciate you're only reflecting  
 2 what you've heard from what the doctors were saying.  
 3 Were they really saying that or were they saying, "If  
 4 we actually had proof of a death from someone who has  
 5 only ever had concentrate or had a lot of concentrate,  
 6 commercial concentrate", that that would be what was  
 7 necessary to change their practice?  
 8 **A.** I'm not sure I entirely follow that but, basically,  
 9 I mean, one was looking at cases as opposed to deaths  
 10 in this instance --  
 11 **SIR BRIAN LANGSTAFF:** Yes, AIDS. I'm sorry.  
 12 **A.** -- and essentially they were aware of the potential of  
 13 the hazard from American Factor VIII concentrates.  
 14 There was no indication at this point in time that  
 15 UK-derived concentrates actually could transmit AIDS.  
 16 It would have been so fundamentally unsettling,  
 17 if you like, to the situation that if it were shown  
 18 that somebody who had only received UK concentrate had  
 19 developed AIDS, it would have no doubt promoted an  
 20 entire rethink of where we were.  
 21 But I guess, I like to think, that even if it's  
 22 not particularly well expressed here, and maybe it  
 23 isn't a particular -- doesn't follow on from the  
 24 previous sentence, that I was reflecting what I had  
 25 heard from others.

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1 **SIR BRIAN LANGSTAFF:** Yes. So what you had heard from  
 2 others was, in effect, expressed in a *non sequitur*,  
 3 but there we are.  
 4 **A.** I would like to think it was others that expressed it  
 5 as a *non sequitur*, not myself. Yes, thank you.  
 6 **MS RICHARDS:** Sir, I was going to move to then look,  
 7 having very quickly skated through the papers (I know  
 8 Dr Walford is familiar with them) to look at the  
 9 minutes of the meeting for which the papers were  
 10 prepared but, given the time, perhaps it might be  
 11 better to do that after the break?  
 12 **SIR BRIAN LANGSTAFF:** Yes. We'll take a break then until  
 13 11.45.  
 14 **(11.15 am)**  
 15 **(A short break)**  
 16 **(11.46 am)**  
 17 **MS RICHARDS:** Dr Walford, just before we look at the  
 18 minutes of the 3 June meeting, you had referred to  
 19 Dr Gunson's letter to the Chief Medical Officer.  
 20 **A.** Yes.  
 21 **Q.** So just for the sake of completeness and not to leave  
 22 that as a loose end we'll just look at that. It's  
 23 NHBT0001067.  
 24 It's 9 June 1983 and it was copied to you at the  
 25 time so it would have come to your attention. It sets

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1 imported from the USA.  
 2 "The Press have been keenly interested in this  
 3 aspect and there is, in my view, no alternative to the  
 4 continuation of this policy in the short-term."  
 5 Then he refers to the new post March  
 6 restrictions in the States. He says:  
 7 "... the importation of the product prepared  
 8 before April, 1983, is being carefully monitored."  
 9 Do you know what he's referring to there?  
 10 **A.** I don't entirely know but of course we were looking at  
 11 that through Medicines Division to try and see what  
 12 the stock position was.  
 13 **Q.** Then he says:  
 14 "In the medium term, [BPL] is being rebuilt ..."  
 15 and refers to self-sufficiency.  
 16 "The necessity of an adequate supply of plasma  
 17 from our volunteer donors to the new laboratory from  
 18 the regional transfusion centres cannot be  
 19 over-emphasised."  
 20 Then he goes on to talk about the Council of  
 21 Europe -- I'll come back to that -- and press  
 22 publicity.  
 23 Now, it's clear from this letter that Dr Gunson  
 24 wasn't advocating a change of approach; indeed, on the  
 25 contrary, he sets out his view: no alternative to

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1 out various matters relating to AIDS. The second  
 2 paragraph begins:  
 3 "The etiology of the disease is not known, but  
 4 there is a strong possibility that the syndrome is  
 5 caused by a transmissible infectious agent and in this  
 6 context it has been implicated in transfusion of blood  
 7 and blood products."  
 8 Then he refers to other cases and the two  
 9 potential cases within England. Then he says:  
 10 "Although relatively few cases of AIDS have, as  
 11 yet, been reported in this country, the significance  
 12 of the condition with respect to the transfusion of  
 13 blood and blood products are two-fold."  
 14 The first point he makes then is in relation to  
 15 trying to prevent high-risk donors and refers to the  
 16 leaflet, and I'll come back to that. You had some  
 17 involvement, I think in the early stages, of the  
 18 preparation of the leaflets, and we'll come back to  
 19 that.  
 20 **A.** Yes.  
 21 **Q.** Then over the page, and this, I think, may be what you  
 22 had had in mind earlier, his point 2 is this:  
 23 "Approximately one-half of the Factor VIII  
 24 concentrate used in the treatment of haemophilia in  
 25 England and Wales at present is derived from plasma

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1 continuation of the policy in the short-term.  
 2 My question is a slightly different one, which  
 3 is not to cast any doubt upon what you were saying  
 4 Dr Gunson's view was as expressed contemporaneously to  
 5 you at the time, my question is this: is there any  
 6 material of which you are aware from this time in  
 7 which the actual ability of Regional Transfusion  
 8 Centres to produce increased volumes of  
 9 cryoprecipitate was assessed or investigated?  
 10 In other words, is there anything in which  
 11 someone's gone to each Regional Transfusion Centre and  
 12 said, "What's your capacity to produce  
 13 cryoprecipitate? How much do you produce? Could you  
 14 produce more? If so, over what period of time? Would  
 15 you need new equipment or have you got the right  
 16 equipment?" Those kind of questions.  
 17 Are you aware of that exercise having been  
 18 undertaken?  
 19 **A.** No, I'm not directly aware of that having been done.  
 20 Clearly, if that was done, I would suppose that the  
 21 NBTS would have records of any requests that arrived  
 22 or any discussions that were held but I'm not  
 23 personally aware.  
 24 **Q.** Thank you.  
 25 So if we then go to the meeting of 3 June which

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1 is at DHSC0002229\_030.  
 2 Dr Walford, I'm conscious I went very quickly  
 3 through the papers but that's really in the interests  
 4 of getting through your evidence. If there's any bit  
 5 of the papers that we would need to go back to, do  
 6 please let me know.  
 7 **A.** Thank you.  
 8 **Q.** I'm conscious you are familiar with them, not only  
 9 having authored them at the time but having recently  
 10 reread them for the purposes of your evidence.  
 11 So this is the meeting. Can I just ask, because  
 12 we'll see what Ms Spencer's intervention is, she's  
 13 recorded as being from MB. What was MB?  
 14 **A.** It was part of Medicines Division.  
 15 **Q.** So if we look further down, paragraph 2 says:  
 16 "Mr Parker explained that the meeting had been  
 17 reared to consider the implications for the Department  
 18 of recent media reports on AIDS and to examine  
 19 possible courses of action."  
 20 The first then is the "AIDS Leaflet", and we'll  
 21 see in the second part of paragraph 3 --  
 22 **SIR BRIAN LANGSTAFF:** Just take a moment.  
 23 **A.** Thank you.  
 24 **MS RICHARDS:** I'm sorry, Dr Walford.  
 25 **SIR BRIAN LANGSTAFF:** Do you want to just repeat that

1 application of legal restrictions would present  
 2 significant practical difficulties ..."  
 3 My understanding, Dr Walford, from your  
 4 statement is that you don't know now what those  
 5 practical difficulties were that she was referring to?  
 6 **A.** No.  
 7 **Q.** Then it said:  
 8 "... suggested that informal discussions with  
 9 companies concerned were more likely to lead to  
 10 successful control."  
 11 Now, we'll look very shortly at the minute you  
 12 produced setting out a range of questions that could  
 13 be posed of companies and the answer that came back.  
 14 Was that the action that was taken in relation to this  
 15 suggestion of informal discussions or were there --  
 16 **A.** I don't know. I mean, I believe my minute asking all  
 17 those questions was really simply probing, as it  
 18 were -- as a result of all the discussions we were  
 19 having, I just felt that there were a series of  
 20 questions that we needed to know the answers to.  
 21 Miss Spencer would have been in a position to know  
 22 what the legal problems were. I have no idea.  
 23 **Q.** If we go to the top of the next page, we can see:  
 24 "It was agreed that Medicines Division and  
 25 Supplies Division should instigate such discussion."

1 question to make sure that Dr Walford heard it.  
 2 **A.** Thank you.  
 3 **MS RICHARDS:** Yes, sir.  
 4 We were just looking at paragraph 3. It refers  
 5 to the leaflet, which I'll come on to, and then it  
 6 says, in the second part of the paragraph:  
 7 "... it was felt that more positive steps should  
 8 be taken at donor sessions and it was recommended that  
 9 RTDs [so Regional Transfusion Directors] should be  
 10 asked to reconsider their decision not to question  
 11 potential donors about the presence of symptoms such  
 12 as night sweats, weight loss etc."  
 13 If we go to the next paragraph, we can see that  
 14 the minuted action is you'll approach the chair of  
 15 directors to ascertain their views?  
 16 **A.** Yes.  
 17 **Q.** We'll look at your subsequent letter in a moment.  
 18 I just want to see what the action was.  
 19 I don't think I need to trouble you with looking  
 20 at the liaison with the Medical Gay Society.  
 21 We then come, bottom of the page, "Control of  
 22 imports". Paragraph 7 looks at this issue of the  
 23 dumping of pre-March concentrates.  
 24 Then we see:  
 25 "Miss Spencer explained that the effective

1 So those are not your division, as it were?  
 2 **A.** No.  
 3 **Q.** Do you know what steps either of those divisions took?  
 4 **A.** Well, they were having discussions with the  
 5 pharmaceutical companies, and I wouldn't have been  
 6 privy to that unless somebody had chosen to give me  
 7 some information as to what they had found and it may  
 8 be that in the answers to my email -- sorry, again, my  
 9 minute -- wish there had been emails -- it may be that  
 10 in the answer to my minute from Dr Fowler or  
 11 Mr Egerton that actually that was a result of some of  
 12 the conversations. They had obviously held  
 13 conversations, yes.  
 14 **Q.** Yes and that's really what I was getting at. Did you  
 15 understand there to be something more by way of  
 16 discussions being proposed here --  
 17 **A.** Yes.  
 18 **Q.** -- or just the kind of discussions we see reflected in  
 19 Mr Egerton's response to you?  
 20 **A.** No, I would have thought that that was just the  
 21 discussions that they were having with the  
 22 pharmaceutical companies.  
 23 **Q.** Then we get to paragraph 9, where you talk about --  
 24 and I think we've really covered this territory  
 25 already, Dr Walford -- your concern or the concern

1 about the consequences of controls on supply.  
2 Heat-treated products, the agreed action -- at  
3 paragraph 11 -- is to "keep a close watch on  
4 developments".

5 And then under the heading "Plasma supply and  
6 Factor VIII production in the UK", there's  
7 a discussion about self-sufficiency and an action that  
8 is writing to the administrators of Regional Health  
9 Authorities pressing -- reminding them of the benefits  
10 of self-sufficiency, pressing them, essentially, to  
11 keep supplying plasma. Is that a fair summary?

12 **A.** Yes.

13 **Q.** Then if we go down to the bottom of the page, we can  
14 see there's reference to research. I don't propose to  
15 ask you anything about that.

16 Then if we go to the top of the next page, we  
17 can see there's a discussion about the Council of  
18 Europe. There's a reference to Dr Gunson's reports.  
19 We'll look at all this shortly, Dr Walford.

20 The agreement is:

21 "... that when the opportunity to comment arose  
22 the potential problems to the UK created by small pool  
23 production and the ban of imports should be brought to  
24 the Council's attention."

25 As we'll shortly see, you made comments on the

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1 weren't involved in looking at those yourself?

2 **A.** Well, not -- I don't think I ever received anything  
3 really contemporaneously. I wasn't involved with The  
4 Haemophilia Society. There will have -- presumably if  
5 any of the Haemofact documents I have now seen were  
6 around in the Department, I might well have seen them,  
7 but I wouldn't know when I had seen them.

8 **Q.** Then we can see paragraph 26:

9 "Miss Spencer reported that the Sub-Committee  
10 [of the Committee on the Safety of Medicine] would be  
11 discussing AIDS ... [on] 13 July."

12 Those are the matters that were discussed, the  
13 plan being to examine possible courses of action.  
14 I just want to explore with you two matters to see  
15 whether you accept that these were not discussed and  
16 if you can assist us with why.

17 **A.** Right.

18 **Q.** The first is this, that there's no discussion evident  
19 from the minutes about any different approaches to the  
20 treatment of haemophiliacs. So there's no discussion  
21 about whether different policies should be adopted for  
22 those -- for different categories of haemophiliacs,  
23 there's no discussion about whether treatment should  
24 be minimised or no prophylactic treatment or  
25 cancelling non-elective surgery. It's right, isn't

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1 draft recommendations --

2 **A.** Yes.

3 **Q.** -- for Dr Gunson to pass back to the Council of Europe  
4 delegates.

5 Then there's a very short discussion recorded in  
6 relation to the redevelopment of BPL at paragraph 21.  
7 Again, I don't think I need to ask you about the entry  
8 under the heading "Homosexual rights groups".

9 Then "Haemophilia Society: "

10 "The meeting acknowledged the part played by the  
11 Society in keeping AIDS in perspective."

12 Are you able to assist us with what's meant by  
13 that comment?

14 **A.** Well, it seems to be self-evident that essentially the  
15 Haemophilia Society was communicating with members and  
16 presumably trying to give them the information that  
17 they have and, indeed, to keep the problem in whatever  
18 was the right perspective. But since I wasn't  
19 involved at all with what The Haemophilia Society were  
20 saying and this is reported by somebody else, I really  
21 can't comment any further.

22 **Q.** You yourself weren't involved in looking at the  
23 materials that were being produced by The Haemophilia  
24 Society which, to some extent at this point in time,  
25 was based on what Professor Bloom was producing. You

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1 it, if there had been such a discussion we'd have seen  
2 some reflection of it in the minutes?

3 **A.** I would suppose so, but of course we would have been  
4 aware of any material that was being put out by the  
5 UKHCDO to its members to minimise. So, for example,  
6 not to treat mild haemophiliacs with concentrate, not  
7 to treat von Willebrand's disease with concentrate,  
8 and to treat children again with cryo if at all  
9 possible.

10 So I think we will definitely have been aware  
11 that The Haemophilia Society was -- sorry, the  
12 Haemophilia Centre Directors were putting out that  
13 material and it really would not have been for  
14 a meeting of officials to suggest any change in policy  
15 for treatment.

16 **Q.** Does that -- in terms of why that's the case, does  
17 that go back to the discussion, Dr Walford, we had on  
18 the first day of your evidence --

19 **A.** Yes.

20 **Q.** -- the clinical freedom and the view that was taken,  
21 rightly or wrongly, and that may ultimately be  
22 a question for the chair, that it wasn't the role of  
23 the Department to issue guidance or advice to  
24 clinicians?

25 **A.** That was exactly the situation on the ground at the

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1 time.

2 **Q.** Then the second matter that we see no reference to in  
3 this meeting, or at least in the minutes, is any  
4 consideration of what patients were being told, other  
5 than perhaps that oblique reference to "the part  
6 played by the Society of keeping AIDS in perspective"?

7 **A.** I don't think -- I mean, I'm relying on the minutes in  
8 the same way as you are here, because I don't have  
9 anything else to go on, and obviously it's not  
10 particularly reported here.

11 Dr Gunson said in his letter to the CMO that  
12 patients were being informed and one of the things  
13 that we do know about is that it was a question of  
14 informing those individuals who needed to know. The  
15 need to know was fundamentally with haemophiliacs as  
16 opposed to anybody else by way of patient group and,  
17 essentially, it would have been our understanding that  
18 the role of the Haemophilia Centre Directors in  
19 looking after their patients would be to discuss this  
20 matter with them. So it wouldn't have been at all for  
21 the Department but it would have been for the  
22 Haemophilia Centre Directors.

23 **Q.** Again, I will want to come back to that issue and  
24 we're look at what Dr Gunson said.

25 There's no discussion also of Dr Galbraith's

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1 re-ascertaining Directors' views about the  
2 desirability or otherwise about symptoms such as night  
3 sweats, unexplained weight loss etc. He promised to  
4 write to all Directors immediately to obtain their  
5 views. I explained that if Directors still felt such  
6 questioning to be inappropriate, we would need to have  
7 a note of the reasoning which had led to this  
8 conclusion. Dr Wagstaff felt that a possible  
9 compromise would be to add these questions to the list  
10 of questions which the donor reads from a card and  
11 then signs. The objection to this Dr Wagstaff felt,  
12 is that in his experience donors either do not read or  
13 do not take in what is written on the card."

14 Just pausing there, do you know what then  
15 happened in relation to this issue?

16 **A.** As far as I'm aware, they didn't ask questions about  
17 symptoms. I can't understand personally the  
18 reluctance but, nevertheless, there was a very strong  
19 feeling amongst the Regional Transfusion Directors  
20 that they wouldn't -- not only would they not ask  
21 about any possible symptoms they also very  
22 particularly would not ask about any sexual habits or  
23 orientation.

24 **Q.** Do you know whether you received the note of the  
25 reasoning that you had requested?

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1 paper to Dr Field in this meeting. Are you able to  
2 assist us why?

3 **A.** No, it seems not.

4 **Q.** Are you able to assist us with why that's the case?

5 **A.** No. Was -- Dr Sibellas was at this meeting, was she  
6 not?

7 **Q.** She was indeed.

8 **A.** So basically that would have been an issue which, if  
9 it was going to be raised, I would have expected her  
10 to raise.

11 **Q.** Then in terms of actions following this meeting,  
12 I just want to pick up on two of them then. The first  
13 is the suggestion that you'd approach Regional -- or  
14 the chair of the Regional Transfusion Directors to ask  
15 them to reconsider what had been, I think, a very  
16 strong reluctance to be questioning donors.

17 **A.** Yes.

18 **Q.** We can see that at DHSC0002231\_051.

19 This is a minute from you dated 6 June, and you  
20 are updating Mr Winstanley on the actions that fell to  
21 you from that meeting.

22 **A.** Mm-hm.

23 **Q.** The first paragraph says:

24 "I have done the following:

25 "i) Spoken with Dr Wagstaff about

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1 **A.** No, I think I had if we -- is there anything else in  
2 this document?

3 **Q.** Not on that issue.

4 **A.** Right.

5 **Q.** There are some other issues. Again, it may simply be  
6 the volume of material hasn't been picked up but  
7 I don't think you've referred to it, there being such  
8 a note in your statement. Again, I'm sure I'll be  
9 corrected if I'm wrong.

10 **A.** Could I ask you also, this meeting is 3 June, was that  
11 after the meeting -- was a meeting in May of Regional  
12 Transfusion Directors that I attended about 18 May,  
13 something like that?

14 **Q.** We're checking all the Regional Transfusion Directors  
15 meeting minutes in the course of the morning,  
16 Dr Walford. So if there is anything which casts any  
17 further light on this issue, we can come back to it in  
18 the course of the day.

19 The next paragraph, you flag up the issue of how  
20 leaflets would be distributed. It's going to be  
21 a relevant issue when Lord Glenarthur gives evidence  
22 later in the week, so I just want to note that you've  
23 asked the question, Dr Wagstaff prefers the handing  
24 out leaflets rather than having them available and he  
25 says: I'll canvass directors' views on that alone.

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1 Then we can see in the next paragraph,  
2 Dr Wagstaff asks about the possibility that Liberton,  
3 so the Edinburgh centre, might be able to process some  
4 English plasma if American imports were to be  
5 restricted. Again, I'm not going to read everything  
6 out there but there's a discussion about that and then  
7 further down that paragraph you say to Mr Winstanley:

8 "Doubtless you will wish to pursue this  
9 possibility with [the Scottish Home and Health  
10 Department]."

11 Obviously, we looked at the earlier issue in  
12 relation to Liberton, yes?

13 **A.** Yes.

14 **Q.** Do you know whether anything further came of this  
15 suggestion that -- on a temporary basis, because of  
16 the situation in relation to AIDS, there might be the  
17 possibility of some additional processing of English  
18 plasma being done in Scotland?

19 **A.** I don't know as a result of this. Obviously, the  
20 action fell to Mr Winstanley.

21 **Q.** In that case, we'll try to take that up elsewhere.

22 Then if we then -- so those were some of the  
23 actions that fell to you from the meeting of 3 June.  
24 In terms of the discussions with pharmaceutical  
25 companies, if we look at your minute at

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1 DHSC0002229\_041. It's a minute of 14 June 1983 from  
2 you to Mr Egerton. In which department or branch was  
3 Mr Egerton based?

4 **A.** I think he was Supply.

5 **Q.** I'm not going to go through each and every question  
6 but you have set out there a range of questions that  
7 could possibly be posed of pharmaceutical companies?

8 **A.** Mm-hm.

9 **Q.** Then if we look at a response at DHSC0002229\_055.  
10 It's dated 28 June 1983 and it's from, I think,  
11 Mr Wigglesworth, copied to you, and it refers to  
12 HSIB, so that's Supplies, is it --

13 **A.** Yes.

14 **Q.** -- having circulated the questions listed in your  
15 minute to suppliers and possible suppliers of  
16 coagulation factor concentrates. Then there's  
17 a summary of the replies, and we'll just look at the  
18 most material one. So paragraph (d) identifies the  
19 five firms supplying blood products in the UK and  
20 paragraph (e) sets out the rough volume of annual  
21 imports. (f) says:

22 "With the exception of Immuno the firms state  
23 that they do not or have ceased to collect in  
24 'Epidemic' areas. All state that their collection  
25 centres are FDA licensed.

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1 "g. The plasma in each case is pooled prior to  
2 processing. In the case of Immuno products, European  
3 plasma and USA plasma are pooled separately.

4 "h. The origin of all plasma is identifiable."

5 Then:

6 "i. Each has given the assurance that future  
7 sales will comply with FDA guidelines. However, Miles  
8 Labs state that [Factor]VIII manufactured from plasma  
9 collected since March '83 will not be available until  
10 August, and Immuno in September '83."

11 Then it says:

12 "The tenth company, Cutter International  
13 Limited, have not yet replied."

14 There's a table over the page I'm not going to  
15 go through it, but just so we can see that that's some  
16 of the information that was summarised on the previous  
17 page.

18 So is it right to understand that the outcome of  
19 these informal discussions was with the qualification  
20 set out in paragraph (i) on that previous page, if we  
21 just go back to it, the companies are saying that  
22 their future sales will be compliant with FDA  
23 guidelines, which might be thought to be a statement  
24 of the obvious, but it doesn't really address the  
25 issue of what had already been --

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1 **A.** No.

2 **Q.** -- supplied to the UK and what might still be held  
3 either --

4 **A.** That's right.

5 **Q.** -- in NIBSC or in Regional Health Authority areas?

6 **A.** Yes. I mean, in essence, it's telling us that  
7 actually there is no such plasma -- no such product  
8 derived from post 23 March plasma in the UK at the  
9 time and that there are significant stocks amounting  
10 to many millions of international units of Factor VIII  
11 that are in the country either waiting NIBSC clearance  
12 or ready for use.

13 **Q.** So as a matter of fact, the overwhelming probability  
14 is that haemophilia centres continued to treat  
15 patients with pre-March plasma for a period of time?

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

17 **Q.** You previously pointed out that a number of the  
18 companies said that they had voluntarily adopted --

19 **A.** Yes.

20 **Q.** -- FDA-type regimes prior to 24 March 1983 --

21 **A.** Yes.

22 **Q.** -- and it's right to say the second page of this  
23 document has got some of the specific dates for some  
24 of the companies.

25 **A.** Yes.

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1 **Q.** Again, I'm not going to go through the detail but just  
 2 to complete the evidence you gave on that.  
 3 Can we then come to the meeting on 13 June 1983.  
 4 Just to explore how that meeting came about, if we  
 5 look at CBLA0000043\_034. This is Dr Joseph Smith's  
 6 letter of 28 March 1983 to Dr Keith Fowler in the  
 7 Medicines Division at the DoH. He says that he thinks  
 8 it would be advisable to consider at a meeting of the  
 9 CSMB (and that's the Biological Subcommittee of the  
 10 Committee on the Safety of Medicines) the problem of  
 11 AIDS in relation to licensed blood products, and he  
 12 suggests it would be very helpful to have Professor  
 13 Bloom there. Then there's a reference in the second  
 14 paragraph to the action of the FDA. Then the request  
 15 in the third paragraph to Dr Fowler is to prepare  
 16 a brief paper on which the discussion might be based.  
 17 I think you say in your statement you didn't see  
 18 this at the time.  
 19 **A.** No.  
 20 **Q.** But you subsequently became aware, I don't think we  
 21 need to look at it, in the latter half of April --  
 22 **A.** That's right.  
 23 **Q.** -- of this proposal.  
 24 It doesn't appear, and I know -- I think you  
 25 have had the opportunity to read the statement from

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1 Syndrome; A new hazard for haemophiliacs?" by  
 2 Dr LK Fowler. I can't remember if I've asked you  
 3 this, Dr Walford, and apologies if I have, what was  
 4 Dr Fowler's area of clinical expertise, do you know?  
 5 **A.** Yes, I think -- clinical expertise, I don't know, but  
 6 I think his responsibility in Medicines Division was  
 7 to report to Dr Holgate on blood and blood products.  
 8 **Q.** But you don't know what his clinical background is?  
 9 **A.** No.  
 10 **Q.** Then if we go over the page -- we just ask you to note  
 11 and you've reflected it in your statement, at the very  
 12 bottom of the second page, and then where he refers  
 13 to, the last two lines:  
 14 "... the most convincing hypothesis so far for  
 15 the aetiology of AIDS is advanced by Sonnabend  
 16 et al ..."  
 17 Then, top of the next page, in that first  
 18 paragraph, he expands upon that and, at the end of the  
 19 first paragraph, he poses the question:  
 20 "In a word, is it not possible that  
 21 'haemophilic' AIDS may be a function of the  
 22 concentrate itself rather than a specific agent  
 23 transmitted by homosexuals with or 'incubating' AIDS?"  
 24 So he was, if I can put it this way, speculating  
 25 that AIDS might not be caused by a transmissible agent

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1 Dr Smith, now Sir Joseph Smith?  
 2 **A.** I got it late last night. I have glanced, no more  
 3 than that.  
 4 **Q.** Well, just to make it clear, I think we haven't asked  
 5 you to read it because we're conscious of how much  
 6 material that you have already processed but, again,  
 7 it would appear from Dr Smith's, Sir Joseph's,  
 8 statement that Dr Galbraith's Action on AIDS report to  
 9 Dr Field was not the trigger for the meeting and,  
 10 indeed, was not the focus of the meeting, albeit that  
 11 Dr Galbraith himself was present at the meeting.  
 12 **A.** That's my understanding too from looking at this.  
 13 **Q.** So if we then look at the materials that were  
 14 available at the meeting, first of all -- so the  
 15 written materials -- there are, I think, two documents  
 16 that you have referred to in your statement and  
 17 Sir Joseph Smith confirms in his statement appear to  
 18 have been the available documents.  
 19 The first is a paper from Dr Fowler at  
 20 DHSC0002229\_059. You referred, to this yesterday or  
 21 the day before, Dr Walford.  
 22 **A.** Yes.  
 23 **Q.** But we didn't I think, in fact, look at it.  
 24 **A.** Yes.  
 25 **Q.** So we can see it's headed "Acquired Immune Deficiency

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1 and a viral infection, a different cause, albeit still  
 2 linked to concentrates?  
 3 **A.** Yes.  
 4 **Q.** Be that as it may, he then goes on to say:  
 5 "Having said this, one cannot ignore other views  
 6 and hope that the problem will go away. The media  
 7 concept of ticking time bomb is a very real one for  
 8 haemophiliacs and no effort should be spared to  
 9 protect them by all practical means."  
 10 Then he refers to the precautions taken so far  
 11 based upon a single unknown virus hypothesis. The  
 12 presumed agent is unknown, can't be tested for. He  
 13 refers to:  
 14 "Exclusion of blood from donors with positive  
 15 tests will remove many homosexual donors who, it is  
 16 said, tend to be good citizens ..." and suggests there  
 17 could be an appeal to homosexuals to exclude  
 18 themselves voluntarily from blood donations, and so  
 19 on, and expresses a concern about the alienation of  
 20 donors.  
 21 Then if we go to the next paragraph, he says.  
 22 "There is some evidence that cryoprecipitate  
 23 made from single donations or very small donor pools,  
 24 is safer than concentrate made from pools of thousands  
 25 of donations" and then says the evidence is "scanty".

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1 Was there any real doubt that cryoprecipitate --  
 2 certainly if there was -- the transmissible agent view  
 3 of aetiology was the correct one, was there any real  
 4 doubt that cryoprecipitate or very small donor pools  
 5 were significantly safer than pools of thousands of  
 6 donations?

