

Tuesday, 28 September 2021

(10.00 am)

**Presentation by Counsel to the Inquiry on the Pharmaceutical Companies (continued)**

**SIR BRIAN LANGSTAFF:** Yes, Mr Hill?

**MR HILL:** We are going to continue today, sir, with the presentation on the Hyland and Travenol products. When I finished on Friday, I was just about to move to Hemofil-M and it's perhaps worth reminding everybody what the product was. It was described by Dr Kingdon in his draft witness statement as being:

"A product produced as a result of the solvent detergent method, which had been licensed from a New York blood centre by Hyland Travenol. He described it as a freeze-dried high purity concentrate in which lipid enveloped viruses were dissolved using the NYBC process, prior to fractionation. The process was adopted in order to inactivate non-A, non-B hepatitis in the plasma pools."

That is the reason why that method was used. If we could have on screen, please, Soumik, SHPL0000409\_072 -- let me try again SHPL0000409\_072.

**SIR BRIAN LANGSTAFF:** 409, did you say?

**MR HILL:** Yes, sir, SHPL0000409.

**SIR BRIAN LANGSTAFF:** I think the 0 in the 409 got

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concerns the crossover between Hemofil-T and Hemofil-M. It says the following with reference to a previous memo:

"Hyland believe that FDA licence could be issued by the end [November] 1987."

We understand that to be a reference to an FDA licence for Hemofil-M.

"Hopefully, UK customers will commence usage on a 'named-patient' basis ..."

**SIR BRIAN LANGSTAFF:** I'm missing something, am I? Where does it say --

**MR HILL:** There's a problem with the referencing again.

Soumik, can we have SHPL0000409\_072.

Yes, sorry, I brought up the wrong document there. So 20 October 1987, an internal Travenol document, Travenol Laboratories, the UK company, with a reference to a memorandum of 12 October:

"Hyland believe that FDA licence could be issued by the end [of November] 1987.

"Hopefully UK customers will commence usage on a 'named-patient' basis once 'M' has FDA approval, premium price makes this very limited.

"Hemofil-T (Heat-treated) [that is the product we were looking at on Friday] not accepted by market place -- poor solubility and record on viral safety.

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missing.

**MR HILL:** Sir, it appears that there seems to be a technical glitch and we can't bring the actual document up, but I think I can describe it to you without presenting it on the screen. It is a memorandum, an --

**SIR BRIAN LANGSTAFF:** Just pause for a moment. Is it a technical glitch which affects only this document or is it a more general one?

**MR HILL:** We checked for documents this morning and they all seemed to be present. We think this document is corrupted.

**SIR BRIAN LANGSTAFF:** Right.

**MR HILL:** Can I just try the next document that we're going to go to and see whether or not this is a more widespread problem. Let's try SHPL0000293\_141.

**SIR BRIAN LANGSTAFF:** Right, we'll just take a break.

**MR HILL:** Thank you, sir.

(10.03 am)

(A short break)

(10.08 pm)

**SIR BRIAN LANGSTAFF:** Right, let's start again.

**MR HILL:** Can we have on screen, please, Soumik SHPL0000409\_072, please. This is an internal Travenol Laboratories document dated 28 August 1987 and it

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"'Armour' (major competitor is Monoclonal productions) do not have FDA licence either ..."

But the marginalia shows that that licence was granted after the memo had been typed.

"In view of the above, we must submit our licence application without delay once data collated ..."

We can see there, sir, again, there is going to be reliance placed on the named-patient basis, at least until a licence is obtained.

On 7 December 1987 -- Thank you, Soumik, that can be taken off the screen.

On 7th December 1987 --

**SIR BRIAN LANGSTAFF:** Can you just help: do we know any more about the record on viral safety referred to there, poor record on viral safety?

**MR HILL:** I understand that to be a reference to the transmission of non-A, non-B hepatitis, which by 1987 was recognised that Hemofil-T was still transmitting non-A, non-B hepatitis.

**SIR BRIAN LANGSTAFF:** Being a poor record which was not accepting -- the marketplace not accepting it would mean that other products, by rival competitors, were better, presumably?

**MR HILL:** Presumably, yes. The market please seems to

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1 have reacted not just to the lack of the good record  
2 on viral safety but also the solubility of the  
3 product.

4 **SIR BRIAN LANGSTAFF:** Yes.

5 **MR HILL:** But certainly by 1987, there was an acceptance  
6 that VIIIY, the NHS product, for example, was --

7 **SIR BRIAN LANGSTAFF:** I follow that that's so in the UK.  
8 Is this memo just talking about the UK? It talks  
9 about FDA approval.

10 **MR HILL:** It does but it is an internal Travenol  
11 Laboratories Limited -- so the UK company --  
12 memorandum. The reference to the FDA, I understand,  
13 in this context, to be useful to them in order to  
14 market the product in the UK, by pointing to the fact  
15 that the FDA have licensed it.

16 **SIR BRIAN LANGSTAFF:** Yes.

17 **MR HILL:** On 7 December 1987, Hyland and Travenol Limited  
18 applied for a clinical trial exemption for Hemofil-M  
19 in conjunction with Dr Savidge at St Thomas' Hospital.  
20 That was granted on 20 January 1988 for a period of  
21 three years, that's SHPL0000496\_191, but, of course,  
22 just a few months that memorandum that we've just been  
23 looking at.

24 The application for the full product licence was  
25 made on 12 June 1989, so some 18 months after that

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1 This is a document from 21 May 1990 from  
2 Patrick Rafferty, who was medical director with  
3 Baxter, to Ron Feakes at Thetford. It's an internal  
4 memo. By this stage the company's name has changed  
5 from Travenol Limited to Baxter Healthcare Limited.

6 What Dr Rafferty says in the memorandum is this:

7 "In my capacity as Medical Director in order to  
8 understand more fully the clinical management of  
9 haemophilia patients and the potential role for highly  
10 purified in the centre of their haemostasis, I have  
11 met with most of the Haemophilia Centre Directors over  
12 the past few months.

13 "Following these meetings I have received  
14 a number of enquiries relating to the effects of  
15 monoclonally purified Factor VIII:C on the levels of  
16 Hepatitis C antibodies in patients ... If this  
17 relationship exists, and if monoclonally purified  
18 Factor VIII:C is confirmed as being effective in  
19 significantly reducing or eliminating the levels of  
20 Hepatitis C antibody in these patients, then as  
21 Medical Director I have a moral obligation to bring  
22 this to the attention of the clinical experts who were  
23 responsible for the management of Haemophilia  
24 patients.

25 "My understanding is that the Baxter

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1 memorandum. The reference is SHPL0000496\_149. The  
2 application was initially refused on regulatory  
3 grounds as it was considered to be a high technology  
4 product under European law and consequently subject to  
5 a separate licensing regime which the product then  
6 went through. The licence was eventually awarded in  
7 1994.

8 I'm not going to go through all of the detail in  
9 respect of that. I will give the references to the  
10 original application, which is SHPL0000496\_149, and  
11 then SHPL0000293\_182 and SHPL0000468\_464, those are  
12 the main documents which show what happened to that  
13 application.

14 Of relevance to the Inquiry is the fact that the  
15 product was still available in this period between  
16 1989 and 1994 when the licensing process was going  
17 through its motions. It was still available on  
18 a named-patient basis.

19 A DHSS note dated 14 November 1989 said that  
20 Baxter were supplying approximately 2 million  
21 international units of their unlicensed product to the  
22 UK each year. We understand that to be a reference to  
23 Hemofil-M. The reference for that is DHSC0003412\_077.

24 Soumik, could we have on screen, please,  
25 SHPL0000293\_141. Page 2 of that document, please.

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1 monoclonally purified Factor VIII:C, Hemofil M, is  
2 currently not yet licensed in the UK -- perhaps you  
3 could advise on of the most ethical approach for me to  
4 take in this regard, whilst meeting appropriate  
5 regulatory requirements."

6 We have a response to that memorandum.

7 **SIR BRIAN LANGSTAFF:** Just one question, on this. It  
8 doesn't say what the relationship between the level of  
9 the hepatitis C antibodies and the progression of  
10 cirrhosis is, whether it means that more antibodies  
11 the less cirrhosis, or the less antibodies the less  
12 cirrhosis.

13 **MR HILL:** No, he doesn't. What I take from this memo is  
14 the view of Dr Rafferty is that Hemofil-M is an  
15 effective product to use to limit the risk of  
16 hepatitis cirrhosis, and the way that Dr Rafferty  
17 expresses himself is that he feels then that he has  
18 a moral obligation to share that information with the  
19 haemophilia clinicians.

20 **SIR BRIAN LANGSTAFF:** Why is he then raising that?  
21 Plainly, as a commercial sales point, it would seem  
22 sensible to highlight it, but the constraint might be,  
23 might it, that that would then fall foul of the  
24 advertising prohibition on a named-patient basis?

25 **MR HILL:** Exactly so, sir. That is what is said in the

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1 reply to Dr Rafferty's letter.  
 2 **SIR BRIAN LANGSTAFF:** I see. So where does that leave his  
 3 moral obligation? To break the law? Or what?  
 4 **MR HILL:** Sir, that is a question for Dr Rafferty.  
 5 **SIR BRIAN LANGSTAFF:** Yes.  
 6 **MR HILL:** If we could have onscreen -- if we look at the  
 7 reply we will see the position that was taken by  
 8 Mr Feakes in response. It's SHPL0000293\_142. The  
 9 date is 1 June 1990. And it's a response to the  
 10 memorandum we've just looked at of 21 May 1990.  
 11 What Mr Feakes says is this:  
 12 "The area of personal representations and  
 13 unlicensed products is one where great care must be  
 14 taken in order to avoid breaking both the acceptable  
 15 Codes of Conduct (eg that of the ABPI) and of the law  
 16 itself. The Department of Health has, in the past,  
 17 prosecuted companies for advertising unlicensed  
 18 products.  
 19 "Part VI of the 1968 Medicines Act (on Promotion  
 20 of Sales and Medicinal Products) clearly indicates  
 21 that only licensed products can be promoted and that  
 22 the spoken word by Company Representatives constitutes  
 23 a form of promotion. Moreover, the legislation under  
 24 which we import Hemofil M (S11984-673) states the  
 25 importer:

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1 other, licensed, products.  
 2 "(iv) Discussing the therapeutic value of  
 3 Hemofil M with a physician is only acceptable if it is  
 4 the physician and not you who initiates the  
 5 conversation.  
 6 "Although this does limit you quite  
 7 substantially, you should apply by these guidelines  
 8 otherwise we could, at the very least, antagonise the  
 9 Department of Health. This might in turn be  
 10 detrimental to our Product Licence Application.  
 11 "Going on to the availability of Hemofil M.  
 12 When asked it is quite acceptable for you to inform  
 13 the physician:  
 14 "(i) we hold small stocks in the UK.  
 15 "(ii) the product is available on a named  
 16 patient prescription basis.  
 17 "(iii) the cost of the product.  
 18 "(iv) contact names in marketing (for further  
 19 information) and regulatory (for prescription release  
 20 details).  
 21 That is Mr Feakes' response to the conundrum  
 22 that has been presented.  
 23 **SIR BRIAN LANGSTAFF:** Can we just go back to the first  
 24 page of this letter.  
 25 Just looking at the legislation:

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1 "Will not add any time issue or cause another  
 2 person to issue any advertisement or make any  
 3 representation in respect of that medical product and  
 4 that he will sell or supply that medicinal product  
 5 only in response to a bona fide unsolicited order.'  
 6 "Thus your actions must be very carefully  
 7 calculated such that you cannot be accused of  
 8 promoting Hemofil M. This is doubly important as  
 9 Baxter received a formal complaint from the DOH  
 10 [Department of Health] in early 1988 concerning our  
 11 stand at the ISBT meeting held at Wembley late 1987  
 12 (promotion of Gammagard). Further transgressions  
 13 could be very serious indeed.  
 14 "To give you a frame-work in which to operate  
 15 you must abide by the following rules:  
 16 "(i) The provision of factual scientific  
 17 information in response to a request from a physician  
 18 does not in itself constitute promotion. Therefore  
 19 you must not offer such information until requested.  
 20 "(ii) You should not approach individual  
 21 physicians with claims of safety for an unlicensed  
 22 product. Such information must be made available  
 23 through the Scientific press, by application of data  
 24 and substantiation by peer review.  
 25 "(iii) You should not set out to derogate

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1 "Will not at any time issue or cause another  
 2 person to issue any advertisement or make any  
 3 representation ..."  
 4 So what this might mean is, is it, that he  
 5 couldn't tell the DHSS, for instance, of the claims he  
 6 was making for the suitability of Hemofil-M with  
 7 a view to them letting the profession know, because  
 8 that would be affecting causing another person to make  
 9 a representation?  
 10 **MR HILL:** That would certainly be an interpretation that  
 11 would be open to a --  
 12 **SIR BRIAN LANGSTAFF:** Well, it would be straight within  
 13 the language that's quoted there, at any rate.  
 14 **MR HILL:** Yes, but there is a ... what Mr Feakes says adds  
 15 one of the solutions to this is to publish your  
 16 information.  
 17 **SIR BRIAN LANGSTAFF:** In a scientific journal.  
 18 **MR HILL:** In a scientific journal. Sharing  
 19 pre-publication information with the DHSS I don't  
 20 think would fall foul of this, unless there was an  
 21 intention for the DHSS to then go on to inform and  
 22 make an advertisement or a representation to various  
 23 clinicians.  
 24 **SIR BRIAN LANGSTAFF:** It's difficult to think of what  
 25 other reason there would be.

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1 **MR HILL:** There may be reason to begin the discussions  
 2 which lead to a product licence, for example,  
 3 discussing how the licence is best approached, what  
 4 form of licensing should -- what format the  
 5 application should take, whether it should be  
 6 a (overspeaking) -- licence and so forth.  
 7 **SIR BRIAN LANGSTAFF:** Yes, I see that might be  
 8 a possibility.  
 9 **MR HILL:** But certainly it wouldn't be open to the company  
 10 to try to work their way around the prohibition by  
 11 using the official channel.  
 12 **SIR BRIAN LANGSTAFF:** Thank you.  
 13 **MR HILL:** I don't intend to say anything further on  
 14 Hemofil-M. Turning to Proplex, this was the  
 15 freeze-dried concentrate that contained Factors II,  
 16 VIII and X, as well as Factor IX. I don't intend to  
 17 go through the licensing story for this product.  
 18 I note only the following: that interest in the  
 19 product in the UK can be traced back to at least  
 20 August 1974. That's OXUH0000630. Dr Biggs there  
 21 appears to have obtained some emergency use on a  
 22 named-patient basis.  
 23 **SIR BRIAN LANGSTAFF:** Do you have that reference again?  
 24 **MR HILL:** OXUH0000630.  
 25 **SIR BRIAN LANGSTAFF:** 630, thank you.

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1 "(i) The number of donations from which plasma  
 2 is pooled for the manufacture of prothrombin complex.  
 3 "(ii) The reasons for, and rate of, rejections  
 4 of donors and donations, centre by centre."  
 5 There are events and further provisos that I  
 6 won't take you through.  
 7 If we could have on screen now, please, Soumik,  
 8 MHRA0033317\_077. This is a response from Travenol  
 9 Limited to a letter that has been sent by the  
 10 Licensing Authority on 29 January 1976 -- we don't  
 11 have that letter, this is the response to it --  
 12 addressed to Dr Andrews, the Senior Medical Officer at  
 13 the Department of Health and Social Security. It  
 14 provides further information that has been requested  
 15 as part of the licensing process. It says:  
 16 "1(a)i. The size of plasma pools used for the  
 17 manufacture of each lot of Factor IX Complex can vary  
 18 up to approximately 6000 litres.  
 19 "1(a)ii. The reasons for rejection of a donor  
 20 or a donation are outlined in the product licence  
 21 application, Part 3, section A. Donors are most  
 22 commonly rejected due to serum protein electrophoresis  
 23 unacceptability or for being positive for Hepatitis B  
 24 surface antigen or for the RPR test. Rejection for  
 25 either the first or last reason given above would

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1 **MR HILL:** In March 1975 a temporary licence was granted to  
 2 import the product. That is MHRA00033317\_093.  
 3 The application for a product licence was made  
 4 on 21 May 1975. MHRA0033317\_095. The licence  
 5 application was considered by the CSM Subcommittee on  
 6 Biologicals in November 1975. So this is a month  
 7 before the World in Action film.  
 8 The medical assessor at that time commented that  
 9 Proplex would appear to have been adequately  
 10 manufactured but is subject to possible contamination  
 11 with hepatitis virus. But the medical assessor  
 12 recommended that subject to approval of quality  
 13 control, licence be granted.  
 14 The sub committee concluded that a product  
 15 licence be granted subject to several conditions, and  
 16 it's perhaps worth looking at that document,  
 17 MHRA003317\_079 -- MHRA0033317\_079. We can see  
 18 November 1975, Subcommittee on Biologicals, a month  
 19 before the World in Action film, well, the previous  
 20 month, we don't know how many weeks exactly:  
 21 "On the evidence before them, the Sub-Committee  
 22 on Biologicals recommend the grant of a product  
 23 licence for this preparation ...  
 24 "Provided that:  
 25 "Information is provided on:

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1 normally only be for a limited period of time."  
 2 You can see in the marginalia on the right-hand  
 3 side is written "no rate of rejections", that  
 4 information was requested by the DHSS but hasn't been  
 5 provided in this letter. We don't know, sir, whether  
 6 that was provided subsequently or not. We haven't  
 7 seen any information that it was but that does not  
 8 mean that it was not.  
 9 Proplex was granted a licence, on  
 10 15 October 1976, SHPL0000232\_001. The timing is  
 11 interesting, sir, in that the original consideration  
 12 by the CSM(B), before the World in Action  
 13 documentaries were broadcast, the letter that was sent  
 14 in January was sent afterwards.  
 15 **SIR BRIAN LANGSTAFF:** But was the information that was  
 16 requested ever actually provided, so far as we know?  
 17 **MR HILL:** We haven't seen any information that it was, but  
 18 we have rather incomplete documentation from that  
 19 period, so we can't say that there wasn't another  
 20 letter that was followed up. Certainly somebody seems  
 21 to have submitted that no information has been  
 22 provided on a rate of projections but we don't know  
 23 whose writing that is.  
 24 **SIR BRIAN LANGSTAFF:** Yes.  
 25 **MR HILL:** The 1978 haemophilia centre annual returns show

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1 that they compiled information from 103 centres. Of  
 2 the 2.2 million units used by Haemophilia Centres to  
 3 treat haemophilia A patients with antibodies during  
 4 1978, only 149,000 of those were Proplex, and that  
 5 compares with 1.9 million units of FEIBA.

6 So we can see that although Proplex is used, it is  
 7 far less popular than FEIBA for inhibitor patients.  
 8 It is not clear from the information in the returns  
 9 how much was used for Factor IX patients.

10 I won't, sir, go through the subsequent history  
 11 of the renewal applications and considerations. We  
 12 can return to that if necessary. The picture is not  
 13 always clear as to when or indeed whether renewal  
 14 applications were considered, but nor is it clear the  
 15 extent to which Proplex remained on the UK market  
 16 during the 1980s.

17 That's to complete what I have to say about the  
 18 licensing of Travenol products. I'm going to turn now  
 19 to the communication of risk associated with those  
 20 products. We've seen some indication of this in the  
 21 documents that we've looked at, but this is to try to  
 22 fill out the narrative a little.

23 If we go back to Hemofil and the original  
 24 version of Hemofil, which was the non-heat treated  
 25 Hemofil, as we have heard, the product licence

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1 morbidity and mortality may be associated with  
 2 hepatitis."

3 You may recall, sir, from Friday, the comment  
 4 made by Dr Thomas, the medical assessor at the time,  
 5 that during the -- in the product application there  
 6 was no attempt made to disguise the risk of hepatitis  
 7 associated with it.

8 **SIR BRIAN LANGSTAFF:** Just looking at that for a moment,  
 9 the fifth line down, starting at the end of the fourth  
 10 line down in the second paragraph, "and the  
 11 concentrate has not been subjected to any treatment  
 12 known to diminish the risk of transmission of  
 13 hepatitis since such treatments greatly increase the  
 14 loss of AHF activity during preparation", which is  
 15 an interesting phrase because it suggests: (a) that  
 16 the company has considered treating the product, (b)  
 17 that it is not saying it can't be done. It is saying  
 18 it's uneconomic or it lessens the amount of  
 19 Factor VIII you get at of the product, not that you  
 20 get none.

21 **MR HILL:** Yes.

22 **SIR BRIAN LANGSTAFF:** So it could, on that interpretation,  
 23 on the words themselves, mean they could produce  
 24 a safer product, does it, only it's just not worth the  
 25 candle?

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1 application was made in November 1972. A label was  
 2 sent with that application, which contained the words  
 3 "Warning, the risk of transmitting hepatitis is  
 4 present". The package leaflet was also contained in  
 5 the application and can we have this on the screen,  
 6 please, Soumik. It's SHPL0000275\_013.

7 We can see this is part of the application and  
 8 it is the draft package leafletting, if we can go over  
 9 to the next page, please, Soumik -- two pages on, to  
 10 the fifth page of the document overall.

11 Under the heading "Cautions" it says:

12 "This concentrate [this is the second paragraph  
 13 down] is prepared from large pools of fresh human  
 14 plasma. Such plasma may contain the causative agents  
 15 of viral hepatitis. There is no known laboratory test  
 16 to demonstrate either the presence or the absence of  
 17 such agents, and the concentrate has not been  
 18 subjected to any treatment known to diminish the risk  
 19 of transmission of hepatitis since such treatments  
 20 greatly increase the loss of AHF activity during  
 21 preparation. The concentrate should, therefore, be  
 22 used when its expected effect is needed in spite of  
 23 the unknown hepatitis risk associated with its use.  
 24 Special consideration should be given to the use of  
 25 the concentrate in newborns and infants where a higher

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1 **MR HILL:** I am reluctant to try to interpret what was  
 2 meant from the warning label without the --

3 **SIR BRIAN LANGSTAFF:** The reason I raise this is whether  
 4 there's any other document that you know of that sheds  
 5 any light on that?