7 **A.** I can't answer for whether there was any reasonable  
 8 doubt. I think probably there were certainly  
 9 publications about patients who had been maintained on  
 10 cryoprecipitate, who also seemed to have abnormalities  
 11 of their immune system, so that the T4/T8 lymphocyte  
 12 ratio was not necessarily totally reversed but was  
 13 actually not what you would expect if the immune  
 14 system was entirely intact.

15 So there was a lot of information flying around  
 16 as to whether or not patients maintained on  
 17 cryoprecipitate were likely to be -- less likely to be  
 18 affected and whether their immune systems looked as if  
 19 they were or were not being affected. But, of course,  
 20 Dr Fowler has said this and not me, so --

21 **Q.** No, and I'm asking you, Dr Walford, frankly, because  
 22 you were present at the meeting as an observer not as  
 23 a participant and most of the people present at the  
 24 meeting are not people -- who were involved and taking  
 25 a decision are not people we can ask about it, so I'm

1 So that is consistent with his response to your  
 2 minutes in May.

3 So that's one of the two documents before the  
 4 committee on 13 July.

5 The second document is at DHSC0001209. It's --  
 6 well, it might be said it's a somewhat curious  
 7 document, and I am going to explain to you why I put  
 8 it in those terms, Dr Walford, in a moment, but we can  
 9 see it is called a "Suggested 'agenda' for discussion  
 10 on AIDS in relation to licensed blood products", and  
 11 it's authored by Dr Smith dated 28 June 1983. He  
 12 says:

13 "The aim of the discussion is to help the  
 14 sub-committee to formulate advice to the CSM on  
 15 whether any action is needed, and if so what action,  
 16 in respect of AIDS and blood products licensed under  
 17 the Medicines Act."

18 Then he refers to the various products. My  
 19 focus, as you will understand, is going to be on  
 20 factor concentrates as opposed to immunoglobulin,  
 21 albumin and hepatitis B vaccines.

22 We can see who is going to be invited to attend  
 23 the committee in addition to its members, so it's  
 24 Bloom, Craske, Galbraith, Gunson and Mortimer.

25 Paragraph 3 is the assumption:

1 afraid it's by default really that I have to pose  
 2 these questions of you rather than the central  
 3 decision-makers at the meeting.

4 Anyway, if we pick it up at the bottom of the  
 5 page, he says:

6 "Even so, if a haemophiliac can be managed on  
 7 cryoprecipitate alone, it clearly makes good sense to  
 8 do so, since it will minimise the number of donors the  
 9 patient is exposed to."

10 Then, over the page, he then goes on to talk  
 11 about the problem of imported concentrate:

12 "More than half of the Factor VIII concentrate  
 13 used in the UK is imported from the US. How do we  
 14 ensure that the risk of transmission of AIDS to  
 15 haemophiliacs is kept as low as possible?"

16 Then he refers to the FDA regulations and,  
 17 picking it up about halfway down that paragraph, he  
 18 says this:

19 "... it behoves us to ensure that concentrate  
 20 imported from the US was not prepared from plasma  
 21 obtained prior to the implementation of FDA  
 22 recommendations."

23 Then he says:

24 "Probably the best means for accomplishing this  
 25 is by the system of stop orders."

1 "... that participants will be familiar with the  
 2 problem and with at least a proportion of the many  
 3 publications."

4 And then this:

5 "This 'agenda' suggests headings for the  
 6 discussion and a suggested first speaker is given. As  
 7 a target for discussion, brief possible conclusions  
 8 are indicated - doubtless these will be changed  
 9 radically."

10 Then what we can see then set out, as he says,  
 11 is there's a subheading, there's a suggested speaker,  
 12 and then there is what appears to be a conclusion,  
 13 formulated perhaps consistently with what he said in  
 14 paragraph 4 as a target for discussion, but a  
 15 suggested conclusion formulated by Dr Smith.

16 Now, I know you weren't involved with putting  
 17 together of this document at all so it may be that you  
 18 can't assist, but you were previously in the Medicines  
 19 Division and I think you had previously prepared  
 20 material for assessment of other products?

21 **A.** Yes.

22 **Q.** Was this a normal way to proceed? Was this how  
 23 meetings would normally and discussions normally be  
 24 structured?

25 **A.** It's difficult to say for me because basically, as an

1 assessor, I would be -- it was quite a formulaic way  
 2 of preparing your document for the Committee to  
 3 consider. It was set out under certain set headings,  
 4 if you like. So they would always have  
 5 a well-prepared paper in front of them so that they  
 6 didn't have to do -- you know, one got over all the  
 7 having to talk to individual bits. So it's not  
 8 totally abnormal to have something like this. I don't  
 9 necessarily recall under each heading there would be  
 10 a suggested conclusion, although he does say he  
 11 suggested the conclusion which he thought might  
 12 potentially be changed, but I -- I mean, this is  
 13 a fairly unusual format, I would say, but I can't just  
 14 extrapolate from what I did, because what I did was  
 15 actually to a formula in terms of how I presented  
 16 cases to the Committee on Safety of Medicines.  
 17 **Q.** Just so that we can get the flavour of how it's  
 18 structured, if we go to page 3 -- and I take your  
 19 point, Dr Walford, that the assistance you might be  
 20 able to give us in relation to this is limited, but we  
 21 can see -- so that others following can understand --  
 22 if we look at paragraph 4, for example, under the  
 23 heading "Consideration of the different operational  
 24 'possibilities' for reducing the risks from clotting  
 25 factor preparations", that the proposition is:

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1 you understand, as far as we understand, the only two  
 2 documents that the subcommittee had on 13 July?  
 3 **A.** As far as I'm aware, but I wonder if you could just  
 4 take us to the section on epidemiology, because it  
 5 says Dr Galbraith to speak to that and I think I ought  
 6 to look and see --  
 7 **Q.** It does. We pick it up at the bottom of the first  
 8 page.  
 9 **A.** The reason I'm asking is I notice, having seen the  
 10 paper then from Dr Smith, he asked for a paper on  
 11 epidemiology to be produced by CDSC, and I'm surprised  
 12 that the only paper that went was the Dr Fowler paper,  
 13 which is obviously not an epidemiological paper, and  
 14 Dr Smith's own paper, but Dr Smith did ask for a paper  
 15 on epidemiology to be produced, and he suggested,  
 16 I think, that maybe Dr Pollock of CDSC could produce  
 17 it. And Dr Galbraith was at this meeting. I cannot  
 18 remember and I haven't seen anything which allows me  
 19 to remember what the conversations were, what was  
 20 said, because there is none of that in any of the  
 21 papers that I've seen.  
 22 But Dr Galbraith would have been at that meeting  
 23 and expressing a view on the epidemiology. So  
 24 I thought it would be quite interesting to see --  
 25 **Q.** Absolutely. So the heading is "Epidemiology. Current

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1 "Withdraw ... concentrates (i.e. use only  
 2 cryoprecipitate ...)."  
 3 The proposed speaker is Professor Bloom, and  
 4 then the putative conclusion is:  
 5 "This step cannot at present be recommended ..."  
 6 and reasons given.  
 7 Then we can see, if we look down the bottom of  
 8 the page, under the heading -- so (iii):  
 9 "Use US blood products as sparingly as  
 10 possible."  
 11 So this might be the treatment techniques -- or  
 12 treatment policy strategies that I've been ventilating  
 13 with you in my questions, Dr Walford.  
 14 "NOTE: This possibility is largely a matter for  
 15 physicians treating haemophilia, but it could in  
 16 theory be decided to modify product licences, e.g.  
 17 'not for use in children with mild haemophilia'.  
 18 The proposed speaker to this proposition, as it  
 19 were, is Professor Bloom, and the suggested conclusion  
 20 is:  
 21 "The uncertain balance of risk/benefit  
 22 considerations in various categories of patient are  
 23 too finely balanced to justify action via licensing:  
 24 the matter should be left to clinical judgement."  
 25 So, in any event, those are, as far as I think

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1 position. Assessment of risk from Factor VIII". You  
 2 are right, the suggested speaker is Dr Galbraith.  
 3 If we go over the page, the suggested conclusion  
 4 is:  
 5 "Recipients of clotting factor concentrates are  
 6 at risk. The degree of risk cannot yet be quantified.  
 7 The risk is likely to be greatest from products  
 8 derived from the blood of homosexuals and IV drug  
 9 abusers resident in areas of high incidence, and in  
 10 those who repeatedly receive concentrates in high  
 11 dosage."  
 12 So I'm afraid that's all we have and you are  
 13 absolutely right to point out that Dr Galbraith was  
 14 there. The evidence doesn't appear to suggest that  
 15 the paper that he had sent to Dr Field was expressly  
 16 considered. Why I think must remain a mystery.  
 17 **A.** Shame, yes.  
 18 **Q.** Now can I then take you, because I want to, again,  
 19 really ask you about it because you were there and  
 20 there are very few people I can ask, but I just want  
 21 to take you then to the record of the conclusions,  
 22 which is at DHSC0001208.  
 23 Dr Walford, we haven't given you the minutes as  
 24 well but the content of the conclusions here is  
 25 identical to the matters set out in the minutes.

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1 A. Mm-hm.  
 2 Q. The minutes simply record, in addition, the  
 3 formalities of who was present and who was observing  
 4 and so on, and those representing you, in any event,  
 5 have the minutes.

6 But this is the document that then went to the  
 7 Committee on the Safety of Medicines when it was  
 8 effectively asked to say whether it agreed.

9 A. Yes.

10 Q. So it's entitled "Summary of main points from  
 11 a consideration of AIDS and licensed blood products by  
 12 CSM(B) 13 July 1983".

13 Then if we go down to where it says "The  
 14 following conclusions were reached", and I don't need  
 15 to ask you about all of them, one is about aetiology  
 16 so:

17 "The cause of AIDS is unknown but an infectious  
 18 aetiology seems likely. A previously unrecognised or  
 19 new agent may be responsible ..." and so on.

20 So I don't think -- I'm not going to ask you to  
 21 go into -- to look further at the detail of that.

22 "(2) Patients who repeatedly receive blood  
 23 clotting-factor concentrates appear to be at risk, but  
 24 the evidence so far available suggests that this risk  
 25 is small."

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1 So that was effectively all there was to go on.  
 2 We had no information about any level of infection.  
 3 That was not manifest as yet as AIDS, for example,  
 4 nor, indeed, how many people who had become infected,  
 5 if they had become infected, would ultimately go on to  
 6 develop AIDS.

7 So it was -- really, we had next to no  
 8 information to go on.

9 I suppose the thing -- obviously, I've thought  
 10 about this an awful lot, and we're probably going to  
 11 come on to it in terms of things that I may have said  
 12 at some stage later, but the one thing that is very  
 13 interesting about this, and it is certainly  
 14 interesting in relation to the information that was  
 15 given in Spence Galbraith's paper, which is that AIDS  
 16 appeared to have been diagnosed in America in a number  
 17 of people in the late 70s, '78/'79, and yet by the  
 18 time I think this group was meeting, I think there may  
 19 have been 11 cases, some small number of cases in  
 20 America in patients with haemophilia, and we had the  
 21 one case in the United Kingdom.

22 Given the ubiquity, the millions of units -- as  
 23 you've pointed out, sir -- that were actually going  
 24 into patients with haemophilia, it seemed  
 25 extraordinary, even allowing for a long incubation

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1 Now, you, I know, were at the meeting as an  
 2 observer. Do you have any independent recollection of  
 3 what the content or shape of the discussion was on  
 4 that occasion?

5 A. Absolutely nothing.

6 Q. We see reference to the risk being small, however,  
 7 appearing in other material including some of your own  
 8 background papers.

9 A. Yes.

10 Q. Is it right to understand, at least from your  
 11 perspective --

12 A. Yes.

13 Q. -- you can't speak to what was in the mind of the  
 14 committee members, I accept -- that that's based upon  
 15 the numbers, was it, the numbers of known cases, and  
 16 the relatively small number of cases?

17 A. Yes. I think one can only say that's all we had to go  
 18 on. It was a very data-poor position to be in. The  
 19 only thing we knew at the time was the number of cases  
 20 of AIDS -- not the numbers of cases of infections but  
 21 the number of cases of AIDS -- that had appeared in  
 22 the haemophiliacs in America and our own experience of  
 23 the one case so far. I don't think we knew even about  
 24 the man in Bristol at this time. We didn't know until  
 25 September I don't think.

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1 period, that there was such low numbers.

2 Now, when I talk about "such low numbers",  
 3 nobody should take it as assuming I think that a few  
 4 here and there was not significant. It was of  
 5 colossal significance to the individuals concerned.  
 6 But, in looking at the data that we had, it was quite  
 7 extraordinary so much American Factor VIII having been  
 8 used over the years and yet so few patients actually  
 9 manifesting as cases of AIDS.

10 Q. In terms of basing an assessment of risk on numbers of  
 11 cases, albeit with the qualification or explanation  
 12 that you've just given, do you accept there's  
 13 a possibility of conflating incidence with risk or --

14 A. Totally and it is what happened. It is what happened.  
 15 I think you might say: yes, but what else was there to  
 16 do? I mean, clearly a caveat should have been entered  
 17 in each case, and I think quite often it was, but --  
 18 "this may be the tip of an iceberg", "this may be  
 19 something which is going to explode and be an enormous  
 20 problem", but it would have to be a caveat since one  
 21 didn't know (a) the level of infection that was  
 22 around, (b) how many infections would actually go on  
 23 to become AIDS or manifest themselves in any of the  
 24 symptoms that might be considered to be AIDS. So it  
 25 was a total vacuum of information and the only

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1 information that we had was numbers, totally  
 2 inadequate though it was and, you're right, the risk  
 3 and the numbers were conflated.  
 4 **Q.** If we just continue with that same paragraph, it talks  
 5 about the risk being:  
 6 "... appears to be the greatest in the case of  
 7 products derived from the blood of homosexuals and IV  
 8 drug abusers resident in areas of high incidence ...  
 9 and in those who repeatedly receive concentrates in  
 10 high dosage. Balanced against the risk of AIDS (and  
 11 of other infections transmitted by blood products) are  
 12 the benefits of their use; in the case of haemophilia  
 13 they are life-saving."  
 14 Now, it's right, of course, to say that  
 15 concentrates could be life-saving in the case of  
 16 haemophilia, but are you able to assist us with  
 17 understanding whether the Committee thought that was,  
 18 as it were, almost invariably the position, because  
 19 the majority of treatment, as I think we've already  
 20 discussed, were to alleviate pain, joints, et cetera,  
 21 but it's not an invariably life-saving treatment, is  
 22 it?  
 23 **A.** I can't interpret for you what the Committee thought  
 24 but I would -- if I might suggest, I know that this  
 25 Inquiry has a group of experts on haemophilia who

1 Committee, knew an awful lot about haemophilia.  
 2 **Q.** Paragraph 3 then talks about:  
 3 "The possibility ... of withdrawing clotting  
 4 factors concentrates ... replacing them with  
 5 cryoprecipitate. It was concluded that this was not  
 6 feasible ... on grounds of supply."  
 7 And I've canvassed that with you already,  
 8 Dr Walford.  
 9 Top of the next page talks about the possibility  
 10 of withdrawing US preparations from the UK, so there's  
 11 an element of repetition there.  
 12 In any event, it goes on to talk about:  
 13 "... the perceived level of risk does not at  
 14 present justify serious consideration of such  
 15 a solution. Efforts are however being made to secure  
 16 UK independence of foreign suppliers of clotting  
 17 factor concentrates. This should reduce markedly,  
 18 although not eliminate, the risks to recipients of  
 19 these products, and the Sub-Committee strongly  
 20 supports this aim."  
 21 Now, that's talking about achieving  
 22 self-sufficiency, as I understand it:  
 23 "Efforts ... being made to secure UK  
 24 independence of foreign suppliers of clotting factor  
 25 concentrates."

1 should be able to assist you with that and should be  
 2 able to go back in history and in time to show you  
 3 what the consequences of untreated or sub-optimally  
 4 treated haemophilia were.  
 5 I think that inadequate treatment of  
 6 haemophilia, severe haemophilia, was life-threatening.  
 7 It didn't always mean that the patient would  
 8 ultimately succumb but there was a potential. I don't  
 9 think that that is an exaggeration but I do feel that  
 10 I'm not well placed to tell you, whereas I do think,  
 11 sir, you have a committee of experts on haemophilia  
 12 who should be able to assist.  
 13 **Q.** The third -- actually, sorry, just before I move on  
 14 from that, of those participating in the meeting,  
 15 whether as members of the Committee or the handful of  
 16 expert advisers, as they were termed, would it be  
 17 right to understand that the person who would have  
 18 been in a position to provide information to the  
 19 committee about benefits of treatment would have been  
 20 Professor Bloom?  
 21 **A.** He was the haemophilia expert that Joe Smith actually  
 22 chose to assist the committee.  
 23 **Q.** And the only haemophilia expert who participated in  
 24 that meeting?  
 25 **A.** That's true. Though Dr Lane, who was a member of the

1 **A.** Yes.  
 2 **Q.** I don't know whether, in the limited time you've had  
 3 to look at Sir Joseph Smith's statement, you picked up  
 4 upon this, but his statement records his understanding  
 5 that self-sufficiency was something that was going to  
 6 be achieved within a matter of months?  
 7 **A.** Oh, yes I did see that. I did see that and it was  
 8 a great surprise to me.  
 9 **Q.** That, on any view, was incorrect.  
 10 **A.** Yes, yes.  
 11 **Q.** So either his recollection is wrong, although it's  
 12 right to note, and others can read Sir Joseph's  
 13 statement, it's a matter -- he explains why it's his  
 14 recollection and it's consistent with evidence he gave  
 15 us elsewhere, but either his recollection is wrong or  
 16 the Committee was misinformed. There's no other way  
 17 of looking at it; would you agree?  
 18 **A.** I don't understand why he came to that conclusion and  
 19 what apparently -- I mean, you have some minutes and  
 20 so on, but I don't know who would have said that.  
 21 I can't think actually of anybody who knew anything  
 22 about the position that we were in, given that we were  
 23 reliant for 50 per cent of our Factor VIII  
 24 concentrates on imports, how anyone could have  
 25 included -- concluded that self-sufficiency was just

1 a matter of months away I don't know, and I would be  
 2 astonished if anybody in the Department at official  
 3 level would have said that.  
 4 **Q.** Then I just want to look at the last sentence of this  
 5 paragraph, paragraph 4:  
 6 "The Sub-Committee was also informed that the UK  
 7 Haemophilia Centre Directors have adopted a policy for  
 8 use of US Factor VIII in order to minimise risks as  
 9 far as possible."  
 10 Now, just pausing there, any information about  
 11 that, would you agree, is most likely to have come  
 12 from Professor Bloom? That would have been the source  
 13 of the subcommittee's --  
 14 **A.** Yes, I expect so, yes.  
 15 **Q.** Then I just want to put up on screen -- Soumik, can we  
 16 do this side by side? So could we have that page on  
 17 one side and then WITN -- ah, you are ahead of me.  
 18 Thank you so much. You read my mind.  
 19 **A.** Right.  
 20 **Q.** So we've got there the letter of 24 June 1983, which  
 21 I know you're familiar with.  
 22 **A.** Yes.  
 23 **Q.** Indeed, we can see the top of the page it says:  
 24 "Please copy to Dr Walford for info."  
 25 Handwritten at the top of that page.

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1 concentrate or other preparations?  
 2 **Q.** In any event, if we just look at the terms of the  
 3 recommendations on that right-hand side, we can see in  
 4 the paragraph numbered 1, which is concerned with mild  
 5 haemophilia, von Willebrand's, and it's simply  
 6 consider treatment with DDAVP --  
 7 **A.** Yes.  
 8 **Q.** -- and a reference to that being, in any case, the  
 9 usual practice of many directors and, I should say,  
 10 Dr Walford, the Inquiry's heard inconsistent evidence  
 11 in relation to usage of DDAVP even by 1983.  
 12 **A.** Yes.  
 13 **Q.** So that's consider DDAVP for those categories. Then 2  
 14 is children and mildly affected patients or previously  
 15 untreated patients, all it says is:  
 16 "... many Directors already reserve supplies  
 17 of ..." and I think we need to read that as "NHS  
 18 concentrates or cryoprecipitate".  
 19 **A.** Mm-hm.  
 20 **Q.** "... and it would be circumspect to continue this  
 21 policy."  
 22 So, at best, it's a good idea to carry on doing  
 23 this if you're already doing it?  
 24 **A.** That's right.  
 25 **Q.** Now if we just look then on the left-hand side, to

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1 **A.** Yes.  
 2 **Q.** This is the only policy for use, as far as we  
 3 understand it, and I think as far as you understand  
 4 it, adopted for use by UK Haemophilia Centre  
 5 Directors.  
 6 **A.** Yes.  
 7 **Q.** You have referred to these recommendations that we see  
 8 at 1 and 2 in your witness statement, and I think in  
 9 the context of discussing clinical freedom. You  
 10 referred to them, I think, as weak recommendations or  
 11 words to that effect?  
 12 **A.** Well, I think, by definition, because they were  
 13 recommendations and not guidance or anything more  
 14 formal, then inevitably that was weak. Essentially  
 15 people were free to take or leave the recommendations,  
 16 But you would have thought that, given a letter like  
 17 this, a great deal of account would be taken of it.  
 18 I would be -- I would have been surprised if that were  
 19 not the policies adopted by the Haemophilia Centre  
 20 Directors.  
 21 I personally think the most problematic thing is  
 22 what about people being treated outside haemophilia  
 23 centres, and how far did this set of recommendations  
 24 emanate to places where the haemophiliacs were not  
 25 known and were -- only occasionally had to visit for

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1 what the subcommittee's understanding appears to be --  
 2 and there's no evidence the subcommittee had this  
 3 letter to consider for itself?  
 4 **A.** No.  
 5 **Q.** The subcommittee says -- it's paragraph 4 on the  
 6 left-hand side, last sentence --  
 7 Sorry, no, it's paragraph 4, Soumik, so top of  
 8 the page.  
 9 "The Sub-Committee was also informed [by  
 10 hypothesis by Professor Bloom] that the UK Haemophilia  
 11 Centre Directors have adopted a policy for use of ...  
 12 Factor VIII in order to minimise risks as far as  
 13 possible."  
 14 I'm really asking for your view as an informed  
 15 observer, as I say, because you weren't  
 16 a decision-maker in this regard. Do you think that  
 17 the policy that, as a matter of fact, had been adopted  
 18 by Haemophilia Centre Directors could accurately be  
 19 described as a policy for use of Factor VIII  
 20 concentrates that would minimise risks as far as  
 21 possible? Because the actual policy didn't go very  
 22 far at all, did it?  
 23 **A.** No, it was advisory, it recommended, it was in no way  
 24 mandatory, and I think I stick by the word that I used  
 25 in my statement which said that it was weak.

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1 Q. Because a policy, to use the subcommittee's words,  
 2 "for use of US Factor VIII in order to minimise risks  
 3 as far as possible", bearing in mind the  
 4 subcommittee's already recognised that those at  
 5 greatest risk are those who receive high amounts of  
 6 concentrate, who are most likely to be severely  
 7 affected haemophiliacs who are not covered by the  
 8 policy in the letter of 24 June at all, unless they  
 9 are newly diagnosed patients.  
 10 A policy to minimise risks as far as possible --  
 11 sorry, minimise use -- use concentrates to minimise  
 12 risks --  
 13 A. Ah I see what you mean.  
 14 Q. -- as far as possible for severe haemophiliacs would  
 15 have to be different, wouldn't it? It would have to  
 16 be something along the lines of no prophylaxis, reduce  
 17 home treatment --  
 18 A. I understand what you're saying now --  
 19 Q. -- treat in emergency circumstances --  
 20 A. Yes.  
 21 Q. -- cancel elective surgery, single batch single  
 22 concentrate dedication policies?  
 23 A. Absolutely. But that of course was not what the  
 24 meeting of 13 September concluded, and there they were  
 25 suggesting no change for people who had been,

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1 A. I have no independent recollection of this meeting.  
 2 SIR BRIAN LANGSTAFF: If I may, this particular paragraph  
 3 is all about risk, isn't it?  
 4 A. Yes.  
 5 SIR BRIAN LANGSTAFF: It talks about the "level of risk  
 6 not at present" justifying withdrawing US product.  
 7 A. Yes.  
 8 SIR BRIAN LANGSTAFF: Then the next three sentences deal  
 9 with risk, and they throw into the equation to assess  
 10 what the risk actually is, the sense that when and if  
 11 we become self-sufficient in making our own  
 12 concentrate, then the risks of US concentrate will, by  
 13 definition, fall away: we have our own risks but we  
 14 won't have the USA's risks.  
 15 A. Yes.  
 16 SIR BRIAN LANGSTAFF: The second part is that there's been  
 17 a change of policy or a policy which ensures that the  
 18 risk is kept as low as possible.  
 19 In terms of the first of those two points, the  
 20 context was that of what was possibly a transmissible  
 21 agent that was thought to be the most likely cause --  
 22 you yourself thought it was the most likely cause.  
 23 A. Yes.  
 24 SIR BRIAN LANGSTAFF: -- which, if it was something which  
 25 had a long incubation period which, was understood at

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1 obviously, severe haemophiliacs, and that consistently  
 2 appearing to be the policy of the UKHCDO for quite  
 3 a long time.  
 4 So I guess I had assumed, and you are quite  
 5 right to say it doesn't say that, that what they were  
 6 talking about here is: how do you stop people who  
 7 shouldn't be getting concentrate, because they are not  
 8 severe, from getting concentrate? Well, there's a set  
 9 of recommendations, if you like, and asking people to  
 10 consider what you should do. It doesn't relate to the  
 11 severe haemophiliacs, and my understanding at the time  
 12 was that because they were all maintained on  
 13 concentrate that there was no change in the policy of  
 14 the UKHCDO.  
 15 Q. So that it's clear -- I am fairly confident you  
 16 understand this, in any event, Dr Walford -- the  
 17 concern I am ventilating through this line of  
 18 discussion with you is a concern that the subcommittee  
 19 may have proceeded on a degree of false reassurance or  
 20 mistaken reassurance that things were being done in  
 21 terms of treatment policies that were not being done.  
 22 That's the reason for raising it.  
 23 I suspect you can't assist us any further with  
 24 that because you don't have an independent  
 25 recollection as an observer --

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1 the time, might take a while to manifest itself in the  
 2 way that epidemics do.  
 3 A. Yes.  
 4 SIR BRIAN LANGSTAFF: So the sense that in a year or two  
 5 or three or four's time there might be sufficient  
 6 production domestically really had nothing to say  
 7 about that risk, did it?  
 8 A. No, the risk as they were defining it was what they  
 9 perceived as the risk at present time, yes.  
 10 SIR BRIAN LANGSTAFF: And the future production of  
 11 self-sufficiency, enough quantities, unless it was  
 12 very, very imminent --  
 13 A. Yes.  
 14 SIR BRIAN LANGSTAFF: -- would have nothing to say on it?  
 15 A. No, it does appear to be another *non sequitur*.  
 16 SIR BRIAN LANGSTAFF: So it's -- yes, it's another  
 17 *non sequitur*.  
 18 A. Yes.  
 19 SIR BRIAN LANGSTAFF: The last looks like misinformation,  
 20 the sense that there's been a change when there hasn't  
 21 been a change.  
 22 A. Yes.  
 23 SIR BRIAN LANGSTAFF: Because the general message being  
 24 sent out from -- as I understand your view of -- and  
 25 at the moment it may well become my own view, of what

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1 is said in the letter of 24 June, is that the UKHCDO  
 2 weak recommendations really were: business as usual.  
 3 **A.** Or slight improvement on business as usual, if you  
 4 like, emphasising how best practice --  
 5 **SIR BRIAN LANGSTAFF:** It gives a nudge.  
 6 **A.** Best practice.  
 7 **SIR BRIAN LANGSTAFF:** Yes, thank you.  
 8 **MS RICHARDS:** Then if we just go back to the document on  
 9 the left-hand side and look at paragraph 5, and it's  
 10 the last paragraph in the subcommittee's conclusions  
 11 I need to ask you to look at, so this is dealing with  
 12 the dumping issue, the March 1983 FDA regulations, and  
 13 the Committee say this:  
 14 "It is advisable that all clotting-factor  
 15 concentrates derived from US plasma sources and  
 16 intended for use in the UK be prepared only from  
 17 material manufactured from plasma collected after new  
 18 regulations were introduced by the FDA on March 23,  
 19 1983. These regulations were introduced specifically  
 20 to minimise the likelihood of collecting blood from  
 21 affected donors. This step is recommended  
 22 notwithstanding the possibility that its practical  
 23 value may be relatively small. It cannot, however, be  
 24 taken until supplies of post-March 23 material can be  
 25 assured. It is recommended that close contact is

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1 and questions have been raised in America that were  
 2 then being passed back via the British Embassy to the  
 3 International Division within the Department of Health  
 4 about was the UK going to ban American concentrates.  
 5 If we need to pick that up we can do so in due  
 6 course. I just want to ask you about the fourth  
 7 paragraph that we see on the page:  
 8 "Incidentally [you say], are you happy with the  
 9 assurances so glibly given by the manufacturers that  
 10 'future' supplies of [Factor]VIII will be derived from  
 11 plasma taken in accordance with the 23 March  
 12 regulations?"  
 13 Then you ask whether more information should be  
 14 obtained. So it would appear that you're expressing  
 15 a degree of -- cynicism may be an unfair word --  
 16 **SIR BRIAN LANGSTAFF:** Scepticism.  
 17 **MS RICHARDS:** -- scepticism, that's the word, thank you --  
 18 as to whether the assurances given, that we looked at  
 19 in that exchange of communications with Mr Egerton --  
 20 could simply be taken at face value.  
 21 **A.** Yes, I mean, I thought it would have been helpful for  
 22 them to have told us when we could have supplies  
 23 actually in the country from material produced in  
 24 compliance with the FDA regulations and I was simply  
 25 probing the issue and asking for it to be probed.

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1 maintained between the Licensing Authority and  
 2 Supplies Division with the aim of introducing this  
 3 step immediately it becomes feasible."  
 4 So is it right to understand that what -- the  
 5 subcommittee wanted action to be taken, in relation to  
 6 not having pre-March 1983 concentrates in use with UK,  
 7 but were articulating the view that there needed to be  
 8 sufficient supplies of post-March material for that to  
 9 happen?  
 10 **A.** Yes. I mean, I think they were still making the point  
 11 that, really, potentially, the benefit of that might  
 12 be marginal but, notwithstanding that, it would be  
 13 a good thing to do but you could only do it once you  
 14 knew you had adequate supplies, so that you didn't get  
 15 the threat that I have been referring to of problems  
 16 for patients with haemophilia who were not going to be  
 17 adequately treated if we didn't have enough  
 18 Factor VIII.  
 19 **Q.** Now, I then just want to pick a handful of bits and  
 20 pieces of material that follow on from this in terms  
 21 of chronology before lunch, and then I'll come to some  
 22 other topics after lunch. If we go to  
 23 DHSC0002229\_097, this is a minute from you, dated  
 24 20 July 1983, to Mr Wrigglesworth and Miss Spencer.  
 25 It refers to a telex received from the British Embassy

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1 **Q.** Then if we could go to DHSC0002353\_020. This is  
 2 a minute from you dated 25 July 1983, again it refers  
 3 to a telex from the British Embassy in Washington.  
 4 We've got various of those materials but I don't think  
 5 it's necessary to go to them with you, Dr Walford, in  
 6 order to understand the issues you were raising.  
 7 You say this:  
 8 "I suggested we should ascertain the outcome of  
 9 a recent FDA meeting ..."  
 10 Just pausing there, do you think that's  
 11 a reference to the 19 July meeting that we looked at  
 12 earlier?  
 13 **A.** I can't be sure. What was the date of this?  
 14 **Q.** This is 25 July.  
 15 **A.** It could be, it could be.  
 16 **Q.** In any event, you carry on:  
 17 "... which was, I believe, to discuss the  
 18 problem of plasma/finished product which pre-dated the  
 19 23 March regulations."  
 20 So still concerned with the, as it were, the  
 21 dumping issue:  
 22 "If there is to be no restriction on the use of  
 23 this material in the USA, I suggest that we should  
 24 follow the same line. If, however, use of this  
 25 material is restricted in some way (eg by the

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1 imposition of a quarantine period), then, provided  
2 supplies are not prejudiced, the UK should presumably  
3 refuse to accept material that is not considered  
4 acceptable for use in the States. You agreed to take  
5 this forward with Dr Fowler."

6 Why was it your view that the UK should follow  
7 the US line rather than ploughing its own furrow?

8 **A.** Now, of course, trying to think what I may have  
9 thought at the time, but I suspect that what I thought  
10 was, if the FDA, which had introduced quite stringent  
11 regulations to control a product, if you like, and in  
12 America they were seeing far more cases, still not  
13 a huge amount, but maybe up to maybe 17 or something  
14 around this time, of cases in haemophiliacs, I took  
15 the view, I believe, that the FDA would not continue  
16 to allow the use of product that they thought to be  
17 unsafe, that it would be rather odd if they did  
18 because I knew them to be a very stringent sort of  
19 regulator.

20 So if they were saying we still think you can  
21 use this material, well then, we did not have more  
22 evidence than they had that we shouldn't go on using  
23 that material.

24 The big problem is if they restricted it in some  
25 way, the chances were that they would be dumping --

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1 have gone on. They were advising the Licensing  
2 Authority. The Licensing Authority did not say we  
3 will withdraw this product. So that was all one had  
4 to go on.

5 **Q.** Just on the question of what steps might practically  
6 have been available, and subject to whatever the  
7 unknown practical difficulties were that Ms Spencer  
8 referred to in the Department's own meeting of 3 June,  
9 but on the question of labelling, stop orders, the  
10 kind of issues floated by Dr Fowler, there's no  
11 express reference to them obviously in the Committee  
12 on Safety of Medicines conclusions on 13 July. So we  
13 don't, I think, know whether any consideration was  
14 given to the specifics on that occasion.

15 Who might be able to cast further light on that  
16 matter, Dr Walford? Would it be a question for  
17 Dr Duncan Thomas at the NIBSC, do you think?

18 **A.** NIBSC could say whether or not any restrictions, any  
19 new labelling requirements were placed on the  
20 products, and the Medicines Division would have been  
21 the division to pursue this, to actually push if they  
22 felt that it was the thing that they wanted, that they  
23 needed to do.

24 I would not have said that for Med SEB, and me  
25 in particular, that I had a particular role in

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1 there would be dumping of their material into the UK.  
2 So we really needed to be very careful if the  
3 Americans were not going to use this product it  
4 certainly couldn't be allowed to find its way into the  
5 UK. But I think that would have been part of my  
6 thinking.

7 **Q.** I understand, absolutely, the second part of what  
8 you've said, if the Americans think it's unsafe we  
9 certainly shouldn't be using it. But can I just put  
10 this to you: just because the Americans think it's  
11 safe doesn't mean that the UK should reach the same  
12 judgement?

13 **A.** Of course it doesn't mean the UK can't have its  
14 independent judgement but, thus far, and the date of  
15 this is 25 July, the Committee on Safety of Medicines  
16 Biologics Subcommittee, on which one relied, however  
17 much in looking back now you feel it was a flawed  
18 meeting, I had nothing more to go on, and neither did  
19 anybody else, than their recommendation that actually  
20 the material should continue -- well, not continue in  
21 use, it wasn't specifically said, but that it would  
22 not be restricted until supplies could be, as it were,  
23 confirmed.

24 There was nothing else, apart from the CSM's  
25 decision that I or any of my colleagues could possibly

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1 following up this state of affairs. Clearly somebody  
2 asked my view and my view was: if the Americans  
3 weren't going to use it, we certainly shouldn't, but  
4 if they were prepared to and knowing the FDA's rigour,  
5 or what I believed to be the FDA's rigour as  
6 a regulator, I thought that it was reasonable to go on  
7 using it ourselves.

8 **Q.** Then if we just pick that up with a slightly later  
9 minute from you, 3 August 1983 at DHSC0002351\_017, so  
10 we can see in the first main paragraph that  
11 information's been gathered about the extent of  
12 manufacturers' stocks in the UK, and it's recorded  
13 that, in the case of three of the manufacturers, all  
14 or a substantial proportion of the stocks:

15 "... has been manufactured from plasma collected  
16 in accordance with the special precautions instituted  
17 by the manufacturers themselves, albeit prior to the  
18 March 1983 FDA requirements."

19 So there's an -- is this right, there's  
20 a substantial proportion of pre-March plasma in the  
21 UK --

22 **A.** Yes.

23 **Q.** -- not yet used?

24 **A.** Yes.

25 **Q.** Your suggestion is, because three of the manufacturers

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1 are saying that they had their own regime of  
 2 measures --  
 3 **A.** Yes.  
 4 **Q.** -- someone should do the exercise of seeing whether  
 5 what they were doing that as good as --  
 6 **A.** That's right.  
 7 **Q.** -- the FDA recommendations or not?  
 8 **A.** Yes.  
 9 **Q.** Then the next paragraph, you then say:  
 10 "The question then is, what, if any, action is  
 11 required in relation to stocks pre-March 1983 material  
 12 which have not been collected under the manufacturers'  
 13 own special requirements? Clearly, it is crucial to  
 14 know the results of the Congressional hearing before  
 15 making any decisions."  
 16 You obviously knew by then that this was  
 17 a matter that was going to be considered by Congress  
 18 in the States:  
 19 "If, by some mischance, the hearing should  
 20 overturn the FDA decision, we shall be on the horns of  
 21 a very nasty dilemma."  
 22 Can I ask you, please, why you characterised it  
 23 in those terms "mischance" and "horns of a very nasty  
 24 dilemma" because Congress might overturn it because it  
 25 thought that was the right and safe course to take for

1 issue, DHSC0000207 is a minute written by you on  
 2 20 September 1983. The second paragraph refers to the  
 3 Congressional hearing, which has now taken place:  
 4 "It did not give rise to any alteration in the  
 5 position in USA what FDA decision to allow the use of  
 6 such material still stands. There would therefore  
 7 appear to be no reason to change our policy over the  
 8 use of such material in the UK."  
 9 So you're essentially consistent with what  
 10 you've previously said: will follow the US line.  
 11 Just bearing in mind that what the Biological  
 12 Subcommittee on 13 July had actually said was it did  
 13 want steps to be taken to prevent the use of pre-March  
 14 plasma, provided the position of supply could be  
 15 secured.  
 16 **A.** Yes.  
 17 **Q.** Did that ever get resolved, to your knowledge?  
 18 **A.** Well, we know that the position -- the supply couldn't  
 19 be resolved, though, of course fortunately there was  
 20 some material that was made by manufacturers according  
 21 to their own specifications, which -- you sent me last  
 22 night the Alpha Pharmaceutical manufacturer's press  
 23 release on this, and so on, where it was saying how it  
 24 was taking its steps to protect -- to, as it were,  
 25 follow the FDA guidance, although it was before the

1 the protection of its citizens.  
 2 **A.** I, of course, now don't know precisely what I was  
 3 thinking but my thought, I suspect, will have been we  
 4 have just had a decision by the Committee on Safety of  
 5 Medicines and the Licensing Authority, which says do  
 6 not withdraw. We have just heard that the FDA is not  
 7 proposing a withdrawal, as it were, and it's now going  
 8 to be debated in Congress. Congress is, of course,  
 9 full of politicians, it's not actually full of  
 10 experts, and they may choose to overturn something  
 11 that an expert group has decided and our own expert  
 12 group has decided.  
 13 In that case, we would be finding ourselves, if  
 14 the -- my thesis was if the Americans won't take this  
 15 material then neither should we, if that would have  
 16 been based on the science. Here, we were having  
 17 congress coming in on whatever basis, I don't know,  
 18 but definitely a political decision and, potentially,  
 19 we would find ourselves with a whole new area of  
 20 problems that we had to deal with.  
 21 I think that's all I was probably saying.  
 22 I couldn't get my head around what we were going to do  
 23 if Congress decided something different from what had  
 24 already been agreed.  
 25 **Q.** Then, just finally before lunch, to round off this

1 FDA guidance was actually promulgated.  
 2 So there was some material which could have been  
 3 used as safely as the FDA mandated material would be.  
 4 But, basically, the supply position remained exactly  
 5 as it was when the CSM considered it. We had  
 6 something like 40 million international units of  
 7 Factor VIII in the country, some of which had been, it  
 8 seems, manufactured in a way which was, to a degree,  
 9 if not compliant with the FDA, actually possibly even  
 10 more rigorous in the case of some of the  
 11 manufacturers, but the rest wasn't, and so that was  
 12 the supply that we had, and the Committee on Safety of  
 13 Medicines, and therefore the Licensing Authority, had  
 14 not said that we shouldn't use that material.  
 15 **Q.** Would it be right to understand that in the absence of  
 16 a labelling process or something equivalent, the  
 17 haemophilia clinicians who were actually using these  
 18 concentrates to treat their patients would have no  
 19 means of knowing whether it was pre or post March pre  
 20 or post the manufacturers' own internal regime?  
 21 **A.** Yes.  
 22 **Q.** Then, just finally, we see you say this:  
 23 "Incidentally, if you haven't already heard,  
 24 a haemophiliac in Bristol has died of AIDS."  
 25 Then you refer to material, Alpha and Immuno,

1 also BPL, also cryoprecipitate, and you say that he  
2 was a mild haemophiliac.

3 You'll recall, Dr Walford, when we looked at the  
4 Reference Centre Directors' meeting of 13 May, the  
5 reference in the minutes to keeping the matter under  
6 constant review, or words to that effect, and you'll  
7 recall Dr Craske saying in his letter to his colleague  
8 at the PHLS, well, if another case comes along then  
9 perhaps the balance of risk, as it were, would change.

10 Did the Department's approach or the steps that  
11 it was taking change at all, once the Department  
12 became aware, as you obviously were by this time, that  
13 a haemophiliac had died and, no doubt -- from this  
14 minute there doesn't appear to be any doubt in your  
15 mind that the cause is AIDS as a result of treatment  
16 with concentrates?

17 **A.** My understanding about this unfortunate man was that  
18 he had died in August. CDSC had not been informed  
19 and, therefore -- I'm not sure what the date of this  
20 thing is.

21 **Q.** 20 September.

22 **A.** Right. So, by September, CDSC had heard about it.  
23 I then reported it or mentioned it at -- I've  
24 forgotten whether it was HCDO meeting or a transfusion  
25 director meeting, but certainly it was discussed and,

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1 implicate the American Factor VIII.

2 So I'm not sure that the situation then  
3 materially changed because what I was saying in the  
4 earlier correspondence was that if there is a case  
5 that has only received BPL Factor VIII, then that  
6 would probably change the whole complexion of things.

7 **Q.** I understand that this might have -- why this raised  
8 questions for the adequacy of the surveillance because  
9 it wasn't known by CDSC?

10 **A.** Yes.

11 **Q.** Just as a matter of fact -- you've answered the  
12 question why but just to get it on the record as a  
13 matter of fact -- this information about what was now  
14 obviously a second confirmed case --

15 **A.** Yes.

16 **Q.** -- whereas previously it had been identified as  
17 a possible case, that didn't lead to any particular  
18 meeting, discussion, consideration of any new or  
19 different policy, did it?

20 **A.** No.

21 **SIR BRIAN LANGSTAFF:** May I just ask in the same vein, the  
22 Inquiry not long ago was examining the Treloar's  
23 School and one of the pieces of information which  
24 I picked up was that on 29 June Dr Hill at the  
25 Birmingham Children's Hospital was told that one of

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1 of course, then you are probably going to come on,  
2 this afternoon, to various reports in the press, but  
3 what this case was was a patient hitherto unknown to  
4 us at all, as actually potentially ill with AIDS, not  
5 having been notified, came to CDSC's attention in  
6 September and was immediately reported to -- I think  
7 it was the HCDO meeting -- I think it was.

8 So the fact of the death, unfortunate though it  
9 was, was not the newsworthy -- if I can put it that  
10 way, without giving any possible offence -- it was  
11 not -- that was not the issue. The issue was there  
12 was a patient with AIDS that we hadn't known about who  
13 had obviously been ill for quite some time. The  
14 actual fact that he had unfortunately succumbed to his  
15 illness didn't change the issue. It was the fact that  
16 there was a case of a haemophiliac and, as we can see,  
17 alas, a mild haemophiliac who had actually developed  
18 AIDS. There was the important issue and then the  
19 question, I think -- the question you're posing to me  
20 is, well, I had said previously if there is a single  
21 case of a patient but it was, in fact, who had  
22 received NHS concentrate that was the concern that I'd  
23 expressed in that earlier meeting. Here we see that  
24 he had received both Profilate and Kryobulin and he's  
25 also had some BPL Factor VIII but, clearly, we would

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1 his patients who was at Treloar's was exhibiting the  
2 stigmata of AIDS.

3 **A.** Right.

4 **SIR BRIAN LANGSTAFF:** Did that information ever reach you?

5 **A.** No.

6 **SIR BRIAN LANGSTAFF:** Should it have done?

7 **A.** Well, it shouldn't necessarily have reached me, it  
8 should have reached CDSC and CDSC should have reported  
9 it to IMCD.

10 **SIR BRIAN LANGSTAFF:** So there may be a problem for us to  
11 look at as to the extent to which the surveillance was  
12 actually picking up cases that it should have picked  
13 up?

14 **A.** Absolutely.

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

16 **MS RICHARDS:** Sir, I've trespassed into everyone's lunch,  
17 I'm sorry, but now is obviously the right moment to  
18 take a break for lunch.

19 **SIR BRIAN LANGSTAFF:** Yes, it is. So we'll take a break  
20 until 2.15.

21 (1.10 pm)

(Luncheon Adjournment)

22 (2.15 pm)

23 **MS RICHARDS:** Dr Walford, I'm going to ask you to look  
24 next at CBLA0000060\_067. This is a document I think  
25

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1 you saw yesterday evening.  
 2 **A.** Yes.  
 3 **Q.** It's a letter to Professor Bloom from Alpha  
 4 Therapeutic, March 1983.  
 5 If we go over the page it's a press release  
 6 saying:  
 7 "Alpha Therapeutic acts to protect haemophiliacs  
 8 from AIDS epidemic."  
 9 Then it talks in the end of the first paragraph  
 10 about Alpha having taken steps to exclude from its  
 11 donor pool persons who may be at high risk of  
 12 transmitting the disease to others and, if we go down  
 13 towards the bottom of the page, we can see the  
 14 penultimate paragraph says:  
 15 "The evidence suggests, although it does not  
 16 absolutely prove, that a virus or other disease agent  
 17 was transmitted to them [that's referring to  
 18 established cases] in the Factor VIII concentrate,  
 19 derived from pooled human plasma which they rely on  
 20 for life - and for sustaining a relatively normal  
 21 lifestyle."  
 22 Then it goes on to talk about some of the steps  
 23 that were being taken.  
 24 Now, I'm not in fact going to ask you about the  
 25 content of it. It's really a question of process.

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1 "As promised I am writing to let you know what  
 2 has happened regarding AIDS at the Council of Europe  
 3 Meeting."  
 4 I don't need that paragraph, thanks, Soumik.  
 5 If we go further down -- thank you -- he says  
 6 there:  
 7 "There is going to be a resolution put to the  
 8 Ministers of the Council of Europe and while this has  
 9 not yet been finalised I can give you the gist ..."  
 10 and he then sets that out.  
 11 Then below numbers 1 to 5 he says this:  
 12 "You can see that what they're leading to is the  
 13 greater use of cryoprecipitate, and we saw two years  
 14 ago that this tends to be the standard product in many  
 15 European countries. Although I put forward the UK  
 16 view of this product the consensus was against us.  
 17 Like you, I do not think BPL could change to  
 18 freeze-dried cryo rapidly and the logistic problems  
 19 would be considerable."  
 20 So that's Dr Gunson alerting you in the middle  
 21 of May to these recommendations.  
 22 **A.** Yes.  
 23 **Q.** Now, if we then look at WITN4461129, please, we can  
 24 see that on 1 June 1985 a number of people within the  
 25 Department, including you -- your name has been

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1 Would you have seen a document like this at the  
 2 time?  
 3 **A.** No.  
 4 **Q.** In Medicines Division, and I know you obviously were  
 5 no longer in the Medicines Division in 1983, but from  
 6 your experience there previously, would this kind of  
 7 material, press releases with important announcements,  
 8 normally come across the desk of the Medicines  
 9 Division?  
 10 **A.** I should think so. I can't be certain but I would  
 11 have thought. So it's appropriate.  
 12 **Q.** We can take that down, thank you.  
 13 I want to move now to ask you --  
 14 **SIR BRIAN LANGSTAFF:** Did Dr Bloom ever mention to you  
 15 that he had received a press release from Alpha which  
 16 said that it thought that AIDS was highly likely to be  
 17 caused by a virus?  
 18 **A.** No recollection of hearing that from him.  
 19 **MS RICHARDS:** I'm going to ask you next a series of  
 20 questions about the Council of Europe recommendations.  
 21 Again, if we can just set the scene with some of the  
 22 contemporaneous documents.  
 23 DHSC0000716.  
 24 This is a letter from Dr Gunson to you,  
 25 16 May 1983, and he says:

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1 handwritten on at the top in addition to the other  
 2 recipients -- were sent the draft recommendation to  
 3 the Council of Europe's -- sorry, the draft  
 4 recommendation that was going to be submitted to the  
 5 Council of Europe's Health Committee, and then the  
 6 second paragraph says:  
 7 "Foreign and Commonwealth Office have asked for  
 8 briefing on the text indicating its acceptability to  
 9 the UK and any amendments we propose, together with  
 10 supporting arguments. Dr H Gunson, our representative  
 11 on the expert committee, has already accepted the main  
 12 principles of the draft recommendation."  
 13 So you and others were being asked to comment?  
 14 **A.** Yes.  
 15 **Q.** Then if we can see your comments they are at  
 16 DHSC0001659?  
 17 **SIR BRIAN LANGSTAFF:** Just one question. You say that's  
 18 1 June. Can we look at the date at the bottom. It  
 19 may be the 7th.  
 20 **MS RICHARDS:** It may be the 7th, you're right.  
 21 **SIR BRIAN LANGSTAFF:** Particularly when it talks about  
 22 next Monday or Monday morning in the text, I suggest  
 23 it probably is the 7th.  
 24 **MS RICHARDS:** Yes, I think that probably does fit with  
 25 what we know about timing. We can double check that.

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1 **SIR BRIAN LANGSTAFF:** Thank you.  
 2 **MS RICHARDS:** Then if we go to DHSC0001659, this is your  
 3 response, Dr Walford, of 13 June 1983. You say you  
 4 have asked for comments:  
 5 "Our main difficulty is with the first paragraph  
 6 of recommendation I. Whilst we would agree that it is  
 7 theoretically desirable to avoid the use of large-pool  
 8 coagulation products wherever it is medically  
 9 appropriate to do so, this is only feasible if  
 10 a satisfactory alternative product is available."  
 11 You then set out a breakdown of the material  
 12 used for treatment, and we see the proportions there  
 13 set out. Then you say:  
 14 "From these figures it can be seen that there is  
 15 no option but to treat the majority of our  
 16 haemophiliacs with large-pool products and thus it  
 17 could be argued that the use of such products is  
 18 specifically indicated for medical reasons since the  
 19 risks of non-treatment are greater than the risks of  
 20 treatment. However, this is a rather dubious  
 21 'let-out' and I think we should prefer to see the  
 22 recommendation re-worded ..."  
 23 Then you give your suggested rewording, which  
 24 is:  
 25 "To avoid, wherever possible ..."

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1 not going to ask you to reread all the preliminaries  
 2 on that page.  
 3 If we go to the third page, if we look at 1 and  
 4 the first insert, so 1 says:  
 5 "To take all necessary steps and measures in  
 6 respect to AIDS and, in particular ..."  
 7 Then this was the draft that you were commenting  
 8 on?  
 9 **A.** Mm-hm.  
 10 **Q.** "To avoid the use of coagulation factor products  
 11 prepared from large plasma pools except when such  
 12 a product is specifically indicated for medical  
 13 reasons ..."  
 14 Now, as I understand the minute that we just  
 15 looked at, you were recommending the insertion of the  
 16 phrase -- either "wherever possible" or "wherever  
 17 practical"?  
 18 **A.** Yes.  
 19 **Q.** And to put that and then take out the words "except  
 20 when such a product is specifically indicated for  
 21 medical reasons"?  
 22 **A.** Well, that was almost tautologous, wasn't it? Because  
 23 basically you avoided it wherever possible or  
 24 practical but if you had to use it it would be for  
 25 medical reasons. No other reason for using it.

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1 Or wherever practicable, you give that an  
 2 alternative I think:  
 3 "... the use of coagulation factor products  
 4 prepared from large plasma pools: this is especially  
 5 important for those countries where self-sufficiency  
 6 in the production of such products has not been  
 7 achieved."  
 8 So I think it's probably going to be slightly  
 9 easier for people to then follow if we look at what  
 10 the text was of the draft and then we can see how it  
 11 changed.  
 12 **A.** Yes.  
 13 **Q.** If we look at DHSC0105313.  
 14 If we look at the date -- so this, I think,  
 15 makes sense of it being the 7th rather than the 1st,  
 16 sir -- we've got 3 June 1983 there, towards the top.  
 17 We can see that you are -- a list of handwritten  
 18 recipients "Copies to" and then the fifth name down is  
 19 "Dr Walford" and then someone's handwritten on:  
 20 "Do you have any comments that you would like me  
 21 to pass on to the UK delegation in Strasbourg,  
 22 please?"  
 23 Then bottom of the page says:  
 24 "The text is as follows ..."  
 25 Top of the next page, draft recommendation. I'm

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1 **Q.** Yes and I understand the logic in relation to that  
 2 last bit. Perhaps the more significant amendment is  
 3 the suggested insertion of the "wherever possible" or  
 4 "wherever practical"?  
 5 **A.** There's an exception made. I mean, it seems to me  
 6 it's saying, broadly speaking, the same thing,  
 7 although what I think it's saying there is not  
 8 terribly sensible, because why on earth would you give  
 9 anybody a large-pool product or, indeed, almost any  
 10 product unless it was indicated for medical reasons?  
 11 So, in a sense -- so obviously avoid except when it's  
 12 "specifically indicated". Well, I think --  
 13 I suggest -- that my suggested amendment, which was,  
 14 "Well, look, try your best to avoid large-pool  
 15 products, but it may not absolutely be possible always  
 16 to avoid" -- and I don't -- and of course they would  
 17 only be taken for medical reasons.  
 18 So I'm not sure I understand the significance  
 19 that you appear to be putting on the change that I was  
 20 suggesting.  
 21 **Q.** The suggested significance -- if we leave aside  
 22 completely the phrase "except when such a product is  
 23 specifically indicated", so forget that. That did  
 24 come out but let's leave that aside.  
 25 **A.** Mm-hm.

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1 Q. You suggested the insertion -- and, as we see when we  
2 look at the final text, this was adopted --  
3 A. Which I didn't know incidentally --  
4 Q. You suggested insertion of the phrase --  
5 A. I didn't know I had such influence.  
6 Q. -- "wherever possible", and the reason you were  
7 suggesting that, as I understand your minute, was not  
8 because of concerns about products being used when  
9 there wasn't a medical indication to do so -- as you  
10 said, in a sense, it's obvious it should only be used  
11 in those circumstances -- it was because the UK would  
12 find it difficult to comply otherwise because you were  
13 reliant on large-pool concentrates?  
14 A. Are you suggesting that that's what I was thinking?  
15 Q. Yes.  
16 A. I don't think that that's the case. Well, I don't  
17 know that that would have been the -- what I was  
18 thinking. I was thinking that we would avoid if we  
19 could but obviously you couldn't avoid in our  
20 circumstance and it seemed to me we were being asked  
21 how does this fit with the UK situation. The UK  
22 situation was that 80 per cent of the product we were  
23 using was large-pool. From the UK's point of view,  
24 totally accept that the avoidance of large-pool a very  
25 good idea, but you do that wherever practicable.