6 **MR HILL:** Not that I'm aware of but it is something we can  
 7 continue to look into. I'm not sure what methods of  
 8 viral inactivation were being used or being thought  
 9 about by the company as of 1972.

10 **SIR BRIAN LANGSTAFF:** Whatever they were, that sentence is  
 11 at least open to that interpretation. Is it better  
 12 open to another one or not?

13 **MR HILL:** It is open to that interpretation, yes.

14 **SIR BRIAN LANGSTAFF:** Yes. Thank you.

15 **MR HILL:** The licence was granted in February 1973, as we  
 16 heard on Friday. The package -- a package leaflet  
 17 dated from 1979 contains a broadly similar warning but  
 18 with some further information about screening tests.  
 19 It may help to have a quick look to that.  
 20 SHPL0001055\_023, please, Soumik. This is, as I say,  
 21 dating from 1979 and we can see the "Warnings"  
 22 section:

23 "This concentrate is prepared from large pools  
 24 of fresh human plasma. Such plasma may contain the  
 25 causative agent of viral hepatitis. However, each

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1 unit of the plasma used in the manufacture of this  
2 product has been found to be nonreactive for  
3 hepatitis B surface antigen ... by radioimmunoassay.  
4 The concentrate has not been subjected to any  
5 treatment known to diminish the risk of hepatitis  
6 transmission since such treatments greatly increase  
7 the loss of AHF activity during preparation. The  
8 concentrate should, therefore, be used when the need  
9 for its expected effect outweighs the hepatitis risk  
10 associated with its use.

11 "This lot, after reconstitution as for use, has  
12 been found non-reactive for hepatitis B surface  
13 antigen ... using a solid phase radioimmunoassay  
14 technique licensed by the US Bureau of Biologics. The  
15 significance of a nonreactive test result with  
16 concentrated antihæmophilic factor has not been  
17 established. Therefore, the product should continue  
18 to be considered to carry a risk in respect to  
19 hepatitis."

20 Turning to Hemofil, I should add, sir, that we  
21 have less information about the data sheets for  
22 Hemofil than we do for the Immuno products that we  
23 looked at last week. That's just the nature of the  
24 type of sources that we have to work with.

25 Turning to heat-treated Hemofil, we heard on

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1 a similarly-phrased warning. It's at page 30 of the  
2 same document, I won't go to it, but it also included  
3 the comment "Although these testing and heating steps  
4 reduce the risk of hepatitis transmission the  
5 possibility of such transmission should be considered  
6 in the use of the product".

7 The data sheet had a similar warning. That's at  
8 page 40 of the same document. The direction sheet  
9 contained a summary of the understanding at that time  
10 of the chimpanzee trials, to which we referred on  
11 Friday, that's at page 29.

12 The amendment to licensing Hemofil-T was granted  
13 on 27 February 1985. The particulars of the licence  
14 included a warning in the same terms as those  
15 contained in the proposed direction sheet and data  
16 sheet, that's MHRA0000087, page 14 of that document.

17 We also have a carton with the expiry date  
18 June 1988, which shows the same wording as the sample  
19 carton that was included in the application. That's  
20 SHPL0001013\_004. You'll note, sir, that in those  
21 warnings, there is no reference to HIV, LAV, HTLV-III,  
22 although, as we heard, Dr Kingdon's view was that  
23 Hemofil-T did inactivate HIV.

24 Hemofil-M, as we've just heard, not licensed  
25 until 1994 but available on a named-patient basis

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1 Friday that, at the time that the original application  
2 for heat-treated Hemofil was considered by the  
3 Committee On Safety of Medicines Subcommittee on  
4 Biologics, it was "strongly deprecated" that leaflets  
5 had been sent to doctors which the committee  
6 considered to be promotional leaflets making  
7 unjustified claims. I won't go back to those.

8 A further application was made on  
9 30 November 1984. The proposed bottle label contained  
10 the words "Warning, the risk of transmitting hepatitis  
11 is present". The carton label contained the  
12 following, SHPL0000283\_005, please, Soumik. It's  
13 page 24 of that document.

14 In the section headed "Warning", a little  
15 further down the page:

16 "Plasma from which this product was derived was  
17 found to be nonreactive for hepatitis B surface  
18 antigen (HBsAG) when tested with licensed third  
19 generation reagents. In addition, the process used in  
20 the manufacture of this product includes a heating  
21 step designed minimise the risk of transmission of  
22 hepatitis. However, no procedure has been shown to be  
23 totally effective in removing hepatitis infectivity  
24 from Antihæmophilic Factor (human)."

25 The proposed direction sheet contained

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1 seemingly from 1987. I'm not going to take you  
2 through the labels that it contained, but we can --  
3 for the transcript, the warnings contained in the  
4 original application are at SHPL0000375\_082, and in  
5 the subsequent revised application, SHPL0000396\_003.

6 Proplex, the application for the product licence  
7 was in May 1975, as we've heard. I won't take you to  
8 the documents, but the proposed direction sheet and  
9 data sheet contain a similar warning to the  
10 contemporary warnings for Hemofil at that time, the  
11 reference is MHRA0033317\_098.

12 I will, if I may, sir, take you to a data sheet  
13 from February 1983, from Proplex, SHPL0000963\_002. If  
14 we look in the central column, at the bottom we can  
15 see it's revised in February 1983 and this has been  
16 printed by the US company, Travenol Laboratories Inc,  
17 and printed in the US, as it states there.

18 If we can go to the next page of the document,  
19 please, Soumik. Under the heading "Warnings", the  
20 second paragraph, again:

21 "This product is prepared from large pools from  
22 human plasma. Such plasma may contain the causative  
23 agent of viral hepatitis. Although each unit of  
24 source plasma used in the preparation of this product  
25 has been found to be nonreactive for hepatitis B

24

1 surface antigen ... by licensed third generation  
 2 reagents, the concentrate has not been subjected to  
 3 any treatment known to diminish the risk of  
 4 transmission of hepatitis. The product should,  
 5 therefore, be administered only when its expected  
 6 effect outweighs the hepatitis risk associated with  
 7 its use."

8 If we go down a couple of paragraphs lower,  
 9 under "Precautions", just above the subheading  
 10 "Laboratory tests", you see a further warning which is  
 11 the last paragraph there:

12 "Special caution should be taken in the use of  
 13 this concentrate in newborns, where a higher morbidity  
 14 and mortality may be associated with hepatitis, and in  
 15 individuals with pre-existing liver disease."

16 Again, terms similar to those we have looked at  
 17 from the 1970s for Hemofil in a document from  
 18 February 1983. It's not clear, on the face of this  
 19 document, whether or not it was a document that was  
 20 used with UK product but that is what the American  
 21 company was printing at that time. A version of the  
 22 leaflet was revised in October 1984. The reference is  
 23 SHPL0001049\_034. The same warning was issued and,  
 24 again, there is no reference to AIDS, HTLV-III, LAV,  
 25 HIV. That is from October 1984. Once more, it's not

25

1 **MR HILL:** Yes.

2 **SIR BRIAN LANGSTAFF:** That's, what, MRHA232001, I think,  
 3 or SPHL232001. If it's 6,000 litres, that's about,  
 4 what, 9,000, 10,000 donations, isn't it?

5 **MR HILL:** Depending on the level of --

6 **SIR BRIAN LANGSTAFF:** Assuming that a donation of plasma  
 7 is about 600-odd millilitres.

8 **MR HILL:** Yes. It's not always clear in the documents  
 9 whether references to donors are intended to  
 10 specifically mean donors or whether it is intended to  
 11 mean litres of plasma or donations. There's a lack of  
 12 precision sometimes.

13 **SIR BRIAN LANGSTAFF:** Well, it does matter.

14 **MR HILL:** It does.

15 **SIR BRIAN LANGSTAFF:** Because if you take, on one view,  
 16 the -- any risk per donation is one and a half times  
 17 as much if you use different measure.

18 **MR HILL:** Yes. What we know from Dr Kingdon, in his  
 19 witness statement that we looked at on Friday, is that  
 20 he referred to plasma pools of up to 15,000 donations.

21 **SIR BRIAN LANGSTAFF:** Yes.

22 **MR HILL:** He was very specifically talking about donations  
 23 there. So whether or not 6,000 donors or 6,000  
 24 donations was meant in circa 1975, by the time of  
 25 Dr Kingdon's statement in 1990, there appears to have

27

1 clear from the face of that document whether or not it  
 2 was used in the United Kingdom.

3 That is all I intend to say on the communication  
 4 of risk in respect of the Travenol products that we  
 5 have been looking at. I will turn now to the question  
 6 of donors.

7 In terms of donor pool sizes, we've heard  
 8 evidence already on this, and I won't go back to it,  
 9 but will just remind you, sir, that Dr Thomas's  
 10 summary of the -- the summary of the report produced  
 11 following the inspection of the Hyland blood banks,  
 12 which we looked at on Friday, said that donor pools  
 13 contained plasma from as many as 6,000 donors. That  
 14 figure was confirmed in a letter from Travenol  
 15 Limited, dated 22 June 1976, about Proplex Factor IX,  
 16 which we looked at earlier today in the licensing  
 17 section. The reference is MHRA003317\_077, and the  
 18 reference for Dr Thomas is DHSC0105593 --

19 **SIR BRIAN LANGSTAFF:** Dr Thomas was talking about 6,000  
 20 donors, did you say? What you showed me earlier  
 21 talked about donations.

22 **MR HILL:** Yes, there is that distinction between  
 23 donations. Whether or not it was an intended --

24 **SIR BRIAN LANGSTAFF:** In fact, litres, I think it was,  
 25 wasn't it? 6,000 litres was what you mentioned?

26

1 been a rise in the pool size up to 15,000 donations.

2 **SIR BRIAN LANGSTAFF:** Unless there is other evidence to  
 3 help interpret, one just has to take the words as they  
 4 come and interpret them on that basis, I think --

5 **MR HILL:** Yes, sir.

6 **SIR BRIAN LANGSTAFF:** -- hasn't one?

7 **MR HILL:** Yes. But I think the evidence does show that  
 8 there was a growth in the size of the donor pools used  
 9 by Travenol.

10 Turning to --

11 **SIR BRIAN LANGSTAFF:** So the growth that you would  
 12 identify would be, what, 6,000 up to --

13 **MR HILL:** Yes.

14 **SIR BRIAN LANGSTAFF:** -- 6,000 litres or donors, depending  
 15 on which, up to 15,000 donations?

16 **MR HILL:** Yes. We don't have any further detail as to  
 17 when, why and with what justification.

18 **SIR BRIAN LANGSTAFF:** Or whether by steps, et cetera?

19 **MR HILL:** Exactly. We can seek to try to find out more  
 20 but I'm not how much we will be able to find out on  
 21 that.

22 **SIR BRIAN LANGSTAFF:** No.

23 **MR HILL:** Turning to the procedures that were used for the  
 24 donors, we heard from Dr Kingdon's statement, his  
 25 evidence about how things were done, the statement was

28

1 dated 1990, and it was sometimes unclear which period  
2 he was talking about in that statement and, out of  
3 fairness to Dr Kingdon, it's important to note that he  
4 joined the company in 1981, so some of what we're  
5 going to look at now took place before his time and he  
6 wouldn't necessarily have known about it. If we could  
7 have on screen, please, Soumik, SHPL0000279\_012.

8 This is a document which is part of what is  
9 called the "Donor Centre Technical Guide". It's  
10 published by Hyland Division of Travenol Inc, so the  
11 American company. We can see that the manual is dated  
12 in the top left-hand corner box "March 25, 1975".  
13 I note that is before World in Action documentaries  
14 were broadcast. That doesn't tell us when the  
15 documentaries themselves were actually filmed. We  
16 don't know which part of 1975 --

17 **SIR BRIAN LANGSTAFF:** This is a revision issued on  
18 30 April 1976?

19 **MR HILL:** This is, the original manual was dated  
20 25 March 1975. This is the second revision to it and  
21 it's 30 April 1976, which is after World in Action  
22 documentary. It says:

23 "Donor requirements -- check list  
24 "Purpose  
25 "To establish the instruction regarding

29

1 adequate permanent donor records."

2 We can see the types of information that were  
3 required in that record, including the donor's name,  
4 permanent donor number, date of donation, bleeding  
5 number, vital signs and then the result of the  
6 syphilis test to be included.

7 "The donor record form is to be reviewed by the  
8 attending physician at least once every four months to  
9 determine continuing suitability of the donor."

10 I won't go through the rest of the document but  
11 we can see what the instruction says there.

12 If we could go, please, to SPHL0000279\_029.

13 This is an information sheet about establishing the  
14 instructions and the use and proper documentation of  
15 Source plasma (human) labelling, the original document  
16 from 15 December 1975, this the third revision dated  
17 29 October 1976. It sets out what should be contained  
18 on the label of the plasma that should be affixed to  
19 every plasma container, and that includes the donor  
20 name, the donor number, the bleeding date, and so  
21 forth.

22 On the next page, we can see that the procedures  
23 are put in place for each label to be accompanied by  
24 16 smaller labels that:

25 "... can be used identification of plasma

31

1 a guideline check list of requirements to be followed  
2 in determining suitability of a donor to qualify for  
3 whole blood or plasmapheresis donation.

4 "Scope

5 "Provisions of this instruction apply to all  
6 Hyland plasma centers."

7 We can see then a list of instructions. We  
8 don't have all of these documents but you can see the  
9 types of area that the different instructions cover:  
10 the fingernail dye examination and fixation, which  
11 I understand to be a method to try to prevent people  
12 donating too frequently; the weight, temperature,  
13 blood pressure, hepatitis B surface antigen tests;  
14 serological tests and physical examination. As I say,  
15 we don't have all of the documents that were part of  
16 that guide at that time, but we do have some documents  
17 which formed part of the guide over the succeeding  
18 years.

19 If we could have SHPL0000279\_031, please,  
20 Soumik, the original variant of this instruction was  
21 30 March 1976, this is the fifth revision dated  
22 11 May 1976 and, again, we can see it's part of the  
23 donor technical guide:

24 "Purpose  
25 "To establish the instruction for maintaining

30

1 segments for testing, donors' bleeding bags,  
2 documentation donor records, summation reports,  
3 VACUTAINER tubes used for special programs, samples  
4 for laboratory testing and donor center logs."

5 Soumik, could we please have SHPL0000279\_018.  
6 This instruction is about establishing the proper  
7 documentation of the whole blood and plasma processing  
8 log. The issue date is 18 January 1977. It is the  
9 second revision of the document that dates from  
10 6 October 1976. We can see the instructions given  
11 about the information that should be recorded, again  
12 including the bleeding number of the patient.

13 I won't go through the large number of other,  
14 similar documents, but we can see from them that there  
15 was a technical guide which contained such  
16 instructions. Obviously what the documents don't tell  
17 us is how those instructions were then implemented on  
18 the ground.

19 Then, jumping forward to October 1983, if we  
20 could have on screen, please, BAXT0000011\_002.

21 This is a document which is entitled "Hyland  
22 Division of Travenol Laboratories Limited, File RA  
23 1002 - October 1983, Source Plasma (Human)", and it is  
24 produced by Travenol Laboratories Limited, so the UK  
25 company rather than the US company.

32

1 If we could turn over to the next page, please,  
 2 Soumik. The contents are set out there. There are  
 3 four sections to it. The first section is about  
 4 product description, donor definition and facility  
 5 requirements.

6 The second section is for donor centre technical  
 7 guide, table of contents, and that is a reference, as  
 8 I understand it, to the same guide that we have just  
 9 been looking at, but this is the version which is now  
 10 in place in 1983.

11 Part three is the establishment licences and  
 12 lists of approved plasma collection centres.

13 Part four is some of the regulations from the  
 14 US.

15 So it appears to be a document that the UK  
 16 company has produced to inform itself or others of the  
 17 way in which the American company goes about  
 18 collecting its blood plasma and whole blood.

19 If we could turn to page 5 of that document,  
 20 please, Soumik. I'm not going to go through all of  
 21 this, it is quite lengthy, but just certain features  
 22 that can be picked out from it. 2c:

23 "Each unit of SOURCE PLASMA (HUMAN) shall be  
 24 nonreactive for hepatitis B surface antigen when  
 25 tested by a suitable test system of third generation

33

1 qualification, a qualification for blood haemoglobin.

2 A requirement -- if we go on to the next page,  
 3 please, Soumik -- of hepatitis B surface antigen  
 4 freedom.

5 If we go down to (n):

6 "Freedom from any disease, other than malaria,  
 7 transmissible by blood transfusion, insofar as can be  
 8 determined by history and examination indicated in  
 9 this section."

10 "(o) Freedom of the arms and forearms from skin  
 11 punctures or scars indicative of addiction to  
 12 self-injected narcotics."

13 And:

14 "(p) Freedom from a history of viral hepatitis."

15 The "General" section states:

16 "Any donor who, in the opinion of the  
 17 interviewer, appears to be under the influence of any  
 18 drug, alcohol, or for any reason does not appear to be  
 19 providing reliable answers to medical history  
 20 questions, shall not be considered a suitable donor."

21 Then "Continued Donor Suitability":

22 "The accumulated laboratory data and collection  
 23 records of the donor shall be reviewed by a licensed  
 24 qualified physician every four months to determine and  
 25 [carefully] certify whether or not the donor may

35

1 sensitivity.

2 "f. A label shall be affixed to each unit of  
 3 source plasma delineating the following information  
 4 ..."

5 It gives the information that should be on the  
 6 label, including the donor number.

7 If we go over to the next page, please, Soumik.

8 This is the section about the suitability and  
 9 safety of donors. And it says:

10 "The suitability of a donor shall be determined  
 11 by a qualified licensed physician or by persons under  
 12 his supervision and trained in determining donor  
 13 suitability."

14 We can see, then, it goes on to describe the  
 15 "Method of Selecting [the] Donor": "Informed Consent"  
 16 and the "Medical Examination", which says this:

17 "Each donor shall be examined by a qualified  
 18 licensed physician on the day of the first donation,  
 19 or not more than one week prior to the first donation,  
 20 and shall be certified to be in good health by the  
 21 examining physician. Medical examinations shall be  
 22 performed at subsequent intervals of no longer than 1  
 23 year."

24 It then goes on to list the qualifications of  
 25 the donor, there is an age qualification, a weight

34

1 continue on the plasmapheresis program."

2 So that is the section about the suitability and  
 3 safety of donors, and you may find interesting, sir,  
 4 the distinction made between when a licensed physician  
 5 has to be involved and when somebody operating under  
 6 the supervision of that licensed physician is  
 7 involved. Supervision is not, so far as I'm aware,  
 8 defined in this document.

9 If we could go, please, to page 10 of the  
 10 document.

11 "Donor Identification System", it says:

12 "A donor identification numbering system shall  
 13 be established that positively identifies each donor  
 14 and relates such donor directly to his blood and his  
 15 plasma as well as to his accumulated records and  
 16 laboratory data. Such systems shall include either  
 17 a photograph of each donor which shall be used on each  
 18 visit to confirm the donor's identified, or some other  
 19 method that provides equal or greater assurance of  
 20 positively identifying the donor."

21 I won't go to it, but at page 15, there is  
 22 a further detail on the donor records that are  
 23 required.

24 Page 18, please, Soumik. I'm not going to go  
 25 through this, but we can see there that it is

36

1 a summary of the FDA licensing procedures that are in  
2 place as of 1983. We then see on page 19 -- please,  
3 Soumik -- the table of contents from the donor centre  
4 technical guide. So the iteration of a document that  
5 we've been looking at previously.

6 If we could go on to page 20, please, Soumik.

7 I won't go through all of these but we can see  
8 a large number of instruction sheets which form the  
9 guide. It goes on for some six pages.

10 Then, please, Soumik if we could go to page 29.

11 This is the list of centres that are used by  
12 Hyland. And it says that:

13 "Plasma used to manufacture Hyland Blood  
14 Products is collected only at Plasma Collection  
15 Centres licensed by the United States Food and Drug  
16 Agency.

17 "The centres and their locations are as  
18 follows ..."

19 It refers to the Hyland Therapeutics Division in  
20 Glendale, California, and Travenol Laboratories Inc in  
21 Deerfield, Illinois, and then a list of locations, all  
22 of which appear to be in the United States.

23 If we go over to the next page, please, Soumik.

24 As I say, all of these appear to be in the  
25 United States. There is one reference about a third

1 companies responded to the risk of AIDS. My focus  
2 today is on how plasma was being collected before  
3 circa 1983, when the risk of AIDS becomes increasingly  
4 apparent. So we will turn back to this material at  
5 a later stage for a different purpose.

6 This document is dated 20 October 1983. It is  
7 an internal memorandum within Travenol and it is sent  
8 from WR Srigley to D Castaldi about a telecom with  
9 Dr Donohue. And Dr Donohue is Dr Dennis Donohue of  
10 the FDA's division of blood and blood products, and it  
11 is around this time that he is speaking to  
12 pharmaceutical companies about the risk of AIDS and  
13 what they are doing about it.

14 What is attached is stated to be:

15 "... the text which I used to define for  
16 Dr Donohue Travenol's policy with regard to the use of  
17 plasma from prison centers.

18 "He expressed his satisfaction with the policy  
19 and appreciation that we responded promptly to him.  
20 He asked that we not send it to him in writing at this  
21 time."

22 "If you have any additional questions regarding  
23 the conversation, I would be happy to discuss it in  
24 detail with you."

25 So it appears to be of the text of a policy that

1 of the way down to Cherry Street Plasma Center, Inc.  
2 There is no additional information provided as to  
3 which city that is in or which state that is in, but  
4 all of the others on the list are in American cities  
5 in American states.