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1 material was as a matter of fact used in the  
2 United Kingdom, and then underneath that you said:  
3 "From these figures it can be seen that there is  
4 no option but to treat the majority ... with  
5 large-pool products ..."  
6 Because that's what you had?  
7 A. Yes.  
8 Q. It's the supply issue again.  
9 A. Yes.  
10 Q. Then you refer to that wording of the exception, and  
11 you say, well, "it could be argued that the use of  
12 such products is specifically indicated for medical  
13 reasons", and that's what you describe as a "dubious  
14 'let-out'", and you suggest then the insertion of  
15 either "wherever possible" or "wherever practicable",  
16 and that's why I'd -- I'd read this as you suggesting  
17 that because the supply situation meant that the UK  
18 had no choice but to treat with large pool  
19 concentrates.  
20 A. My understanding was that the UK was -- the UK was  
21 being asked, comment on this, how would this  
22 recommendation affect your situation, as they were  
23 asking other countries, of course, not just the UK.  
24 We were asked to comment from the point of view of the  
25 situation in the UK. One could have said well let's

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1 So -- and because, in fact, the "except when  
2 such a product is specifically indicated for medical  
3 reasons", I don't think you can dissociate the two  
4 phrases because clearly we were using -- the country  
5 was using large-pool products specifically indicated  
6 for medical reasons.  
7 Obviously, that wouldn't necessarily have been  
8 the case for a mild haemophiliac. Clearly we know  
9 that that was not the appropriate way of treating  
10 patients with mild haemophilia, but the generality of  
11 the use of the concentrates was obviously for patients  
12 with severe bleeding disorders, and I don't really  
13 see -- I think it's a kind of a semantic proposition,  
14 that you're possibly putting more emphasis on than  
15 I necessarily intended. I said something in my  
16 previous minute about something being a "dubious  
17 'let-out'".  
18 Q. Yes.  
19 A. It might be better to look at that because I can't  
20 remember what it was I --  
21 Q. Yes, of course. DHSC0001659 again.  
22 A. Oh, I know now.  
23 Q. My reading of this, Dr Walford, and if you say it's  
24 wrong, then please say so, but my reading of this was  
25 you were saying -- you've given the figures as to what

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1 accept that one because you've got this exception, if  
2 it's indicated for medical reasons, you can go on  
3 using it. I thought that that was bit tendentious,  
4 that was a dubious let-out. So to be more precise,  
5 from a UK point of view, and I didn't know that  
6 actually this resolution that had been adopted,  
7 actually, at the end of the day, it would be more  
8 honest, if I can put it that way, to just say wherever  
9 you can avoid, but not to rely on the let-out that  
10 naturally it's being used for medical reasons.

11 So I suspect I was trying to use -- I was trying  
12 to not to rely on what I thought was a rather stupid  
13 sub-clause and to try and say, well, for us, that is  
14 the practical situation.

15 **SIR BRIAN LANGSTAFF:** May I perhaps suggest that, being  
16 semantic, the problem might be the word "specifically"  
17 because, obviously, the use of products is indicated  
18 for medical reasons but the "specifically" might  
19 suggest that it is an exception, that there has to be  
20 an exceptional reason for a particular case, as  
21 opposed to a generality where as far as practicable,  
22 as far as possible, you try to avoid use of the  
23 product.

24 Might that have been what was in your mind?  
25 A. Well, I couldn't necessarily say but, as far as I was

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1 concerned, we had some 2,000 or so patients with  
 2 haemophilia, which was severe. I didn't see, given  
 3 the state of the supplies that we had, that we had any  
 4 alternative but to give some 2,000 or so patients, and  
 5 maybe more, I don't know the exact numbers, large-pool  
 6 products and, therefore -- I mean, whilst you could  
 7 see that if only exceptionally you had to give one or  
 8 two patients for medical reasons this material, then  
 9 the use of the word "specific" would be perhaps  
 10 helpful.

11 But this was across the board for the patients  
 12 who were coming to haemophilia centres. The vast  
 13 majority of those who attended haemophilia centres  
 14 attended because they were severe haemophiliacs.  
 15 Otherwise, they were not going to be constantly being  
 16 reviewed by the centres.

17 So there were large numbers of patients who  
 18 needed to have this material and my thoughts, rightly  
 19 or wrongly, at the time is this is a really silly form  
 20 of words that was being proposed and I thought that  
 21 I was being helpful in making it what I thought was  
 22 a more accurate form of words as to how the UK  
 23 responded to this particular recommendation.

24 **MS RICHARDS:** Before we look at the text of the final  
 25 recommendation, because there's then a separate issue

1 asked to comment.

2 **Q.** Then if we look at the final text, it's MACK0000307,  
 3 if we go to the second page, we can see it there set  
 4 out, that there's the heading, recommendation number  
 5 R(83)8 of the Committee of Ministers to Member States,  
 6 et cetera, et cetera.

7 If we just go down that page, I'm not going to  
 8 ask you anything about the detail here but there's  
 9 some basic principles set out and then, if we go over  
 10 the page, thank you. So we see there the  
 11 recommendations:

12 "Recommends the governments of member states:

13 "I. to take all necessary steps and measures  
 14 with respect to [AIDS] and in particular:

15 "-- to avoid wherever possible the use of  
 16 coagulation factor products prepared from large plasma  
 17 pools; this is especially important for those  
 18 countries where self-sufficiency in the production of  
 19 such products has not yet been achieved ..."

20 So the UK's suggested rewording is what was  
 21 adopted in the final recommendation, as you'll see.

22 But it's the next bit I want to ask you about. You  
 23 will see that the third recommendation is about blood  
 24 donors -- providing blood donors with information?

25 **A.** Yes.

1 I want to ask you about arising from that, can I just  
 2 ask you this: what was the general approach within the  
 3 Department, if you are able to speak to that, to  
 4 something like this, a Council of Europe  
 5 recommendation? Was it something that was seen as  
 6 important to comply with or was it seen as something  
 7 that was aspirational -- I'm talking generally here,  
 8 rather than necessarily this very one -- or, indeed,  
 9 was it just seen as something to pay lip service to?

10 **A.** No, I would think that would be -- that latter point  
 11 would be a misrepresentation of the Department. If  
 12 there was a Council of Europe series of  
 13 recommendations on something and they wouldn't be  
 14 recommending on something trivial, I would suggest  
 15 that the Department would do its best to take things  
 16 seriously.

17 But we need to bear in mind that there had been  
 18 a recommendation for self-sufficiency going way back,  
 19 albeit from the WHO to the early 1970s. People -- the  
 20 Department tried to comply. It would certainly not  
 21 seek to do other than comply but, clearly, our  
 22 country, just as other countries, were always given  
 23 the option to comment and, at the end of the day,  
 24 a recommendation might well be amended in the light of  
 25 the comments received from countries that had been

1 **Q.** That's the leaflet issue --

2 **A.** Yes.

3 **Q.** -- which I will briefly ask you about.

4 **A.** Yes.

5 **Q.** The second recommendation is, with that preface of  
 6 taking "all necessary steps and measures ... and in  
 7 particular":

8 "-- to inform attending physicians and selected  
 9 recipients, such as haemophiliacs, of the potential  
 10 health hazards of haemotherapy and the possibilities  
 11 of minimising these risks ..."

12 So it's a recommendation to tell two different  
 13 cohorts, clinicians, the treating clinicians and  
 14 patients, and to tell them about, as it were, two  
 15 things, potential health hazards and possibilities of  
 16 minimising these risks. That's what I want to ask you  
 17 about.

18 Did the Government take any steps to provide,  
 19 first of all, the treating clinicians the attending  
 20 physicians with information about hazards or the  
 21 possibilities of minimising the risks?

22 **A.** As far as I'm concerned, and I think a key word in  
 23 there is "selected recipients", we are -- in terms of  
 24 large-pool products, we are only talking about  
 25 patients with coagulation disorders and specifically

1 haemophilias A and B. So, essentially, it was well  
2 known in the UK that the UK Haemophilia Centre  
3 Directors, who were treating such patients, knew all  
4 about large-pool products and they knew all about, as  
5 much as anybody else did, about the risks of AIDS from  
6 there.

7 So they would be what I would describe as the  
8 attending physicians and the selected recipients, in  
9 my view, would be patients with haemophilia who needed  
10 to know.

11 **Q.** I don't dissent from that but the question is, did the  
12 government -- did the Department, to your knowledge  
13 take any actual steps itself -- and if you can deal  
14 with clinicians first of all and then patients  
15 separately -- any steps itself to inform clinicians  
16 about either of these matters, the potential health  
17 hazards in relation to AIDS, because that's what,  
18 we're talking about we're not talking about broader  
19 health hazards, or to inform clinicians about the  
20 possibilities of minimising those risks?

21 **A.** Well, as I've mentioned before, it was not the role of  
22 the Department to inform physicians or recipients  
23 about a specific risk or hazard. That was left to the  
24 relevant medical professionals. Dr Gunson, who was  
25 the consultant adviser in blood transfusion to the

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1 Directors -- or got a good sense of what the Reference  
2 Centre Directors knew because you'd attended that  
3 meeting, for example, in May 1983 but if we look at  
4 what was known by the much larger number of  
5 haemophilia directors and other clinicians because --

6 **A.** Yes.

7 **Q.** -- there were haemophilia clinicians who are not  
8 themselves members of what you have correctly pointed  
9 out was a directors' organisation.

10 **A.** Yes.

11 **Q.** They had met in September of 1982 at a point in time  
12 at which AIDS is mentioned in passing and Dr Craske is  
13 going to look into it. Obviously, there's then the  
14 correspondence from Dr Craske --

15 **A.** Yes.

16 **Q.** -- and I accept you're aware of that being sent out,  
17 and then they don't meet again as a directors'  
18 organisation until September or October 1983. So are  
19 you essentially relying upon the letters sent by  
20 Craske, Bloom, Rizza in March and June 1983?

21 **A.** Well, that would have been one source. I find it  
22 quite difficult to believe that although you talk  
23 about the Reference Centre Directors knowing, Craske  
24 had put out a report himself and he was doing the  
25 surveillance for the UKHCDO, not for the reference

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1 CMO, wrote to him to say that patients are being  
2 informed.

3 **Q.** I will look at that with you in a moment.

4 **A.** So why would there have been -- I mean, you're going  
5 to propose the reason to not --

6 **Q.** Am I right in understanding the answer to my question,  
7 did the Department do anything to inform clinicians of  
8 these matters --

9 **A.** No.

10 **Q.** -- the answer's no?

11 **A.** That's right.

12 **Q.** The reason is, I think is what you are saying, if  
13 I paraphrase, because you expected they would already  
14 know it?

15 **A.** Well, expected they would be told by their treating  
16 clinicians.

17 **Q.** Sorry, I'm just talking -- I'm not making myself clear  
18 enough, it's my fault, Dr Walford. Leave aside what  
19 patients are told for the moment, completely. I'm  
20 going to deal --

21 **A.** Oh, the consultants? Well, we knew the Haemophilia  
22 Centre Directors knew very well what was going on.  
23 They were telling us very often, so we knew.

24 **Q.** Forgive me, how did you know? You knew -- you  
25 yourself may well have known what the Reference Centre

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1 centres specifically, so they had a mechanism. The  
2 mechanism was the surveillance by Craske and the  
3 reports -- or the reports that he made and also the  
4 fact that it's inconceivable to me that people  
5 treating patients with haemophilia would not have been  
6 aware by that stage that AIDS was an issue and was  
7 an issue for haemophiliacs.

8 Therefore, I would have expected that they would  
9 have all been aware, not specifically of this  
10 directive, for sure, but of the concern that there was  
11 about potential transmission of AIDS and also would,  
12 when relevant, speak to their patients about it.

13 **Q.** But the second limb of the category of information  
14 which it's said the Government should pass on is about  
15 possibilities of minimising risks.

16 **A.** Yes.

17 **Q.** Now, other than the letter of 24 June 1983 which --  
18 the weak recommendations which I won't put up on  
19 screen again, is there any other evidence that the  
20 Department or that you at the Department were aware of  
21 which would show that clinicians -- haemophilia  
22 clinicians as a cohort had information about different  
23 ways of minimising risks?

24 **A.** I think to answer that question I might have to say,  
25 well, in September, when the HCDO met again, if it was

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1 in September, you would need to remind me what was  
2 said then, but this is June, I think.

3 **Q.** Yes.

4 **A.** Right. So in September there was probably further  
5 discussion at that HCDO meeting. I cannot believe  
6 that there wasn't, actually.

7 **Q.** It was an October 1983 meeting and I don't think you  
8 were present at that one, as a matter of fact. We  
9 have looked at it on a number of occasions.  
10 Dr Chisholm says let's revert to cryoprecipitate and  
11 Professor Bloom says no, let's not.

12 **A.** Yes, so they are all talking about it they are, they  
13 are definitely all talking about it.

14 **Q.** Let's -- sorry, just before I turn to the question of  
15 information to patients, did the Department ever take  
16 any steps to contact relevant professional bodies,  
17 medical Royal Colleges or anything like that to see  
18 what information was being provided by then?

19 **A.** I'm not aware that we did.

20 **Q.** Can I then turn to the question of the provision of  
21 information to patients, and I absolutely accept your  
22 premise that we're talking about patients with  
23 haemophilia --

24 **A.** Yes.

25 **Q.** -- for the purposes of what's set out here.

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1 basically I don't think we put out specific  
2 information either to Haemophilia Centre Directors or  
3 to patients.

4 **Q.** You have referred, I think, on more than one occasion  
5 to what Dr Gunson had said, and so I think, in  
6 fairness, we should look at that, which is at  
7 CBLA0001710. So this is Dr Gunson's report of 13 June  
8 to the Central Blood Laboratories Authority and it's  
9 a report on the discussions that had been taking place  
10 in the Council of Europe. If we go to the second  
11 page, he says three lines down:

12 "I think that it is important to comment on  
13 these recommendations since although these  
14 recommendations can be supported in principle, there  
15 are certain problems in implementation."

16 Then he deals with the first one, and I've  
17 canvassed that with you already, Dr Walford. Then he  
18 says, in relation to the second one, he says this, and  
19 I think this is what you had in mind in your earlier  
20 evidence:

21 "Physicians and patients, especially  
22 haemophiliacs, are being informed of the risks of  
23 AIDS."

24 Then he goes to talk about the leaflet for  
25 donors.

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1 Obviously, there may be a wider question about the  
2 provision of information to patients receiving  
3 transfusions.

4 **A.** Yes.

5 **Q.** I think it's right to understand from everything that  
6 you've said, and from all the material we've looked at  
7 and from the discussion in your statement, that the  
8 Department did not itself take any steps either to  
9 provide information to haemophilia patients or to  
10 ascertain itself what haemophilia clinicians were, in  
11 general, telling their patients?

12 **A.** I think that's probably right. I don't have --  
13 I can't provide evidence in one direction or the  
14 other. I have no knowledge of -- if you are perhaps  
15 proposing that, maybe, a CMO letter should have gone  
16 out, if that's the proposition, well, obviously I can  
17 talk to why CMO letters didn't tend to go out on this  
18 sort of matter but -- and, in fact, the very first CMO  
19 letter that did go out about AIDS went out in 1985 --  
20 **Q.** Yes.  
21 **A.** -- so not around about this time. That was in many  
22 respects for a different reason and under a different  
23 CMO.

24 But, as far as I'm aware, and there may be  
25 others in the Department who could help on this,

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1 **A.** Yes.

2 **Q.** So it's a single sentence, which asserts:  
3 "Physicians and patients, especially  
4 haemophiliacs, are being informed of the risks of  
5 AIDS."

6 **A.** Yes.

7 **Q.** How would Dr Gunson know, he's not a haemophilia  
8 clinician, he's not a member of UKHCDO, I think he may  
9 well be able to know what Regional Transfusion  
10 Directors are doing, how would he know what the  
11 practice was amongst haemophilia clinicians in  
12 relation to providing information to their patients  
13 about the risks of AIDS?

14 **A.** And the date of this --

15 **Q.** June 1983.

16 **A.** The reason I asked for the date is that, of course, he  
17 was working together with quite a number of  
18 Haemophilia Centre Directors and others on the plasma  
19 supplies. He had a working party, so he was certainly  
20 in contact directly with some Haemophilia Centre  
21 Directors, whether or not -- and that he reported.  
22 I think in about June 1981 his report came out. So  
23 it's roughly of the same order.

24 So he was in contact. It's of great sadness to  
25 me actually that Dr Gunson, who was a marvellous man,

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1 and I never knew him to say anything that he didn't  
2 believe to be true, isn't here, because of course  
3 unfortunately he died, but basically he would not have  
4 said that if he didn't know. I don't know how he knew  
5 but he would not have said it if he didn't know.

6 **Q.** The evidence that the Inquiry has received  
7 overwhelmingly from individuals and, it has to be  
8 said, largely, I think, corroborated by those  
9 clinicians from whom the Inquiry has been able to  
10 obtain evidence, would indicate that patients were not  
11 given that information.

12 **A.** Well, the only thing I can say is that, as I said  
13 before, Dr Gunson will have been of the view, and  
14 under the firm view, that actually patients were being  
15 informed, but he might have thought about it in some  
16 sort of general way as opposed to was every  
17 haemophilia clinician making sure they called up their  
18 patients and talked to them. That may be  
19 a difference. He was talking about the generality,  
20 I would suggest, not the experience that sadly seems  
21 to have occurred with a number of patients we've heard  
22 during the Inquiry.

23 **Q.** Was it the Department's -- again, I'm now using that  
24 in a very loose term, and you're an individual not  
25 a representative of the entire Department, but you

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1 adviser, decided to take steps to make sure that  
2 patients were being informed.

3 It would not have fallen necessarily to me or to  
4 anybody in Med IMCD to make that proposal.

5 **Q.** Do you recall if you ever asked Professor Bloom --  
6 because there'd have come a point in time when you  
7 were conscious of an issue because of the Council of  
8 Europe recommendation. Did you ever, do you think,  
9 ask Professor Bloom, "Are patients being given this  
10 information?"

11 **A.** I didn't have that degree of close contact with  
12 Professor Bloom. You've seen pretty well all the  
13 correspondence that I'm aware of and telephone calls,  
14 so I was not in frequent discussion with  
15 Professor Bloom at all.

16 **Q.** Looking back now, do you think it was a failure on the  
17 part of the Department -- and I use that term  
18 deliberately now, I'm not talking about you  
19 individually, because there were a whole range of  
20 civil servants and doctors with differing  
21 responsibilities -- a failure on the part of the  
22 Department not to take some steps in accordance with  
23 the council of Europe recommendation to ensure that  
24 patients had the requisite information to enable them  
25 to make an informed decision about balance of risks?

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1 have said in your statement that the prevailing  
2 culture at the time was, it wasn't the Department's  
3 job to become involved in what was seen as a matter,  
4 again, of clinical freedom, it was for the clinician  
5 to decide what information to give to his or her  
6 patient?

7 **A.** Yes.

8 **Q.** Again I don't know whether you can answer this or not.  
9 Was the assumption that was made by you, your  
10 colleagues, that clinicians would be telling their  
11 patients about risks and possible ways of minimising  
12 those risks because that was the right, ethical thing  
13 to do, or was it something that you just didn't think  
14 about because the Department's culture was "We don't  
15 get involved in this, it's a matter for clinical  
16 freedom"?

17 **A.** From this remove, I have no idea what I was -- may  
18 have or may not be thinking about that. Certainly  
19 I would have known that this was a matter for the  
20 field authorities, if I can put it that way, to deal  
21 with and not the Department of Health, and it may have  
22 been -- in many respects, if there was going to be  
23 some sort of broadcast information to doctors, this  
24 would have been a matter for the Chief Medical Officer  
25 who would have, in discussion with his consultant

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1 **A.** It would only have been a failure if it had been the  
2 normal process, the normal procedure, for the  
3 Department to intervene in this sort of way, with --  
4 after all, there was a plethora of conditions, in each  
5 case, important findings, important developments  
6 taking place. The Department could not -- and did  
7 not -- provide relevant information to clinicians  
8 about clinical matters of that kind. It was simply  
9 not set up to do and it did not do it.

10 So if you're asking me was that a failure, we  
11 should have done it because that's what we normally  
12 did, the answer is it wasn't a failure because it's  
13 not what we normally did.

14 **Q.** But the plethora of conditions probably didn't have  
15 a specific Council of Europe recommendation which the  
16 Department had signed up to or that the Government had  
17 signed up to, with the Department's knowledge, which  
18 included a recommendation that the Government take all  
19 practical steps to inform patients both of the risks  
20 and of the possibilities of minimising that risk.  
21 Doesn't that set it out from what might have been the  
22 normal approach of the Department?

23 **A.** Well, I appreciate that -- I mean, I appreciate the  
24 point you're making but if that were the case it would  
25 not have been -- have fallen to me, and I don't know

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1 to whom it would have fallen, to actually make sure  
2 that this particular Council of Europe recommendation  
3 was promulgated. This was way above the sort of level  
4 that I was operating at.

5 If this is a governmental issue, then that  
6 matter fell to be considered at the top of the Office  
7 and with the Chief Medical Officer.

8 **Q.** So the question of meeting that recommendation  
9 ultimately would have fallen, you think, on the  
10 shoulders of the Chief Medical Officer? If anyone was  
11 going to do it, it would be the Chief Medical Officer?

12 **A.** But I'm not clear whether or not this went anywhere  
13 near ministers, because it seems to me that this --

14 **Q.** It did.

15 **A.** It did?

16 **Q.** Yes.

17 **A.** Okay, but I didn't know that.

18 **Q.** No, no. We'll see that tomorrow with Lord --

19 **A.** So what I'm trying to say is that I didn't know what  
20 had happened to it. It was something I was asked to  
21 comment on. I commented. We've seen what the outcome  
22 of that was. Therein ended my role. And if it did go  
23 to ministers, then there was presumably a conversation  
24 between ministers and deputy or permanent secretaries,  
25 and the CMO even, and that's where the decisions would

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1 I think, indeed, to Mr Patten as well.

2 If we go a further two pages on -- I'm not going  
3 to go through the detail of it but I'm showing you  
4 this really because the "no conclusive proof"  
5 formulation doesn't appear in this background paper  
6 that's being, it would seem, supplied to  
7 Lord Glenarthur in June of 1983. So that's, as it  
8 were, the starting point.

9 Now, if we then go to DHSC0002229\_085, we can  
10 see this is an answer given by Lord Glenarthur in the  
11 House of Lords on 14 July 1985, and if we go --

12 **SIR BRIAN LANGSTAFF:** '83.

13 **MS RICHARDS:** '83, I'm so sorry.

14 If we go a tiny bit further down the page and we  
15 look at the left-hand side, we can see it says:

16 "The Parliamentary Under-Secretary of State ...  
17 (Lord Glenarthur) ..."

18 Then it's -- the second paragraph starts with  
19 "The Medical Research Council", and then the last  
20 sentence of that paragraph:

21 "Although there is no conclusive evidence that  
22 AIDS is transmitted by blood or blood products, the  
23 department is considering the publication of  
24 a leaflet ...", et cetera.

25 Now, I will be asking Lord Glenarthur more about

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1 have been taken or not.

2 **Q.** Let me make it clear, I asked the question of you not  
3 because I was seeking to suggest it was your personal  
4 responsibility to implement the Council of Europe  
5 recommendation, it was asking for your reflection on  
6 a very -- as a very experienced clinician and civil  
7 servant on what the Department should or shouldn't  
8 have done.

9 **A.** Understood.

10 **Q.** Penultimate topic on AIDS and then one further matter  
11 I want to ask you about.

12 The line to take of "no conclusive proof".

13 **A.** Yes.

14 **Q.** We looked at the origins of it or what may have been  
15 the origins of in the early May 1983 yesterday with  
16 the suggested draft for the Prime Minister which  
17 wasn't in the end utilised. So can I then pick up  
18 your own involvement at DHSC0002309\_123.

19 So we can see here reference to a paper prepared  
20 by you giving some information on AIDS that's going to  
21 be provided to Lord Glenarthur, and then the paper  
22 itself is at DHSC0002229\_054.

23 We can see there you are providing it to all  
24 Med SEB professional staff, 28 June. We think it's  
25 the same paper as was sent to Lord Glenarthur and

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1 this tomorrow but do you know, at this distance of  
2 time, if you were involved in the drafting of the  
3 suggested answer for Lord Glenarthur?

4 **A.** No, I wasn't involved in this, as far as I know, but  
5 it's -- subsequently Lord Glenarthur is asked by -- is  
6 it --

7 **Q.** Baroness Masham.

8 **A.** -- Baroness Masham about cryoprecipitate.

9 **Q.** That's when you become involved as far as you're  
10 aware?

11 **A.** Yes.

12 **Q.** So then let's go to that. You wrote some wording for  
13 Lord Glenarthur for a suggested response to  
14 Baroness Masham.

15 DHSC0001109.

16 It's dated 20 July 1983:

17 "Herewith some wording for the reply by  
18 Lord Glenarthur to Baroness Masham ..."

19 One of the issues was cryoprecipitate. So your  
20 first paragraph is about cryoprecipitate. Don't need  
21 to ask you about that.

22 Then the second paragraph says:

23 "There is no conclusive proof that AIDS can be  
24 transmitted by blood, cryoprecipitate or Factor VIII  
25 concentrates but the assumption is that such

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1 transmission may be possible."  
 2 So I will get to a question eventually but  
 3 I just want to go through the documents. You here  
 4 say -- you are using the "no conclusive proof"  
 5 formula -- I want to come back to you about that --  
 6 but you have added here a qualifying clause:  
 7 "... but the assumption is that such  
 8 transmission maybe possible."  
 9 That's your draft.  
 10 **A.** Yes.  
 11 **Q.** Can we then go to DHSC0002309\_032?  
 12 **SIR BRIAN LANGSTAFF:** I think it's also -- the use there  
 13 is not that AIDS is transmitted by blood but AIDS can  
 14 be. That's the formulation there.  
 15 **A.** Yes.  
 16 **SIR BRIAN LANGSTAFF:** If there's a difference it might be  
 17 material, but shall we --  
 18 **A.** Well --  
 19 **SIR BRIAN LANGSTAFF:** Just an observation but let me move  
 20 on.  
 21 **A.** Okay.  
 22 **MS RICHARDS:** So if we then go to DHSC0002309\_032, this is  
 23 a minute dated 26 July, it's copied to you, and if we  
 24 just go further down the page we can see the date and  
 25 the fact that it's copied to you.

1 **Q.** Then if we go to the final letter that's sent to  
 2 Baroness Masham, WITN4461147. This is  
 3 Lord Glenarthur's letter of 30 August 1983. If we go  
 4 to the third paragraph we can see the final draft is:  
 5 "There is, in fact, no conclusive proof that  
 6 AIDS can be transmitted by blood, cryoprecipitate or  
 7 Factor VIII concentrates."  
 8 So, again, a statement there without the  
 9 qualification of your original draft.  
 10 Do you have any concerns about the removal of  
 11 that qualification so that one has here the fairly  
 12 strong statement of no conclusive proof?  
 13 **A.** Well, I guess I would always have concerns if  
 14 I thought a piece that I had written had actually been  
 15 amended and I hadn't been aware that it was going to  
 16 be amended. So if something is attributed to me and  
 17 I didn't know or hadn't spotted, shall I say, because  
 18 if you say I saw it I might have done, but I suspect  
 19 I might not have reread something I was told I'd  
 20 already written, but one is always concerned. It must  
 21 be like a journalist writing for the newspaper when  
 22 the subeditor takes out a very crucial phrase. So it  
 23 looks like a crucial phrase, in my view, was taken  
 24 out. I don't know why or how. But clearly it would  
 25 concern me if something's been attributed to me which

1 Then its directed to Mr Joyce, who I think was  
 2 in Lord Glenarthur's private office probably, but we  
 3 can establish that with him tomorrow, and it says:  
 4 "I understand Miss Edwards is replying  
 5 separately ...", et cetera, et cetera.  
 6 So if we go over the page, we can see this is,  
 7 I think as we understand it, trying to as best we can  
 8 to put the bits and pieces of paper together, the  
 9 draft contribution to the reply emanating from  
 10 Mr Parker, emanating from HS1:  
 11 "I should emphasise that there is no conclusive  
 12 proof that AIDS can be transmitted by blood,  
 13 cryoprecipitate or Factor VIII concentrates."  
 14 So your qualifying clause has been omitted from  
 15 this draft.  
 16 **A.** Yes.  
 17 **Q.** Do you know why?  
 18 **A.** No, I don't think I was aware that it was.  
 19 **Q.** I mean, we think you might have been copied into this  
 20 but -- assuming it accompanied the minute on the  
 21 preceding page? Do you have any memory of whether you  
 22 spotted that the draft had been amended or attached  
 23 any significance?  
 24 **A.** I don't know whether I would have actually reread  
 25 something that I was supposed to have written, no.

1 is not strictly what I wrote.  
 2 **Q.** If we then move from August to DHSC0002235\_048. So if  
 3 we look at the article on the top of the page first of  
 4 all, "US blood caused Aids", the date we can see has  
 5 been handwritten on there, 1 November 1983, and this  
 6 refers to the Bristol case, as we have called this  
 7 individual.  
 8 **A.** Yes.  
 9 **Q.** "The British haemophilic who died from Aids almost  
 10 certainly caught the disease from contaminated  
 11 supplies of blood clotting agent Factor VIII, imported  
 12 from the US, doctors report today."  
 13 Then we see the third paragraph on the left-hand  
 14 side there, it records Dr Helena Daly, Dr Geoffrey  
 15 Scott, who were the treating clinicians at the Bristol  
 16 Haemophilia Centre saying:  
 17 ""It seems highly probable that the development  
 18 of Aids was related to this treatment. This case  
 19 provides further evidence for a link between blood  
 20 products and Aids' ..."  
 21 Then if we zoom back out, we'll see there's  
 22 a cross marked behind that paragraph, and then if we  
 23 go down to the bottom of the page, someone has  
 24 written:  
 25 "Dr Walford.