6 I don't know if there is any significance to the  
7 lack of information about the Cherry Street Plasma  
8 Center.

9 As we saw from the contents page, the document  
10 also contains extracts from the US Code of Federal  
11 Regulations concerning food and drugs, but I'm not  
12 going to go to those.

13 We can take that off the screen, thank you,  
14 Soumik.

15 That is the documentation that I wish to show  
16 you about the internal processes, at least as written,  
17 by Hyland and Travenol at the time of the 1970s and  
18 1980s.

19 I would like to turn now to the issue of the use  
20 of plasma from prisons.

21 Could we have on screen, please, Soumik,  
22 CGRA0000291.

23 Some of this material, sir, is -- are documents  
24 that we will come back to in November when we're  
25 dealing with the way in which the pharmaceutical

1 was explained orally to Dr Donohue about what Travenol  
2 were doing in respect of plasma from prisons.

3 If we go to page 2, you'll see the document is  
4 headed "Proposed Text for Conversation with Donohue",  
5 but we can see from the memorandum that this is the  
6 text that appears to actually have been used in the  
7 conversation.

8 What it says is this:

9 "We had previously made the decision to  
10 discontinue the purchase of plasma from licensed  
11 centers in prisons. To that end we have chosen not to  
12 renew any pre-existing contracts with such centers  
13 after this year. Following my conversation with you  
14 yesterday, we have decided that we will promptly  
15 discontinue the use of such plasma for the manufacture  
16 of coagulation factors. We have pools in process this  
17 week which contain plasma drawn in prison centers. As  
18 of the end of this week, we will not make any  
19 coagulation factors from any of the prison plasma  
20 which remains in our possession or which we are  
21 contractually bound to purchase through the remainder  
22 of the year: no further plasma pools used for  
23 coagulation factors will contain prison plasma. Any  
24 intermediate fractions manufactured from plasma pooled  
25 this week, or in previous weeks, would be processed to

1 final product."  
 2 That is what the company -- now I remind you,  
 3 sir, it's the American company -- is telling the FDA  
 4 in response to Dr Donohue's overtures about this  
 5 issue.  
 6 My submission, it's clear from this statement  
 7 that Hyland and Travenol had previously manufactured  
 8 coagulation factors from plasma obtained from  
 9 prisoners. The statement doesn't define which  
 10 concentrates were produced this way, but there's no  
 11 suggestion that prison plasma was intentionally  
 12 excluded from any particular products or that it was  
 13 not used in particular markets such as the  
 14 United Kingdom.  
 15 The date of that document is 20 October 1983.  
 16 **SIR BRIAN LANGSTAFF:** On 24 March '83, which would be some  
 17 seven months earlier, the FDA had recommended to  
 18 pharmaceutical companies they shouldn't make any more  
 19 product from those donors thought to be in a high risk  
 20 group.  
 21 **MR HILL:** That's correct, sir.  
 22 **SIR BRIAN LANGSTAFF:** It doesn't say whether prisoners in  
 23 the United States penal institutions were thought to  
 24 be members of a high risk group, but it's implicit in  
 25 this document that, at least by October, they were

1 You can see the first page there shows what this  
 2 document is: the deposition of Edward Shanbrom MD,  
 3 30 October 2002.  
 4 I won't go to it, but internal page 10 of that  
 5 transcript contains the potted history of his CV that  
 6 I have just given you.  
 7 If we could -- please, Soumik -- turn to page 7  
 8 of our electronic document. This is page 43 internal  
 9 of the transcript. I will just read through the  
 10 questions and answers that were given in this  
 11 deposition:  
 12 **"Question:** ... do you recall specifically whether  
 13 or not Hyland had a plasma collection operation [within]  
 14 the Angola prison in Louisiana?  
 15 **"Answer:** Yes.  
 16 **"Question:** Did you become aware whether or not  
 17 Hyland had a plasma collection arrangement with the Cook  
 18 County jail system?  
 19 **"Answer:** No.  
 20 **"Question:** Other than Angola Prison, were you aware  
 21 of any other prison facilities for which Baxter, aka  
 22 Hyland, was procuring plasma directly or indirectly?  
 23 **"Answer:** I don't think so.  
 24 **"Question:** Did you ever express any objection to  
 25 people at Baxter about the use of prison plasma?

1 thought to be a riskier group from which to take  
 2 plasma. But it looks as though between March and  
 3 October they went on doing it.  
 4 **MR HILL:** Yes, sir, I think that is the only inference  
 5 that can be drawn from the document: the reference to  
 6 the fact that the discontinuation hasn't taken place  
 7 as of 20 October but is due to take place in that  
 8 week.  
 9 **SIR BRIAN LANGSTAFF:** They say in terms that they've got  
 10 some in the pipeline, they're making product from it,  
 11 and they're going to market it.  
 12 **MR HILL:** Yes. It is still ongoing at that time.  
 13 **SIR BRIAN LANGSTAFF:** Yes.  
 14 **MR HILL:** The March FDA recommendations are something that  
 15 we will come back to.  
 16 **SIR BRIAN LANGSTAFF:** Yes.  
 17 **MR HILL:** There is evidence that in the 1970s, objections  
 18 were raised to the practice of using prison plasma.  
 19 Edward Shanbrom was a doctor who worked for Hyland as  
 20 medical director and director of research between  
 21 approximately 1965 and 1975.  
 22 On 30 October 2002 he gave a deposition as part of  
 23 some litigation in the United States, and I'd like to  
 24 turn to that now, please, Soumik.  
 25 It's CGRA0000495.

1 **"Answer:** Yes.  
 2 **"Question:** Did you express them to the president?  
 3 **"Answer:** Yes.  
 4 **"Question:** And what was the nature of your  
 5 objections?  
 6 **"Answer:** That hepatitis was present at the prison.  
 7 **"Question:** Was it, to your belief, more rampant  
 8 within prison population than it was within the general  
 9 population?  
 10 **"Answer:** No, just at Angola.  
 11 **"Question:** Just Angola. Have you ever that  
 12 occasion to learn anything about the incidence level of  
 13 hepatitis in prisons other than at Angola Prison?  
 14 **"Answer:** No.  
 15 **"Question:** But did you happen to believe that at  
 16 Angola it was particularly high?  
 17 **"Answer:** Yes.  
 18 **"Question:** What was the -- if you can recall, the  
 19 name of the president at Baxter at that time when you  
 20 expressed these objections?  
 21 **"Answer:** I think it was both Fred Marquart and his  
 22 successor shortly -- their president, Norm Achen.  
 23 **"Question:** What were their reactions to your  
 24 objections?  
 25 **"Answer:** I was fired.

1 "Question: Okay. So would it be fair to say in  
2 that part of the -- of the collection of things that led  
3 to your termination, involved your objections about  
4 using prison plasma from Angola Prison?

5 "Answer: I'd like to think so, but I don't really  
6 know.

7 "Question: Would you say that your objections were  
8 strongly expressed?

9 "Answer: Very strongly.

10 "Question: And did you urge that Baxter cease using  
11 plasma collected from Angola Prison?

12 "Answer: Yes."

13 It's important to note, sir, that the Inquiry's  
14 copy of this deposition is incomplete and it doesn't  
15 include any cross-examination of the witness. This is  
16 what we would call his evidence-in-chief.

17 **SIR BRIAN LANGSTAFF:** Yes.

18 **MR HILL:** I'm conscious of the time, sir. I have probably  
19 about five minutes more on prison plasma. I don't  
20 know if you would like me to continue or take a break  
21 now?

22 **SIR BRIAN LANGSTAFF:** Well, let's finish prisons before we  
23 take a break, a jail break.

24 **MR HILL:** If we could have, please, Soumik, CGI0000290,  
25 please.

45

1 to the need for plasmapheresis establishment owners  
2 and operators to operate in less desirable areas,  
3 prisons and locations where plasma is available at low  
4 costs."

5 This section is highlighted in the text.

6 "The NHF, we believe, has a clear responsibility  
7 to support organisations that act in the best interest  
8 of the patient population even when it may result in  
9 slightly higher costs. There has been a strong  
10 tendency over the past couple of years to support  
11 those organisations that offer the lowest cost, rather  
12 than support those who invest in improving the safety  
13 and efficacy of today's, as well as tomorrow's,  
14 products for the treatment of haemophilia."

15 Over to the next page, please.

16 "Hyland continues to be committed to leadership  
17 in haemophilia therapy worldwide. We manufactured the  
18 first AHF concentrate and provided the first  
19 heat-treated AHF. Hyland developed the first product  
20 for treatment of inhibitor patients. Hyland has  
21 invested heavily in rDNA Factor VIII research and  
22 development and was the first to begin human clinical  
23 trials of that material. We were the first  
24 manufacturer to provide a quality home care for  
25 treatment of patients with haemophilia in this

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1 This is a letter written on 3 June 1987, from  
2 Carl E Brooks, president of -- well, it's stated --  
3 it's on the -- the heading is "Hyland Therapeutics  
4 Division Travenol Laboratories, Inc". I'm not sure if  
5 Carl E Brooks was president just of the Hyland  
6 division or whether he was president of Baxter  
7 overall, but certainly a senior executive within the  
8 relevant company.

9 It's sent to Charles J Carman, the chairman of the  
10 AIDS Task Force of the National Haemophilia  
11 Foundation, and it is in response to a television  
12 documentary which had recently been shown, the 20/20  
13 programme. And you can see in the first paragraph  
14 that Mr Brooks is saying that he's pleased that NHF  
15 recognises that the programme was "highly biased and  
16 distorted".

17 I'd like to pick up the letter, please, from the  
18 third paragraph, which says this:

19 "We feel that Hyland/Travenol has at all times  
20 been responsible in its actions on behalf of the  
21 people who live with haemophilia. You and the NHF  
22 must recognise that the whole treatment community  
23 shares in the responsibility for some of the  
24 situations that exist today. By demanding the lowest  
25 possible price for coagulation factors, you contribute

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1 country. We were the first manufacturer to screen all  
2 plasma in compliance with the German BGA requirements  
3 in 1985 and behaved in a responsible fashion by not  
4 using material rejected for Germany's ALT requirements  
5 in any other market as several other US manufacturers  
6 did. Soon, we hope to market a new high purity, viral  
7 safe AHF purified from plasma using monoclonal  
8 antibody affinity purification technique and improved  
9 viral inactivation technology. Hyland/Travenol  
10 decided prison locations were not the best for  
11 collecting source plasma several years ago and decided  
12 to cancel contracts with all prison sources.  
13 Certainly, based on information available today, no  
14 one can argue that prisons are locations where there  
15 are more than the usual population of what we now  
16 agree are 'high risk groups'. Further, over the past  
17 four or five years, we have either sold or closed down  
18 Hyland owned centres that are in these less desirable  
19 areas and have cancelled contracts with independent  
20 centres located in these areas or insisted on their  
21 relocation."

22 **SIR BRIAN LANGSTAFF:** Just pause there for a moment. What  
23 does that -- how do you interpret the second from last  
24 sentence?

25 "Certainly, based on information available today,

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1 no one can argue that prisons are locations where  
2 there are more than the usual population of what we  
3 now agree are 'high risk groups'."

4 What's it saying?

5 **MR HILL:** As I understand it, he is saying that the prison  
6 population mirrors the general population in terms of  
7 potentially high-risk donors. I don't know if that is  
8 a reference to levels of hepatitis C or, as it would  
9 then have been known, non-A, non-B hepatitis, or if it  
10 is a reference to levels of AIDS or HIV in the prison  
11 population. But it seems to be an argument that there  
12 is no particular risk that associates with  
13 a population of prison donors as compared to  
14 a population of donors drawn from the general public.

15 **SIR BRIAN LANGSTAFF:** And it seems to lead on to the  
16 description, "we have either closed or sold Hyland  
17 owned centres that are in these less desirable areas",  
18 "these" being a reflection back to prisons with no  
19 more than the usual population of high risk groups?  
20 I don't quite understand what's being said.

21 **MR HILL:** I don't know if a reference to these "less  
22 desirable areas" is a reference to prisons or is  
23 a reference to the point that was being made on the  
24 previous page, which is that the desire for low cost  
25 haemophilia product has led to manufacturers obtaining

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1 of the NHF, the treaters and the patients, even if it  
2 does cause Hyland's costs to increase somewhat. I  
3 also trust that you will appropriately deal with those  
4 manufacturers who fail to comply through refusal to  
5 purchase or use their products and services."

6 That is the letter of --

7 **SIR BRIAN LANGSTAFF:** It seems to imply, there, that it is  
8 yet to move its collection sites to what it describes  
9 as "more desirable locations" and it is -- until the  
10 NHF got on the case, it was using brokered plasma,  
11 buying plasma from plasma brokers.

12 **MR HILL:** Yes.

13 **SIR BRIAN LANGSTAFF:** Is there any reference in the  
14 Travenol Limited -- what's the date of this?  
15 3 June '87.

16 **MR HILL:** Yes.

17 **SIR BRIAN LANGSTAFF:** The document that we saw earlier  
18 from Travenol Limited setting out the identity of the  
19 places from which plasma was collected, does it  
20 mention anything about buying from brokers?

21 **MR HILL:** I don't think that it does. I will go back and  
22 check that, and I will check Dr Kingdon's statement.  
23 The phrasing of the letter is that it seems to be  
24 a response to something that has been asked of  
25 Travenol by the National Haemophilia Foundation. The

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1 plasma from "less desirable areas". My initial  
2 reading of it was that it's a reference to that  
3 earlier point that was being made, rather than to the  
4 prison group. He's saying that we've done both, as it  
5 were.

6 **SIR BRIAN LANGSTAFF:** What do you mean, the point where  
7 the author blames the customer for the lack of safety  
8 of the product --

9 **MR HILL:** Yes.

10 **SIR BRIAN LANGSTAFF:** -- because he wants it cheap?

11 **MR HILL:** Yes. Yes, so the reference on the first page is  
12 to the need for plasmapheresis establishments, as the  
13 author saw fit, to be operated in "less desirable  
14 areas". So I took that reference of the second page  
15 to be a comment that those plasmapheresis centres had  
16 been closed down, as well as the ones in prisons.

17 **SIR BRIAN LANGSTAFF:** Then you were going to turn to the  
18 last paragraph?

19 **MR HILL:** Yes, the last paragraph says:

20 "I trust, Charles, that just as Hyland led the  
21 way in vacating prisons and will conform with your  
22 request to move our collection sites for plasma to  
23 more desirable locations, as well as refuse to use  
24 'brokered plasma' where quality of collection cannot  
25 be adequately assured, that we will have the support

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1 refusal to use brokered plasma doesn't necessarily  
2 imply an acceptance that brokered plasma was used in  
3 the past. It's saying that --

4 **SIR BRIAN LANGSTAFF:** Well, does it not? I mean, it's:  
5 "... just as Hyland led the way in vacating  
6 prisons [leading the way] will conform with your  
7 request to move our collection sites ... as well as  
8 refuse to use 'brokered plasma' ..."

9 **MR HILL:** I don't read that as being an acceptance of --

10 **SIR BRIAN LANGSTAFF:** Of past use -- just saying that we  
11 are agreeing to refuse to use. But it hasn't said, as  
12 it might have otherwise said, "We don't ever use it".

13 **MR HILL:** It hasn't in this letter, no. I will check,  
14 though, with Dr --

15 **SIR BRIAN LANGSTAFF:** I take your point. It doesn't say  
16 in terms "We have been using it, we're now going to  
17 stop", but it perhaps would have been more in tone  
18 with the rest of the letter if it had said, "We led  
19 the way in not using it at all".

20 **MR HILL:** Yes. It doesn't say that. But again, this  
21 letter clearly demonstrates that prison plasma had  
22 been used by Hyland Travenol in the past.

23 **SIR BRIAN LANGSTAFF:** Yes.

24 **MR HILL:** That, sir, is all I was going to say about the  
25 use of prison plasma at this stage. It's, as I say,

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1 something we will come back to in November.  
2 **SIR BRIAN LANGSTAFF:** We will take a break then, until  
3 five to 12.

4 (11.29 am)

5 (A short break)

6 (11.55 am)

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MR HILL:** Sir, on the question of whether Hyland used  
9 plasma brokers, that's an area that we're going to  
10 conduct some further research into and we will get  
11 back to you on that question, either in the coming  
12 week or so, or in November it might be helpful just to  
13 go to what Dr Kingdon said at CBLA0000011\_005, and  
14 it's page 5 of that document, please, Soumik. This  
15 comes with the same caveat as previously stated: that  
16 this statement dates from 1990, and it's not clear  
17 whether the situation being described is that as of  
18 1990 or for how much before that time. Paragraph 12,  
19 please, Soumik. What Dr Kingdon said was:

20 "The industrial manufacturers fractionate plasma  
21 collected from plasmapheresis centres around the  
22 United States. Hyland processes plasma collected from  
23 plasmapheresis centres owned and operated by Hyland  
24 throughout the United States and in addition, a number  
25 of independent contractors collect and process plasma

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1 further evidence, was one of the sources of blood and  
2 blood plasma for the American market, the other being  
3 blood banks, community blood banks, as well as the  
4 commercial fractionators. It doesn't help, really,  
5 with the question of contractors, and it doesn't help  
6 with the question of brokers, at least at a time  
7 previous to the date which this was referring to,  
8 which was the 1990s, was it?

9 **MR HILL:** The statement dates from 1990 --

10 **SIR BRIAN LANGSTAFF:** It appears to be describing what is,  
11 ie at 1990, as to what was, as opposed to which it  
12 doesn't really say very much, except in respect of the  
13 American Red Cross arrangements. Have I misunderstood  
14 it?

15 **MR HILL:** No, I think that's correct. The tense used is  
16 "Hyland processes", present tense:

17 "... plasma collected from plasmapheresis centres  
18 owned and operated by Hyland throughout the  
19 United States and in addition, a number of additional  
20 contractors collect and process plasma under contract  
21 in compliance with standards set by Hyland."

22 So as of 1990, there are Hyland-owned plants and  
23 plants that operate to Hyland's standards, and no  
24 reference to a third category of plasma brokers.  
25 Whether that was the case at earlier points in time is

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1 under contract in compliance with standards set by  
2 Hyland. Hyland also custom fractionates all fresh  
3 frozen plasma collected by the American Red Cross  
4 under a plasma fractionation contract. Under that  
5 contract, all American Red Cross plasma is  
6 fractionated in accordance with the process created by  
7 Hyland although it is subsequently marketed and sold  
8 under a different name. This arrangement has been in  
9 effect since July 1985. Prior to this American Red  
10 Cross plasma was fractionated under contracts with a  
11 number of commercial manufacturers. Although the  
12 final product was sold as American Red Cross  
13 concentrate the product varied depending on which  
14 manufacturer was used to manufacture any particular  
15 batch."

16 I take from that, that American Red Cross plasma  
17 was not used in Hemofil, because that was a product  
18 that was marketed under Hyland's own name, so it  
19 doesn't seem to be --

20 **SIR BRIAN LANGSTAFF:** Well, the American Red Cross plasma  
21 would have been plasma collected from voluntary  
22 donors, I think --

23 **MR HILL:** Yes.

24 **SIR BRIAN LANGSTAFF:** -- and for the purposes of the Red  
25 Cross, which my current understanding, subject to

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1 not and by this statement, but Dr Kingdon wouldn't  
2 necessarily have been addressing that question in his  
3 statement. We have to do further research on it.  
4 That is -- I read that section, really, to remind us  
5 of the position that pertained as of 1990, but we  
6 don't know that that had been the position.

7 **SIR BRIAN LANGSTAFF:** Yes.

8 **MR HILL:** The Red Cross plasma is, it seems to me,  
9 something of a red herring for this Inquiry in its  
10 terms of reference.

11 **SIR BRIAN LANGSTAFF:** Well, it may have mattered for the  
12 particular case for which he prepared this statement.

13 **MR HILL:** Yes. Yes, but it doesn't seem to be something  
14 that was used in products that were sold in the UK.

15 **SIR BRIAN LANGSTAFF:** No, not so far as we are aware.

16 **MR HILL:** Quite. I'd like to turn now, sir, to the  
17 question of the use of plasma from outside the  
18 United States. Could we have on screen, please,  
19 Soumik, PJON0000054\_001. This is a document dated  
20 2 February 1979, it is a report of a production visit  
21 to two plants, the Lessines plant in Belgium, which,  
22 as we've heard, was a Hyland fractionation centre, and  
23 a Swiss Red Cross plant as well, which I needn't  
24 trouble you with. It's Lessines that is of interest  
25 to us.

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1 The report is produced by C Chard. At that  
2 stage, Dr Chard was the scientific services manager  
3 for Travenol Limited, the UK-based company. He  
4 subsequently became the scientific and regulatory  
5 affairs manager for Travenol Limited.

6 Another name that is mentioned in the top  
7 left-hand corner is G Hardy. Dr Hardy had been  
8 Dr Chard's predecessor as scientific services manager  
9 for Travenol Limited. I'm not entirely sure what  
10 Dr Hardy's position was as of February 1979, but he  
11 clearly was still involved to some extent in the  
12 company. The report is distributed to a number of  
13 people, including AW Barrell who was the manager  
14 director of Travenol Limited, and it was marked to be  
15 confidential.

16 Before we go through the report, I will just  
17 flag up one point. There is reference made to  
18 Buminate, which is an albumin product that Travenol  
19 produced, so it is not a Factor VIII concentrate, and  
20 I just flag that for when we're going through. The  
21 first page of the introduction to the report from  
22 Dr Chard is as follows:

23 "The full report of my visit to Lessines and the  
24 Swiss Red Cross is attached.