1 "Have you seen? On X -- is it OK for me to  
 2 continue to say 'there is no conclusive proof that the  
 3 disease has been transmitted by American blood  
 4 products'."  
 5 Can we just zoom out again. We've got a date  
 6 there at the bottom that looks like it might be  
 7 23 November:  
 8 "PS Congratulations on your promotion."  
 9 Then above that is what I understand to be your  
 10 handwriting.  
 11 **A.** That's right.  
 12 **Q.** "Mr Green  
 13 "Thanks. Yes it is OK."  
 14 **A.** Yes.  
 15 **Q.** So November 1983 you are endorsing the continuation of  
 16 this line "no conclusive proof". Why?  
 17 **A.** Because I was answering Mr Green's -- incidentally  
 18 I didn't really know who Mr Green was at that time and  
 19 I don't think I ever met him but he was in HS, I find.  
 20 I was answering the question: does this particular  
 21 report make any difference in terms of what we are  
 22 saying? That report, as I've now found out and have  
 23 found out since Lord Penrose asked me about it, that  
 24 report in The Observer -- or was it The Guardian?  
 25 **Q.** Guardian, I think.

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1 may well be the case.  
 2 This was a very shorthand bit of question and  
 3 answer. Somebody scribbling on a journal, on a hot  
 4 photocopy of a newspaper, pointing out to me, as it  
 5 were, what he thought to be a new development, but it  
 6 wasn't a new development and, therefore, I simply said  
 7 yes, you know, nothing has changed.  
 8 **Q.** So it's not a broader question that you are answering  
 9 then. The broader question: is this an okay line to  
 10 be --  
 11 **A.** I was answering does this change anything, because  
 12 there's a big cross, in other words have you seen on  
 13 X, cross, because the patient was reported as having  
 14 died, is it okay? As I mentioned before, the fact of  
 15 this case, the fact that there was a patient who had  
 16 been suffering from AIDS was the most important fact,  
 17 a UK patient. The fact that, as we know, so many  
 18 patients who actually did get AIDS actually died was  
 19 not -- was, of course, of monumental consequence to  
 20 the family of the individual but was not -- made no  
 21 difference to policy, if you like, because the policy  
 22 area, if we had been changing anything, should have  
 23 been when we realised that there was another --  
 24 a second case of AIDS.  
 25 So this is a truncated bit of exchange with

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1 **A.** That report in The Guardian, the same report had  
 2 occurred -- or the death of this unfortunate patient  
 3 had been reported a month earlier in October in The  
 4 Guardian. It was the same case that had been reported  
 5 in September to the various bodies that it was  
 6 reported to and, basically, there had been no  
 7 suggestion by anybody over that period of time that --  
 8 I mean, nothing new had occurred because of this  
 9 report in The Guardian, to which he was drawing my  
 10 attention in November, from September, when we knew  
 11 about this case. So it was not a revelation.  
 12 Unfortunately, Mr Green didn't know that and,  
 13 basically, shorthand, perhaps I should have explained  
 14 in more detail, it would clearly -- I dearly wish  
 15 I had explained in more detail, but actually this  
 16 report X doesn't change what it is that we had been  
 17 saying.  
 18 But my -- the caveat or rather the rider I would  
 19 put on that is that, pretty well, as far as I know,  
 20 every time I talked about no conclusive proof,  
 21 I always added a rider but it's either looking  
 22 increasingly likely or it appears that this may be  
 23 taking place. My -- my line, if I can put it that  
 24 way, since I didn't device the first line was always  
 25 to put a qualification that it's looking likely or it

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1 somebody whom I didn't know who seemed not to be up to  
 2 speed with what was going on.  
 3 **Q.** Just look further up at the article again. The X is  
 4 not by -- I may be reading far too much into this but  
 5 the X is not by the date, the X is by the fact that  
 6 two haemophilia clinicians are saying it seems highly  
 7 probable that the development of AIDS was related to  
 8 this treatment. Now, as a matter of semantics, highly  
 9 probable and conclusive are not the same thing;  
 10 I accept that.  
 11 **A.** Yes.  
 12 **Q.** But isn't that what you are being asked to reflect on?  
 13 **A.** Well, I don't know about that but I do know that  
 14 actually these clinicians or at least Dr Scott had not  
 15 reported this case which is why CDSC hadn't known  
 16 about it, because the clinician himself was not  
 17 convinced that it was a case of AIDS. So he's now  
 18 saying this to reporters and he may have said it the  
 19 week before, or the month before, but I didn't read  
 20 into that, into this exchange that we did, which is  
 21 obviously quite a hasty one, basically that there was  
 22 anything more than we now have another case, which  
 23 looks as if it's related to American Factor VIII, the  
 24 fact of the patient's death was not of the essence in  
 25 relation to the policy, it was the fact that there was

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1 another case.  
 2 That other case had been, as it were, factored  
 3 in to the knowledge in the wider world of haemophilia  
 4 that that case had occurred and that had been  
 5 factored in in September and not when The Guardian  
 6 chose to report it.

7 **Q.** Picking up on that, should then, in your view, the "no  
 8 conclusive proof" line have been abandoned at the  
 9 point at which the second case became apparent as  
 10 a case of AIDS?

11 **A.** I remain of the view, although I didn't compose that  
 12 line, I remain of the view that we did not have  
 13 conclusive proof, and you might say, well, what is  
 14 conclusive proof and I think I referred yesterday to  
 15 the fact that, if you had been able to determine  
 16 a virus in a particular donation and you had been able  
 17 to find that virus in the recipient, you've got to the  
 18 point which you have got conclusive proof.

19 As you saw from the American -- the discussion  
 20 in America, as you will see if you do look at the MRC  
 21 discussions, nobody was saying that this was  
 22 absolutely conclusive. People were constantly  
 23 wondering what was going on and, clearly, I felt, and  
 24 you can see from various other correspondence, that  
 25 I felt increasingly it was likely that this was

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1 then, recognising that you're not -- and I wasn't  
 2 seeking to suggest that you were the originator of the  
 3 line -- we don't currently know who was -- can you  
 4 help us in understanding why the Department took  
 5 a line which emphasised the absence of conclusive  
 6 proof rather than explaining what you have told us was  
 7 your own view, and was the mainstream view within the  
 8 Department, that there was a likely connect cause?

9 **A.** No, I can't particularly but, basically, if the line  
 10 had been appropriately qualified, I would have no  
 11 qualms about it at all. The fact that it wasn't  
 12 appropriately qualified on each occasion obviously is  
 13 very unfortunate because it might sound as if it's  
 14 much too definite, if you will, even though the words  
 15 don't say that, the words say "no conclusive proof",  
 16 they don't say "no proof at all", "no conclusive  
 17 proof", but if it were qualified with but it looks  
 18 likely and we are taking this, that and the other  
 19 step, whatever that might be, I would have said that  
 20 that's a perfectly correct and proper --  
 21 scientifically correct and proper way to put out  
 22 something publicly.

23 Now, I'm sure you'll be bringing me to look at  
 24 the leaflet ultimately, where you will see my almost  
 25 preferred way of expressing matters, in order to leave

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1 happening. But I had no conclusive proof and nobody  
 2 had any conclusive proof.

3 Whilst it may sound -- it may sound dismissive,  
 4 that's what it sounds, it wasn't intended to. It was  
 5 we don't know beyond a peradventure, we have no  
 6 iron-clad proof that this is what is happening.

7 **Q.** That could be said that that's effectively a trite  
 8 fact: until you can test, you have no conclusive  
 9 proof.

10 **A.** Yes.

11 **Q.** Indeed, I think the evidence that we will hear  
 12 tomorrow or Friday may suggest that this line was  
 13 abandoned after you've left but before there is what  
 14 you would have regarded as conclusive proof in the  
 15 form of an ability to test but, in any event, that's  
 16 after your time.

17 What was the point of this line? Why did the  
 18 Department want to emphasise the absence of conclusive  
 19 proof, which may be true in a narrow technical sense,  
 20 rather than the presence of a likely risk?

21 **A.** Well, as I've made very clear, this wasn't my line, it  
 22 was the Department's line, and the line was qualified  
 23 in most instances and should have been qualified in  
 24 all instances.

25 **Q.** Can I ask the question in a slightly different way

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1 no ambiguity.

2 **Q.** I'm actually going to take the leaflet very quickly  
 3 because I think your involvement was at that beginning  
 4 and you were then, as it were, copied in but not  
 5 central to the process and we're going to be looking  
 6 at it in some detail with both Lord Glenarthur and  
 7 Lord Clarke.

8 You, I think, have anticipated what I wanted to  
 9 ask you next. The leaflet poses a question about  
 10 transmission, and answers it with the words "almost  
 11 certainly, yes", and you've, I think, said in your  
 12 statement, well, donors needed something that was  
 13 clear and unambiguous.

14 **A.** Yes.

15 **Q.** Didn't the patients who were going to be exposed to  
 16 that risk or the public --

17 **A.** Yes.

18 **Q.** -- also deserve something clear and unambiguous, which  
 19 this was not?

20 **A.** The point I was trying to make about the blood  
 21 transfusion leaflet, and actually I went further with  
 22 Dr Gunson, went further than the science would lead  
 23 us, because you've talked about the leaflet that  
 24 ultimately was sent, but that was not the leaflet that  
 25 Dr Gunson and I prepared, because we were so concerned

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1 that donors would still continue to turn up, even  
 2 though they were active homosexuals, who had recently  
 3 had sex with other men -- I didn't expect too many  
 4 drug abusers to turn up, but I thought that there had  
 5 to be some way of really dissuading donors. It had to  
 6 be completely stark, black and white, no ambiguity.

7 So when Dr Gunson and I -- and he was of the  
 8 same mind with me -- prepared the first draft of the  
 9 leaflet, it didn't say "almost certainly, yes" it said  
 10 "yes, it can".

11 Now, that was going further than the science  
 12 really allowed and you might say, correctly -- it was  
 13 correctly reined back because it really was not  
 14 scientifically correct. We didn't know. But the  
 15 thought that you were preparing a leaflet for donors  
 16 which was in any way wishy-washy or ambiguous, so that  
 17 they could pick it up and think, well, you know,  
 18 I don't know, and we really wanted to make it  
 19 abundantly clear, potentially, if you give blood now,  
 20 you may infect -- your blood may transmit AIDS.

21 So there was a, sort of, almost horses for  
 22 courses and, in that case, I think we did go further  
 23 than the evidence really would let us go and, in  
 24 a sense, rightly, were hauled back by whoever drafted  
 25 the second version of the leaflet.

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1 configurations of this in various ministerial  
 2 statements -- I don't think that would necessarily be  
 3 misleading. The question is who was actually  
 4 receiving these messages? These messages were by and  
 5 large promulgated as part of PQs or in Parliament.

6 **Q.** They were in Parliament, they were press releases,  
 7 they were communications with other members of either  
 8 the House of Commons or the House of Lords who  
 9 presumably were raising things because they thought  
 10 they were matters of wider public interest or of  
 11 interest to individual constituents.

12 **A.** And you've just reminded me -- thank you -- of a very  
 13 pertinent fact, and that is that when the leaflet was  
 14 actually promulgated, which was the donor leaflet, not  
 15 for the wider public, it was accompanied by a press  
 16 release which the Department put out. Now, the  
 17 leaflet was agreed to be a UK leaflet, but both the  
 18 DHSS and SHHD agreed to put out their own press  
 19 releases. Our press release you have undoubtedly got.  
 20 SHHD chose to use the formulation "no conclusive  
 21 proof". They didn't have to. Nobody was insisting  
 22 that they did. They had their own CMO, their own  
 23 scientific advisers, but they chose to use that  
 24 formulation. They absolutely were free to do their  
 25 own press release and it differed in other respects,

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1 But you see where my thoughts lay; in other  
 2 words, I would have been -- wanted to have a greater  
 3 degree of qualifying all these messages than actually  
 4 turned out to be the messages that were actually  
 5 conveyed by ministers or by the Department in general.  
 6 But it wasn't my call.

7 **Q.** Can I just then explore before we leave this topic two  
 8 propositions in relation to the "no conclusive proof"  
 9 line for your comment or reflection. It had the  
 10 potential at least, did it not, to create a false  
 11 sense of security or to mislead? Those receiving it  
 12 might get the wrong message, in other words, because  
 13 they're not being told what was actually the  
 14 Department's view, which was that AIDS is probably  
 15 caused -- transmitted through blood and blood  
 16 products. Do you have any observations on that?

17 **A.** I think appropriately qualified, so that it's  
 18 perfectly obvious that we're -- nobody is disregarding  
 19 the possibility, "no conclusive proof", that is  
 20 correct. It's correct scientifically. You'd only get  
 21 conclusive proof at a time when you could actually  
 22 test and determine what had happened. But, "The  
 23 Department is doing X and Y, including producing  
 24 leaflets, including doing whatever it was we were  
 25 doing, if you like" -- and I saw various

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1 but they chose to use that formulation also.

2 **Q.** The second aspect I wanted to explore with you is  
 3 this: it might be said that the Department chose as  
 4 this line to take this formulation of "no conclusive  
 5 proof" rather than saying, in positive terms, "we  
 6 think it's likely", because that excused a failure on  
 7 the part of the Department to take more radical  
 8 action. Do you have any observations on that  
 9 suggestion?

10 **A.** It's a suggestion, Ms Richards, but I can't  
 11 necessarily say -- I've never heard it expressed in  
 12 that way and I would have no reason to believe that  
 13 that's what they were doing it for.

14 **Q.** Can I then take the question of the AIDS leaflet, and  
 15 I'm going to take it, for present purposes, I think  
 16 fairly quickly --

17 **A.** Yes.

18 **Q.** -- because we've dealt with it in detail in your  
 19 statement and because we're going to hear a lot about  
 20 it over the coming days with other witnesses. So  
 21 I just want to establish really without, I think,  
 22 having to go to too many of the documents, or  
 23 necessarily any of the documents, what it was -- what  
 24 your involvement was.

You attended a meeting of Regional Transfusion

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1 Directors at which this issue was raised --  
 2 **A.** Yes.  
 3 **Q.** -- and I understand it's a meeting of which you've  
 4 got, in contrast to some others, a distinct  
 5 recollection --  
 6 **A.** Yes, unfortunately I have.  
 7 **Q.** -- because there was a degree of adverse or hostile  
 8 reception. Can you just elaborate upon that?  
 9 **A.** Yes. Although we saw the other day that my presence  
 10 in the Haemophilia Reference Centre Directors' meeting  
 11 was not particularly welcomed, I wasn't aware of that,  
 12 I wasn't made to feel terribly unwelcome. When  
 13 I invited myself or asked to go to the Regional  
 14 Transfusion Directors' meeting, because I wanted to  
 15 persuade -- together with Dr Gunson, to persuade them  
 16 that there had to be a leaflet for donors,  
 17 because already knew that there was reluctance to do  
 18 that, I do remember, because it was not comfortable,  
 19 that the chair of the meeting at that time said words  
 20 to this effect, and they might have even been a bit  
 21 stronger, "Since Dr Walford has wished herself on us,  
 22 I suppose we had better hear what she has to say."  
 23 Now this is not a particularly helpful  
 24 introduction to whatever it is you're going to say,  
 25 and what I had to say was deeply unwelcome to the

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1 purpose. It was what I, as it were, was talking about  
 2 earlier, it was ambiguous. You really weren't sure  
 3 what they were trying to say to donors.  
 4 And so I spoke to Harold Gunson and said, "This  
 5 is just not strong enough", and he absolutely agreed,  
 6 and he agreed that he, and I think probably with his  
 7 colleague from Edgware Blood Transfusion -- I get that  
 8 impression from papers I've subsequently seen, I don't  
 9 know if I knew then -- redrafted, and then what you  
 10 had then was the redraft that had been redone by  
 11 Harold Gunson.  
 12 **Q.** It was sent, I think -- circulated round the  
 13 Department. You sent it to Mr Winstanley?  
 14 **A.** Yes.  
 15 **Q.** And then it would appear that the Department's own  
 16 information division got involved --  
 17 **A.** Yes.  
 18 **Q.** -- and there's toing and froing about the wording --  
 19 **A.** Yes.  
 20 **Q.** -- which I'm not going to ask you about, but if we  
 21 just go to a memo from Mr Winstanley, there's just one  
 22 point I wanted to ask you about.  
 23 It's DHSC0002321\_018.  
 24 So it's Mr Winstanley, its dated 8 June 1983.  
 25 It's to a Mr Windsor in the ID, information

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1 transfusion directors because I was there to say we in  
 2 the Department believed that there should be a leaflet  
 3 for donors and it should say in no uncertain terms  
 4 that people who might be at additional risk for AIDS,  
 5 or in what was called higher risk groups, particularly  
 6 male homosexuals, should not donate blood and should  
 7 be excluded from donation.  
 8 As I anticipated, that went down very badly. It  
 9 is fortunate that Dr Gunson had actually written in to  
 10 the meeting beforehand to make some suggestions about  
 11 the potential of what material should go in the  
 12 leaflet, and it may be that you are going to show us  
 13 anything from that meeting, but basically he offered  
 14 four options, I think, and two of them were turned  
 15 down out of hand, and then another two I don't recall  
 16 what they were precisely.  
 17 But with great reluctance they agreed to  
 18 a leaflet and they said they would prepare one and  
 19 that it would then come to the Department, and I think  
 20 I probably stressed that it needed to come quite fast  
 21 and the Department would pay for the printing if that  
 22 was helpful. When I did eventually get the leaflet,  
 23 the draft that they produced, it was some time --  
 24 I remember feeling very impatient and why hadn't it  
 25 turned up -- it was really not adequate for the

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1 department. He says in paragraph 2:  
 2 "... there are some things that are either  
 3 incorrect or misleading."  
 4 Because the information department had made  
 5 various revisions.  
 6 I'm not going to ask you to go through those  
 7 now, we've got the document.  
 8 If we go over the page, if we look at the last  
 9 paragraph, paragraph 5, he then says:  
 10 "To sum up then, I think we can accept your text  
 11 subject to the comments above, but it is essential to  
 12 act without delay. As it is, the time for printing  
 13 and distribution seems painfully slow."  
 14 Then there's an issue about printing and  
 15 payment. So it would appear Mr Winstanley's already  
 16 concerned it's taking too long?  
 17 **A.** Yes, it was.  
 18 **Q.** Because, of course, as every day or week went by  
 19 a donor, a high-risk donor, might be giving blood,  
 20 infecting the donor pool, if the blood's used for  
 21 blood products, or a transfusion might be given to  
 22 a recipient of transfusion and be infected with AIDS?  
 23 **A.** Yes.  
 24 **Q.** Now I'm not going to go through the detail of what  
 25 then happened because I can do that with

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1 Lord Glenarthur tomorrow --  
 2 **A.** Yes.  
 3 **Q.** -- but we will see when we look at the evidence  
 4 tomorrow there's then a paper and a revised leaflet  
 5 that went to Lord Glenarthur and finally, after some  
 6 toing and froing, which I won't trouble you with, it's  
 7 September by the time the leaflet is -- I think it's  
 8 the beginning of September but it's nonetheless  
 9 September by the time the leaflet is ready.  
 10 **A.** Yes.  
 11 **Q.** It's a press release by Mr Clarke and so on. That was  
 12 too long, wasn't it?  
 13 **A.** Much too long.  
 14 **Q.** Then can you just assist with this, I want to ask the  
 15 same question of Lord Glenarthur and Mr Clarke, but  
 16 it's an issue on which ministers got quite involved in  
 17 the nitty-gritty?  
 18 **A.** Yes.  
 19 **Q.** Yet, by contrast, we've seen other issues such as the  
 20 Galbraith paper, the decision of the Biological  
 21 Subcommittee on the Committee of Safety of Medicines,  
 22 it's seemingly not going to ministers, or at least not  
 23 going to Lord Glenarthur, subject to the anything he  
 24 tells us tomorrow.  
 25 **A.** Yes.

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1 and I'm only maybe interpreting stuff but this is --  
 2 you frequently ask me to interpret and so I'm doing it  
 3 this time -- huge sensitivity over the sexual side of  
 4 things, that basically whatever you do you must not  
 5 ask donors about their sexual behaviour. Now, that  
 6 was probably linked to because that will be a big  
 7 turnover to donors and you may lose donors accordingly.  
 8 But I mean, I could be wrong. My interpretation  
 9 was that there was a bit more to this and the  
 10 reason -- and maybe I'm doing it with a degree of  
 11 retrospection because, subsequently, Mrs Thatcher  
 12 became terribly concerned that there was going to be,  
 13 and actually prohibited, a survey of the sexual habits  
 14 of the population, that I think the Wellcome Trust or  
 15 some such body was going to conduct, and she wasn't  
 16 having it. I suspect there was a degree of  
 17 sensitivity because this was an area of great  
 18 sensitivity involving the homosexual population,  
 19 involving sexual practices, which were having to be  
 20 spelt out increasingly, and I do actually amongst some  
 21 of the few bits of briefing that I recall giving  
 22 ministers, was having to be very explicit on some of  
 23 the things that I was just learning. I was a page  
 24 ahead of them in learning these things.  
 25 So that I think there was this overtone to do

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1 **Q.** What's the rhyme or reason as to what goes to  
 2 a minister and what they get interested in and what  
 3 doesn't?  
 4 **A.** I wish I knew, actually. Occasionally, it did seem --  
 5 I didn't spot the particular logic. We discussed the  
 6 other day why on earth did the question of a steering  
 7 group of the CBLA, or whatever it was, why on earth  
 8 did that have to go to ministers?  
 9 I don't think I ever really fully understood  
 10 which goes to the fact that I probably never had the  
 11 sort of administrative training that my administrative  
 12 colleagues had, and I just accepted that some things,  
 13 if they thought had to go, as you know, submissions to  
 14 ministers, then they had to go. So I'm not sure that  
 15 I ever really understood the inwardness of it.  
 16 This was a very interesting one, though, because  
 17 of the degree of intimate involvement that a whole  
 18 variety of ministers seemed to take and I'm not  
 19 entirely sure why. I mean, clearly there was worry  
 20 about the Blood Transfusion Service and that it might  
 21 be impacted adversely and that, therefore, there would  
 22 be a reduction in the number of donors wanting to give  
 23 blood and that was not an unreasonable thing to be  
 24 worried about.  
 25 Then there seems to have been a big sensitivity,

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1 with sexuality and homosexuality and, of course,  
 2 potentially drug abuse as well. So it was a terribly  
 3 sensitive subject.  
 4 **MS RICHARDS:** Sir, I've got about, I think, 15 minutes  
 5 more questions for Dr Walford of my own. It's  
 6 a matter for you, for Dr Walford's convenience, and  
 7 the convenience of others, whether I continue now then  
 8 I can essentially get all my questions done and then  
 9 we can have a decent break because I will need to  
 10 consider questions from Core Participant. It does  
 11 mean a slightly longer day.  
 12 **SIR BRIAN LANGSTAFF:** Let me ask Dr Walford because you  
 13 are the person who has got to answer the questions.  
 14 **A.** Yes -- alas.  
 15 **SIR BRIAN LANGSTAFF:** The alternatives are these: we can  
 16 have a break now, which I am sure you could probably  
 17 do with or -- because counsel then will come back for  
 18 15 minutes but then we would have another break. The  
 19 reason for the break then is to give an opportunity,  
 20 having considered everything that you have said thus  
 21 far, for those Core Participants, representatives who  
 22 have been listening, to suggest to Ms Richards further  
 23 questions that she may want to ask you. It's what we  
 24 do for every witness, you may have seen.  
 25 That takes probably about half-an-hour, I would

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1 think, in terms of break here, because you have three  
 2 days of evidence to think about. So the choice is  
 3 stop now, come back for 15 minutes or thereabouts,  
 4 break for another half hour or so and come back and  
 5 finish whenever we finish, or we go on now for  
 6 15 minutes, then have the break and finish whenever we  
 7 finish. So it's quicker, if you like, to go on but  
 8 it's entirely a matter for you and what you feel like.

9 **A.** That's very kind. I'm very conscious of the fact that  
 10 people have been sitting here. I, at least, have  
 11 a semi-active role. I'm very conscious of the fact  
 12 that people are sitting here and they must be dying  
 13 for a break but, as far as I'm concerned, I'm happy to  
 14 go with whatever anybody else wants to do. My  
 15 personal preference, but it's not to influence anybody  
 16 else, is that I would prefer to press on frankly than  
 17 have a break and then another break, and so on, but  
 18 I'm absolutely in anybody's else's hands and if  
 19 there's some way of ascertaining what the audience  
 20 would like, I mean, frankly, I'm happy to go with it.

21 **SIR BRIAN LANGSTAFF:** I tell you what I shall do. I will  
 22 take the flak, rather than have it rest on you --

23 **A.** Okay.

24 **SIR BRIAN LANGSTAFF:** -- and I will decide to give anyone  
 25 who wants to, to have a break now, five minutes, to

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1 **Q.** Then you say this:  
 2 "If they go ahead, this could put the cat  
 3 amongst the pigeons. Is it worth mentioning at this  
 4 stage to ID and SOL C?"

5 I assume that's a reference to your information  
 6 division and to the legal department?

7 **A.** Yes.

8 **Q.** Why did you use the phrase, and what did you mean by  
 9 it, "If they go ahead, this could put the cat amongst  
 10 the pigeons"?

11 **A.** I meant that it was quite likely to go to -- to impact  
 12 back, if you like -- this was a case in Bristol, were  
 13 likely to be significant consequences, probably  
 14 involving our lawyers as well. I suspect it was  
 15 a loose phrase after having enjoyed a meeting of the  
 16 Haemophilia Reference Centre Directors and I just  
 17 thought, well, this is going to cause mayhem really  
 18 if, in fact, there is a lawsuit and the Committee on  
 19 Safety of Medicines has just said we're not doing  
 20 anything about product.

21 I think -- I don't think you can put a more --  
 22 or at least I wouldn't put a more serious construction  
 23 on it than a loose way of talking.

24 **Q.** The first paragraph refers to Professor Bloom reading  
 25 out:

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1 have a short break and, otherwise, we will press on.

2 **MS RICHARDS:** We will take 5 minutes, shall we?  
 3 A five-minute comfort break.

4 **SIR BRIAN LANGSTAFF:** Comfort break, and then we press on.  
 5 (3.35 pm)

6 (A short break)

7 (3.43 pm)

8 **MS RICHARDS:** Dr Walford, I'm going to ask you to look now  
 9 at a document at DHSC0002231\_059. It's dated  
 10 19 September 1983 and we can see it's a minute from  
 11 you to Mr Winstanley, "Meeting of Haemophilia  
 12 Reference Centre Directors, 19 [September] 83", and  
 13 you refer to having invited yourself to that meeting  
 14 to hear the latest on AIDS. Just two bits I wanted to  
 15 ask you about.

16 Paragraph 2 says this:  
 17 "The relatives of the haemophiliac who died of  
 18 AIDS in Bristol have taken legal advice and are keen  
 19 to sue the manufacturers (Alpha and Immuno) of the  
 20 commercial [Factor] VIII concentrate which he received  
 21 in 1981."

22 Pausing there, this is something you'd been told  
 23 in the meeting I think is the obvious reading of this  
 24 minute.

25 **A.** Mm-hm.

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1 "... a letter which he has prepared for The  
 2 Haemophilia Society to send its members (ie an up-date  
 3 on his earlier letters). I haven't got a copy of the  
 4 letter but it sounded reasonable and, hopefully, will  
 5 not create any new problems."

6 Can you assist us with understanding what you  
 7 mean by saying it won't create any new problems?

8 **A.** No, of course, because I can't remember what the  
 9 letter said. I don't know. Again, I'm merely saying  
 10 I heard a letter being read out. It didn't seem to  
 11 lead to any particular consequential for us in the  
 12 Department. But, again, it's putting quite a lot of  
 13 weight on an informal note just telling Winstanley  
 14 on -- what had happened in the meeting.

15 **Q.** We can take that down now. I want to ask you now  
 16 about a separate topic which is about the collection  
 17 of blood from prisons.

18 **A.** Yes.

19 **Q.** We look at three documents and then I can ask you some  
 20 general questions about it.

21 So the first is PRSE0004345. It's dated  
 22 27 July 1983 and it's from JB Brown MB2. Do you know  
 23 what MB2 was?

24 **A.** Part of Medicines Division.

25 **Q.** Then if we look at the top of the page, addressed to

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1 Mr Parker at HS1:  
 2 "Use of blood from prisons.  
 3 "1. At a recent meeting of Medicines Division's  
 4 Inspection Action Group concern was expressed about  
 5 the collection and use of blood from borstal  
 6 institutions and prisons. Blood Transfusion Centres  
 7 in Scotland were making use of these sources  
 8 (particularly prisons) and some, at least, of the  
 9 English Blood Transfusions Centres were also  
 10 understood to do.  
 11 "2. The Group considered this practice to be  
 12 highly questionable because of the incidence of  
 13 homosexuals and homosexual activity in prisons and the  
 14 present unease about the incidence of AIDS among this  
 15 group of people.  
 16 "3. The Group asked to be advised of  
 17 Departmental policy on the practice of collecting and  
 18 using blood from borstals and prisons and I shall be  
 19 grateful if you will let me have a note about this  
 20 which I can pass on."  
 21 If we just go back to the whole document, can we  
 22 just look at the full document -- yes, so that  
 23 handwriting at the bottom of the page:  
 24 "Mr Winstanley  
 25 "Please ..."