25 "The following are key points arising from the

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1 Then paragraph 7 "Conclusion":

2 "If Lessines is inspected (this is a possibility  
3 if a variation to source, Buminate 5% from Swiss Red  
4 Cross, is submitted) it is highly likely that the  
5 import of all Lessines manufactured Hyland product  
6 will be stopped until the areas are upgraded. This is  
7 a high risk area for the company and was avoided by  
8 the inspectors during their visit only because they  
9 were not aware we imported Hyland products from  
10 Lessines. There is little possibility of a UK  
11 inspector allowing Lessines to manufacture Hemofil for  
12 the UK market."

13 Those are the sections of the report that I wish  
14 to highlight, sir. I think it's worth making the  
15 point that it appears from the report that the  
16 products that were being produced in Lessines and  
17 imported to the United Kingdom were albumin products,  
18 Buminate products, not Hemofil. There was clearly  
19 some suggestion within the company that Lessines might  
20 be used to produce Hemofil and that may or may not be  
21 the reason why Dr Chard was sent out to inspect  
22 Lessines, but you will have seen his conclusion that  
23 there was little possibility of a UK inspector  
24 allowing Lessines to manufacture Hemofil for the UK  
25 market.

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1 report:

2 "The Lessines Hyland facility does not meet UK  
3 requirements for aseptic processing.

4 "If Lessines is inspected imports of Hyland  
5 products to the UK will probably not be allowed to  
6 continue, ie Buminate 5% and 20% from Lessines are at  
7 risk.

8 "There is no possibility of importing Lessines  
9 manufactured Hemofil made under present conditions.

10 "Our UK licence suggests that plasma originates  
11 in the US. In fact plasma originates from other  
12 sources outside the US, eg Lesotho and Belize -- this  
13 information should be submitted to the DHSS or plasma  
14 from these sources should not be used for UK  
15 products."

16 If we could turn now to page 3 of the full  
17 report. Paragraph 5, it contains a little more  
18 information about the plasma sourcing. Dr Chard wrote  
19 that:

20 "The UK licence files refer to US produced  
21 plasma. In fact plasma is received also from Lesotho  
22 and Belize, plasma from Lesotho was readily visible in  
23 the plasma freezer. As this plasma is routinely used  
24 for UK product it is important that either we inform  
25 the UK DHSS or discontinue using this plasma."

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1 We don't know, sir, what steps, if any, were  
2 taken in respect of Dr Chard's comments that the DHSS  
3 should be informed about the source of --

4 **SIR BRIAN LANGSTAFF:** Well, just look at the last sentence  
5 on that page, if we can just go back to it, Soumik.

6 That suggests that you're right: that at that  
7 stage Hemofil was not being made in Lessines for the  
8 UK market, because otherwise it wouldn't necessarily  
9 be framed quite as it is.

10 **MR HILL:** There is other evidence which I haven't troubled  
11 you with that Lessines was used to label the bottles  
12 of Hemofil that were shipped over from the United  
13 States, but they had been -- the product itself had  
14 been manufactured in the United States, so it was  
15 purely an external process that was going on at  
16 Lessines at that time.

17 **SIR BRIAN LANGSTAFF:** Yes, so it was sort of a bottling  
18 plant, in effect, was it, or ...

19 **MR HILL:** Yes. Placing the labels that were required for  
20 the UK product onto it --

21 **SIR BRIAN LANGSTAFF:** I see.

22 **MR HILL:** -- at Lessines.

23 We do have a further document, SPHL0000276\_036,  
24 which indicates that thought was being given in the  
25 company as of 1981, so two years after Dr Chard's

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1 report, to the possibility of using Lessines to  
 2 manufacture Hemofil.  
 3 Could we have on screen, please, Soumik,  
 4 SHPL0000276\_036.  
 5 This is an internal memorandum, again. We can see  
 6 it is from Dr Chard to a number of other individuals  
 7 within Travenol. For reference, it's -- from a head  
 8 of notepaper -- from Travenol Laboratories Limited, so  
 9 the UK company.  
 10 It says this:  
 11 "The planned inspection of Lessines by DHSS  
 12 Medicines Inspectors for approval to source Hemofil  
 13 from Lessines was postponed until September at  
 14 Lessines's request.  
 15 "We have now officially received confirmation  
 16 that the Hemofil variation will not be approved until  
 17 an inspection has been carried out."  
 18 One further document to bring to your  
 19 attention --  
 20 **SIR BRIAN LANGSTAFF:** Just before we go there, may just  
 21 ask, the reference to Dr Chard's report shows that it  
 22 comes from Peter Jones or is relating to Peter Jones.  
 23 **MR HILL:** Yes.  
 24 **SIR BRIAN LANGSTAFF:** Do we know how it came into his  
 25 possession?

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1 dates from 1983. You'll recall from Dr Kingdon's  
 2 statement that the use of overseas plasma had ceased  
 3 circa 1978 and was no longer being used by the  
 4 mid-1980s.  
 5 **SIR BRIAN LANGSTAFF:** That wouldn't fit with the date of  
 6 this visit to Lessines, would it?  
 7 **MR HILL:** It does and doesn't, in the sense that it's  
 8 a 1979 document but the reference is to plasma from  
 9 Lesotho being found in the freezer.  
 10 **SIR BRIAN LANGSTAFF:** Yes.  
 11 **MR HILL:** And my understanding is that plasma which is  
 12 said to be significantly out of date can be used for  
 13 albumin production in the way it can't be used for  
 14 production of other materials. So while that plasma  
 15 was, according to Dr Chard, present in Belgium in  
 16 1979, it's not clear when that plasma was collected.  
 17 **SIR BRIAN LANGSTAFF:** No, but then that might be so of  
 18 most fresh frozen plasma unless there's a date on it.  
 19 **MR HILL:** Yes, Dr Chard doesn't say anything about the  
 20 date on which it was collected.  
 21 There is a document we will come to in a second  
 22 which refers to a Lesotho plant and when it was  
 23 closed, which I think was 1976. So if that is  
 24 correct, then the plasma must have been taken as of  
 25 1976 and was still in the deep freeze in Lessines in

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1 **MR HILL:** I don't know that, sir. We can try to find out.  
 2 **SIR BRIAN LANGSTAFF:** Certainly, he makes reference to  
 3 Lesotho and Belize in a report which I think you may  
 4 have shown us yesterday.  
 5 **MR HILL:** Yes. Yes, he does.  
 6 There is also a reference to Belize in the meeting  
 7 of February 1984, to which we've made reference  
 8 before. This is a meeting at NIBSC of officials from  
 9 the UK, officials from the US and fractionators,  
 10 documents to which we will return in some detail at  
 11 a later stage, but for now if we could have PRSE --  
 12 **SIR BRIAN LANGSTAFF:** If we go back -- just on the same  
 13 vein, if we go back to the list of places from which  
 14 plasma comes, which Travenol Ltd in Thetford set out,  
 15 there's no suggestion of any of those centres being  
 16 situated in Belize or Lesotho?  
 17 **MR HILL:** No, the only one that isn't expressly stated to  
 18 be in the United States is the Cherry Street --  
 19 **SIR BRIAN LANGSTAFF:** Where you just don't know?  
 20 **MR HILL:** We don't know.  
 21 **SIR BRIAN LANGSTAFF:** Yes.  
 22 **MR HILL:** If we could have onscreen, please, PRSE0003071,  
 23 and page 5 of that document.  
 24 The thing that I should add, sir, about the  
 25 Travenol Ltd list of all the centres is that that

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1 1979. I cannot comment on how likely that is.  
 2 The document we have onscreen, this is from  
 3 February 1984. As I say, it's this meeting between  
 4 various fractionators and officials.  
 5 At the bottom of page 5, we have a contribution  
 6 from Dr Ashworth of Cutter. And he described  
 7 collection procedures at plasmapheresis centres used  
 8 by the four main US companies. It seems  
 9 overwhelmingly likely that Hyland/Travenol would have  
 10 been included within those four major companies.  
 11 "There are some 340 plasmapheresis stations in  
 12 42 states, employing 6,000 people. Approximately  
 13 a third of these centres are owned by the companies,  
 14 and the rest supply plasma under contract. All  
 15 plasmapheresis stations in the United States are  
 16 licensed by the FDA, as is the centre in Belize."  
 17 Unfortunately the document doesn't say anything  
 18 more about what that centre in Belize is. It's also  
 19 notable that we are dealing with a description of what  
 20 was being done at that time, February 1984, rather  
 21 than a historic overview of how plasma had been  
 22 collected in the past.  
 23 One final point of note about that last document  
 24 is that that was a statement that was made in the  
 25 presence of UK officials and US officials. So there

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1 was no effort to hide the centre in Belize. It is  
 2 referred to expressly.  
 3 Soumik, please can we have SHPL0000735\_006.  
 4 A document that we will return to at a later  
 5 stage about the response to the risk of AIDS but here  
 6 used just to help us understand the way in which  
 7 plasma was collected historically.  
 8 It is dated 23 August -- I think that's 1985,  
 9 yes -- 1985. It is an internal Hyland memorandum from  
 10 the American company, Travenol Laboratories Inc.  
 11 In terms of "Plasma Sourcing", it states:  
 12 "We have committed that we will not use plasma  
 13 from high risk sources such as:  
 14 "prisons or  
 15 "geographic areas which are considered to be  
 16 high risk, ie San Francisco, Hollywood and New York  
 17 City.  
 18 "We do not obtain plasma from third world  
 19 countries.  
 20 "Lesotho, [South] Africa was closed in 1976 (our  
 21 only African plasma centre).  
 22 "The Mexico City plant (which used Mexican  
 23 sourced plasma) was closed in 1981.  
 24 "Puerto Rico was closed in 1980."  
 25 No reference is made here to Belize. It's also

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1 was then the vice president of regulatory affairs and  
 2 quality control at Travenol, and later moves to  
 3 Armour, wrote to Harry M Meyer, the director of the  
 4 National Centre for Drugs and Biologics at the FDA,  
 5 and this was about the use of plasma, but was obtained  
 6 from the homosexual community.  
 7 The reference is CGRA0000246, please, Soumik.  
 8 Again, I understand this to be part of the  
 9 process by which the FDA was seeking to inform itself  
 10 and seeking to influence the behaviour of the  
 11 pharmaceutical companies as of September 1982 in  
 12 response to the increasing knowledge of the risk of  
 13 AIDS, and we'll see a reference to Dr Donohue again,  
 14 who we referred to earlier.  
 15 What Dr Rodell said in this letter is:  
 16 "During a recent telephone conversation,  
 17 Dr Dennis Donohue expressed concern existing within  
 18 the Office of Biologics, regarding the use of Source  
 19 Plasma (Human) obtained through specific recruiting  
 20 efforts aimed at the homosexual community. Dr Donohue  
 21 requested assurance that such plasma would not be in  
 22 the manufacture of Antihemophilic Factor (Human) until  
 23 the situation regarding Acquired Immune Deficiency  
 24 Syndrome (AIDS) was more clearly defined.  
 25 "Hyland Therapeutics Division, Travenol

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1 important to note that the fact that plasma had  
 2 previously been obtained from what were described in  
 3 this document as "third world countries" doesn't  
 4 necessarily indicate that that plasma was used in  
 5 Hemofil or any product that was on the UK market. We  
 6 simply don't know.  
 7 **SIR BRIAN LANGSTAFF:** What's the document addressing  
 8 generally, under "Plasma Sourcing"?  
 9 **MR HILL:** It is entitled "Outline of Product Safety Work".  
 10 **SIR BRIAN LANGSTAFF:** Yes.  
 11 **MR HILL:** I read this document to be part of a wider  
 12 response as of 23rd of -- 1986, a stocktaking of where  
 13 they are on the safety methods that are being used at  
 14 that time, in respect of plasma collection and plasma  
 15 use.  
 16 **SIR BRIAN LANGSTAFF:** Yes.  
 17 **MR HILL:** The point there, that this is where I have got  
 18 the date of 1976 for closure of Lesotho from. But we  
 19 can see, by comparing that document to Dr Chard's  
 20 report, that if Lesotho was closed in 1976, there was  
 21 still frozen plasma in Lessines in 1979.  
 22 I'm going to turn now to the question of the  
 23 effort to recruit donors from gay populations, or  
 24 areas in which there was a high level of gay donors.  
 25 In September 1982, Dr Michael Rodell, \*\* who

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1 Laboratories Inc is not engaged in any recruitment  
 2 programmes targeting the homosexual community for  
 3 plasma that may be used in the production of  
 4 Antihemophilic Factor (Human). Consequently we are  
 5 able to offer such assurance to you.  
 6 "We do wish to point out, however, that there  
 7 may be recruiting efforts of this type by  
 8 organisations collecting Whole Blood (Human), as part  
 9 of ongoing donor recruitment programs. Since  
 10 quantities of Recovered Plasma to be used in  
 11 fractionation do result from such activities, and  
 12 fractionators would be unaware of the origin of the  
 13 plasma, the probability for inclusion of this plasma  
 14 in routine manufacture does exist."  
 15 A couple of points to pick up from this  
 16 document, sir. The first is that the concern about  
 17 directly seeking to recruit gay donors comes from the  
 18 context of the fact that gay donors were found to have  
 19 a high level of hepatitis B antigen in their blood,  
 20 which was useful in providing vaccination products  
 21 against hepatitis B, therefore that plasma was of use  
 22 for that specific purpose.  
 23 Dr Donohue's concerns, as I read them from this  
 24 letter, are that donors who were selected for that  
 25 purpose were also having their plasma used for the

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1 general production of Factor VIII materials, despite  
2 the fact that it would be rich in hepatitis B antigen.  
3 Obviously, by September 1982, gay donors were  
4 considered to be high risk because of the emergence of  
5 AIDS.

6 A point to pick up from the final sentence --

7 **SIR BRIAN LANGSTAFF:** What is interesting about that is

8 I well understand why obtaining plasma from those  
9 communities thought to have a greater prevalence of  
10 hepatitis B in order to produce a vaccine suitable for  
11 use against hepatitis B might, if the same plasma or  
12 a surplus plasma were then used for other purposes,  
13 give rise in that plasma of a greater risk of  
14 hepatitis B.

15 But the risk which Dr Donohue is talking about  
16 here in September 1982, 15 September '82, is the risk  
17 of AIDS.

18 **MR HILL:** Yes, that's the specific context of this letter.

19 **SIR BRIAN LANGSTAFF:** Yes.

20 **MR HILL:** Although, as we will go on to see, there is  
21 certainly some criticism that this practice was ever  
22 engaged in.

23 **SIR BRIAN LANGSTAFF:** Yes.

24 **MR HILL:** We will come on to the reason as to why.

25 There appears to have been some internal

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1 anti-HBs, but does not use it in their fractionation,  
2 it is sold to Alpha. Mike has told Donohue that he  
3 thinks Hyland excludes homosexual plasma from AHF but  
4 he wanted to check their procedures before making  
5 a solid voluntary commitment. My guess is that Hyland  
6 will make the commitment."

7 So, as I say, that precedes the previous

8 document that we have just looked at, and Hyland go on  
9 to make the commitment.

10 **SIR BRIAN LANGSTAFF:** Precedes? This is 30 September.

11 **MR HILL:** 30 August.

12 **SIR BRIAN LANGSTAFF:** Oh, August. Beg your pardon, my  
13 fault. Thanks.

14 **MR HILL:** The reference, though, when taken together, is  
15 that while Hyland can say that it doesn't make factor  
16 concentrates using blood collected from donors who are  
17 recruited because they're gay, there is a reference to  
18 it being sold to Alpha, and it's not clear what Alpha  
19 then does with the product, from this document.

20 If we could go, please, to CGRA0000655.

21 This is a document dated 9 December 1982. It is  
22 again from Dr Rodell, Vice President of Regulatory  
23 Affairs and Quality Control at Hyland. It is sent to  
24 Charles J Carman, Chairman of the Board, and  
25 Dr Louis M Aledort, Medical Coordinator (*sic*) of the

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1 discussion within fractionators around this time, in  
2 fact slightly before it, about this issue, and we can  
3 see that from an internal memorandum from Cutter,  
4 another company, a rival of Hyland Travenol. It is at  
5 BAUM0000008\_1, please, Soumik. We will come on to  
6 deal with Cutter in due course this week, so I won't  
7 go into the names.

8 BAUM0000008 -- sorry, not underscore, just  
9 page 1 of the document. My mistake, thank you.

10 I won't go into those names, Cutter is a firm  
11 that we will deal with in due course. The opening  
12 line gives the context:

13 "Dr Donohue of FDA-BoB has asked you (Cutter) to  
14 voluntarily exclude plasma collected from known  
15 homosexuals from pools used in the production of Koate  
16 and presumably Konyne."

17 If we go down to the next paragraph, please.  
18 I'm only interested, for present purposes, in what  
19 this tells us about Hyland. It tells us that:

20 "Hyland (Mike Rodell) has had a policy that any  
21 plasma collected from a donor having a history of  
22 hepatitis (the disease, HBsAG positive, or in close  
23 association with others having the disease) are  
24 excluded from use in the manufacture of AHF.  
25 Currently Hyland collects plasma from homosexuals for

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1 National Haemophilia Foundation. It is responding to  
2 a letter of 2 November 1982 on various points.

3 I'm going to turn to the second page of the  
4 first paragraph. In this letter, Dr Rodell says, and  
5 I quote:

6 "Within the past several months, we have made  
7 a commitment to withhold from AHF manufacture any  
8 plasma obtained as a result of specific recruiting  
9 activities aimed at the gay community. You are no  
10 doubt aware of a significantly greater incidence of  
11 high titered anti-HBs plasma among homosexuals, likely  
12 due to close personal contacts with members of that  
13 community having clinical hepatitis B infections.  
14 Such plasma is of great need in the production of HBIG  
15 [hepatitis B immune globulin]; however, we no longer  
16 allow this plasma to enter those pools leading to AHF  
17 manufacture."

18 If we go down a couple of paragraphs, it says:

19 "I must point out that we, and other  
20 manufacturers, produce AHF derived from source  
21 material other than plasma donation. A significant  
22 amount of AHF is derived from Recovered Plasma,  
23 resulting from whole blood programs. Since  
24 manufacturers do not control the recruiting activities  
25 of collectors of whole blood, I cannot comment on the

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1 characteristics of their donors, other than that they  
2 represent the general population."  
3 The point from the first paragraph is the way in  
4 which the comments are phrased, firstly, that the  
5 commitment is made within the past several months and,  
6 second, from the final sentence, that the company no  
7 longer allows plasma collected from gay donors to  
8 enter pools leading to AHF manufacture. Again, the  
9 phrasing is interesting because it doesn't say that  
10 Travenol or Hyland produces the products from those  
11 donors, but there is reference to allowing the plasma  
12 to enter pools leading to AHF, anti-haemophilic  
13 fraction, manufacture.

14 **SIR BRIAN LANGSTAFF:** Just pause for a moment. It does  
15 seem to suggest, doesn't it, that Travenol Hyland is  
16 producing AHF derived from source material, other than  
17 plasma donations -- "we and other manufacturers", it  
18 says.

19 **MR HILL:** Sorry, sir, where is --

20 **SIR BRIAN LANGSTAFF:** The second-last paragraph:  
21 "I must point out that we ... produce AHF derived  
22 from source material other than plasma donations."

23 **MR HILL:** Yes. So the first point is about the use of  
24 plasma from gay donors.

25 **SIR BRIAN LANGSTAFF:** Yes.

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1 contradictory. However --

2 **MR HILL:** Everybody is in the general population, if one  
3 defines the general population --

4 **SIR BRIAN LANGSTAFF:** Yes, but I think "representing the  
5 general population" would seem to be in the same  
6 proportions as the general population, that's the  
7 sense of it.

8 **MR HILL:** Yes.

9 **SIR BRIAN LANGSTAFF:** If you recruit specific people from  
10 within the general population, the result will not be  
11 representative of the general population. It will be  
12 unrepresentative.

13 **MR HILL:** Yes.

14 **SIR BRIAN LANGSTAFF:** It will be skewed.

15 **MR HILL:** Yes.

16 **SIR BRIAN LANGSTAFF:** That's why I'm not -- it seems to me  
17 to be an internally contradictory statement --

18 **MR HILL:** Yes.

19 **SIR BRIAN LANGSTAFF:** -- as it's written.

20 **MR HILL:** As it's written, yes. The only point I would  
21 make is that this is a letter which -- I am using it  
22 for the purpose of looking at the gay population --

23 **SIR BRIAN LANGSTAFF:** Yes.

24 **MR HILL:** -- and this is an extra bit, as it were, about  
25 a slightly different --

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1 **MR HILL:** The second point here is that, yes, in this  
2 letter, there is a reference to the fact that Hyland  
3 have been using plasma which is obtained from -- as  
4 the discarded product from whole blood donation  
5 collected by others --

6 **SIR BRIAN LANGSTAFF:** Yes.

7 **MR HILL:** -- and they use that.

8 **SIR BRIAN LANGSTAFF:** And they don't know where it came  
9 from --

10 **MR HILL:** They --

11 **SIR BRIAN LANGSTAFF:** -- because they don't control the  
12 characteristics of the donors.

13 **MR HILL:** "Since manufacturers do not control the  
14 recruiting activities of collectors of whole blood,  
15 I cannot comment on the characteristics of their  
16 donors other than that they represent the general  
17 population."

18 **SIR BRIAN LANGSTAFF:** I'm not sure how that actually  
19 follows. Because if he accepts they might be  
20 recruiting from the population, why would they  
21 represent the general population? He doesn't know,  
22 does he?

23 **MR HILL:** Other than in a broad sense --

24 **SIR BRIAN LANGSTAFF:** I mean, it's a phrase but it does  
25 seem to me that those two comments are slightly

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1 **SIR BRIAN LANGSTAFF:** I think what you showed me is that  
2 the letter is saying, "We don't use -- we don't target  
3 the gay population for the purposes of obtaining  
4 plasma which we use for AHF; we don't manufacture AHF  
5 from any plasma we get from that source; we can't  
6 speak to whether there may be some in other material  
7 which we do use, because we don't control its  
8 collection".

9 **MR HILL:** Yes, the other point is that, although Hyland  
10 have, within the past several months, made that  
11 commitment, in the past --

12 **SIR BRIAN LANGSTAFF:** Yes, in the past they were doing it.

13 **MR HILL:** Well, they were allowing plasma to enter pools  
14 from which concentrate was made.

15 **SIR BRIAN LANGSTAFF:** So they were doing it in the past.

16 **MR HILL:** They might not have been making --

17 **SIR BRIAN LANGSTAFF:** They were making no conscious effort  
18 to prevent it.

19 **MR HILL:** They weren't necessarily making the product.  
20 The previous document referred to the fact that the --  
21 and it's a Cutter document providing hearsay evidence  
22 of what Hyland were doing. That said that currently  
23 Hyland collects plasma from homosexuals for anti-HBs  
24 (anti-surface antigen of hepatitis B), but does not  
25 -- (overspeaking) --

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1 **SIR BRIAN LANGSTAFF:** If we go back to the first  
 2 paragraph, what it seems to be saying is:  
 3 "Within the past several months, we have made  
 4 a commitment to withhold from AHF manufacture any  
 5 plasma obtained as a result of specific recruiting  
 6 activities aimed at the gay community."  
 7 You're right, that doesn't say that we were  
 8 doing it previously. But the last sentence:  
 9 "Such plasma is of great need in the production  
 10 of HBIG; however, we no longer allow this plasma to  
 11 enter those pools leading to AHF manufacture."  
 12 In other words, previously they were allowing it  
 13 to enter the pools.  
 14 **MR HILL:** Yes, but the only issue is whether or not they  
 15 were the ones who then went on to make that  
 16 concentrate. It may have been that Hyland itself  
 17 didn't make the concentrate but sold the plasma to  
 18 Alpha, who then went on to make the concentrates.  
 19 **SIR BRIAN LANGSTAFF:** I see.  
 20 **MR HILL:** That is what the memorandum from Cutter would  
 21 imply. But that, of course, is hearsay evidence about  
 22 what Hyland were doing. The phrasing of this is  
 23 interesting in that it doesn't say, if one looks at  
 24 that last sentence, after the semicolon, it doesn't  
 25 say, "however, we no longer allow this plasma to be

1 **MR HILL:** "Within the past several months, we have made  
 2 a commitment to withhold from AHF manufacture",  
 3 et cetera, et cetera.  
 4 **SIR BRIAN LANGSTAFF:** Yes, thank you. I've got there.  
 5 **MR HILL:** Another point to make about this letter is that  
 6 it describes no longer allowing plasma to enter the  
 7 pools leading to AHF concentrate. So that plasma is  
 8 no longer going to go into those pools. It doesn't  
 9 say what is happening to such plasma that is already  
 10 in the pools.  
 11 You'll recall of course, sir, Dr Kingdon's  
 12 evidence about how it could take six months to a year  
 13 before a donation appeared in a factor concentrate,  
 14 and one point when talking about AIDS testing --  
 15 sorry, HIV testing for the plasma donations, he refers  
 16 to it being two years between the step being  
 17 introduced and product still being on the shelf,  
 18 because of the product's shelf life.  
 19 I mentioned earlier, sir, there was a criticism  
 20 of the practice as a whole. If we look at  
 21 CGRA0000404, this is a supplemental expert witness  
 22 report from Dr Donald Francis MD DSc. This is part of  
 23 US litigation and it should be borne in mind that this  
 24 is an expert report on behalf of the plaintiffs in  
 25 that litigation.

1 used by us to make a concentrate"; it refers to "we no  
 2 longer allow this plasma to enter those pools leading  
 3 to AHF manufacture".  
 4 **SIR BRIAN LANGSTAFF:** So this first paragraph is capable  
 5 of covering both self-products and selling on to  
 6 Alpha.  
 7 **MR HILL:** Yes, it could be either. It is only when you  
 8 combine it with the previous document with Cutter that  
 9 perhaps the wording used here takes on a particular  
 10 resonance.  
 11 **SIR BRIAN LANGSTAFF:** It may or may not be that Cutter is  
 12 describing what then happened with the excess plasma  
 13 which Hyland weren't using -- Travenol weren't using  
 14 for their own purposes.  
 15 **MR HILL:** Yes. The document of the 30 August 1982, the  
 16 Cutter document, says:  
 17 "Currently Hyland collects plasma from  
 18 homosexuals for anti-HBs but does not use it in their  
 19 fractionation. It is sold to Alpha."  
 20 That's describing a situation as of August 1982.  
 21 **SIR BRIAN LANGSTAFF:** Yes.  
 22 **MR HILL:** This memorandum or this letter, sorry, from  
 23 December 198 --  
 24 **SIR BRIAN LANGSTAFF:** Later on, and so it may be saying,  
 25 "We've stopped selling on to Alpha".

1 Dr Francis says, the first paragraph of this  
 2 witness report:  
 3 "I am a physician specializing in epidemiology  
 4 and virology. For over twenty years, I was employed  
 5 by the United States Centers for Disease Control."  
 6 I wouldn't go through the rest of his career  
 7 there.  
 8 If we could go, please, to the next page,  
 9 paragraph 4. What Dr Francis says is this:  
 10 "Defendants" --  
 11 He is talking about the fact that he has learnt  
 12 that defendants Cutter and Baxter collected plasma  
 13 from urban homosexual men for hepatitis B  
 14 immunoglobulin, HBIG, production and used that same  
 15 plasma in the manufacture of Factor VIII and Factor IX  
 16 concentrates. That is the factual premise upon which  
 17 his comments are based. Of course, Dr Francis himself  
 18 can't speak to whether that was done. That is the  
 19 basis on which he makes these comments.  
 20 He says:  
 21 "Defendants could not have selected a higher  
 22 risk population for transmission of AIDS than  
 23 Hepatitis B positive urban homosexual men. These  
 24 donors were infected with Hepatitis B in direct  
 25 correlation to their number of sexual partners. Those

1 at highest risk of Hepatitis B were also at the  
 2 highest risk for all other sexually transmitted  
 3 diseases, including AIDS.  
 4 "By the mid-1970s, it was well known to  
 5 defendants and the scientific community, that urban  
 6 homosexual men had an exceptionally high prevalence of  
 7 Hepatitis B. This population provided a source of  
 8 plasma with high titers of Hepatitis B antibodies,  
 9 which defendants used for the manufacture of HBIG,  
 10 a product prescribed to create passive immunity to  
 11 Hepatitis B. By the same time, it was also well known  
 12 that a substantial proportion of this population  
 13 engaged in a lifestyle of sexual promiscuity involving  
 14 multiple partners, which caused widespread sexually  
 15 transmitted diseases, including not only Hepatitis B,  
 16 but also Hepatitis C (then unidentified and described  
 17 as 'non-A non-B' or 'NANB' hepatitis) cytomegalovirus  
 18 (CMV), and Epstein Barr disease. Thus, the same  
 19 conduct that made urban homosexual men valuable HBIG  
 20 plasma donors caused multiple other diseases that made  
 21 this population inappropriate donors for any other  
 22 blood or plasma product."

23 That was the view of Dr Francis. Of course, the  
 24 litigation will have heard other evidence from other  
 25 witnesses as well. That is all I'm going to say about

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1 obviously Dr Craske was well aware of the outbreak  
 2 before that -- there were 58 cases, Dr Craske said, of  
 3 hepatitis in people with haemophilia.

4 And his Lancet article -- which is published in  
 5 August 1975, so published after this memo was  
 6 produced, but obviously Dr Craske was well aware of  
 7 the situation before that -- The Lancet article is at  
 8 PRSE0001794, and it refers to the outbreak taking  
 9 place between April and June 1974. That is the  
 10 context.

11 What Dr Bidwell says is that:

12 "Dr Rizza has just told me that Dr Josephson,  
 13 who is the medical director of Travenol, is coming to  
 14 the [United Kingdom] on Monday, 9th June. They are  
 15 concerned about the reports of hepatitis associated  
 16 with the Hyland product and if invited to do so I will  
 17 join in the discussion in Dr Rizza's office. There is  
 18 a meeting to be organised by Travenol on the 10th when  
 19 others involved in the story of hepatitis associated  
 20 with the Hyland product will be present. This will  
 21 probably be held in London and Dr Rizza thinks he  
 22 should go and hopefully we may find out any  
 23 conclusions."

24 If we can now turn, please, to OXUH0001590\_001.

25 We can see a note of that meeting which was

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1 donors and Hyland Travenol at this point.

2 It leads to the final selection of documents.

3 This is something of a smorgasbord of documents from  
 4 various sources showing some of the communication that  
 5 Hyland Travenol had with the United Kingdom and  
 6 clinicians and Government at various times, so I'm  
 7 afraid we will be hopping around a bit, but there are  
 8 some documents which may be of interest within this  
 9 selection.

10 If we could begin with, Soumik, with  
 11 CBLA0005720.

12 We can see from the top of this document that  
 13 it's a memorandum sent from Dr Bidwell to Dr Maycock,  
 14 Dr Bidwell of the Protein Fractionation Laboratory in  
 15 Oxford to Dr Maycock who, among the other hats that he  
 16 wore, was the director of BPL at the time.

17 The date is 23 May 1975. The context, as I read  
 18 the document, is the outbreak of hepatitis that has  
 19 been reported by Dr Craske in respect of the use of  
 20 factor concentrates, and in particular Hemofil.

21 We saw, in the World in Action documentary --  
 22 I'm not sure if we showed it on Friday but we've seen  
 23 it before -- Dr Craske talking about the outbreak and  
 24 the fact that it is linked to Hemofil, and at the  
 25 time -- the documentary was broadcast in December, but

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1 produced by Dr Cleghorn of the National Blood  
 2 Transfusion Service. The note is marked to be  
 3 confidential and it states this:

4 "On 10th June last I chaired an informal meeting  
 5 at which we discussed the problem of hepatitis  
 6 following the administration of AHG concentrates. A  
 7 list of those attending is attached.

8 "Dr Craske presented the results of his  
 9 epidemiological survey and there was further comment  
 10 on the virological aspects by Drs Banatvala and Dane.  
 11 It was clear that not only identifiable hepatitis B  
 12 was involved but also presumptive A and/or other  
 13 varieties.

14 "Dr Josephson on behalf of Travenol Laboratories  
 15 stated that the incidence of hepatitis B was explained  
 16 by manufacture of stock-piled plasma, the donors of  
 17 which had been screened only by CEP. He suggested  
 18 that it was unlikely that the problem was confined to  
 19 the Hemofil and events subsequently have shown this to  
 20 be true, at least in respect of Kryobulin."

21 "After considerable discussion, it was agreed  
 22 that while we could expect a drop in the cases of  
 23 hepatitis B as material screened by HA and RIA  
 24 techniques came through, the problem of non-B  
 25 hepatitis would remain."

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1 The attendance list of the meeting -- if we  
2 could have this on screen, please, Soumik -- is  
3 NHBT0101337\_008.

4 We can see those present included Dr Rogers,  
5 Dr Stern, Professor Ingram, Dr Peter Jones, Dr James,  
6 Dr Stableforth, Dr Craske, Dr Dane.

7 I pause there to note that that is the doctor  
8 whose correspondence we looked at last week about  
9 Immuno and hepatitis.

10 Dr Banatvala, Dr Josephson from Travenol,  
11 Dr Cleghorn, who made the note, Mr Pugh, from  
12 Travenol, and Mr Mee from Travenol. Those are both  
13 from Travenol Limited, the UK company.

14 Dr Johnson, we can see, is from  
15 Travenol International, the American company.

16 Mr De Vreker, again, from the International  
17 company, did not attend the meeting. Dr Rizza and  
18 Dr Bloom -- and you'll recall from the note made by  
19 Dr Bidwell that there may have been a separate meeting  
20 with Dr Rizza in Oxford.

21 **SIR BRIAN LANGSTAFF:** Could you just go back to the page  
22 before, please. And before.

23 **MR HILL:** The note is at OXUH --

24 **SIR BRIAN LANGSTAFF:** No, the page before this. Same  
25 document.

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1 SHPL0000276\_141.

2 The next three documents are, in effect, a worked  
3 example of an adverse reaction being noted. We can  
4 see that the first document is from Professor Ingram  
5 at St Thomas' Hospital, dated 25 November 1975. It is  
6 sent to Dr Hardy, then the scientific services manager  
7 at Travenol Limited. Dr Hardy was one of the names  
8 that was copied into Dr Chard's report on the Lessines  
9 facility.

10 Professor Ingram is writing to Dr Hardy to inform  
11 him that a patient (the name is given) that has  
12 received a quality of Hemofil has developed jaundice.

13 The record of the Hemofil received is given.

14 It's noted that that patient has received other  
15 blood products between 5 August and 17 November, and  
16 then details are given of the jaundice which has been  
17 found.

18 SHPL0000276\_138, please, Soumik.

19 4 December 1975. Dr Hardy writing to the DHSS,  
20 enclosing the correspondence between Professor Ingram  
21 and himself which refers to a case of jaundice which  
22 occurred while a patient was receiving Hemofil and  
23 other blood products. So we can see that that is  
24 being notified to the DHSS by the company.

25 If we could have SHPL0000276\_140.

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1 **MR HILL:** That is the first page of this document.

2 **SIR BRIAN LANGSTAFF:** Oh, so it will be, yes,  
3 OXUH0001590\_001. Thank you.

4 I just want to understand what's being said in the  
5 second last paragraph there. Because I note that  
6 a Dr Dane has given an agreement --

7 **MR HILL:** I understand this --

8 **SIR BRIAN LANGSTAFF:** -- to a number of people in the  
9 pool.

10 **MR HILL:** I understand this to be a reference to, in fact  
11 what we have just been talking about, using pooled  
12 plasma with high hepatitis B antigen levels as a way  
13 of creating a product which can then be used as  
14 essentially a vaccine to try to prevent infection.

15 **SIR BRIAN LANGSTAFF:** I see.

16 **MR HILL:** So here, perhaps counterintuitively, the  
17 suggestion was originally that you need a pool of  
18 30 such donors to be able to make an effective  
19 product. Dr Dane says he would rather have a pool  
20 which is nearer to 100 but people think that that was  
21 impracticable.

22 **SIR BRIAN LANGSTAFF:** I see.

23 **MR HILL:** So a slightly different issue.

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

25 **MR HILL:** If we can turn, please, now, Soumik, to

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1 Dr Hardy, of course, referred to correspondence,  
2 not just a letter, from Professor Ingram --  
3 correspondence -- and it's fair to say this implied  
4 his reply, as well, which is also dated  
5 4 December 1975, which thanks Professor Ingram for the  
6 letter.

7 Notes that the patient did receive other blood  
8 products during the time in which the jaundice  
9 developed, and says that:

10 "With regard to the Hemofil batches quoted in  
11 your letter, I can tell you the batch number [he gives  
12 the number] is in fact the same batch [of concentrate]  
13 number [he gives the other number as well]."

14 There seems to be a mistake in labelling in that  
15 one had the US product label and the other had the  
16 UK product label.

17 "I can confirm that both the final product and  
18 all the plasma used in the manufacture of this Hemofil  
19 was tested by the radio-immuno assay technique for  
20 hepatitis B antigen, both by Hyland Laboratories and  
21 (in the case of the final product) by the Division of  
22 Biological Standards laboratories in Hampstead".

23 So if a product has been tested, I think it's  
24 implied in the letter, although not stated, that the  
25 results of those tests were negative because otherwise

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1 the product would not have been used.

2 We can see that this case of hepatitis has been  
3 reported, both to the company and to the DHSS, but, as  
4 so often in these cases, the patient has been using  
5 multiple blood products, and the tests which have been  
6 conducted, on the donations and the final product, as  
7 of 1975 there is a question as to how sensitive those  
8 tests were.

9 Turning to a separate subject, and that is  
10 correspondence with the Government in and around 1979  
11 about the possibility of Travenol becoming involved in  
12 fractionation within the United Kingdom, so not just  
13 importing the products but producing them commercially  
14 within the UK as well, an internal DHSS note records  
15 that in or around 1979 Travenol approached the then  
16 Parliamentary Under-Secretary of State of the DHSS,  
17 Eric Deakins, to discuss the possibility of setting up  
18 a fractionation plant in the United Kingdom.

19 Travenol were one of three commercial companies  
20 who are said in this note to have been interested in  
21 this. The others appear to have been Cutter and the  
22 Swedish company, Kabri. That's K-A-B-R-I.

23 The references are DSC0003743\_131, and  
24 DHSC0002313\_054.

25 A meeting of officials and Mr Deakins took place

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1 react strongly against any attempt to use donated  
2 blood commercially.

3 "2.2. It might lead to increased pressure to  
4 collect plasma only from donors [as opposed to plasma  
5 and blood], but this practice (which is common in the  
6 USA) was still very controversial and in some respects  
7 ethically questionable.

8 "2.3. Although factor 8 was the main component  
9 of interest to the NHS, there were some 20 derivatives  
10 from blood plasma and the extent of their use and cost  
11 in the NHS was not known. Enquiries were being made  
12 about the use of these products in the NHS, and  
13 a decision on the possibilities for collaboration  
14 could not effectively be made until the results were  
15 available.

16 "3. It was agreed that officials should meet  
17 Travenol's representatives to discuss their proposals  
18 in more depth. It was felt that the only real scope  
19 for co-operation at the moment would be if  
20 they processed the blood plasma collected by the NBTS,  
21 and were paid for doing so, but returned all the  
22 products to the NHS. This would probably lower their  
23 unit costs a little and afford them the prestige of  
24 supplying the NHS."

25 "[The Parliamentary Under-secretary] would wish

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1 to discuss the Travenol proposal on 29 January 1979.

2 If we could have on screen, please, DHSC0002313\_055.

3 We can see the date of the meeting is in the top  
4 line. Present are the Parliamentary Under-Secretary  
5 of State, Mr Brechin, Mr Dutton, Mr Harley, Mr Jones  
6 and Dr Waiter.

7 Dr Waiter I understand to have been the  
8 predecessor of Dr Walford in the position of the  
9 medical officer within the DHSS.

10 Mr Dutton is a name regularly seen on these  
11 papers at this time as well, also working within the  
12 same section of the DHSS, as was Mr Harley.

13 In paragraph 1 it says:

14 "It was established that Travenol's proposals  
15 would probably be to process blood plasma donated by  
16 volunteers in Britain and provide the NHS with its  
17 Factor 8 requirements at no cost. However, Travenol  
18 would doubtless then wish to extract albumin and other  
19 remaining components and sell them at considerable  
20 profit.

21 "2. Whilst the haemophilia lobby were very  
22 strongly pressing for increased production of  
23 Factor 8, there were a number of drawbacks to the  
24 proposal.

25 "2.1. It was felt that volunteer donors would

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1 to be kept informed of the outcome of the meeting."

2 The date of the note is 1 February 1979.

3 Fair to say, sir, this is very much at an early  
4 stage in the discussions between Travenol and the  
5 DHSS.

6 Worth noting, though, that these discussions are  
7 taking place in January 1979. So that is at the  
8 tail end of the Callaghan Government rather than the  
9 Thatcher Government. Also before Dr Walford was in  
10 post. We picked up the story from when Dr Walford  
11 came to post.

12 The meeting between Travenol and DHSS officials  
13 took place on 19 March 1979. The reference for it is  
14 DHSC0000047. I won't take you to it, sir. It's fair  
15 to say that there were some exploratory discussions  
16 about the way in which Travenol could either work in  
17 partnership with BPL or manufacture a plant on its  
18 own, the question of whether Travenol would need to  
19 import plasma, and Travenol saying that it would, in  
20 order to make the prospect viable, and the need then  
21 to ensure that a distinction was drawn between NHS  
22 plasma and imported plasma.

23 Those were the types of issues that were  
24 discussed.

25 Mr Deakins was kept informed of that meeting in

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1 a minute which was dated DHSC0002313\_057. Mr Harley  
2 proposed that further work had to be done and further  
3 information gathered before any subsequent decisions  
4 were taken. And a somewhat non-committal letter was  
5 drafted in response to Travenol. And that is  
6 DHSC0002313\_058.

7 July 1979 saw the election of the Thatcher  
8 Government, and Dr Vaughan became the Minister of  
9 State for Health. In an internal minute, he noted  
10 that Travenol were said to have "put a collaboration  
11 scheme to us, which was not pursued", that's what is  
12 written in the minute. That's DHSC0002313\_010. And  
13 so we see Dr Vaughan showing an interest in the  
14 proposal that has been made and seeking to obtain  
15 further information about it.

16 The response of the civil servants to that,  
17 which is at DHSC0002313\_012, is to place it within the  
18 wider context of a discussion that was then ongoing  
19 about the future of BPL -- the role, if any, of  
20 a commercial partner to BPL. And we can see that the  
21 issue then gets subsumed within that wider discussion.

22 We can see Mr Birrell (?), \*\* the managing  
23 director, writing to Dr Vaughan, on 13 February 1980,  
24 DHSC0000858, in which he seeks to encourage further  
25 engagement with the company. Again, it seems that

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1 Limited. These were complaints that BPL was being  
2 held to a lesser standard than commercial firms. He  
3 complained about dual standards and contrasted the  
4 most rigorous standards required of commercial  
5 companies with the position of BPL. This is in the  
6 context of the Critical Medicines Inspectorate Report  
7 and, indeed, a critical 1981 World in Action  
8 documentary.

9 The final document in respect of Hyland and  
10 Travenol is HSOC0029671\_046. This is a Haemophilia  
11 Society document of a meeting dated 12 February 1976  
12 in which the Society have received confirmation from  
13 Travenol Laboratories that they will provide some help  
14 to the Society, but the committee were, and I quote,  
15 "very disappointed" to learn that it was far less than  
16 they had originally been led to believe. Travenol  
17 were paying for the printing and mailing of the  
18 programme and registration forms of the congress, the  
19 printing and mailing of the first issue of the  
20 new-style news bulletin and the provision of treatment  
21 materials to be used during the Society's congress.