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1 selection and [something] of Blood donors and will try  
 2 to explain that avenue. He will copy his response to  
 3 MI to us ..."  
 4 So there has been some liaison, in any event,  
 5 between, it would seem, the Department in the form of  
 6 Mr Winstanley and the Scottish Home and Health  
 7 Department I think?  
 8 **A.** Yes.  
 9 **Q.** Then there's a memo from Mr Winstanley copied to you  
 10 and this is really where I want to then ask you of  
 11 your involvement. It's at PRSE0004729, and this is  
 12 dated 23 August 1983, Mr Winstanley to Mr Brown. It  
 13 says:  
 14 "I am replying on behalf of Mr Parker to your  
 15 minute ...  
 16 "It is difficult to advise any particular  
 17 Departmental policy on the collection of blood from  
 18 borstals and prisons at the moment. It is for  
 19 individual Regional Transfusion Directors to determine  
 20 how and from where donations are sought in the light  
 21 of the targets they need to achieve and the numbers of  
 22 donors on their panels.  
 23 "However, Transfusion Directors have been aware  
 24 of the dangers of relying too heavily on prisons as  
 25 a source of donations for some time ie prior to the

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1 **A.** "Consult".  
 2 **Q.** "... consult with Dr Walford and reply direct on by  
 3 myself."  
 4 So that's the first document.  
 5 Then if we go to PRSE0003281, we've got a note  
 6 there which is 26 August 1983, I think. I'm not sure  
 7 if it's obvious who this is from, but anyway:  
 8 "Mr Winstanley, DHSS, rang. He has received an  
 9 enquiry Medicines Inspection re Departmental Policy on  
 10 donor sessions in prisons and borstals given there is  
 11 now AIDS. (He explained that England and Wales have  
 12 tended to shy off in fact ..."  
 13 **A.** "... in fact because of Hepatitis ..."  
 14 **Q.** "... because of Hepatitis but he ..."  
 15 "... wouldn't know?"  
 16 **SIR BRIAN LANGSTAFF:** "... he wondered ..."  
 17 **MS RICHARDS:** "... wondered what Scottish position was."  
 18 Then there's a reference to an RTD meeting.  
 19 "I summarised ..."  
 20 Surmised?  
 21 "... summarised to Mr Winstanley what was said  
 22 then and referred to the general position. He was  
 23 interested in the reference to the ..."  
 24 I can't read the next word.  
 25 "... approaching the [working party] on

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1 advent of AIDS as a cause of concern, because of the  
 2 risk of hepatitis in prisons, (also connected with the  
 3 higher incidence of homosexuality) which can be spread  
 4 through blood transfusion. Nevertheless, although  
 5 most Regions, especially those with no shortage of  
 6 donors, may not need to use prisons, there is at least  
 7 one which has to view them as a major source of  
 8 donations in order to meet targets.  
 9 "AIDS has now of course called the wisdom of  
 10 continuing to view prisons as a source of blood even  
 11 further into question, and the Directors are due to  
 12 discuss it at their next meeting in September. If the  
 13 risks are now considered too great to justify  
 14 continued collection from prisons, some measures will  
 15 be needed to compensate for the loss of that source of  
 16 donors, perhaps, for example, a system whereby Regions  
 17 with no need to rely on prisons can take extra blood  
 18 to be transferred to those Regions for whom the loss  
 19 of prison as a source of blood will cause  
 20 difficulties.  
 21 "I shall of course advise you of any  
 22 developments which occur. I gather that this problem  
 23 has been debated by Transfusion Directors in Scotland,  
 24 but no particular policy line emerged. We shall  
 25 obviously need to liaise closely with Home Office also

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1 since they have in the past been very much in favour  
2 of blood donation by prisoners."

3 We can see, if we look at the bottom of the  
4 page, Mr Winstanley's minute is copied to you.

5 Now, this would appear to indicate that the  
6 practice of collecting blood from prisons was still  
7 ongoing in England and Wales, not in all areas, but in  
8 at least one, and was still ongoing in Scotland.

9 There appears to be a suggestion of the Department,  
10 the DHSS, having no particular policy in relation to  
11 that.

12 Can you cast any further light on this issue?

13 **A.** I had absolutely no idea that we collected blood from  
14 prisoners. Of course, it's a bad idea and, basically,  
15 it shouldn't have been going on. Scotland, I think,  
16 did much more but I wasn't aware, until this issue  
17 came up, that we were actually doing that, nor did  
18 I think, at the time -- the time I found out about the  
19 Home Office being quite keen for -- was it -- no, it  
20 was the homosexuals that they were quite keen to  
21 encourage, as well, I think. I can't remember, there  
22 was some sort of reference to the Home Office on  
23 3 June meeting, the Home Office needing to be informed  
24 about something, but basically, as far as I can  
25 recall, I have -- I had no knowledge that, at the

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1 patient-doctor relationship.

2 **Q.** So it's potentially a reflection and an adverse  
3 consequence of what you described, I think, earlier  
4 and in your statement as collection of loose  
5 fiefdoms --

6 **A.** Yes.

7 **Q.** -- with there being no unifying National Blood  
8 Transfusion Service as a legal entity?

9 **A.** Yes.

10 **Q.** There's reference there to it's going to be discussed  
11 at the Regional Transfusion Directors meeting in  
12 September. You address this in your statement and  
13 I raise it just so that we can correct something.

14 **A.** Yes.

15 **Q.** The references you gave in your statement to  
16 a directors' meeting and to an internal minute from  
17 you are actually references to the Haemophilia Centre  
18 Directors' meeting in September of --

19 **A.** So I got the wrong meeting, have I?

20 **Q.** Yes. Don't worry about that at all. It's a matter  
21 I have raised with Ms Grey, there's no criticism with  
22 you in raising it. It's the wrong references.

23 We haven't then troubled you with additional  
24 documents but when one looks at the Regional  
25 Transfusion Directors' next meeting, because there was

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1 time, Regional Transfusion Centres were going out to  
2 prisons and collecting bloods from prisoners, because  
3 it seems like thoroughly bad idea.

4 **Q.** The problem, in a sense, thrown up by Mr Winstanley's  
5 response is it doesn't appear to be envisaged that the  
6 Department is going to do anything about it.

7 **A.** That's true.

8 **Q.** Do you think the Department should have been doing  
9 something about it?

10 **A.** My personal preference would have been for the  
11 Department to say this must stop.

12 **Q.** Would you agree that, irrespective of what was known  
13 by this time in relation to AIDS, this was a terrible  
14 idea, in any event --

15 **A.** It was a terrible idea.

16 **Q.** There's a reference there to it being essentially down  
17 to individual Regional Transfusion Directors. Is that  
18 another manifestation of the clinical freedom --

19 **A.** Not the clinical freedom the transfusion directors'  
20 freedom because RTDs, as I've explained before, really  
21 were not actually managed but they were overseen by  
22 their Regional Health Authority but, essentially, RTDs  
23 were fairly autonomous. So it was just another  
24 manifestation of a degree of autonomy but not clinical  
25 autonomy as UKHCDO such because that's relates to the

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1 one, whether it was September or October, it's not  
2 discussed.

3 **A.** Right.

4 **Q.** Do you have any idea about what happened in relation  
5 to these policy?

6 **A.** No. If it isn't written down in the minutes of the  
7 meeting then either it was discussed and only  
8 cursorily and somebody didn't minute it or it wasn't  
9 discussed but I wouldn't -- I don't remember anything  
10 about it at all.

11 **Q.** Then do you know what the position was in relation to  
12 the collection of blood from the military, either in  
13 England and Wales or in Scotland?

14 **A.** No.

15 **Q.** Can I then come to the role -- just go back to the  
16 role of the Chief Medical Officer briefly, and the  
17 issue of Chief Medical Officer letters. We can look  
18 at the examples of letters if it would be helpful to  
19 you, Dr Walford, but, broadly speaking, you've  
20 identified two letters of some relevance in the sense  
21 that they are "Dear Doctor" letters from the Chief  
22 Medical Officer. There's one in 1982 in relation to  
23 the hepatitis B vaccine?

24 **A.** Yes.

25 **Q.** Then there's one, which you referred to in your

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1 evidence already today, in 1985 in relation to AIDS.

2 **A.** Mm-hm.

3 **Q.** In what circumstances -- and I'm really asking you to  
4 recall here not just upon your own involvement in the  
5 Department at this time -- but your own later  
6 involvement as a Deputy Chief Medical Officer?

7 **A.** Yes.

8 **Q.** In what circumstances was it the practice of the Chief  
9 Medical Officer to issue "Dear Doctor" letters?

10 **A.** I think it was pretty rare. I mean, that is to say it  
11 occurred several times in any given year and there  
12 should be a whole archive of "Dear Doctor" letters in  
13 the Department so, in effect, you can, as it were,  
14 check on all this.

15 Mostly, they would be to do with what I would  
16 call a wider public health issue, not a specific issue  
17 related to a specific group of patients needing  
18 a specific sort of care. So it would be to do with  
19 vaccines. Vaccines was one that the CMOs did write  
20 letters about.

21 The interesting thing about the letter that  
22 Sir Donald Acheson wrote about AIDS, actually, the  
23 first "Dear Doctor" letter, if you like, about AIDS,  
24 which was in 1995 (*sic*), it may throw some light on  
25 what I'm saying now that I think just towards the end

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1 **Q.** I won't put it on screen but for anyone's reference,  
2 in terms of legal representatives, it's  
3 DHSC0002327\_016.

4 Can I ask you to consider two matters in  
5 relation to the sending of the "Dear Doctor" letter or  
6 equivalent by the CMO at an earlier stage and why  
7 perhaps it should have been considered.

8 This was a new disease, as the later letter from  
9 Sir Donald Acheson says. It was a disease with a very  
10 high mortality rate, a disease about which, as you  
11 have said, there was much uncertainty, that had the  
12 potential to affect very profoundly an identifiable  
13 cohort of patients and I'm dealing for the purposes of  
14 this first scenario with patients receiving factor  
15 concentrates but, obviously, in the context of a much  
16 bigger public health issue.

17 **A.** Yes.

18 **Q.** Wouldn't the emergence of that be really -- would have  
19 been a very good thing for the Chief Medical Officer  
20 to share such information as there was because not all  
21 doctors would have had access to the same sources of  
22 information that the Department had?

23 **A.** Well, I agree with you. I mean, essentially, we have  
24 focused here necessarily on patients with haemophilia.  
25 By the time the CMO was writing that letter in 1985

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1 of the letter there's a whole lot of very useful  
2 information and there's a section from CDSC describing  
3 the latest state of epidemiology, but then there's  
4 a form of words just towards the very, very end of the  
5 letter, and you may or may not have it here I may have  
6 brought it in with me, which says -- and he's saying  
7 to doctors in the field, as it were, in the NHS,  
8 "I have taken the liberty of writing to you about this  
9 because AIDS is a new disease". It's an extraordinary  
10 form of words because what he's saying is "I wouldn't  
11 normally do this but because AIDS is this new disease"  
12 and obviously he felt, rightly in my view, that there  
13 was a need for this dissemination, that he felt he had  
14 to almost beg their pardon for having intervened in  
15 this way and having written to them. And I just  
16 thought that was extremely revealing and I thought it  
17 actually -- it actually said all I could reasonably  
18 say about how a letter from the CMO to doctors was, as  
19 it were, viewed and it was not usually in relation to  
20 a particular disease.

21 **Q.** Just so that we have -- you're almost absolutely  
22 verbatim on this:

23 "I take the liberty of sending this information  
24 because AIDS is a new disease."

25 **A.** Yes.

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1 there was still only three patients with haemophilia,  
2 two of whom I knew about in my time and there had  
3 obviously been one other. But there were really quite  
4 large numbers of homosexual men and also drug addicts  
5 and also spouses and some children, by then, who had  
6 developed AIDS, and this was a completely new disease.

7 So I agree with you that, in this particular  
8 instance, where it's not a question of saying, well,  
9 here's a new development about a disease that you all  
10 know about, or whatever, this is a brand new disease,  
11 frankly, it's the start of a new pandemic, not -- you  
12 know, you don't actually normally realise you're at  
13 the beginning of a pandemic until you are right in it,  
14 but that's what was happening and I think it would  
15 have been a good thing to do to have written out  
16 sooner than was the case, particularly as one saw the  
17 numbers of cases in non-haemophiliacs going up, so  
18 that it became of a much broader general interest than  
19 of a select group who might be presumed to be being  
20 told about it by their clinicians.

21 **Q.** If we leave aside for a moment that group that I've  
22 already canvassed with you at some length, and whether  
23 information should have been given by the Department  
24 or the CMO to haemophilia clinicians, leave those  
25 aside, you yourself have flagged up, as a particular

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1 concern, those patients who might be receiving --  
 2 being treated with concentrate, treated with blood  
 3 products in hospitals that were not haemophilia  
 4 centres?  
 5 **A.** Yes.  
 6 **Q.** Indeed, the Inquiry has heard some evidence of that  
 7 and of people being infected in consequence.  
 8 **A.** Yes.  
 9 **Q.** Neither the CMO nor the Department could have made any  
 10 assumption about the state of knowledge of those  
 11 hospitals, could they?  
 12 **A.** That's so.  
 13 **Q.** Then there's also -- if one then goes on to a wider  
 14 population level, any member of the public at any time  
 15 might find themselves potentially in need of  
 16 a transfusion?  
 17 **A.** That is right.  
 18 **Q.** Again, the circumstances in which a transfusion might  
 19 come to be given are so many and varied and they can  
 20 involve all sorts of different disciplines, not just  
 21 specialist haematologists, so those two scenarios  
 22 might have been particular reasons why some form of  
 23 CMO "Dear Doctor" intervention might have been very  
 24 helpful.  
 25 **A.** I agree.

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1 questions for you.  
 2 You've said in your statement, you've said in  
 3 your oral evidence, understandably on a number of  
 4 occasions, I was a medical officer, I was giving  
 5 advice, I was not part of the administrative  
 6 hierarchy, which actually ultimately either took the  
 7 decisions or put the matter up for the Minister to  
 8 take the decisions?  
 9 **A.** Mm-hm.  
 10 **Q.** I understand that. It may be that a theme that  
 11 emerges from the evidence of the ministers who are  
 12 going to be giving evidence tomorrow, next week might  
 13 be "We weren't the experts, we were just the  
 14 politicians, we relied on the medical or scientific  
 15 advice that was given to us". So there might be  
 16 an element of, on the one hand the medical officer  
 17 saying, well, it's down to you, and the Minister  
 18 saying, well, no sorry it's down to the medical  
 19 advice. Do you have any observations to make on that?  
 20 **A.** Well, I think perfectly reasonable for a minister --  
 21 if he or she is to be appropriately briefed they must  
 22 expect on a scientific matter, such as we have here,  
 23 just as our current Government ministers rely on  
 24 Chris Whitty and other medical advisers, the DCMOs, to  
 25 give their best possible advice, I think it's

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1 **Q.** By the time you were Deputy Chief Medical Officer,  
 2 which I think was 1989 to 1992, was it that the  
 3 approach to clinical freedom in relation to clinicians  
 4 or the hands-off approach to the NHS, both of which we  
 5 talked about on Monday, had those changed at all by  
 6 1989 or the early 1990s?  
 7 **A.** Well, I'm possibly better placed to talk about the NHS  
 8 because, as well as being DCMO, I had this role as  
 9 being the Director of Healthcare on the NHS Management  
 10 Executive, which was also slash Medical Director of  
 11 the NHS in England and, therefore, I found myself  
 12 writing out, on some occasions certainly, to doctors  
 13 or to health authorities, if you will, about specific  
 14 issues, operational issues.  
 15 Those -- what I would be writing would not have  
 16 replaced "Dear Doctor" letters on the professional  
 17 line coming from the CMO. But there was more  
 18 management of the NHS by the time I'd got to be DCMO  
 19 and that is after the Griffiths report, the NHS  
 20 Management Executive was set up, Duncan Nichol was  
 21 that chief executive, equivalent to Sir Simon Stevens  
 22 now, and basically we tried, we purported to do a bit  
 23 more hands-on management of the NHS than had been done  
 24 previously.  
 25 **Q.** Now, I've just lastly got a handful of more general

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1 absolutely right that -- ministers are right that they  
 2 have to rely on the scientific advice that they're  
 3 given and, of course, they should challenge it if they  
 4 are unhappy because they are hearing things from  
 5 elsewhere that doesn't seem to chime with what's being  
 6 given. But I don't see how it's possible for  
 7 a minister to take a view on a particularly thorny  
 8 scientific issue -- and this was a very thorny  
 9 scientific matter -- without seeking to get the best  
 10 possible advice that he can get.  
 11 Now, to the extent that that is the role of the  
 12 CMO, to ensure that the advice that is coming up  
 13 through the medical and scientific echelons of the  
 14 Department of Health, is properly supported by advice  
 15 that they are getting from experts -- because as I've  
 16 said before -- you know, one really can't repeat it  
 17 too much -- most doctors in the Department of Health  
 18 were not specifically expert in their particular  
 19 field. They became very knowledgeable, we all became  
 20 fairly knowledgeable, but they weren't necessarily  
 21 expert. Their job was to go out and collect as much  
 22 information and try to interpret it as well as they  
 23 could to help the administrators put up their  
 24 submission or to brief ministers face-to-face.  
 25 Certainly throughout my career I did brief

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1 ministers face-to-face but almost certainly as  
2 a member of a team, with administrative colleagues,  
3 and I expected to give my best possible advice but my  
4 best possible advice I expected to be based on  
5 whatever I had been able to glean from the experts in  
6 the field.

7 **Q.** Second general question is this, who -- and this is  
8 again really asking for your comment, your  
9 observation, not just from the period that we've been  
10 focusing on, '77 through to '83, but given that you  
11 have been involved in the public sector and the NHS in  
12 a range of roles over the years -- who, in terms of  
13 person -- I don't mean named person, I mean their  
14 role, Secretary of State, Chief Medical Officer,  
15 clinician -- what person or organisational body, in  
16 your view, had the overarching responsibility for  
17 ensuring safe delivery of NHS treatment in the late  
18 70s and early 80s?

19 **A.** That is an extraordinarily difficult question, and  
20 just at the end of the session. A very difficult  
21 question.

22 For safe delivery of care. Well, in technical  
23 terms there is no doubt but that the Secretary of  
24 State for Health or, at my time, for Health and Social  
25 Security, had that ultimate responsibility. So

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1 Government in the health sphere, and it's hard to know  
2 precisely where you should locate the priorities. But  
3 with regard to the MBTS in particular, it was for  
4 regions in the organisation, as we then had, to  
5 determine how much money they were going to accord  
6 their Regional Transfusion Service. And the  
7 interesting thing was that some regions were so much  
8 more generous to their Regional Transfusion Centres  
9 than others. So that was almost -- it was their  
10 tranche of money; how they divided it up in terms of  
11 the priorities in the NHS between the Blood  
12 Transfusion Service and all their other priorities was  
13 a matter for Regional Health Authorities and their  
14 regional chairmen and, as I say, it was very variable.  
15 It depended what region you were in, how well funded  
16 your Regional Transfusion Centre was.

17 **MS RICHARDS:** Sir, those are the questions I had for  
18 Dr Walford but obviously we do now need a further  
19 break, a longer break, so that I can consider  
20 suggestions from recognised legal representatives and  
21 Core Participants.

22 **SIR BRIAN LANGSTAFF:** Well, are you likely do you think to  
23 need about 40 minutes?

24 **MS RICHARDS:** The nod from behind leads me to think  
25 there's probably a lot for me to look at, so yes,

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1 I don't think there is -- I don't think that should be  
2 debatable. That was where the ultimate responsibility  
3 lay. How that became then translated into action,  
4 obviously that's where the levers, I suspect,  
5 became -- as we once said in a different context, for  
6 the NHS -- like rubber levers. The levers were not  
7 fit for purpose.

8 **Q.** Then, finally, you have talked in your witness  
9 statement, and you mentioned it again in the course of  
10 your evidence, about financial constraints.

11 **A.** Yes.

12 **Q.** The elephant in the room. Is it the case, and again  
13 I'm really asking for your overall perspective as  
14 someone who had reasonably close involvement in the  
15 issues for an important period of time, is it the  
16 case, do you think, that funding for the safety of  
17 blood and blood products was not a sufficiently high  
18 priority?

19 **A.** I can't express it in terms of priority. I think  
20 I did explain in my statement that funding of the NHS  
21 wasn't high enough up Government priorities. I think  
22 the percentage of GDP was somewhere around about  
23 3.75 per cent, being -- compared with now, which we  
24 know is, forgetting Covid, very much higher than that.  
25 So there was an enormous range of priorities for

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1 please. I'm sorry that means a longer day.

2 **SIR BRIAN LANGSTAFF:** I'm sorry about that, doctor, but  
3 we'll take a break in that case until 5 to 5.

4 **MS RICHARDS:** Thank you, sir.  
5 (4.13 pm)

(A short break)

6 (5.01 pm)

**Questions by CORE PARTICIPANTS**

7 **MS RICHARDS:** Dr Walford, last lot of questions, and  
8 because these have come from a number of different  
9 sources, they are going to dot around from topic to  
10 topic so there won't be a chronological automatic  
11 link.

12 First question, and this focuses on your time,  
13 1977 through to 1983: were you aware, did you have any  
14 knowledge about the practices of US pharmaceutical  
15 companies in terms of obtaining plasma from third  
16 world countries in central or South America or  
17 elsewhere?

18 **A.** I wasn't particularly aware, my sort of key  
19 preoccupation was with American plasma, but I don't  
20 know that I knew specifically that material was coming  
21 from third world countries, though if I reflect on  
22 that now I'm assuming that the WHO resolution, or the  
23 World Health Authority resolution which said become  
24  
25

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1 self-sufficient so that -- in terms -- you don't  
 2 deplete the plasma supplies of other countries, they  
 3 would mostly be referring to countries in the  
 4 developing world rather than necessarily America.  
 5 **Q.** But you didn't have any specific knowledge?  
 6 **A.** I didn't have any specific knowledge.  
 7 **Q.** What about other sources in terms of donors within the  
 8 USA or, indeed, elsewhere? Did you have any knowledge  
 9 of prison collection of blood in the States, for  
 10 example, that that was a possible source of the plasma  
 11 that was being used by the American pharmaceutical  
 12 companies?  
 13 **A.** I think I only became aware of the sort of places that  
 14 were undertaking plasmapheresis and the sort of donors  
 15 they might be getting blood from when the AIDS issue  
 16 became apparent. I'm not aware that I knew very much  
 17 about it beforehand.  
 18 **Q.** What about the size of the US plasma pools? Can you  
 19 recall what your broad understanding was of their  
 20 size?  
 21 **A.** I knew they were pretty large.  
 22 **Q.** Did you have --  
 23 **A.** Thousands and thousands of donations.  
 24 **Q.** Was it your understanding that they were significantly  
 25 larger than the pools used in the UK?

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1 you about, a difference in terms of the characters of  
 2 the Chief Medical Officers, so Sir Henry Yellowlees  
 3 and Dr Donald Acheson. Are there any reflections or  
 4 observations you have about any difference of approach  
 5 as between the two of them?  
 6 **A.** Well, I had very little contact, that I can recall,  
 7 with Sir Henry. The times I sort of recall seeing him  
 8 were in the big town hall meetings, so to speak, where  
 9 he was meeting with all doctors. I really didn't have  
 10 very much contact with him, that I can easily recall.  
 11 I must have had more than the complete blank which  
 12 I draw.  
 13 He was less -- well, let me contrast.  
 14 Donald Acheson was a really distinguished  
 15 epidemiologist, and this was his absolute love and it  
 16 was to the forefront of his thinking and how he  
 17 actually interacted with the medical staff in his  
 18 division. I don't know actually what Sir Henry's  
 19 background was in terms of discipline but one didn't  
 20 have a particular sense of what that might be.  
 21 The area where I know he, as it were, made his  
 22 biggest impact on public health, because this I do  
 23 remember quite clearly, was on lead in petrol, and he  
 24 was very influential within the Department on getting  
 25 the Government to move to remove lead from petrol,

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1 **A.** Yes.  
 2 **Q.** I've asked you a number of questions and so I'm not  
 3 repeating those about your perception of the  
 4 advantages of concentrates in terms of treatment of  
 5 people with haemophilia.  
 6 **A.** Yes.  
 7 **Q.** I think it's probably clear from some of the documents  
 8 and from your statement, but I wanted to check, are  
 9 you there talking about really the position of people  
 10 with severe haemophilia?  
 11 **A.** Yes.  
 12 **Q.** So do you accept that the advantages you articulated  
 13 would be much less significant for those who had  
 14 moderate or mild haemophilia?  
 15 **A.** Yes, I would say that the disadvantages of pooled --  
 16 large-pool products outweighed the advantages for mild  
 17 haemophiliacs and probably moderate haemophiliacs,  
 18 depending on the circumstance, and the circumstance  
 19 would have to be major surgery or a terrible trauma.  
 20 But I would have thought that, really and truly, we're  
 21 talking here for large-pool products for severe  
 22 haemophiliacs.  
 23 **Q.** You have talked about your perception of the different  
 24 approaches of Dr Tovey and Dr Gunson. You I think  
 25 possibly alluded in passing to, but then I didn't ask

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1 because he felt that this was actually potentially  
 2 poisoning children, because the lead was in the  
 3 environment.  
 4 **Q.** Then the issue of central purchasing, so central  
 5 purchasing for commercial concentrates, which we've  
 6 alluded to or referred to in your evidence.  
 7 **A.** Yes.  
 8 **Q.** You have referred to it being a concern of the  
 9 National Blood Transfusion Service, such as it was,  
 10 I think for over a number of years --  
 11 **A.** Yes.  
 12 **Q.** -- for safety reasons?  
 13 **A.** Yes.  
 14 **Q.** And I think you've helped us understand what those  
 15 safety reasons were in relation to an element of it,  
 16 which was non-haemophilia centres using  
 17 factor concentrates --  
 18 **A.** Yes.  
 19 **Q.** -- and no-one having a record or being able to trace  
 20 that through?  
 21 **A.** Yes.  
 22 **Q.** Were there other safety considerations that fed into  
 23 the question of central purchasing?  
 24 **A.** I think the whole point was having a proper database.  
 25 If you are going to give a potentially hazardous

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1 substance, and all blood and blood products are  
2 potentially hazardous -- thank goodness not normally  
3 realised in an actual eventuality -- you really have  
4 to have very good record-keeping, because you need to  
5 be able to trace a batch from its inception, if you  
6 like, through to -- well, not exactly inception  
7 because that's the pharmaceutical industry's role, but  
8 from its initial use through to the end user through  
9 to anything else that might have happened to it.

10 So in blood product terms and in whole blood and  
11 any other blood component you need to have very, very  
12 good records so that you can trace back or do  
13 a look-back or withdraw further batches of the same  
14 material if you think that the material has caused  
15 a patient ill health.

16 **Q.** We saw perhaps most vividly evoked in that  
17 correspondence between Professor Bloom and Dr Jones  
18 the reaction at least of some of the Reference Centre  
19 Directors to that. Did you explain to them that the  
20 potential move to central purchasing was because of  
21 safety concerns?

22 **A.** Well, I must have explained something because  
23 I promised them that I would take their views back and  
24 explain their views to the centre, if you like. We  
25 obviously did have a conversation about it. They were

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1 **A.** Well, I mean, that would potentially open another  
2 Pandora's Box but the most important of those products  
3 from -- if we think about it now in terms of patient  
4 safety, would have been the Factor IX for the  
5 haemophilia B patients because, although -- it's  
6 important to recognise although there were very many  
7 fewer haemophilia B patients than haemophilia A.  
8 A severe haemophilia B was just as severe as  
9 haemophilia A. So there had to be an arrangement  
10 whereby the starting material for Factor IX, which is,  
11 in fractionation terms, the cryoprecipitate  
12 supernatant, found its way to BPL so that they could  
13 then work on it to make Factor IX because the Regional  
14 Transfusion Service couldn't make Factor IX.

15 **Q.** In terms of albumin, for example, which could be heat  
16 treated?