22 It was agreed to accept those offers but, as  
23 I say, some disappointment expressed about the level  
24 of support that was being offered by Hyland Travenol  
25 at that time.

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1 there was some debate about how that letter should be  
2 replied to, but some civil servants suggesting, in  
3 marginalia, that the reply should be made, and I quote  
4 "rather more non-committal". That is the same  
5 reference.

6 As we know, nothing ultimately came of  
7 commercial involvement within fractionation of the UK,  
8 and a relatively early decision was taken that, if  
9 there were to be any commercial involvement, it should  
10 be with a British company. Travenol, the  
11 international branch of Travenol, which would be the  
12 one who would be required to be involved, obviously  
13 did not meet that description. I note in passing,  
14 sir, that Mr Birrell \*\* in 1984 wrote a number of  
15 letters to Lord Glenarthur and to individuals within  
16 the DHSS, which we discussed during Lord Glenarthur's  
17 evidence.

18 Finally, from Mr Birrell, \*\* the reference --  
19 sorry, I've misplaced that reference for the moment.  
20 Yes, the reference is DHSC0026448 and DHSC0032854.  
21 I don't ask for these documents to be brought up. But  
22 these are letters from Mr Birrell \*\* to the  
23 superintendent at the Medicines Inspectorate at the  
24 DHSS and to John MacGregor MP who appears to have been  
25 the local MP for Mr Birrell \*\* and/or Travenol

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1 That, sir, concludes the presentation on Hyland  
2 Travenol. As I say, the presentation on Immuno is  
3 distinct because they were separate companies at the  
4 time, although they've been dealt with together in  
5 this section of the timetable. There are, of course,  
6 a number of loose ends which we've identified during  
7 the course of this presentation, which we will come  
8 back to in due course.

9 **SIR BRIAN LANGSTAFF:** Yes. Well, thank you very much.  
10 Well, we will take a break then, now, until  
11 two o'clock. Two o'clock.

(1.05 pm)

(The Luncheon Adjournment)

(2.00 pm)

15 **MS RICHARDS:** Sir, we turn this afternoon to Armour. The  
16 themes and issues that I'll be exploring in relation  
17 to Armour today and tomorrow, we'll start with a brief  
18 explanation of its corporate structure. I'll then  
19 look at the licensing history, insofar as relevant to  
20 the Inquiry's terms of reference, and some of the  
21 product details.

22 I'll then look at matters relating to donors,  
23 selections, screening and pool sizes. Then  
24 communication of risk by way of product inserts, data  
25 sheets and the like, and to some extent, explore

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1 interactions between Armour and relevant third  
2 parties, such as haemophilia Centre Directors in the  
3 United Kingdom.

4 As Mr Hill explained last week, in early  
5 November, one of the hearings in early November, we  
6 will be exploring in more detail, and across the full  
7 range of pharmaceutical companies who imported factor  
8 concentrates into the UK, their knowledge of the risk  
9 and the way in which they chose to respond or not  
10 respond to risks in relation to both hepatitis and  
11 HIV. So although the documents that we look at will  
12 obviously touch on those issues, there will be a much  
13 more detailed examination of that in November.

14 In relation to Armour, one issue of particular  
15 significance is that of seroconversions from its  
16 heat-treated product, how it responded to that  
17 information, and the chain of events and decisions  
18 that resulted in the withdrawal of the heat-treated  
19 product from the UK market. Again, I will be touching  
20 on the handful of documents relating to that, but that  
21 will be the subject of a more detailed explanation and  
22 exploration at the November hearing.

23 It's also important to bear in mind that you  
24 will be hearing from a witness in relation to Armour,  
25 Mr Christopher Bishop, who worked for Armour in the

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1 investigations or involvement in litigation in the US  
2 or here, or both, who may well be able to identify  
3 documents that I don't refer to, and we very much  
4 welcome any suggestions of any further material that  
5 we should consider.

6 So starting with the corporate structure, Armour  
7 is an American -- or was an American pharmaceutical  
8 company founded in 1951 in Kankakee, Illinois in the  
9 States. It prepared, amongst other products, factor  
10 concentrates in the United States which were  
11 distributed to the United Kingdom through  
12 a United Kingdom company called Armour Pharmaceutical  
13 Company Limited. It changed its name a number of  
14 times and so I'll look at that shortly.

15 The information that we have in relation to  
16 Armour's corporate history is largely drawn from  
17 a witness statement of a Ms Samantha Silver, the  
18 reference -- we don't need to put it up at the moment,  
19 Soumik, but the reference is WITN3422001. Ms Silver  
20 is a partner in Kennedys Law, instructed by Armour in  
21 relation to the Inquiry, and provided a statement to  
22 assist in setting out Armour's corporate history, and  
23 she confirms in her witness statement she's also  
24 reviewed relevant material at Companies House for the  
25 purpose of providing that witness evidence.

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1 United Kingdom. He will be giving evidence to the  
2 Inquiry in early November. We will see his name come  
3 up in a number of documents that we look at today and  
4 tomorrow, a number of themes will need to be explored  
5 with him and you'll obviously wish to hear his  
6 evidence before drawing any conclusions in relation to  
7 the Armour material.

8 The focus of the material that we look at this  
9 afternoon and tomorrow in relation to Armour will be  
10 contemporaneous documents, so documents from the 1970s  
11 and 1980s, there are a number of secondary sources,  
12 books, journalistic investigations, subsequent  
13 litigation, subsequent inquiries such as the Krever  
14 Inquiry Report, which you'll no doubt wish to consider  
15 and draw on in due course but I'll be focusing, for  
16 the purpose of today and tomorrow, on the  
17 documentation as it existed at the time.

18 As Mr Hill has already made clear, it's  
19 an incomplete picture. There's a lot of material that  
20 we do have but there's also unfortunately a lot that  
21 we don't have.

22 In that regard, we're very conscious that there  
23 are Core Participants who are highly knowledgeable in  
24 relation to the activities of pharmaceutical  
25 companies, whether from their own research and

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1 There is also a statement from  
2 a [Ms] Rajinder Bassi -- again, we don't need to pull  
3 it up now, but it's WITN6391001 -- a partner in a law  
4 firm called Kirkland & Ellis International, who  
5 represent Revlon Inc in their current incarnation, and  
6 [Ms] Bassi provided [her] statement largely in  
7 response to the written statement that the Inquiry  
8 received from Jason Evans.

9 Just looking first of all at Armour on  
10 an international plain, since its foundation in 1951,  
11 Armour has been owned by several different parent  
12 companies. In 1970, we understand it was purchased by  
13 Greyhound and then Greyhound in 1977 sold Armour to  
14 Revlon. And then, in 1986, the William H Rorer  
15 Group -- R-O-R-E-R -- purchased Armour from Revlon.

16 So far, so straightforward. The position is  
17 inevitably a little more complicated than that.  
18 Ms Bassi's statement suggests that a company called  
19 Pantry Pride acquired 90 per cent of Revlon's shares  
20 in November 1985 and that, shortly afterwards, because  
21 Pantry Pride was not interested in non-cosmetic  
22 companies, Armour, together with a couple of  
23 associated organisations which I'll turn to, Plasma  
24 Alliance and Meloy Laboratories, were sold, she says,  
25 to the Rorer Group in January 1986, and you will

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1 recall Ms Bassi making the point, she says that the  
2 current Revlon was incorporated in April 1992 and has  
3 in order operated in the pharmaceutical or healthcare  
4 centre.

5 Picking up the timeline, in any event, for  
6 Rorer's purchase of Armour in January 1986 the next  
7 relevant event was in -- I'm not quite sure of the  
8 date -- 1990, a French pharmaceutical company,  
9 Rhône-Poulenc acquired and merged with Rorer and the  
10 name was changed to Rhône-Poulenc Rorer. There was  
11 then in the mid-1990s a joint venture between Armour  
12 and Behringwerke, the German company, and a joint  
13 venture called Centeon was set up, and that took over,  
14 we understand, the role of supplying factor  
15 concentrates to the United Kingdom.

16 Ms Silver's statement sets out the subsequent  
17 corporate history of the parent companies of Armour  
18 and Behringwerke, subsequent mergers and the like, but  
19 I don't think I need to go into those. For anyone who  
20 is interested in following through to the present day,  
21 the statements are available.

22 I then turn to the particular position of Armour  
23 in the United Kingdom. Armour Pharmaceutical Company  
24 Limited was incorporated in the UK in 1959. In 1982,  
25 Ms Silver's statement suggests that Armour

1 Soumik.

2 We see here a document from 1982, Armour  
3 Pharmaceutical Company Limited.

4 If we then go to ARMO0000145. I'm sorry, we  
5 don't need to look at the text of the document, I'm  
6 just seeing how the company name appears over the  
7 years.

8 We can see this is now May of 1984. We've still  
9 got Armour Pharmaceutical Company Limited.

10 If we then go to ARMO0000157, this is a product  
11 licence -- we'll be looking at the licensing history  
12 in due course, but this June of 1985 and it's granted  
13 to Armour Pharmaceutical Company Limited.

14 Then, lastly, if we go to DHSC0002432\_033, this  
15 happens to be a letter from Mr Bishop to the  
16 Parliamentary Under-Secretary of State in  
17 December of 1990. It's still Armour Pharmaceutical  
18 Company Limited.

19 Just, then, in terms of other organisations  
20 within the overall group, Meloy Laboratories Inc,  
21 M-E-L-O-Y Laboratories, Inc, became part of the  
22 Armour/Revlon Health Care Group's research and  
23 development division in the 1970s, and we'll see  
24 a handful of references to those as we look through  
25 some of the documents.

1 Pharmaceutical Company Limited changed its name to  
2 Revlon Health Care Limited, and that then in 1986 when  
3 Rorer purchased Armour, Revlon Health Care Limited  
4 changed its name to Rorer Health Care Holdings. She  
5 says that that particular limited company was  
6 dissolved in 2010.

7 We'll see, as we look through the documents from  
8 the 1980s, that sometimes the documents reference  
9 Armour Pharmaceutical Company Limited and sometimes  
10 they reference Revlon, sometimes the Rorer name  
11 appears, and sometimes more than one of those names  
12 appear on the same document.

13 I should also draw attention to the fact that,  
14 again, according to Ms Silver's statement, at the same  
15 time that Armour Pharmaceutical Company Limited  
16 changed its name to Revlon Health Care Limited, a new  
17 company, also called Armour Pharmaceutical Company  
18 Limited, was formed, and thereafter underwent several  
19 name changes as the parent companies changed.

20 If we just look at a handful of documents it  
21 does appear that Armour Pharmaceutical Company Limited  
22 remained the relevant operative subsidiary in terms of  
23 the supply of blood products in the UK in the course  
24 of the 1980s.

25 So if we just look at ARMO0000094, please,

1 Then probably of the greatest direct relevance,  
2 Plasma Alliance, which was a plasma collection  
3 organisation, was owned by Armour. So 1975 for  
4 something called Blood Plasma Services was purchased  
5 by Armour, and then Armour acquired further  
6 plasmapheresis centres in the States, which were then  
7 rationalised into this one subsidiary, Plasma  
8 Alliance.

9 Again, we'll look at some of the document as we  
10 go through the themes. As at 1980 it would appear  
11 that Plasma Alliance operated 22 plasma centres to  
12 collect, test and ship plasma to Armour's headquarters  
13 in Kankakee, that plasma being derived from paid  
14 donors. We'll look at the information we have in  
15 relation to donors in due course.

16 Just in terms, then, of where the documents that  
17 the Inquiry has have come from -- and again, we're  
18 grateful to Ms Silver for the statement she provides  
19 and the explanation she provides in relation to  
20 that -- it would appear that, to the extent that  
21 Armour documentation survives, it survives because it  
22 was preserved for the purposes of litigation, either  
23 in the States or in the UK, and that's Ms Silver's  
24 understanding. She sets out her understanding in the  
25 statement that, during the entire period that

1 Factor VIII was sold, records were kept in hard copy  
2 form and archived in Illinois and Pennsylvania and  
3 then, rather later, in New Jersey.  
4 Armour's shipping records pre-dating 1980 were,  
5 she understands, that's Ms Silver understands,  
6 destroyed in the normal course of business, save to  
7 the extent that they've been retained for the purposes  
8 of litigation. Ms Silver's not aware of what Armour's  
9 retention and destruction policies were.  
10 So it's not clear how Armour archived documents  
11 generally, only that the documents we have we largely  
12 seem to have because they have been kept for the  
13 purposes of responding to litigation.  
14 We'll see as we look at the documents a number  
15 of names, as we consider Armour in more detail.  
16 Obviously Mr Bishop, who I've already mentioned. Some  
17 of the names that we'll see crop up will  
18 be: SG Brooks, who was head of regulatory affairs for  
19 part of the relevant period for Armour Pharmaceutical  
20 Company Limited in the UK; WJ Tarbit, who worked in  
21 the registration department for Armour Pharmaceutical  
22 Company Limited; K Fitch, chairman and managing  
23 director of Armour Pharmaceutical Company Limited;  
24 Mr Bishop I've already mentioned; and then  
25 Michael Rodell in the States, vice president of

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1 The product I'm principally concerned with is  
2 Factorate. For the benefit of the transcriber that's  
3 F-A-C-T-O-R-A-T-E. That was the concentrate produced  
4 for the treatment of haemophilia A by Armour in the  
5 States. In the period with which we're primarily  
6 concerned, Armour was not producing a Factor IX  
7 concentrate for supply to the United Kingdom. There  
8 is -- and I'll come on to it very briefly, there was  
9 a Factor IX product, Mononine, licensed in the UK in  
10 around 1993, but in the seventies and eighties it's  
11 Factorate that we're concerned with.  
12 So if we go to ARMO0000001, please, Soumik.  
13 We will see here details of the Factorate  
14 product, which was the first product for which Armour  
15 received a product licence in the United Kingdom. The  
16 product licence number, and we'll see it referenced as  
17 we go through the materials on a number of occasions,  
18 was 0231/0038.  
19 This is the application made by Armour for  
20 a product licence in the UK in March 1975. The  
21 application is in two volumes. We don't need to open  
22 the other one but I'll just read the reference out for  
23 the transcript. It's ARMO0000002. And that second  
24 volume contains a number of clinical studies which  
25 were provided to the Licensing Authority. But it's

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1 regulatory and technical affairs, Revlon Health Care  
2 Group; and then Mr Robert Christie, director of  
3 clinical science at Revlon Health Care UK, and Armour  
4 Pharmaceutical Company Limited.  
5 Just to give a flavour of how we will sometimes  
6 see more than one company name appear on a document,  
7 rather unhelpfully, if we look at ARMO0000374, if we  
8 just look at the top of the page we can see this  
9 happens to be a document from April 1985. We've got  
10 Revlon Health Care (UK) Limited, Armour Pharmaceutical  
11 Company Limited and, indeed, a third company, Berk  
12 Pharmaceuticals Limited, on that single document.  
13 Then if we go to AMRO0000151, this is  
14 August of 1984, we have Revlon Health Care (UK)  
15 Limited at the top of the page, and then, at the  
16 bottom of the page, Armour Pharmaceutical Company  
17 Limited.  
18 So it's not always easy to understand what the  
19 precise relationships are, but in any event they were  
20 plainly closely associated companies at the most  
21 material time for the purposes of the Inquiry's  
22 investigations.  
23 So with that short and not necessarily  
24 particularly clear account in relation to corporate  
25 matters, I'm going to turn then to product licensing.

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1 this document at ARMO0000001 that we find the most  
2 relevant information.  
3 We get a sense of the range of information  
4 provided from the index, so section A of the material  
5 is entitled "Active Constituent".  
6 If we go over the page, there's a section on  
7 "Finished Products", and we're going to come to  
8 particular parts of the application in a moment.  
9 If we go to the bottom of the third page we can  
10 see the date in the bottom right-hand corner,  
11 March 1975, and the application is being submitted by  
12 Armour Pharmaceuticals Co. Ltd.  
13 If we go to the next page, and we zoom into the  
14 top half to start with, this is the application form.  
15 The proposed licence holder is Armour  
16 Pharmaceutical Co Ltd, the role of the proposed  
17 licence holder is described as the "person who imports  
18 or procures its importation", and then, bottom of the  
19 screen, we can see that the name of the product is  
20 Factorate. And this was an application signed by the  
21 head of regulatory affairs, Mr Brooks.  
22 If we go to the next page, we'll see the product  
23 particulars. We don't need to go through the detail  
24 of it but you'll see there in very broad outline  
25 terms: uses, recommended dose, contra-indications,

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1 et cetera. We'll see what's said by way of warning  
2 shortly.  
3 If we go to the next page we can see the heading  
4 "Supplementary Particulars" and the "Manufacture"  
5 explains that:  
6 "Factorate is manufactured from fresh frozen  
7 human plasma which when tested is found to be negative  
8 for hepatitis B antigen activity."  
9 So that's our first reference to testing in  
10 relation to hepatitis B, and that's the testing of the  
11 plasma.  
12 Then we'll see, at paragraph (c) on that page:  
13 "The Name & Address of Place of Manufacture  
14 Assembly."  
15 That's Armour Pharmaceutical's manufacturing  
16 headquarters in Kankakee, Illinois, in the States.  
17 If we turn to page 6, please -- sorry, if we  
18 turn to page 16, please, Soumik. There's an awful lot  
19 of detailed information in this so I'm just going to  
20 alight on certain points of particular relevance.  
21 This is a section about the "Method of  
22 Manufacture, "Description of the Manufacturing  
23 Process". And then you'll see at stage 4:  
24 "The final product is re-checked for hepatitis  
25 associated antigen."

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1 Just pausing there, there are number of  
2 references, as we will see in the material, to  
3 essentially donor selection processes, and there is  
4 a little more detail in some of the later documents  
5 than we have here, but it is still not entirely clear  
6 precisely what was drawn out by way of personal  
7 history, what physical examinations were undertaken.  
8 It becomes a little clearer what tests were undertaken  
9 on the blood.  
10 And you will see the qualifying words "insofar  
11 as can be determined". Then it continues:  
12 "Donors with a history of viral hepatitis, or an  
13 event of exposure to hepatitis within the normal  
14 incubation period, shall be excluded."  
15 If we go to the bottom of the page, we see  
16 a heading "Collection and Processing of Blood":  
17 "Blood collection clinics supplying human plasma  
18 under these specifications and licensed by the  
19 US Department of Health, Education and Welfare, Food  
20 and Drug Administration, must comply with applicable  
21 requirements defined in the Code of Federal  
22 Regulations, Title 21, Part 600. Non-licensed clinics  
23 supplying human plasma under these specifications must  
24 also comply with these regulations ..."  
25 So that might be thought to suggest that, at

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1 So what's described is a process whereby the  
2 plasma is checked and then the final product is  
3 re-checked for hepatitis-associated antigen. That is,  
4 of course, a reference to hepatitis B.

5 If we go next to page 24, we can see that part  
6 of the material supplied to the UK Licensing Authority  
7 with the licence application is this document  
8 entitled, "Raw Material Specifications", drawn up in  
9 October 1973 by the manufacturer, so Armour in  
10 Kankakee in Illinois. And we will see, if we just  
11 look at the description in the first paragraph, it  
12 says:

13 "Plasma for Fractionation, Normal, (Human), is  
14 the liquid portion of whole blood ..." et cetera,  
15 et cetera.

16 Then pick it up in the fourth line:

17 "... drawn from adult humans by plasmapheresis  
18 who have not been immunised to produce specific  
19 antibodies ..."

20 Then if we skip down three lines:

21 "... and who, at the time the blood is drawn,  
22 are in condition physically to give blood, insofar as  
23 can be determined by personal history, by physical  
24 examination and by appropriate tests on the day the  
25 blood is collected."

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1 this point, and this is a document from October 1973,  
2 Armour obtained its blood from both licensed and  
3 non-licensed clinics. This, I think, pre-dates its  
4 acquisition of the Plasma Alliance plasmapheresis  
5 centres.

6 **SIR BRIAN LANGSTAFF:** And there's no reference to them  
7 owning the clinics themselves?

8 **MS RICHARDS:** Not at this point in time or in this  
9 document, no. We know that by 1980 they certainly  
10 did, but the precise dates upon which they were  
11 acquired are not clear.

12 If we go to the top of the next page, the first  
13 paragraph explains that:

14 "Blood shall be drawn from acceptable donors by  
15 licensed physicians or by specially trained assistants  
16 under their direct supervision. Determination of the  
17 suitability of the donor is the responsibility of the  
18 licensed physicians and must be made by them or under  
19 their supervision."

20 Then if we go to the bottom of the page, we can  
21 see the heading "Records", and so this relates to  
22 records of donors:

23 "Adequate records detailing the medical history  
24 of the donor, all physical examinations given him, and  
25 appropriate release statements he signs must be

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1 maintained. And, adequate systems identifying the  
2 blood, plasma, and serum, and correlating them with  
3 records supplied to Armour Pharmaceutical Company and  
4 records at the donor centre, must also be maintained.

5 "Records of all donors represented in the plasma  
6 supplied to Armour Pharmaceutical Company must be  
7 maintained for a period of at least six (6) months  
8 after the latest expiration date of the products  
9 prepared from the plasma. A period of twelve  
10 (12) years is recommended".

11 So something of a difference in terms of  
12 magnitude between the recommendation of 12 years and  
13 the requirement of six months.

14 Over the page, there is further requirements and  
15 stipulations in relation to records relating to  
16 shipments of plasma to Armour. So you'll see from the  
17 first paragraph they:

18 "... must be accompanied by records that include  
19 adequate donor identification ..." et cetera.

20 Then if we go to the next page, please, we move  
21 to a heading towards the bottom of the page entitled  
22 "Plasma" -- sorry, I should actually just draw  
23 attention, above that, to "Facilities Inspection",  
24 where it says:

25 "Bleeding and processing establishments, and all

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1 If we then go forward a number of pages, Soumik,  
2 to page 94, we can see here a section of the material  
3 with the licensing application headed "Hepatitis  
4 Associated Antibody".

5 And there is then, if we go to the top of the  
6 page, under the heading "Biological Principles of the  
7 Procedure", a description of the technique used to  
8 measure the hepatitis B antigen levels in the serum,  
9 using what's described there as a sandwich principle.

10 Then, two pages further on, please, Soumik, to  
11 page 96. Under the heading "General", if we pick it  
12 up a few lines down, it says this:

13 "Although the association of infectivity and  
14 a positive result for Hepatitis B Antigen is strong,  
15 it is recognised that presently available methods for  
16 Hepatitis B Antigen detection are not sensitive enough  
17 to detect all infectious units of blood or all  
18 possible cases of hepatitis."

19 Then it goes on to explain how false positive  
20 results may be obtained and gives two different --  
21 a description of two different types of false positive  
22 results.

23 So that's the most salient parts of the  
24 licensing application, the first licensing application  
25 made in March 1975.

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1 processing equipment and records will be available for  
2 inspection, during regular business hours, by  
3 designated representatives of Armour Pharmaceutical  
4 Company."

5 That's an entitlement by Armour to inspect the  
6 establishments from whom it obtains plasma.

7 And then the next sentence also explains that  
8 inspection will be available by designated  
9 representatives of the Food and Drug Administration.

10 Then if we go to "Plasma Properties", we'll see  
11 it says, "Plasma for Fractionation", and then there  
12 are number of elements set out.

13 If we go over the page we see point 7 is:

14 "Shall be free of Hepatitis B antigen as tested  
15 on individual units by Radio-Immuno Assay."

16 If we then turn to page 31, this is a further  
17 section of the licence application headed "Quality  
18 Control Checks made at Each Stage in the Process".  
19 Stage 4, you'll see from the bottom there, is:

20 "The lyophilised material is examined according  
21 to the Finished Product Specification provided in  
22 Section 11. It is also checked for Hepatitis B  
23 associated antigen."

24 So that is presumably a reference to what we saw  
25 described as the re-checking of the finished product.

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1 If we then look at how that licensing  
2 application was considered by the Licensing Authority  
3 and some of the further conditions that were  
4 contemplated, we start at DHSC0105603, please.

5 If we go to the second page, what we have here  
6 is a report from the medical assessor, Dr Andrews.  
7 It's a report dated 16 October 1975. We don't need to  
8 go to it now but the date is on page 8 or so of the  
9 document.

10 We can see that Dr Andrews here essentially  
11 summarises the application. So we've got the heading  
12 "Summary, Report and Recommendation", and Dr Andrews  
13 then sets out a number of matters relating to the  
14 application. If we go over to the fourth page,  
15 please, Soumik.

16 We can pick it up at the top of the page, under  
17 "Contra-indications and warnings", so again this is  
18 still Dr Andrews summary of the application:

19 "There are no known contra-indications to AHF  
20 but the risk of transmitting viral hepatitis is  
21 present since no completely reliable laboratory test  
22 is yet available for detecting the presence of  
23 hepatitis virus."

24 Then, towards the bottom of the page, there's  
25 a paragraph headed "Labelling", and we'll come on to

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1 the question of product labels later, and then  
 2 "Chemistry and Pharmacy", and under the heading  
 3 "Methods of manufacture", the report says:  
 4 "Blood is drawn from acceptable donors by  
 5 licensed physicians and the plasma obtained using  
 6 plasmapheresis techniques must conform in all respect  
 7 to the applicable requirements for source of plasma  
 8 (human) defined in the USA Code of Federal  
 9 Regulations. This applies to licensed and unlicensed  
 10 clinics. A copy of these are not included in the  
 11 submission. Adequate records detailing the medical  
 12 history of the donor, all physical examinations given  
 13 him and appropriate release statements are kept for  
 14 a recommended period of 12 years."

15 Then if we go to the next page, we can see under  
 16 the heading "Plasma properties", paragraph 7.2, again,  
 17 Dr Andrews is summarising the application:

18 "The plasma is ...  
 19 "7. Is free of hepatitis B antigen as tested on  
 20 individual units by Radio-Immuno Assay".

21 Then if we go to the next paragraph, 7.3, he  
 22 describes there the four pages of preparation, and we  
 23 see Stage 4, he summarises:

24 "The final product is tested for freedom from  
 25 hepatitis associated antigen."

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1 shelf life.

2 "It is recommended that subject to approval of  
 3 the quality control situation that a product licence  
 4 be granted."

5 So that's Dr Andrews' recommendation.

6 If we then turn to DHSC0105604\_002, we can pick  
 7 up here the consideration of Armour's application by  
 8 the Subcommittee on Biologicals at their meeting on  
 9 12 November 1975. If we go a little further down the  
 10 agenda, we can see item 5 on the agenda is  
 11 "Consideration of applications" and the fourth  
 12 application is for Factorate, the product licence  
 13 number there set out.

14 If we go over the page, we can see the minutes  
 15 of the meeting, just draw attention to paragraph 2,  
 16 "Confidentiality". Perhaps not so relevant for the  
 17 purposes of considering the individual licensing  
 18 applications but you may wish to bear in mind, sir,  
 19 when you consider the Subcommittee on Biologicals'  
 20 July 1983 decision on the question of whether imports  
 21 from the States should be banned at that point in  
 22 time, confidentiality was always regarded as highly  
 23 important by the Committee on the Safety of Medicines  
 24 and its subcommittee, and so those who were present at  
 25 meetings were not supposed to discuss the content of

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1 If we then go, I think it should be, two pages  
 2 further on. Yes. So we get the date of the report  
 3 from here, 16 October, and we can see the comment from  
 4 Dr Andrews, having summarised the application material  
 5 for the relevant sub committee. Dr Andrews then says  
 6 this:

7 "It is not quite clear who is the supplier of  
 8 the donated plasma ..."

9 Then, I'm afraid we can't read the next bit.

10 "... would appear that this could be a number of  
 11 units (licensed and unlicensed) which work to FDA  
 12 standards. It is also not clear whether the tests for  
 13 hepatitis surface antigen is carried out on individual  
 14 donations at the time of donation or during the  
 15 routine examination of patients undergoing  
 16 plasmapheresis. The company have been asked for  
 17 information on this point together with a request for  
 18 clarification of the place where quality control tests  
 19 are carried out. It would appear that the manufacture  
 20 of the product is satisfactory though the manufacturer  
 21 has not as yet been inspected."

22 It's not clear who that's a reference to  
 23 inspection by, whether it's by the FDA or equivalent  
 24 or inspected by the UK Licensing Authority.

25 Then there's a reference to stability data and

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1 what had gone on at meetings.

2 You'll see here that reminder being given  
 3 "Confidentiality":

4 "The Chairman reminded members that the material  
 5 they received was of a highly confidential nature and  
 6 should not be made available to outside contacts."

7 Then if we look at the bottom of the page,  
 8 section 5 of the minutes, "Consideration of  
 9 applications", and that refers to the applications  
 10 being considered. The consideration of this  
 11 application is in an appendix to the minutes at  
 12 DHSC0105604\_005. If we go closer we'll see then the  
 13 recommendation:

14 "On the evidence before them the Sub-Committee  
 15 on Biologicals recommend the grant of a product  
 16 licence for this preparation for the purposes  
 17 indicated in the application, provided that ..."

18 Then number of conditions were set out.

19 "1. Information is provided on:

20 "i. The number of donations from which plasma  
 21 is pooled for the manufacture of the product.

22 "ii. The reasons for, and rate of, rejection of  
 23 donors, or donations, centre by centre."

24 There were a number of other requirements set  
 25 out at paragraphs 2 through to 5, including product

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1 labelling and compliance with the batch release  
2 procedure but, for present purposes, it's the request  
3 for information about pool sizes and rejection of  
4 donors that's most relevant.

5 So that's the recommendation of the Subcommittee  
6 on Biologicals.

7 What happened next was that the Committee on  
8 Safety of Medicines considered the application in  
9 November 1975, date unclear. We don't have the  
10 Committee on Safety of Medicines' actual decision but  
11 they effectively, we'll see from another document in  
12 a moment, it would seem, approved it, subject to those  
13 conditions.

14 This is November 1975. What, of course, then  
15 happened was the broadcast of the World in Action  
16 documentaries, on 1 and 8 December 1975, and this led  
17 to an enhanced consideration being given to Armour's  
18 product licence application by the Licensing Authority  
19 with, as we shall see shortly, the involvement of the  
20 Minister of State for Health.

21 So if we pick it up at MHRA0004180, this is not  
22 specific to Armour's application but is a meeting  
23 which considers the World in Action documentary. So  
24 this is described as a note of a meeting of the  
25 Divisional Management Group held on 9 December 1975.

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1 "Mr Tringham reported that a television 'World  
2 in Action' film had made criticisms of Travenol's  
3 production of 'Factor VIII' in the USA. The  
4 criticisms were in conformity with an inspection  
5 report carried out on behalf of the Division."

6 Again, that's obviously dealing with Travenol  
7 there rather than Armour.

8 "The Minister of State had been briefed [and the  
9 Minister of State at the relevant time was  
10 Dr David Owen] and was concerned about the supply of  
11 the Factor and about the hazards of using it."

12 If we go to the next page we see then Armour is  
13 referred to:

14 "A similar product manufactured by Armour had  
15 recently been cleared by the CSM [Committee on Safety  
16 of Medicines]; Supply Division were anxious that it  
17 should be licensed as it would be available at a lower  
18 price than the Travenol product. There was some doubt  
19 as to whether the collection of blood products for  
20 either product was satisfactory. Dr Holgate said that  
21 he doubted whether inspection of the American  
22 collecting centres would be useful. What was needed  
23 was to strengthen the requirements in the product  
24 licence, and to insist on returns from each collecting  
25 centre including the rate of rejection of donors or

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1 It's not entirely clear what the Divisional Management  
2 Group was, but it seems that it was a group within the  
3 Medicines Division of the Department of Health,  
4 certainly some of the names -- Dr Harris, Dr Holgate  
5 and others -- are familiar from that.

6 Just before we look at the discussion on the  
7 documentary, flag up paragraph 1.2, which is  
8 a reference to the minutes of a previous meeting,  
9 where it says:

10 "It was agreed that the first sentence [of the  
11 minutes of the previous meeting] should read  
12 'Dr Holgate said that shortage of funds inhibited  
13 visits to manufacturers' premises abroad'."

14 So we'll obviously need to see if we've got the  
15 full set of minutes but you'll recall Dr Walford's  
16 evidence, she had a recollection of going on one  
17 inspection visit when she was at the Medicines  
18 Division but this would appear to suggest that the  
19 Licensing Authority was inhibited by lack of funds  
20 from conducting its own routine inspections to  
21 premises abroad.

22 In any event, if we go to the bottom of the  
23 third page of these minutes, very bottom paragraph, we  
24 see the heading "Blood Coagulation Factors for  
25 Haemophilia":

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1 donations."

2 Just pausing there, sir, you will no doubt have  
3 picked up the reference there to the Supply Division  
4 being keen to have product cheaper than the Travenol  
5 product, and the Medicines Division there expressing  
6 doubt as to whether the collection of blood products  
7 for either the Travenol product or the Armour product  
8 was satisfactory.

9 Then we pick it up in the next paragraph:

10 "The story of the television film was that  
11 Britain could be self-sufficient in Factors for  
12 haemophilia within a few years. The Department in  
13 1972 had allocated £500,000 and had bought the  
14 equipment needed for production. However there were  
15 some difficulties. Neither of the production units  
16 had applied for product licences. The SHHD [the  
17 Scottish Home & Health Department] had written to the  
18 factory at Liberton and Medicines Division had  
19 reminded HS2 Division that though the Lister Institute  
20 of Preventative Medicine (Elstree) had a contract with  
21 the Department, this did not give them exemption from  
22 the requirement to hold a product licence. Mr  
23 Tringham emphasised that his concern was to regularise  
24 the situation, not to stop production. The  
25 haemophilia patients' group were protesting at the

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1 delays in the commissioning plant. The Supply  
2 Division were concerned that in the meantime doctors  
3 might develop brand preferences for the imported  
4 products. Dr Holgate said that doctors would prefer  
5 the British products as being safer. Indeed, once  
6 a pure supply is available, doctors will want to use  
7 the product in situations in which the currently  
8 available Factors would be too great a risk."

9 So an insight there into the thinking of the DoH  
10 as at 1975.

11 If we then turn to how that played out in terms  
12 of the consideration of Armour's application for  
13 a product licence, we can see from DHSC0003742\_077  
14 a minute dated 16 January 1976 from Mr Tringham, in  
15 what's described as the Medicines Branch. It's headed  
16 "Factor VIII product licence applications" and it  
17 refers in the first paragraph to a meeting with  
18 Dr Owen. We haven't got any other record of that  
19 meeting that I'm presently aware of, and we may be  
20 able to find it or we may not have it. I don't know.  
21 But it says this:

22 "At the meeting with Dr Owen in connection with  
23 the Television programme about Factor VIII, he  
24 indicated that he would wish to see any further  
25 applications for product licences to authorise the

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1 their attitude to some of the matters covered in the  
2 submission, and I formed the impression that in  
3 practice they would be able to accept the conditions  
4 mentioned at the end of the submission; but of course  
5 this may depend upon the attitude of the American  
6 company."

7 So if we then turn to the submission itself,  
8 DHSC0003742\_078. So "Factor VIII -- Application by  
9 Armour Pharmaceutical Co Limited":

10 "This submission concerns the application for  
11 a product licence under the Medicines Act 1968 by  
12 Armour Pharmaceutical Company Limited in respect of  
13 Factorate, their brand of the antihaemophilic factor  
14 (Factor VIII). The application was considered by the  
15 Committee On Safety of Medicines ... at their meeting  
16 in November 1975 ..."

17 So, sir, that's the evidence we have as to the  
18 committee's overall consideration:

19 "... they advised that a product licence should  
20 be granted subject to the acceptance by the company of  
21 certain conditions. No action has yet been taken on  
22 this advice.

23 "Summary of application.

24 "Armour Pharmaceutical Co Limited submitted  
25 a product licence application for Factorate on

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1 importation of Factor VIII."

2 Pausing there, you'll recall the evidence given  
3 by some of the politicians from whom you've heard in  
4 the 1980s was very much that ministers would not or  
5 should not become involved in the consideration of  
6 licensing applications. This, by contrast, is  
7 an example of Dr Owen, as Minister of State for Health  
8 in 1976 indeed becoming involved in matters relating  
9 to a licensing application.

10 So picking up the paragraph:

11 "Accordingly, we have prepared a submission  
12 about the application from Armour Pharmaceutical Co."

13 We'll look at that submission in a moment.

14 "I understand that Supply Division have received  
15 a 'very favourable' tender from the company for the  
16 supply of Factor VIII to haemophilia centres  
17 [presumably that means cheaper] but, of course, action  
18 on this depends upon the granting of a product  
19 licence.

20 "While the submission was being typed I received  
21 a telephone call from a representative of the company  
22 inquiring as to the outcome of their application.  
23 I told them that we should probably be writing to them  
24 in the near future. In the course of the conversation  
25 I was able to sound the company's representative about

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1 2 April 1975. The application states that ..."

2 Then various matters are then set out, that the  
3 manufacturing takes place at the factory in Illinois,  
4 reference there to testing for hepatitis B antigen of  
5 the plasma, human plasma being supplied by blood  
6 collection centres licensed or unlicensed, but were  
7 required to comply with the Code of Federal  
8 Regulations.

9 Carry on down the page, subparagraph (d) refers  
10 to checking the donations for freedom from hepatitis  
11 associated antigen, and (e) refers to:

12 "Labelling will contain a warning to the effect  
13 that the product is prepared from pooled human plasma  
14 and that despite careful selection of donors it may  
15 contain causative agents of viral hepatitis."

16 So that's this ministerial submission summary of  
17 the application.

18 The committee's --

19 **SIR BRIAN LANGSTAFF:** He refers to non-licensed centres as  
20 being outside the USA.

21 **MS RICHARDS:** Ah, can we go back up to that?

22 **SIR BRIAN LANGSTAFF:** "... non-licensed clinics (that is  
23 to say clinics outside the USA)."

24 So that's his understanding of that phrase.

25 **MS RICHARDS:** Yes, it is. I don't think there's anything

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1 in the material I've seen that suggests that his  
2 understanding is correct -- or, sorry, suggests  
3 whether his understanding is correct or not but we can  
4 check.  
5 **SIR BRIAN LANGSTAFF:** Yes, I suppose the question would be  
6 whether any clinic is allowed to operate as a centre  
7 within the USA without being licensed. If it isn't,  
8 then non-licence would have to be outside the USA,  
9 I suppose.

10 **MS RICHARDS:** Yes, yes.

11 **SIR BRIAN LANGSTAFF:** So the question then might arise as  
12 to compliance with the Code of Federal Regulations is  
13 checked and monitored.

14 **MS RICHARDS:** Yes. I imagine we ought to be able to find  
15 out the answer to that, because you'll recall from the  
16 licence application material, the provisions of the  
17 Code of Federal Regulations that were said to apply to  
18 unlicensed clinics were set out. So provided we can  
19 get hold of the Code of Federal Regulations from 1975,  
20 we'll hopefully be able to find the answer to your  
21 point, sir.

22 So then picking it up at the bottom of the page,  
23 we can see:

24 "The [Committee on Safety of Medicines], on  
25 recommendation of their Sub-Committee of Biological

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1 appearing before or making written representations to  
2 the Committee.

3 "In view of the minister's interest action on  
4 the lines has not yet been taken and we have  
5 considered whether any other conditions would be  
6 appropriate."

7 Then if we go to the next paragraph and just  
8 zoom in:

9 "A representative of NIBSC has recently visited  
10 the fractionation plant but there has been no formal  
11 inspection by DHSS either of the plant or of the  
12 premises used for collection. In light of experience  
13 of inspection of other companies producing blood  
14 products in the USA it is not considered that time and  
15 money would be well spent in inspecting the clinics  
16 where blood is collected. Inspectors could be shown  
17 only the best and even the worse might be run highly  
18 efficiently on the day of visit. While an experienced  
19 inspector might deduce the truth there can be no  
20 certainty of this. It ..."

21 That might be --

22 **SIR BRIAN LANGSTAFF:** "Seems best".

23 **MS RICHARDS:** Yes.

24 "... seems best to assume that all blood products  
25 of this nature coming from the USA may be obtained

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1 Products, advised that a product licence be granted  
2 subject to the following ..."

3 The first is about the method of assays and  
4 standard of calibration. Then (b) is:

5 "The following conditions being observed:

6 "(1) Information should be provided by the  
7 licence holder on

8 "(i) The number of donations from which plasma  
9 is pooled for the manufacture of each batch of product  
10 [so pools sizes].

11 "(ii) The reasons for and rate of rejection of  
12 donors or donations ..."

13 So those are essentially the conditions that the  
14 Subcommittee on Biologicals had recommended and this  
15 submission suggests that the Committee on Safety of  
16 Medicines reached the same view.

17 If we then go down the page to the next heading,  
18 "Licensed action", the submission continues:

19 "The normal action on receipt of advice by the  
20 Committee in these circumstances would be to invite  
21 the company to amend their application to incorporate  
22 the conditions proposed. If they agreed a licence  
23 would then be issued on this basis. If the applicant  
24 did not agree the conditions could not be enforced  
25 without first giving the company the opportunity of

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1 from plasma taken under the worst circumstances and  
2 any protective measures should be achieved by other  
3 means."

4 Top of the next page.

5 "The applicants are of high repute as  
6 manufacturers. Visits need only be made to the  
7 fractionation plant in order to verify the ability of  
8 the quality control staff to carry out the necessary  
9 tests and assays and, in cases of dubiety, to verify  
10 the records held at the centre and to ascertain that  
11 information supplied to the licensing authority in the  
12 UK is substantially correct.

13 "The applicant has been required, in accordance  
14 with section 19(3) of the Act to give an undertaking  
15 to permit the premises to be inspected by or on behalf  
16 of the licensing authority. If a licence is granted,  
17 inspection visits can therefore be undertaken at any  
18 time to Armour's premises.

19 "This undertaking does not however extend to the  
20 premises not belonging to Armour (in the USA or not)  
21 where the donations are taken. It might be prudent to  
22 secure a similar undertaking on the inspection of such  
23 premises.

24 "Both the manufacturing premises and the  
25 collection centres (wherever situated) are subject to

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1 inspection by the FDA. There are however grounds for  
2 doubting whether the stringent provisions of US law  
3 are in fact fully enforced. In this connection  
4 Dr Theodore Cooper, US Assistant Secretary for Health,  
5 has written to the [Chief Medical Officer] about US  
6 procedures (ANNEX B) ..."

7 We will look at Annex B, it doesn't say anything  
8 about Armour but it's of interest generally.

9 "... it should be possible in the ensuing  
10 correspondence to obtain further information on this  
11 point."

12 Then the next heading in the submission is  
13 "Source of donations":

14 "It may be worth considering whether limitations  
15 should be placed on the sources from which blood is  
16 obtained.

17 "One possibility would be to authorise the  
18 marketing of the product only if it is derived from  
19 blood given by volunteers without payment. It is  
20 understood that over 50% of blood used in the USA is  
21 given voluntarily. It seems likely however that  
22 a restriction of this nature would affect the  
23 economics of the supply arrangements and would be  
24 unacceptable to the applicant. In any case it might  
25 be difficult to show that in fact blood from paid

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1 "Such a condition could be combined with the  
2 condition envisaged in [paragraph] 9 as to the  
3 undertaking to allow inspection of donation centres,  
4 the approval under [paragraph] 13(2) being conditional  
5 on the giving of such an undertaking."