17 **A.** Yes, albumin could be heat-treated, so one would be --  
18 I suppose it would be open to this country to have  
19 purchased albumin because it was considered, at that  
20 time, pretty safe because it was heat-treated.  
21 Immunoglobulins, which was the other one that you  
22 mentioned, they were not heat-treated but they, for  
23 some reason -- and nobody exactly understood why --  
24 had not been associated with the transmission of  
25 hepatitis -- I'm talking here hepatitis -- and had not

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1 pretty fixated, I believe, on the fact that this must  
2 be yet another plot on the part of the Department to  
3 control the purchase so that in fact there would be  
4 some cost-saving and that Department or the RTCs would  
5 then say, "Well, no, you cannot have this concentrate"  
6 or "You must have that concentrate", and there they  
7 were really concerned about their clinical autonomy,  
8 that they must be free to purchase the right product  
9 for their particular patient.

10 Now, as I said, I tried to make clear to them  
11 that that wasn't the purpose of all this but I did  
12 come back to the Department and say that there was  
13 some sort of almost wilful misunderstanding on their  
14 part. So I had obviously tried to explain. It didn't  
15 work, though.

16 **Q.** Then, again, I've asked you number of questions about  
17 reverting to cryoprecipitate, not going back over  
18 those, but you identified as a potential problem the  
19 effect that there would be on the production of other  
20 blood products, albumin, immunoglobulin, if plasma was  
21 being retained in RTCs for the purpose of generating  
22 cryoprecipitate rather than being sent to BPL.

23 Was any consideration ever given to the  
24 possibility of obtaining those other blood products  
25 from elsewhere, commercial sources, importing them?

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1 been associated and there were various theories about  
2 that, basically, the fraction that they came out of in  
3 the fractionation process, I think it was fraction 2,  
4 from memory, that they may have been complexed --  
5 we're talking here immunoglobulins so they made  
6 antibody and any antigen or virus that might have been  
7 around -- might have been complexed together and one  
8 neutralised the other. But nobody actually understood  
9 why they hadn't been associated and they hadn't.  
10 I think it was pretty clear from everything I've read  
11 that intramuscular immunoglobulin had not been  
12 associated to any significant extent with the  
13 transmission of non-A, non-B or hepatitis B for that  
14 matter.

15 **Q.** Then on the issue, again, of clinicians' jealousy  
16 guarding their autonomy, and then you talked about the  
17 perception from the haemophilia clinicians of the  
18 Department as an outsider --

19 **A.** Yes.

20 **Q.** -- was that suspicion of the Department specific to  
21 haematology or was it a more general suspicion of  
22 clinicians'?

23 **A.** It's a sort of -- it's almost a headquarters  
24 phenomenon. I mean, anybody out in the field  
25 distrusts headquarters. The motives are always

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1 malign -- or thought to be. Essentially I think it  
 2 would have been the same in any condition.  
 3 Professionals as a group guarded their autonomy, and  
 4 I'm not just talking about individual patient and  
 5 doctor, I'm talking about the body of professionals  
 6 such as doctors who did not believe that Government  
 7 departments should interfere in their proper province  
 8 of whatever specialty they were involved in.

9 **Q.** The next question is in relation to Professor Bloom.  
 10 There were many renowned haematologists in the  
 11 United Kingdom, there were a number of leading  
 12 haemophilia clinicians. Do you have any sense as to  
 13 why, when one looks across at these various  
 14 committees, groups, organisations, the Central Blood  
 15 Laboratories Authority, he became a member of that,  
 16 for example, there's a common thread to so many of the  
 17 committees and working parties which was  
 18 Professor Bloom --

19 **A.** Yes.

20 **Q.** -- do you know why and -- why there wasn't a view to  
 21 try to seek a wider range of expertise?

22 **A.** Well, you would have thought that would be useful, but  
 23 I would suggest he was on these various committees  
 24 *ex officio*, if you like. He was the elected chair to  
 25 represent UK Haemophilia Centre Directors. If the

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1 be very helpful if they hadn't been -- had been  
 2 written by Peter Jones, the implication being that he  
 3 had a particular agenda.

4 Now, firstly, I didn't know that he'd written  
 5 the article and, secondly, I wouldn't have known he  
 6 had a particular agenda. We would not have been in  
 7 a position, I don't think, to select or take a view as  
 8 to who would be best to represent directors.

9 **Q.** Now going back in time to the Medicines Division and  
 10 your time there, the product information leaflets.

11 **A.** Yes.

12 **Q.** Who were they for, patient or clinician?

13 **A.** Both. So you would have a particular product leaflet  
 14 for doctors, who were prescribing the product. This  
 15 applied to pharmaceuticals as well as biologicals in  
 16 exactly the same way and it applies today. You have  
 17 your leaflets for professionals and you have your  
 18 patient inserts, that's what they are called. So you  
 19 have your medicament -- you will have seen this  
 20 yourself -- and there is always a patient leaflet in  
 21 there, and that should describe the range of adverse  
 22 reactions and other things that the patient might be  
 23 wanting to know about the medicine they're about to  
 24 take.

25 **Q.** Then you may have covered this in your oral evidence,

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1 Department had then turned round and said, "Well, you  
 2 may think that your elected chair is the person who  
 3 should be representing your views but we have other  
 4 ideas about it", I don't suppose that would have been  
 5 particularly welcome.

6 But essentially he was occupying a role. Had  
 7 somebody else been occupying the role, they would have  
 8 been invited in. And he was a very eminent  
 9 haemophilia -- not only clinician but researcher. He  
 10 was well-respected.

11 **Q.** Was any consideration ever given, that you can recall,  
 12 to what might have been the benefits of having a wider  
 13 range of representation, so that you weren't only  
 14 hearing from the same voice?

15 **A.** Well, on first principles I absolutely agree with you.  
 16 When you look across the range of meetings that  
 17 Professor Bloom was involved in, I mean, I don't know  
 18 how he found time to do anything else, quite frankly,  
 19 because he was on every committee that I can remember  
 20 looking at. So clearly it would have been good.  
 21 Obviously, a series of other clinicians, including,  
 22 for example, Peter Jones -- and you drew to my  
 23 attention something that I didn't know, that  
 24 The Lancet article -- The Lancet editorial -- and  
 25 unfortunately the editorials were anonymous, it would

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1 so my apologies if this is a repetition, but it  
 2 relates to the Medicines Inspectorate within the  
 3 Medicines Division.

4 **A.** Yes.

5 **Q.** Did it do inspections of PFC or of Regional  
 6 Transfusion Centres in Scotland or was there  
 7 a separate inspection regime for Scotland?

8 **A.** Well, I don't actually know but if -- from first  
 9 principles, if the Licensing Authority -- well,  
 10 Secretaries of State for England and Wales and  
 11 Secretary of State for Agriculture and for Scotland,  
 12 then I'm assuming that their writ would probably have  
 13 run in Scotland as well.

14 **Q.** And then, just still on the theme of Scotland, do you  
 15 recall ever providing advice directly, I don't mean  
 16 necessarily in person but in the knowledge that your  
 17 advice was being given directly, to ministers  
 18 responsible for the Scottish Home and Health  
 19 Department?

20 **A.** Absolutely not.

21 **Q.** Another topic now, DHSS Small Grants Fund. Do you  
 22 have any recollection as to what in very broad terms  
 23 was the size of the fund?

24 **A.** No, unfortunately. Small is really my recollection.

25 **Q.** In hindsight, and this touches on the questions I was

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1 asking you about Professor Bloom and his dominance, as  
2 it were, over the various committees, in hindsight do  
3 you think you got a full understanding of what might  
4 have been the range of views of haemophilia  
5 clinicians?

6 **A.** I think I might have got that range of views I suppose  
7 by attending the various meetings that I did attend.  
8 I mean, I listened attentively, contributed from time  
9 to time. So obviously he was having to represent what  
10 he viewed as a consensus. I had no reason to think  
11 that somehow or other I was prevented from hearing  
12 a range of views.

13 **Q.** Do you know what, if any, consideration was given by  
14 the Department to hepatitis B core screening as  
15 a surrogate marker for HIV?

16 **A.** Well, it was considered. It was not considered by the  
17 Department, I don't think, so much as considered by  
18 the professionals in the field, because obviously this  
19 was one issue. If you were looking to see if you  
20 could, as it were, spot a potentially infected donor  
21 but you didn't have a test for HIV itself or you  
22 didn't even know that HIV existed, potentially the  
23 sort of person who might be able to transmit or more  
24 liable to transmit AIDS would be somebody who had had  
25 hepatitis B because we've learnt together that the

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1 Transfusion Centres, although there was an intention,  
2 as you explained to us, to do so, how was the  
3 Department able to know or check if the plasma that  
4 was being collected in the United Kingdom was safe and  
5 safe practices were being adopted?

6 **A.** Well, we had to rely on the guidance that the Regional  
7 Transfusion Service was working to. I mean, they did  
8 have quite a number of protocols and, you know,  
9 absolute tests that must be done. So, insofar as the  
10 testing across the board was pretty unified, I don't  
11 think it's fair to characterise the Regional  
12 Transfusion Centres as being so entirely footloose and  
13 fancy free that they did not all follow a very  
14 stringent protocol for testing, because they did, and  
15 so every one of them would be testing for the things  
16 that we knew they were testing for.

17 **Q.** But in terms of collection practices, such as  
18 prisons --

19 **A.** That I think we knew less about. We would have to  
20 make individual enquiries if somebody approached us to  
21 say, well, what's going on in region X.

22 **Q.** Then was any assessment done in or by the spring of  
23 1983 of the likelihood of AIDS being or getting into  
24 the UK donor population, given the ease of  
25 transmissibility of AIDS and the realities of

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1 epidemiology of the two infections followed very  
2 similar lines.

3 So whilst by this time all donations were being  
4 actually screened for hepatitis, surface antigen and  
5 the antibody probably together but certainly screening  
6 out those who had, as far as one could see,  
7 hepatitis B infection, the core hepatitis -- the  
8 anti-hepatitis core antigen still could persist even  
9 if the hepatitis surface antigen had disappeared and  
10 there was no evidence of antibody.

11 So if you used that as a potential marker, then  
12 potentially you might eliminate some donors who you  
13 really didn't want to donate.

14 I think the arguments were then that, if you did  
15 that, you were quite likely to reduce the amount of  
16 blood available from donations by a very considerable  
17 extent, something like 10 per cent. I could be wrong  
18 about that figure but it was quite a considerable,  
19 sizeable amount of blood that would be lost if you did  
20 that.

21 **Q.** Given that, as you told us, that there was no  
22 overarching National Blood Transfusion Service and you  
23 had Regional Transfusion Centres and Directors as  
24 individual fiefdoms, and that in the early 1980s the  
25 Medicines Inspectorate was not yet inspecting Regional

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1 international travel?

2 **A.** I don't know how one would have done that assessment.  
3 You couldn't diagnose it. The only thing you could  
4 possibly do is to try to make sure that you could keep  
5 out as many donors who might be in the risk category  
6 for AIDS as possible. But there's no way of working  
7 out, as far as I can see, whether or not that was  
8 being done successfully.

9 Could you repeat your question --

10 **Q.** Yes, you will appreciate I'm asking a question posed  
11 by others, so I can't necessarily articulate it in any  
12 different way.

13 Was any assessment done in or by the spring of  
14 1983 of the likelihood or the risks of AIDS either  
15 already being in or getting into the UK donor pool,  
16 given the reality of international travel and the ease  
17 of transmissibility of AIDS because my question to you  
18 very much focused on the American problem of imported  
19 concentrates, so it's the domestic risk?

20 **A.** Yes, I don't know how they would have done such  
21 an assessment and if you think that it took until  
22 September '83 to get a leaflet out, which was trying  
23 to make sure that donors -- inappropriate donors  
24 didn't donate, I can't think of a single way in which  
25 that assessment could have been done.

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- 1 **Q.** If, contrary to what you have explained was your  
2 understanding and the Biological Subcommittee's  
3 understanding in 1983 if it had been logically  
4 feasible and practical to revert to a wide use of  
5 cryoprecipitate, either locally in RTCs or through  
6 BPL --
- 7 **SIR BRIAN LANGSTAFF:** Do you mean logically or  
8 logistically?
- 9 **MS RICHARDS:** Logistically, sorry. Yes, logistically.  
10 I misread it, I'm sorry. That's the problem with  
11 reading late in the day other people's writing.  
12 Would it have been the right thing to do to go  
13 down that route in 1983?
- 14 **A.** If we had enough cryo?
- 15 **Q.** Yes.
- 16 **A.** And it didn't impact on the Factor IX production and  
17 albumin and the immunoglobulin?
- 18 **Q.** Yes.
- 19 **A.** If -- we did very seriously consider could we somehow  
20 or other arrange for small-pool product, because small  
21 pools carry, obviously, less risk than the large  
22 pools. We were advised very clearly by Dr Lane and  
23 also Dr Gunson that small-pool products couldn't be  
24 used.  
25 I think it's still important to realise that you

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- 1 decriminalised only just over a decade before, and  
2 that injecting drug misuse remained a criminal  
3 offence.  
4 Do you think it's likely, or possible, that the  
5 association of AIDS with homosexuals might have  
6 contributed to the resistance of some Haemophilia  
7 Centre Directors in accepting a link between AIDS in  
8 the haemophilia community?
- 9 **A.** I really couldn't comment on that.
- 10 **Q.** I don't know whether you will be able to answer this  
11 Dr Walford but I'll ask it. It's what was the source,  
12 as far as you can recall, of your knowledge or belief  
13 about the incidence of brain bleeds in haemophiliacs?
- 14 **A.** Well, obviously I will have read. I would have read  
15 reports or publications. That would have been my  
16 source. I was never -- I never personally  
17 encountered, as a patient, a haemophiliac who had had  
18 a bleed into the brain, but my understanding was that  
19 that was one of the most likely causes of death from  
20 a bleed.
- 21 **Q.** I think the next question probably follows logically  
22 from your -- the fact that you had no comments on the  
23 relevant part of the Council of Europe recommendation  
24 and from other things you have said but I'll ask it  
25 anyway.

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- 1 would still have to use or need to use concentrate on  
2 a number of cases.  
3 But certainly if supply had been no  
4 consideration, if there had been plenty of cryo, then  
5 it would be a perfectly reasonable and logical thing  
6 to say that's bound to be safer in terms of the  
7 UK population. The UK population, even if it has some  
8 donors in it who are actually incubating AIDS, if you  
9 like, carrying AIDS, it's bound to be less than the  
10 American concentrate, and you will be giving smaller  
11 pools, so hopefully you will be protecting patients  
12 better.
- 13 **Q.** Now, in your witness statement, I'm not going to put  
14 it up on screen because it is just one sentence but if  
15 you want to look at it, it is paragraph 86.53 I think,  
16 but it's on the issue of leafleting donors.
- 17 **A.** Yes.
- 18 **Q.** And some of the other measures that Dr Gunson had  
19 proposed and Regional Transfusion Directors rejected.  
20 You say that:  
21 "... the resistance from Directors arose from  
22 concerns about deterring donors from donating or  
23 causing them offence ..."  
24 And you refer to the stigmatising nature of  
25 homosexuality, the fact that it had only been

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- 1 Do you accept that patients, in particular  
2 haemophiliacs, always had the right to know about the  
3 risks of the products they were being treated with and  
4 the right to be informed of possible ways of  
5 mitigating that risk?
- 6 **A.** Absolutely.
- 7 **Q.** You were involved in medical education at a slightly  
8 later stage of your career.
- 9 **A.** Yes.
- 10 **Q.** Do you know what, if any, steps were being taken in  
11 the late 1980s/early 1990s to ensure that risks from  
12 blood and blood products were part and parcel of the  
13 medical curriculum?
- 14 **A.** No. Actually I had nothing to do with the  
15 undergraduate curriculum at all. It was postgraduate  
16 medical education that my work was involved with.
- 17 **Q.** Then in that period of time when you were Deputy Chief  
18 Medical Officer, so '89 to '92, before you went off to  
19 the Public Health Laboratory Service, do you know  
20 what, if any, steps were being taken to provide  
21 knowledge to the public or to clinicians about  
22 diagnosing non-A, non-B hepatitis or, indeed,  
23 hepatitis C, as it had by that point come to be known?
- 24 **A.** Well, I think -- with regard to hepatitis C, I think  
25 of course there was, round about that time, and I've

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1 been shown the papers, there was a non-A, non-B -- or  
2 hepatitis C look-back exercise, was then being carried  
3 out, which was -- its intention was to try to trace  
4 anyone who might have hepatitis C, not necessarily  
5 associated with blood products or blood but who might  
6 have developed hepatitis C, to find out who they were,  
7 to give them the opportunity for testing, and for --  
8 if necessary, referral on to liver departments.

9 **Q.** Are you aware of any steps being taken by the  
10 Department from the late 70s through, really, to the  
11 beginning of the 1990s, so in the multiple different  
12 capacities in which you were working, to influence or  
13 shape blood transfusion practice? So leave aside  
14 treatment with factor concentrates, but to perhaps try  
15 to ensure that people were not given transfusions  
16 unless absolutely necessary or were given all  
17 necessary advice and information about risks?

18 **A.** Yes. I can't remember the exact date, but at some  
19 stage the National Blood Authority was established.  
20 That then subsequently became the NHS Blood and  
21 Transplant, so there were stages in the evolution of  
22 that National Health Service and its overarching  
23 management.

24 Essentially, I would have supposed, although  
25 I wasn't associated with the work of the National

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1 example, in which case you'd want to rein that back,  
2 but my own personal sort of understanding was that it  
3 meant we should have enough plasma from our own  
4 voluntary donors to supply the needs of the  
5 haemophiliac population.

6 **Q.** At some point in the course of your evidence yesterday  
7 or on Monday, I think we looked at a document which  
8 talked about the reporting of cases of jaundice or  
9 hepatitis --

10 **A.** Yes.

11 **Q.** -- that was associated with non-A, non-B --

12 **A.** Yes.

13 **Q.** -- to the appropriate person within the Department,  
14 and we talked about that and you said you thought it  
15 would be the consultant adviser?

16 **A.** Yes.

17 **Q.** I omitted to ask you then, so I am asking you now,  
18 about the yellow card system.

19 **A.** Yes.

20 **Q.** How did that operate in this period 1977 to 1983, as  
21 far as you can recall?

22 **A.** I don't know how well it operated during that period.  
23 It was certainly up and running when I was in  
24 Medicines Division. It was early days for it but we  
25 did have a yellow card system and every British

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1 Blood Authority, that they would have been developing  
2 more and more sophisticated haemovigilance  
3 surveillance, which -- as I talked about, the serious  
4 hazards of transfusion. There was a virological  
5 safety, a blood committee. Things certainly improved  
6 as the time went on, but I can't -- because I can't  
7 fix the timeline, but absolutely I think the safety of  
8 blood was ramped up progressively as time went on.

9 **Q.** Back to self-sufficiency. Do you recall whether in  
10 the late 70s, beginning of the 1980s, when you were  
11 most closely involved with this issue, whether there  
12 was a clear understanding within the Department and  
13 those with whom they were interacting about what  
14 self-sufficiency actually meant, and did it include  
15 ensuring home treatment for all or include  
16 prophylactic treatment for all?

17 **A.** Well, I don't know that I ever personally queried it.  
18 I sort of had my own view. I thought we needed to use  
19 home-grown plasma to provide for whatever it was our  
20 patients, the haemophiliac patients, or anyone else  
21 who needed blood products, needed. Clearly, there is  
22 a distinction to be drawn between in need and absolute  
23 need, if you can define it, and a demand which might  
24 be or might not be appropriate. So it might have been  
25 that there was a luxurious waste of product, for

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1 pharmacopoeia, which was the sort of document which  
2 described the composition of all drugs contained  
3 a yellow card, which could be taken out and completed  
4 by the medical practitioner and sent back into the  
5 Department.

6 Now, obviously, it was only as good as people  
7 were prepared to use the yellow cards but it was  
8 a form of, obviously, surveillance after the drugs had  
9 been licensed. How much the cards were used by the  
10 Blood Transfusion Service, I just don't know.

11 **Q.** Would there have been, as far as you're concerned,  
12 an expectation that clinicians encountering  
13 post-transfusion hepatitis should report it using the  
14 yellow card scheme?

15 **A.** Well, I don't know whether they did or would, probably  
16 because they, as we saw at the time, it was so well  
17 understood, unfortunately, that post-transfusion  
18 hepatitis occurred, so it wasn't something that was  
19 a novel adverse reaction that needed -- you needed to  
20 alert Medicines Division that, look, here is  
21 a product, it's been licensed and suddenly we're  
22 finding that patients have all got thrombocytopenia,  
23 or something, their platelets have dropped through the  
24 floor. Those are cases that need to be reported.

25 If you have got an ongoing thing, and

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1 post-transfusion hepatitis, and the Chairman was good  
 2 enough to give me a paper dating from 1953 last night  
 3 to read, where, of course, post-transfusion  
 4 hepatitis B was well known, I doubt that that  
 5 reporting system would have been used because it would  
 6 be considered to be a fact that was known to everybody  
 7 that, unfortunately and hopefully unavoidably  
 8 post-transfusion hepatitis did happen.

9 **Q.** Hopefully the last question from me. It involves  
 10 looking back at a document we looked at on Monday or  
 11 Tuesday, NHBT0000068\_049. These are the minutes of  
 12 a "Working Party on Post-Transfusion Hepatitis",  
 13 25 June 1981. Can we go to page 5, please, Soumik.  
 14 Paragraph 4 -- yes, thank you, that's perfect.  
 15 I think we looked at this but there's a question  
 16 I didn't expressly ask you. So it's the paragraph  
 17 that says:

18 "Dr Craske concluded by saying that there was  
 19 little information about the incidence of symptomless  
 20 hepatitis and the relative risks of hepatitis due to  
 21 different brands of Factor VIII and IX."

22 Then there's the reference then to the  
 23 prospective study of patients, which I think I did ask  
 24 you about.

25 **A.** Mm-hm.

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1 patient, at the time that you were taking the sample  
 2 for their own clinical needs, do you mind if we retain  
 3 some of this sample to test for other things, and you  
 4 might specify what you were going to test for.

5 There was always a problem that you didn't  
 6 necessarily know what you were going to need to test  
 7 for until a circumstance arose, and I think that did  
 8 occur with AIDS, or HIV, as then it was the question.  
 9 Of course you didn't know that you were going to want  
 10 to test for HIV because you'd never heard of HIV but  
 11 you could perhaps get round that with a catch-all  
 12 consent that would you be happy if we store some of  
 13 the sample if it's left over from taking it for your  
 14 clinical needs, so that we can use it in any future  
 15 investigation or research, which would get round that  
 16 particular problem.

17 But in the days that we're talking about and  
 18 when this work was being done, it didn't appear to be  
 19 even a consideration. It was simply common practice  
 20 and considered to be good practice because you were  
 21 then in a position to say, well, you know, a year ago  
 22 did this patient who is now exhibiting this particular  
 23 problem have evidence of it in the serum and we hadn't  
 24 looked for it? So it was good practice. But  
 25 I certainly recognise that times changed and the

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1 **Q.** Then this:

2 "... and to provide a collection of well  
 3 documented sera and other specimens for the use in  
 4 development of serological tests for non-A, non-B  
 5 hepatitis."

6 **A.** Mm-hm.

7 **Q.** The question is this, and you were one of the DHSS  
 8 representatives, I think, at this meeting: did you see  
 9 at the time, and if you didn't do you see now, any  
 10 ethical issues associated with the collection of  
 11 stored sera or other specimens?

12 **A.** The specimens would have been taken for -- not  
 13 specifically for this test, for this surveillance, if  
 14 you will, the specimens would have been taken for the  
 15 clinical benefit of the patient. What I think is  
 16 being referred to here is the storing of the remainder  
 17 of a sample.

18 I mean, this was absolutely common practice. It  
 19 was considered to be good practice and it was  
 20 considered to be bad practice if you didn't do it.

21 Now, of course, ethics change and, over the  
 22 years -- and we've seen discussion of this in the  
 23 Inquiry, that what was at one stage considered not  
 24 only normal practice but good practice came to be seen  
 25 as unethical practice if you hadn't actually asked the

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1 ethics of the situation changed too.

2 **Q.** So would this be right: applying the ethical standards  
 3 of the time, it would, even by those standards, only  
 4 have been acceptable to collect sera or other  
 5 specimens if that was for the clinical benefit of the  
 6 patient?

7 **A.** It had to be for the clinical -- otherwise you were  
 8 doing a clinical trial.

9 **Q.** At the time the consent issues, that the Inquiry has  
 10 talked about and doing this without patients'  
 11 knowledge or consent, had not expressly occurred to  
 12 you -- and I'm really asking about your knowledge, I'm  
 13 not expecting you to speak for the entire medical  
 14 profession, but your knowledge --

15 **A.** No, and I think another way I could look at it is that  
 16 in haematology departments, nothing to do with  
 17 haemophilia, you collected an enormous amount of blood  
 18 samples and there was always something left over.  
 19 Those samples were really valuable, because how else  
 20 did you calibrate the machinery? If you had those  
 21 left over samples you had an option: either you  
 22 said -- and I don't think this is what we said to  
 23 ourselves at the time -- we have to get consent to  
 24 have them used to calibrate the machinery or we have  
 25 to throw them away. And it would be literally the

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1 choice: do you use them for good and sufficient  
2 purpose in them having been taken for the clinical  
3 care of the patient, a bit of sample is left over, can  
4 you use those to calibrate the machine so that you get  
5 accurate readings for the next time you want to use  
6 the machine, or do you just throw them away?  
7 Throwing it away seemed actually possibly more  
8 unethical than using it to calibrate the machine so  
9 that you got the right result. But we didn't, at the  
10 time, think about getting consent.  
11 Subsequently, even more that purpose, it became  
12 a requirement, if you like, to make sure that you got  
13 consent.

14 **MS RICHARDS:** Sir, those are the questions I am proposing  
15 to ask of the multiple questions that I have been  
16 invited to consider. Let me just turn to see if  
17 Ms Grey has anything. No.

18 Sir, do you have any questions?

19 **Questions from SIR BRIAN LANGSTAFF**

20 **SIR BRIAN LANGSTAFF:** Just one or two very general  
21 questions from me, if I may, Dr Walford.

22 The first one is really rather general. You  
23 were a civil servant, albeit a doctor, in a chain  
24 which went up to the Minister who took ultimate  
25 responsibility for everything that happened in The

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1 I certainly recall with some pleasure, actually,  
2 the exchanges of views that I could have with  
3 Mr Clarke, who was only too happy to hear a differing  
4 view and to have an exchange of -- a proper exchange,  
5 as opposed to: you are a civil servant and you should  
6 know your place.

7 **SIR BRIAN LANGSTAFF:** The second question, again, is  
8 a very general one. One of the difficulties, it might  
9 be thought, for those who need treatment for their  
10 haemophilia and it may be for other blood disorders --

11 **A.** Yes.

12 **SIR BRIAN LANGSTAFF:** -- is that they are not large in  
13 number. The division of the country into Regional  
14 Health Authorities, and quite a number, would tend to  
15 ensure that those Regional Health Authorities had  
16 concern, in particular, for the mainstream interests  
17 in their region.

18 **A.** Yes.

19 **SIR BRIAN LANGSTAFF:** What system might be better designed  
20 to serve the interests of what is a minority, whose  
21 interests need to be served, but if one applies the  
22 broad democracy of it, the local subsidiarity of it,  
23 it would simply get ignored, or wouldn't get very well  
24 looked after.

25 **A.** Yes. Well, there was an organisational arrangement

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1 Health Service.

2 **A.** Yes.

3 **SIR BRIAN LANGSTAFF:** It's often said that the role of the  
4 Civil Service is to speak truth unto politicians.

5 **A.** Yes.

6 **SIR BRIAN LANGSTAFF:** Are there any particular truths that  
7 you would have wished, reflecting back on your time in  
8 the Civil Service, to have been expressed to  
9 politicians in respect of the matters we are  
10 considering in this Inquiry?

11 **A.** Well, I think, insofar as I was briefing politicians  
12 face-to-face, I expressed my views. I believe  
13 I would -- I never felt inhibited about expressing my  
14 views. One needed to actually be there to do it and  
15 I wasn't always there. Let me take an example,  
16 an easy one if you like, that had I had the  
17 opportunity to be face-to-face with ministers over the  
18 rebuilding of BPL, I would have made my view that  
19 really we had no alternative but to rebuild BPL and  
20 that all this penumbra, this extraordinary amount of  
21 debate about the subject, was really surplus to  
22 requirements, because we needed to do it. I think for  
23 those ministers that I have had dealings with, should  
24 they be giving evidence, I hope they would be able to  
25 say that I did.

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1 called the Supra-Regional Services, and that was  
2 designed precisely to do what you say. So for rare  
3 diseases and possibly diseases not distributed  
4 uniformly round the country in any particular way,  
5 there were arrangements made whereby one particular  
6 region, for example, might host the central entity  
7 which was dealing with patients with particular rare  
8 disease.

9 It's one of the things, for example, when  
10 I mentioned in my statement that I was involved with  
11 setting up the regional bone marrow transfusion  
12 service, and these were being -- it was initially  
13 being treated as a supra-regional service because  
14 there were so few bone marrow transplant units, but  
15 they needed to be funded to a considerable extent.

16 So there was a number, a small number, of  
17 Supra-Regional Services which were set up specifically  
18 to deal with your particular point, that otherwise you  
19 would have patients in some part of the country who  
20 were really losing out because nobody was focusing on  
21 them.

22 **SIR BRIAN LANGSTAFF:** We've heard in this Inquiry how some  
23 people with haemophilia moved closer to Oxford, for  
24 instance --

25 **A.** Yes.

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1 **SIR BRIAN LANGSTAFF:** -- because they felt they were  
 2 guaranteed rather better treatment.  
 3 **A.** Yes.  
 4 **SIR BRIAN LANGSTAFF:** That wouldn't have been necessary  
 5 unless the region had been in some way not treating  
 6 them quite so well as others.  
 7 **A.** I mean, you really need a critical mass of patients  
 8 with a particular illness to know how to treat them  
 9 well. I mean, it was always one of the problems that,  
 10 for example -- again, let me take one from my time in  
 11 the Department.  
 12 Surgeons, general surgeons, were treating breast  
 13 cancer wherever the patients turned up in the  
 14 hospital, and the results were poor. The only time  
 15 that you got improvements were where you had  
 16 a critical mass of patients, you had the appropriate  
 17 research being done, the funding from the research  
 18 councils and -- Medical Research Council Trials Unit.  
 19 If you didn't have -- with rare-ish conditions, if you  
 20 didn't have centres of excellence and expertise, the  
 21 patients would come off very badly. It might be that  
 22 they were more conveniently served by their local  
 23 district hospital, but you wouldn't really want to end  
 24 up there because there wasn't the expertise.  
 25 **SIR BRIAN LANGSTAFF:** Yes. Thank you.

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1 **SIR BRIAN LANGSTAFF:** Leave aside the last.  
 2 **A.** Yes.  
 3 **SIR BRIAN LANGSTAFF:** Let me just deal with each of the  
 4 other four.  
 5 **A.** Mm-hm.  
 6 **SIR BRIAN LANGSTAFF:** The selection of donors in this  
 7 country, from what you have said -- and I just want to  
 8 know if this is right or not -- the selection of  
 9 donors was largely left to regions who might vary  
 10 considerably in the practice of who they took blood  
 11 from?  
 12 **A.** Yes.  
 13 **SIR BRIAN LANGSTAFF:** You've described them as fiefdoms.  
 14 They might ask different would-be donors different  
 15 questions as to whether they should or shouldn't give  
 16 blood, hence the reluctance of many to ask about  
 17 certain practices; is that right?  
 18 **A.** Well, there was guidance, and I haven't got the  
 19 chapter and verse on that, but undoubtedly there was  
 20 guidance put out about the sort of questions that  
 21 should be asked of donors. The sort of approach you  
 22 should take, by -- the Blood Transfusion Service  
 23 should take towards donors. I don't think it was  
 24 really the Wild West, as it may have appeared, and  
 25 I certainly hope I didn't contribute to that -- the

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1 Let me turn to something else, and it does  
 2 reflect on the document which I sent through to you.  
 3 I didn't want you to spend a lot of time just browsing  
 4 through the whole of it but this was a report from WHO  
 5 in 1952, published in 1953 as it happens.  
 6 **A.** Yes.  
 7 **SIR BRIAN LANGSTAFF:** But it was dealing with the measures  
 8 that might be taken to, amongst other things --  
 9 **A.** Yes.  
 10 **SIR BRIAN LANGSTAFF:** -- might be taken to reduce  
 11 hepatitis.  
 12 **A.** Hepatitis B, yes.  
 13 **SIR BRIAN LANGSTAFF:** Well, serum hepatitis. They didn't  
 14 know it was hepatitis B, did they, at the time?  
 15 **A.** No, but that was the term that, over many years, was  
 16 used for hepatitis B. But you are quite right, they  
 17 couldn't test for it.  
 18 **SIR BRIAN LANGSTAFF:** So, so far as serum hepatitis was  
 19 concerned, the first of those of the  
 20 recommendations -- there were five I think -- and  
 21 I want to go through each of them in turn. There  
 22 was: donor selection; there was pool size, control of  
 23 pool size; treatment of plasma; records and  
 24 record-keeping; and the sterilisation of equipment.  
 25 **A.** Yes.

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1 sort of feeling that it was an uncontrollable state of  
 2 affairs.  
 3 I think the Inquiry will be able to find  
 4 guidance, quite a bit of guidance, which was being  
 5 used across the board in the Blood Transfusion  
 6 Service.  
 7 **SIR BRIAN LANGSTAFF:** I mean, I suspect that there was  
 8 a degree of commonality of behaviour but also a degree  
 9 of exceptionality. So it might be not quite  
 10 a postcode lottery, I wouldn't want to use that  
 11 phrase, but it did differ from region to region?  
 12 **A.** To an extent it must have done because they were  
 13 fairly autonomous, but I think there was a general  
 14 understanding on the part of Regional Transfusion  
 15 Directors -- and they did meet together and they had  
 16 met together for many years -- of what was and was not  
 17 the right sort of the practice.  
 18 But it will be possible to find out from the  
 19 Blood Transfusion Service what guidance was available  
 20 from what date. Now, obviously they probably don't  
 21 have stuff going back to 1952 --  
 22 **SIR BRIAN LANGSTAFF:** Of course, the principles or the  
 23 suggestions by WHO are generalisable to any serious  
 24 virus that might be transmitted by blood or blood  
 25 products?

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1 A. Yes, absolutely.

2 **SIR BRIAN LANGSTAFF:** So, so far as donor selection is

3 concerned, it took the efforts you have described as

4 being too slow, to issue the leaflet, to advise people

5 to defer and not give donations if they fell into

6 certain high risk groups.

7 A. Yes.

8 **SIR BRIAN LANGSTAFF:** So it might be said that it was less

9 than entirely satisfactory from the point of view of

10 controlling infection through blood.

11 A. That's true but of course we need to remember that for

12 many, many years, the Blood Transfusion Service was

13 testing, for example, for syphilis, which might be --

14 at the time be considered as stigmatising, if you

15 will. So, actually, I believe it would be quite

16 useful, certainly not to rely on what I can say about

17 which is not as much as you obviously would need, to

18 see what the National Blood Transfusion can tell you

19 how a -- Service can tell you about how matters were

20 harmonised, to a degree, and the times in which they

21 were not harmonised, but I'm not sure I can help.

22 **SIR BRIAN LANGSTAFF:** We are yet to come, I think, to that

23 evidence.

24 So far as pool sizes were concerned, I think the

25 WHO had in mind a maximum of 300 donors to a pool,

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1 something transmitted by blood, which was viral --

2 A. Yes.

3 **SIR BRIAN LANGSTAFF:** -- which was causing non-A, non-B,

4 the subject close to your heart.

5 A. Yes. Yes, on non-A, non-B, I think it might be worth

6 saying that there is some evidence from the material

7 that I've seen that, after you got past, some say,

8 250/300 donors, 300 donations having been received by

9 the patient, then even in the UK non-A, non-B was

10 probably inevitable. That's because of the

11 prevalence, the wide prevalence of non-A, non-B, as it

12 turned out in the population, which once one could

13 measure it, was about 0.5 per cent.

14 **SIR BRIAN LANGSTAFF:** Otherwise, it might seem that as

15 awareness of the virus was increasing in one branch of

16 those who had knowledge and the other branch,

17 manufacturing the product, was actually steadily

18 increasing the pool size.

19 A. That's right.

20 **SIR BRIAN LANGSTAFF:** Who would have been in the position

21 to have said, "Look, you are telling me the risk

22 increases with the pool size, Dr Owen told us when he

23 came that that's what he thought, but lo and behold

24 you are actually increasing pool size"?

25 A. Yes, yes. I think your question would be, as it were,

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1 maybe even less?

2 A. It was less. I think talking about ten donors in

3 a pool.

4 **SIR BRIAN LANGSTAFF:** Am I pretty right in my

5 understanding that it was, by and large, by 1970, it

6 was still having that sort of pool size and then it

7 began rapidly to increase with the demands of

8 producing factor concentrate domestically?

9 A. Yes, I think it was from the, sort of, late '70s the

10 pool size for UK -- UK fractionation -- sort of grew

11 from 400 and then incrementally grew to 1,000 and then

12 maybe I think at maximum, but again that would need

13 checking, to about 5,000, which of course compared

14 favourably, you might say, with the size of the pools

15 in America.

16 **SIR BRIAN LANGSTAFF:** That was going to be my next

17 question. Obviously, you may not have known precisely

18 how large the American pools were but they were, for

19 commercial efficiency --

20 A. Yes, yes.

21 **SIR BRIAN LANGSTAFF:** -- they were rather larger?

22 A. Very much.

23 **SIR BRIAN LANGSTAFF:** So throughout the 1970s, the picture

24 would be one of increasing pool size but also

25 increasing awareness of the fact that there might be

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1 best addressed to the Licensing Authority because

2 essentially this was a product issue. If the -- and

3 of course NIBSC, and I gather you will be hearing from

4 NIBSC, that -- for reasons which I can't determine and

5 I don't know, the fact that there were large-pool

6 size, that the large-pool size did appear to increase

7 the risk both of non-A, non-B and of, obviously when

8 we came to it, of AIDS, that this wasn't something

9 that the Licensing Authority had decided to say "We

10 cannot accept products made from pools this big", now,

11 that would have been for them to make that call.

12 **SIR BRIAN LANGSTAFF:** The third one was the treatment of

13 plasma. Now, we know that, so far as albumin

14 production was concerned, that was treated.

15 A. Heat-treated.

16 **SIR BRIAN LANGSTAFF:** And it may have been some

17 immunoglobulins had some form of treatment. But as

18 a matter of fact, until the rise of pasteurisation,

19 early attempts, and heat treatment in the early 80s,

20 nothing was actually done to treat -- successfully to

21 treat plasma --

22 A. Yes.

23 **SIR BRIAN LANGSTAFF:** -- in respect of the viral risks of

24 hepatitis or whatever?

25 A. If you're referring to coagulation factor concentrates

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1 like Factor VIII and --  
 2 **SIR BRIAN LANGSTAFF:** Yes.  
 3 **A.** The problem was that that was a very, very complex  
 4 thing to do.

5 **SIR BRIAN LANGSTAFF:** I think we'll probably ask the  
 6 fractionators about it.

7 **A.** Yes.

8 **SIR BRIAN LANGSTAFF:** All I am really saying is, as  
 9 a matter of fact --

10 **A.** As a matter of fact, yes, albumin was treated and  
 11 could be sterilised at 60 degrees for a number of  
 12 hours, and it worked. As a matter of what happened  
 13 during the course of the time that I know about, if  
 14 you will, essentially non-A, non-B appeared not to be  
 15 very heat-susceptible, and basically an enormous  
 16 amount of work had to go into trying to find a way to  
 17 protect the protein and at the same time to destroy  
 18 the non-A, non-B.

19 I'll just finish by saying, because it seems to  
 20 me such a great pity, that because of the experience  
 21 that fractionators had with trying to get rid of  
 22 non-A, non-B and finding that they had to heat for  
 23 a very long time at a high temperature and protecting  
 24 the protein and major loss of yield, and because you  
 25 could not actually test for HIV and therefore you

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1 the hospital blood banks rather than at the Regional  
 2 Transfusion Centres, and we were sort of alerted to  
 3 this by a scandal, if that's the right word, at the  
 4 National Heart and Chest Hospital, I think it was  
 5 called in those days, where there appeared to be  
 6 potentially some sale of blood to the private sector  
 7 going on and I was asked to get in touch with  
 8 Dr Wagstaff to get it investigated very quickly. It  
 9 turned out that the record-keeping at the Regional  
 10 Transfusion Centres was not bad at all and they knew  
 11 where they had sent the blood.

12 What was a problem was that the record-keeping  
 13 at the hospital blood banks was not good and they were  
 14 supposed to return outdated plasma to the Regional  
 15 Transfusion Centres and they were certainly supposed  
 16 to say what was the end user of whatever was the unit  
 17 of blood, and that information wasn't getting back  
 18 consistently to Regional Transfusion Centres and that  
 19 was obviously a major issue which needed attention.

20 **SIR BRIAN LANGSTAFF:** That would apply to -- really, you  
 21 emphasise it, I think in an answer you gave to counsel  
 22 just before the end, that the successful means of  
 23 controlling what might be a real threat in blood has  
 24 to depend critically upon good records, and we didn't  
 25 really have as good a system as we might have done.

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1 couldn't do a spiking test to put HIV into plasma,  
 2 heat it up and see if you could get rid of it, the  
 3 assumption -- it took an awful lot longer to introduce  
 4 heat-treated coagulation factor, certainly  
 5 Factor VIII, than it might have done, because HIV  
 6 turned out to be much more susceptible to heat.  
 7 Unfortunately, though, before you could test for HIV,  
 8 you couldn't do the experiments which showed that it  
 9 was. So you might have introduced heat-treated  
 10 concentrate sooner in order to deal with AIDS even if  
 11 you couldn't deal with non-A, non-B. But it was two  
 12 epidemics proceeding in parallel.

13 **SIR BRIAN LANGSTAFF:** The fourth, the question of records,  
 14 you've dealt with your concerns about record-keeping  
 15 in your statement.

16 **A.** Yes.

17 **SIR BRIAN LANGSTAFF:** And for those who want to refer to  
 18 it, it's your section 41, page 120. I don't think we  
 19 need to go there and look at I because you know very  
 20 well what you have written.

21 **A.** I can remember.

22 **SIR BRIAN LANGSTAFF:** But you had quite a number of  
 23 concerns about the absence of records or the poor  
 24 record-keeping.

25 **A.** Yes, well, it was largely the poor record-keeping at

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1 **A.** Absolutely.

2 **SIR BRIAN LANGSTAFF:** That, I think, is what you are  
 3 saying.

4 **A.** Yes.

5 **SIR BRIAN LANGSTAFF:** Right. The last question -- the  
 6 last area of questions that I want to ask you about --  
 7 I'm sorry to take so long -- but is about the sources  
 8 of information which came in to the various  
 9 departments of the Civil Service that were looking at  
 10 the questions of blood. Obviously there were aspects  
 11 of your work which overlapped with the aspects of HS1,  
 12 HS2 of Med IMDB, and so on.

13 Did information ever reach you, for instance, or  
 14 if so, when, about the activities of Luc Montagnier in  
 15 Paris, the report of 20 May 1983, that he had  
 16 discovered a viral particle associated with -- in the  
 17 usual classical way that scientists draw attention to  
 18 something that might be causal -- associated with the  
 19 symptoms of AIDS?

20 **A.** Mm-hm.

21 **SIR BRIAN LANGSTAFF:** When did you first hear of that, do  
 22 you remember?

23 **A.** Well, I would have read about it because obviously  
 24 I was then all eyes and ears trying to find out as  
 25 much as I could.

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1 I would have read about it. It was written up.  
 2 It didn't receive the kind of, you know, thunder clap,  
 3 this is it, and of course, as you know, then it wasn't  
 4 until Gallo isolated what appeared to be the same  
 5 entity and then there was a huge spat between the men  
 6 as to who got there first but, certainly, I knew about  
 7 it and, of course, I think, probably through the MRC  
 8 hepatitis, or the MRC working party that I was on,  
 9 I think they spoke about it.

10 But I had read about it at the time and  
 11 I actually think I probably mentioned it in one of the  
 12 briefing papers. I think we saw it just not so long  
 13 ago, which said, the question is: is this HTLV-III  
 14 entity actually the cause of AIDS or is it a passenger  
 15 which is opportunistic, if you like, which is there  
 16 like so many of the other viruses that were associated  
 17 with patients who developed AIDS, and it just happened  
 18 to be a fellow traveller, if you like, and not the  
 19 causal agent. For some time there was debate about  
 20 whether it was the causal agent.

21 **SIR BRIAN LANGSTAFF:** That presumably will be after Gallo  
 22 had done his work --

23 **A.** Yes.

24 **SIR BRIAN LANGSTAFF:** -- because that's where the name  
 25 HTLV-III came from, as I understand it.

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1 Finland, in Denmark, in Sweden, in Italy, in Germany,  
 2 that might be of interest to you in SEB --

3 **A.** Yes.

4 **SIR BRIAN LANGSTAFF:** -- would you expect to be told?

5 **A.** Yes.

6 **SIR BRIAN LANGSTAFF:** By that branch?

7 **A.** Hopefully. Hopefully, yes.

8 **SIR BRIAN LANGSTAFF:** Would they know what to look out for  
 9 and how would they do that?

10 **A.** Well, they would obviously be picking up intelligence,  
 11 and I don't know how that intelligence would be  
 12 related to them, but presumably they would have been  
 13 hearing the Council of Europe reports, and there were  
 14 some reports then on how many cases that there were.

15 But there was something that you've just  
 16 prompted me to think about, if I could now just call  
 17 it to mind, and that was, of course, we did get some  
 18 intelligence back from Dr Gunson, who was also  
 19 reporting back from the international conferences --  
 20 oh, yes, I know what it was. It was -- what came to  
 21 me as a real surprise was that Med IMCD had some kind  
 22 of relationship, intelligence-exchanging relationship,  
 23 with the scientific adviser at the American embassy.  
 24 And I had no idea that they had that, and that is  
 25 where I think they were getting quite a lot of their

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1 **A.** Yes, but I see that I was briefing about it at the  
 2 time, actually.

3 **SIR BRIAN LANGSTAFF:** So do you think you knew about LAV  
 4 or Montagnier's description of the same particle?

5 **A.** Yes, I think I probably did, yes. It didn't somehow  
 6 come as a surprise to me, yes.

7 **SIR BRIAN LANGSTAFF:** Do you happen to know whether you  
 8 learnt about it before the committee on the -- the  
 9 Biological Subcommittee of the CSM?

10 **A.** I probably -- well, whenever it was published.  
 11 I don't know when it was published actually.

12 **SIR BRIAN LANGSTAFF:** It was -- 20 May '83 it was  
 13 published in Science, I think.

14 **A.** Right. Well, I probably knew about it round about the  
 15 same time.

16 **SIR BRIAN LANGSTAFF:** The other question is, I notice one  
 17 of the papers we looked at that there was an  
 18 international division --

19 **A.** Yes.

20 **SIR BRIAN LANGSTAFF:** -- in the Department.

21 **A.** Yes.

22 **SIR BRIAN LANGSTAFF:** Now, that would pick up intelligence  
 23 from other health systems around the world?

24 **A.** Yes.

25 **SIR BRIAN LANGSTAFF:** So if matters had been happening in

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1 information about what was going on in America, this  
 2 Dr Norton, whom I'd never heard of before, and  
 3 I didn't know that Dr Field had, as it were, his  
 4 finger on the pulse in that way. That was an --  
 5 interesting.

6 Whether or not the international division also  
 7 had their agents scattered around in other countries,  
 8 I have no idea.

9 **SIR BRIAN LANGSTAFF:** So you picked up about Spain from  
 10 reading The Lancet, those haemophiliacs in Spain who  
 11 had AIDS --

12 **A.** Well, I didn't, alas, pick it up, because I think  
 13 I didn't know about the -- when The Lancet published  
 14 that, it was late April or something of that sort.

15 **SIR BRIAN LANGSTAFF:** Yes.

16 **A.** I did not pick it up at that time because I never  
 17 necessarily got The Lancet as The Lancet was  
 18 published. That's one of the reasons why I just don't  
 19 know how -- I don't know how it was that that briefing  
 20 was prepared that we were talking about before.  
 21 I think -- obviously somebody had picked it up from  
 22 The Lancet, but it wasn't me. So I did find out about  
 23 it, of course, subsequently, and Spence Galbraith  
 24 referred to it, but at the time I hadn't read it.  
 25 I didn't actually read The Lancet on the dot because

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1 didn't have it on the dot.

2 **SIR BRIAN LANGSTAFF:** The practices of other European

3 countries, which might have been inclined to take

4 a concentrate from commercial suppliers, they would

5 have been known, would they, through the international

6 division, through to you, or how would that

7 information have come?

8 **A.** Well, I don't know what the international division

9 knew, to be honest, but I know what Gunson reported

10 back and of course we also then got (and it turned

11 out, unfortunately, misleadingly) some information

12 through from Professor Bloom, who was doing his own

13 survey and, as you know, he reported back and he said

14 that there had been no cases in Germany, although the

15 German use of concentrate was something -- ten times

16 the use -- American concentrate was ten times the use

17 in the UK and he reported there were no cases.

18 That was of considerable comfort, I have to say,

19 because it seemed -- you know, wasn't sure what the

20 phenomenon was we were looking at but Germany wasn't

21 experiencing it, apparently, from the survey that he'd

22 done.

23 **SIR BRIAN LANGSTAFF:** Yes. Well, that's all that I have

24 to ask.

25 **MS RICHARDS:** Dr Walford, no more questions from me. Is

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1 course, I am profoundly sorry.

2 **MS RICHARDS:** Thank you, Dr Walford.

3 Sir Brian.

4 **SIR BRIAN LANGSTAFF:** We've asked a lot of you in so many

5 ways, and I need to put on record my thanks to you for

6 all that. I have to say that one of the demands that

7 we have placed upon you, and which you have gladly

8 accepted, as your last words indicate, is going

9 through with meticulous attention a huge bundle of

10 documents, many of which you will have seen before but

11 some of which you haven't, and your mastery of those

12 and attention to detail, I have to say, is hugely

13 impressive.

14 **A.** Thank you.

15 **SIR BRIAN LANGSTAFF:** I wish that all witnesses that

16 I have heard had been as diligent.

17 Your retention and memory, again something which

18 began so many years ago for you, and you've done so

19 many other things since, is something which I stand in

20 some awe of. You've been ready to accept matters

21 where they needed to be accepted. You haven't been

22 frightened to express your pretty firm views on

23 a number of topics and you've done all this while

24 being challenged by your voice, which hasn't given

25 out. I think you have warmed to your topic but I see

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1 there anything you would like to add?

2 **A.** Well, if anyone can stand hearing any more from me,

3 I could say one or two words, if you permit me.

4 I just want to say that for those of you who

5 have read my statement, at the beginning of my

6 statement I said that I hoped that this Inquiry would

7 produce some long-sought answers for the people who

8 have suffered so much and for whom the lack of clear

9 answers to their questions has contributed so much to

10 their distress, which is why, in my evidence over the

11 past days and in my very detailed statement, I have

12 tried to use, to the greatest extent possible,

13 evidence from the contemporary notes, not simply from

14 my memory, which was obviously deficient in many

15 respects.

16 I've also tried, in my evidence, to explain the

17 context in which those records were created. It was

18 a very different world, not just technologically but

19 from a societal point of view also.

20 So I hope that in some small way my testimony

21 has been helpful in providing some of those answers.

22 But what I really want to say is that if there is

23 anything that I said, or did, or did not say, or did

24 not do that has contributed in any way to the

25 suffering of those affected or their families then, of

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1 your husband is laughing at the thought your voice

2 might ever give out! Perhaps I'm doing you

3 an injustice.

4 In any event, thank you very much for all that

5 and for giving us your time, which brings me to the

6 last matter, which I'm sorry that we have to finish so

7 late, but thank you for your perseverance, again

8 without any sense of complaint. So thank you.

9 **A.** Thank you, sir. Thank you.

10 **MS RICHARDS:** We have Lord Glenarthur giving evidence

11 tomorrow with a 10.00 start.

12 **SIR BRIAN LANGSTAFF:** So 10.00. 10.00 tomorrow.

13 (6.15 pm)

14 (Adjourned until 10.00 am the following day)

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<p><b>MS RICHARDS: [36]</b> 1/5 8/1 9/1 10/8 10/21 10/25 17/4 20/4 53/6 53/17 57/24 58/3 101/8 103/17 116/16 116/24 118/19 120/20 120/24 121/2 129/24 147/13 149/22 172/4 174/2 174/8 178/17 195/17 195/24 196/4 196/9 213/9 225/14 245/25 247/2 248/10</p> <p><b>SIR BRIAN LANGSTAFF: [127]</b> 7/24 8/17 10/5 10/9 10/23 14/17 15/5 15/7 16/16 16/25 17/5 18/7 19/5 19/24 20/3 49/11 50/25 51/9 51/12 51/16 51/24 52/1 52/11 53/1 53/12 57/22 57/25 99/2 99/5 99/8 99/16 99/24 100/4 100/10 100/14 100/16 100/19 100/23 101/5 101/7 103/16 115/21 116/4 116/6 116/10 116/15 116/19 118/14 120/17 120/21 121/1 128/15 147/12 149/12 149/16 149/19 172/12 172/15 173/21 173/24 174/4 178/16 195/22 196/2 213/7 225/20 226/3 226/6 227/7 227/12 227/19 228/22 229/1 229/4 229/25 230/7 230/10 230/13 230/18 231/1 231/3 231/6 231/13 232/7 232/22 233/2 233/8 233/22 234/4 234/16 234/21 234/23 235/3 235/14 235/20 236/12 236/16 236/23 237/2 237/5 237/8 238/13 238/17 238/22 239/20 240/2 240/5 240/21 241/21 241/24 242/3 242/7 242/12 242/16 242/20 242/22 242/25 243/4 243/6 243/8 244/9 244/15 245/2 245/23 247/4 247/15 248/12</p> <p><b>'70s [1]</b> 234/9 <b>'77 [1]</b> 193/10 <b>'78 [1]</b> 87/17</p>	<p><b>'78/'79 [1]</b> 87/17 <b>'79 [1]</b> 87/17 <b>'83 [8]</b> 8/18 71/9 71/10 147/12 147/13 193/10 212/22 242/12 <b>'89 [1]</b> 216/18 <b>'92 [1]</b> 216/18 <b>'agenda' [2]</b> 79/9 80/5 <b>'dangerous' [1]</b> 34/2 <b>'dump' [1]</b> 37/16 <b>'Epidemic' [1]</b> 70/24 <b>'future' [1]</b> 103/10 <b>'haemophiliac' [1]</b> 75/21 <b>'incubating' [1]</b> 75/23 <b>'It [1]</b> 152/17 <b>'let [3]</b> 121/21 126/17 127/14 <b>'let-out' [3]</b> 121/21 126/17 127/14 <b>'not [1]</b> 82/17 <b>'possibilities' [1]</b> 81/24 <b>'post [1]</b> 46/23 <b>'rare [2]</b> 5/24 7/22 <b>'there [1]</b> 153/2 <b>'tip' [2]</b> 9/15 10/17</p> <p>...</p> <p><b>[2]</b> 12/6 31/21</p> <p><b>0</b></p> <p><b>0.5 per cent [1]</b> 235/13 <b>006 [1]</b> 35/23 <b>016 [1]</b> 187/3 <b>017 [1]</b> 108/9 <b>018 [1]</b> 167/23 <b>019 [1]</b> 44/6 <b>020 [2]</b> 47/13 104/1 <b>030 [1]</b> 57/1 <b>032 [2]</b> 149/11 149/22 <b>034 [1]</b> 73/5 <b>038 [1]</b> 42/16 <b>041 [1]</b> 70/1 <b>048 [1]</b> 152/2 <b>049 [1]</b> 221/11 <b>051 [1]</b> 66/18 <b>052 [1]</b> 35/4 <b>054 [1]</b> 146/22 <b>055 [1]</b> 70/9 <b>059 [2]</b> 74/20 174/9 <b>067 [1]</b> 116/25 <b>085 [1]</b> 147/9 <b>097 [1]</b> 102/23</p> <p><b>1</b></p> <p><b>1 June [2]</b> 42/17 120/18 <b>1 June 1985 [1]</b> 119/24 <b>1 November 1983 [1]</b></p>	<p>152/5 <b>1,000 [1]</b> 234/11 <b>1-3 [1]</b> 6/21 <b>1.10 pm [1]</b> 116/21 <b>10 [2]</b> 5/23 48/7 <b>10 per cent [1]</b> 210/17 <b>10.00 [5]</b> 1/2 248/11 248/12 248/12 248/14 <b>100 per cent [2]</b> 4/22 4/24 <b>1000 [1]</b> 6/12 <b>11 [4]</b> 6/2 49/1 61/3 87/19 <b>11.15 [1]</b> 53/14 <b>11.45 [1]</b> 53/13 <b>11.46 [1]</b> 53/16 <b>12 [1]</b> 6/7 <b>12 months [1]</b> 6/20 <b>120 [1]</b> 238/18 <b>122 [1]</b> 31/1 <b>123 [1]</b> 146/18 <b>13 [1]</b> 121/3 <b>13 July [5]</b> 63/11 79/4 83/2 107/12 111/12 <b>13 July 1983 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