6 **SIR BRIAN LANGSTAFF:** It seems a little odd to say in one  
7 paragraph "they might be open for inspection but it  
8 probably doesn't happen", and then to say, "Well,  
9 perhaps we should ask for the same".

10 **MS RICHARDS:** Yes.

11 **SIR BRIAN LANGSTAFF:** But there we are.

12 **MS RICHARDS:** Yes, what the practical utility would be in  
13 terms of improving safety is --

14 **SIR BRIAN LANGSTAFF:** It may be better than not having the  
15 undertaking.

16 **MS RICHARDS:** But whether it actually increases the safety  
17 of the product --

18 **SIR BRIAN LANGSTAFF:** Is questionable.

19 **MS RICHARDS:** Yes.

20 Then paragraph 16:

21 "Here again, it is possible that the applicant  
22 would be unwilling to accept such a condition for  
23 commercial reasons but the limitation would appear to  
24 be practicable."

25 Then there's a heading "General conditions":

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1 donors is necessarily less safe than from unpaid  
2 donors."

3 So that's considered and, as it were, rejected,  
4 for the reasons given. Then it continues:

5 "An alternative approach would be to limit the  
6 sources geographically. The licence could relate to  
7 material obtained either at either --

8 "(1) licensed clinics in the USA.

9 "(2) Centres in other named countries,  
10 specifically approved by the UK licensing authority."

11 If we go over the page, top of the page:

12 "On this basis, approval would be given in  
13 respect of other countries if sufficient was known of  
14 the local conditions including enforcement  
15 arrangements to give some confidence in the product.  
16 The point is that in the USA each clinic must be  
17 specifically licensed ..."

18 So again, that's the Department's Licensing  
19 Authority's understanding.

20 "... and therefore presumably some check is  
21 carried out. For collecting centres outside the USA,  
22 all that is known is that they are open to the  
23 inspection by the Bureau of Biologics, but in view of  
24 the distances involved it is unlikely that all centres  
25 are inspected regularly, if at all.

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1 "There are at present regulations under the  
2 Therapeutic Substances Act ... about the manufacture  
3 of blood products. These were made many years ago,  
4 but were not of any practical effect until  
5 importation began -- because they were not regarded as  
6 legally binding on the Crown, the only effective  
7 supplier. They cover basic requirements, including  
8 the medical supervision of collection and checking the  
9 health of donors.

10 "In this respect they are more stringent than  
11 the US regulations but in general they are much less  
12 detailed and do not incorporate references to modern  
13 test requirements."

14 Then paragraph 18 explains that those  
15 regulations, the Therapeutic Substances Act  
16 regulations are, in any event, about to be superseded  
17 by new regulations:

18 "... and it seems desirable that the opportunity  
19 should be taken to give effect to more up to date and  
20 specific requirements on the general lines of the US  
21 regulations. In so far as the products are already  
22 subject to these regulations, this will make no  
23 practical difference but it will assist in dealing  
24 with products imported direct into the UK from  
25 countries other than the USA."

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1 Then there's a heading of "Other sources of  
 2 supply":  
 3 "Three other companies have product licences in  
 4 respect of imported Factor VIII and two other  
 5 applications under consideration. Brief particulars  
 6 are given in ANNEX C."  
 7 Top of the next page:  
 8 "In addition Factor VIII is now available from  
 9 the UK National Blood Transfusion Service. Until  
 10 recently the Medicines Acts controls were not applied  
 11 formally to NHS production. Arrangements for its  
 12 application were promulgated in the Summer of 1975;  
 13 these involved administrative measures in England and  
 14 Wales and formal licensing in Scotland. In fact  
 15 however at the present moment no formal action under  
 16 the Medicines Act has been taken in respect of the  
 17 preparation of Factor VIII. Although it is not  
 18 suggested that anything is amiss in this connection,  
 19 it must be borne in mind that some embarrassment might  
 20 arise if an applicant were to ask whether the UK  
 21 product had received the same scrutiny at his product.  
 22 "If any of the additional requirements mentioned  
 23 in this submission are to be added to the Armour  
 24 licence it would clearly be right to impose the same  
 25 conditions in respect of other similar products. New

1 should be granted accordingly.  
 2 "Agreement is also sought to the proposition  
 3 that, as outlined in [paragraph] 21, such conditions  
 4 should be applied to other licence holders."  
 5 So that's the submission that was apparently  
 6 sent to the Minister of State for Health, who would  
 7 still have been Dr David Owen at that point in time.  
 8 If we then pick matters up, still in  
 9 January 1976, we see a meeting takes place with the  
 10 Minister, following his consideration of the  
 11 submission, and that's at DHSC0003742\_076. So we can  
 12 see the date of the meeting is 21 January 1976.  
 13 Present, number of names Dr Owen, Minister of State,  
 14 and then we've got, amongst others, Dr Tringham and  
 15 Dr Andrews -- presumably, although it's not an  
 16 uncommon name, the Dr Andrews who had done the medical  
 17 assessment for the Medicines Division -- and  
 18 Dr Waiter, whose name we see on a lot of material from  
 19 this time.  
 20 Paragraph 1:  
 21 "The meeting had been called at Dr Owen's  
 22 request following his consideration of a submission  
 23 about an application from Armour Pharmaceutical  
 24 Company to supply Factor VIII to haemophilia centres."  
 25 Then we see some matters set out from the

1 general requirements as contemplated in [paragraph] 18  
 2 would achieve this result. Alternatively, the  
 3 companies can be asked to accept the conditions  
 4 individually and if they did not action could be taken  
 5 under section 28(3)(h) of the Medicines Act to vary  
 6 the licences on the grounds that the standards are no  
 7 satisfactory."  
 8 Then "Matters for decision":  
 9 "It seems necessary first to decide whether  
 10 a visit of inspection should be carried out before  
 11 determining the licence application. If, as suggested  
 12 in [paragraph] 6, it is agreed that no visit should be  
 13 made at this stage, decisions are sought as to whether  
 14 the company should be asked, in addition to the  
 15 conditions imposed by the CSM, to agree that --  
 16 "(a) Plasma should be obtained only from donor  
 17 centres in the USA, or in other countries specified in  
 18 respect of which the licensing authority is satisfied  
 19 as to the arrangements ...  
 20 "(b) DHSS Inspectors may visit collecting  
 21 centres ...  
 22 "The Minister of State is asked to agree that  
 23 subject to the company accepting the conditions  
 24 proposed by the CSM and conditions (a) & (b) above, if  
 25 he considers them appropriate, a product licence

1 discussion:  
 2 "i. The price being quoted by Armour  
 3 Pharmaceuticals was 8p per unit which compared with  
 4 10p and 12p from other sources. If a licence was  
 5 granted, no quantity would be specified and the  
 6 Haemophilia Centres are free to go to anyone of the  
 7 approved suppliers.  
 8 "ii. Even though this product was cheaper, it  
 9 would not necessarily be favoured by doctors because  
 10 of the fact that, as it had a lower solubility than  
 11 Hemofil it could not be injected but would have to be  
 12 infused, which represented in itself an additional  
 13 overall cost. Solubility was one of the essential  
 14 criteria that had to be satisfied if the medical  
 15 profession were to generally adopt a Factor VIII  
 16 product and Dr Owen said it was crucial that the  
 17 supplies that we were to produce ourselves fulfilled  
 18 this criteria. At present, the products coming from  
 19 the Elstree Plant were not of a sufficient solubility  
 20 and in this respect they were inferior to the Scottish  
 21 product. Dr Owen asked that the Scottish Laboratory  
 22 and Elstree should get together to discuss their  
 23 processes and to share their technology and he asked  
 24 for a progress report on this within 1 month."  
 25 Over the page:

1 "Dr Owen agreed that negotiations could start  
2 with Armour Pharmaceutical but he asked that it should  
3 be spelt out that the overall policy of the British  
4 Government was, in line with the WHO [World Health  
5 Organisation] recommendation, to aim for  
6 self-sufficiency."

7 So although this note doesn't make it entirely  
8 clear, it looks as though the Minister was endorsing  
9 the course identified in the submission.

10 So we see the Department actioning that by  
11 letter to Armour on 27 January 1976 at ARMO0000004.  
12 This a letter from the Licensing Authority within the  
13 Department to Mr Brooks, the head of regulatory  
14 affairs at Armour. It says:

15 "Before determining your application in respect  
16 of Factorate (Factor VIII) the licensing authority  
17 requires the following information ..."

18 Then there are a number of matters set out  
19 reflecting the various conditions identified by the  
20 Committee on Safety of Medicines and by the Department  
21 itself. The relevant ones, for present purposes, are  
22 at b:

23 "Confirmation that the following conditions will  
24 be observed.

25 "i. Information will be provided by the licence

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1 per batch to give a pooled plasma of approximately  
2 1,000 litres."

3 So that's the information that's provided in  
4 relation to pool size.

5 Then, in terms of the information about  
6 rejection of donors, what's said is this:

7 "The rejection rate at blood collection centres  
8 is below 1% for accepted donors. The only data  
9 available concerns those rejected for blood pressure,  
10 temperature, and other illnesses on the day of the  
11 donation. No data is available on rejections caused  
12 by other medical examinations."

13 So that's the sum total of the information given  
14 in relation to rejection of donors.

15 **SIR BRIAN LANGSTAFF:** Centre by centre?

16 **MS RICHARDS:** Yes, the request is centre by centre,  
17 precisely.

18 Then if we go over the page -- thank you,  
19 Soumik, it's already there -- paragraph (f):

20 "We confirm that the plasma will be only from  
21 donor centres in the USA, and from USA sources."

22 Now, the first part of that sentence is  
23 obviously clear in linguistic terms: donor centres in  
24 the USA and from USA sources. I am afraid at the  
25 moment, sir, I don't understand what that means.

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1 holder on the number of donations from which plasma is  
2 pooled for the manufacture of each batch of the  
3 product, and the reasons for and the rate of rejection  
4 of donors or donations centre by centre."

5 So that's the condition that the subcommittee  
6 and the Committee on Safety of Medicines had  
7 identified.

8 Then if we go over the page, top of the next  
9 page:

10 "Confirmation that plasma will be obtained only  
11 from donor centres in the USA or in other countries  
12 specified in respect of which the licensing authority  
13 is satisfied as to the donation arrangements, being  
14 premises in respect of which you provided an  
15 undertaking that they may be inspected by or on behalf  
16 of the [UK] licensing authority."

17 So that is the condition that effectively  
18 emerges as a result of the minister's interest in the  
19 Armour application.

20 The response from Armour is at ARMO0000005.  
21 A letter dated 2 February 1976. If we go towards the  
22 bottom of the page -- they respond to the other  
23 conditions, which I needn't take up time with. At the  
24 bottom of the page:

25 "The number of donations is approximately 1,540

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1 **SIR BRIAN LANGSTAFF:** Well, if it were donor centres in  
2 the USA, and from USA sources, meaning people who live  
3 in the USA, that would stand to reason. But I think  
4 it probably means -- as I would interpret it, but  
5 I accept it is not entirely clear -- other places  
6 within the USA where you can buy plasma or obtain  
7 plasma.

8 **MS RICHARDS:** That certainly would fall or be capable of  
9 falling within the language.

10 **SIR BRIAN LANGSTAFF:** Which could include, therefore,  
11 plasma imported into the USA from somewhere else,  
12 wherever.

13 **MS RICHARDS:** Yes, possibly. We'll see what's set out in  
14 the product licence in a moment but that's the  
15 correspondence that ensues.

16 Now whether -- that may well not be the sum  
17 total of the correspondence. We don't have,  
18 currently, a further exchange of correspondence, but  
19 it may be that it exists, and again, as Mr Hill  
20 indicated, there are a number of threads we need to  
21 try to follow through and see if we can find out more  
22 information.

23 **SIR BRIAN LANGSTAFF:** It could be other sources than donor  
24 centres which themselves are USA-centred, but it's not  
25 clear at all.

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1 **MS RICHARDS:** When we go to the actual licence, the  
 2 licence more closely reflects the language of the DHSS  
 3 letter. So if we go to ARMO0000320, please.  
 4 If we go to page 7, Soumik. This is the actual  
 5 licence granted in March 1976, so:  
 6 "Product licence No. 0231/0038 ... granted under  
 7 and subject to the provisions of the Medicines Act ...  
 8 to  
 9 "Armour Pharmaceutical Company Limited ..."  
 10 et cetera.  
 11 And we'll see it continues for a period of  
 12 five years. If we just go down, we see the date,  
 13 25 March 1976, so a few weeks after the correspondence  
 14 we looked at.  
 15 If we go over the page, we can see what  
 16 I understand to be a schedule to the licence,  
 17 "Particulars of the products to which the licence  
 18 relates". Don't need to go through any of that.  
 19 Then if we go to the next page, part 2 of the  
 20 schedule is "Further provisions subject to which the  
 21 licence has been granted". If we look down to  
 22 paragraph 6, we can see it says:  
 23 "Information shall be provided by the licence  
 24 holder on the number of donations from which plasma is  
 25 pooled for the manufacture of each batch of the

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1 doesn't make clear what in practice it meant, beyond  
 2 the very skeletal information provided in Armour's  
 3 February letter.

4 So obviously one of the matters that you'll wish  
 5 to consider in due course, sir, will be the extent to  
 6 which this enhanced consideration of Armour's  
 7 application in fact resulted in any greater  
 8 reassurance as to the safety of the product.

9 **SIR BRIAN LANGSTAFF:** Yes.

10 **MS RICHARDS:** So that's the licensing application, the  
 11 original licensing application, and the grant of the  
 12 licence in relation to Factor VIII in 1976.

13 **SIR BRIAN LANGSTAFF:** Just a matter of interest, have we  
 14 any -- on that last point, have we any material which  
 15 might suggest that the DHSS wrote to Armour saying,  
 16 "Can you please let us know centre by centre what the  
 17 rejection rate is and why"?

18 **MS RICHARDS:** Not that I have seen. That doesn't mean it  
 19 doesn't exist. Again, it's possible it exists and we  
 20 haven't found it, or it exists and we don't have it,  
 21 or that it doesn't exist. So it's one of those  
 22 further loose ends that we will want to try to  
 23 reassurance ourselves as to, but there may be no  
 24 matter.

25 **SIR BRIAN LANGSTAFF:** Well, I can understand why we might

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1 product, and the reasons for and the rate of rejection  
 2 of donors or donation centre by centre."

3 So that replicates the language of the condition  
 4 identified by the Committee on Safety of Medicines.  
 5 But what's not clear is whether, in fact, that  
 6 required Armour to do anything other than it had  
 7 already done in that letter from February, which was  
 8 to answer in very general terms the request for  
 9 further information or whether there was any ongoing  
 10 requirement beyond that. We've certainly not seen in  
 11 the material that we've been able to examine any  
 12 evidence of the further submission of data, pursuant  
 13 to any kind of ongoing requirement.

14 Then if we look at paragraph 7 we see the  
 15 condition that was outlined in the ministerial  
 16 submission:

17 "Plasma shall be obtained only from donor  
 18 centres in the United States of America or in other  
 19 countries specified in respect of which the licensing  
 20 authority is satisfied as to the donation arrangements  
 21 being premises in respect of which the licence holder  
 22 has provided an undertaking that they may be inspected  
 23 by or on behalf of the United Kingdom licensing  
 24 authority."

25 So that, again, replicates the language, but

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1 not have a document which is held or one would expect  
 2 to be held by Armour but if it was sent from the DHSS  
 3 here in the mid-seventies, you'd expect at least  
 4 a carbon copy of it.

5 **MS RICHARDS:** Yes, although we know there are some  
 6 DHSS materials that have never been found, and that  
 7 was apparent from the evidence we heard from  
 8 Lord Glenarthur, Lord Clarke and Lord Fowler.

9 **SIR BRIAN LANGSTAFF:** Yes.

10 **MS RICHARDS:** It may well be that there is further  
 11 material but currently we've not got it, or not found  
 12 it.

13 If we then look within this same document  
 14 reference, Soumik, to page 5, we'll see that over the  
 15 following years -- this is at paragraph 10 -- there  
 16 were a number of subsequent variations to the licence.  
 17 You've got the dates there. The variations by letter.

18 We don't have a clear understanding, I'm afraid,  
 19 of what those variations are. I've seen an example of  
 20 one which is not of any great moment. I think it was  
 21 about the methods of reconstitution. But in any event  
 22 there were variations from time to time.

23 If we then go to the second page of this  
 24 document we can see there a renewal of the product  
 25 licence. So you'll recall the date of the grant was

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1 25 March 1976. It's then renewed. Date of renewal is  
 2 25 March 1981. So five years on. The oddity is that,  
 3 if you go further down, the renewal is dated  
 4 31 July 1984. And, I'm afraid, we don't understand at  
 5 present why that is the case.  
 6 In any event, the schedule which appears to be  
 7 attached to this product licence renewal is on the  
 8 next page, and if we go one page further on, this is  
 9 in the particulars of the products to which the  
 10 licence relates. Paragraph 6, we'll see there  
 11 reference to hepatitis:  
 12 "Factorate is prepared from human plasma, each  
 13 donation of which has been found negative for  
 14 Hepatitis B Surface Antigen (HBsAg) by the  
 15 radioimmunoassay (RIA) method. In addition, this lot,  
 16 after reconstitution has been tested and found  
 17 negative by the RIA method. However, since no  
 18 completely reliable laboratory test is yet available  
 19 to detect all potentially infectious plasma donations,  
 20 the risk of transmitting viral hepatitis is still  
 21 present."  
 22 That's Armour's first product, Factorate.  
 23 I'm going to turn next to the second plasma  
 24 product for which it sought and obtained a licence,  
 25 which was High Potency Factorate in 1978, but perhaps,

1 a product licence for High Potency Factorate, and  
 2 we'll see the separate licence there 0231/0044.  
 3 If we go over the page, we can see the licence  
 4 itself and the date of grant is 13 June 1979.  
 5 In terms of supplemental conditions or  
 6 requirements, page 3 sets out what I think are largely  
 7 the standard conditions of the product licence at the  
 8 time. So paragraph 1 refers to compliance with  
 9 various statutory requirements. Paragraph 2 is  
 10 leaflets shall comply with the requirements of the  
 11 Medicines (Leaflets) Regulations 1977, likewise labels  
 12 shall comply with the medicines labels regulations  
 13 1976. Paragraph 3:  
 14 "The product shall not be recommended to be used  
 15 for any purposes other than those specified in Part 1  
 16 of this Schedule as Uses."  
 17 4 is:  
 18 "The specification ... shall be in accordance  
 19 with the information contained in the application ...  
 20 "5. The product shall be manufactured only in  
 21 accordance with the method given in the application  
 22 for this product licence."  
 23 No separate or additional conditions appear to  
 24 have been imposed in relation to this particular  
 25 product.

1 given the time, we can come to that after the break.  
 2 **SIR BRIAN LANGSTAFF:** Let's take a break and come back at  
 3 twenty to four. I hope that gives everyone enough  
 4 time. Twenty to four.  
 5 **(3.13 pm)**  
 6 **(A short break)**  
 7 **(3.40 pm)**  
 8 **MS RICHARDS:** Could we have ARMO0000021.  
 9 We'll see this is November 1978, and this is  
 10 Armour's application for a separate product licence  
 11 for its High Potency Factorate:  
 12 "Please find enclosed six copies of Volume I and  
 13 II of our Submission for a Product Licence for our new  
 14 high potency form of Factor VIII, to be identified as  
 15 High Potency Factorate."  
 16 Then the second paragraph:  
 17 "Reference to our previous submission [so that's  
 18 the product application licence that we looked at  
 19 before the break] will confirm that we examined this  
 20 product for quality and safety in a similar manner  
 21 that previously agreed."  
 22 That application for a product licence was  
 23 successful, as we will see from ARMO0000036. This is  
 24 the Licensing Authority's confirmation, 13 June 1979,  
 25 that the authority had been given for the grant of

1 If we go to the application, which is at  
 2 ARMO0000023. If we go to page 3, it's a similar form  
 3 to that which we looked at before the break, so the  
 4 name of the product is High Potency Factorate, if we  
 5 go down the box to 7, "Details of [previous]  
 6 applications", reference is made to the Factorate  
 7 licence and then, at the very bottom of the page, we  
 8 can see the date of the application,  
 9 20th November 1978.  
 10 If we go a further two pages on, please, we'll  
 11 see there are some supplementary details in relation  
 12 to "Product Literature":  
 13 "Labelling and Package Insert  
 14 "Details ... are as attached.  
 15 "Data Sheets  
 16 "It is intended to defer final drafting until  
 17 the licence is granted."  
 18 I'll come on to some aspects relating to  
 19 labelling and data sheets in due course, and if we  
 20 just turn over the page, we can see the draft package  
 21 insert that was included with the application. If we  
 22 go to page 10, we can see that it was proposed that  
 23 the warning should read as there set out:  
 24 "Factor VIII is prepared from human plasma, each  
 25 donation of which has been found negative for

1 hepatitis B surface antigen ... by the  
2 radioimmunoassay ... method. In addition, each batch,  
3 after reconstitution as recommended on page 3, has  
4 been tested and found negative by the RIA method.  
5 However, since no completely reliable laboratory test  
6 is yet available to detect all potentially infectious  
7 plasma donations, the risk of transmitting viral  
8 hepatitis is still present."

9 Just pausing there, and we will see other  
10 references to hepatitis B in very similar form to the  
11 references in the 1975 application, the original  
12 application, for Factorate. We're now, of course, in  
13 late 1978, all the references we see are in the  
14 context of hepatitis B. There's the general reference  
15 there to viral hepatitis and that risk being still  
16 present. But there is nothing in the material  
17 submitted to the Licensing Authority that we have seen  
18 which addresses specifically any issues relating to  
19 non-A, non-B hepatitis, the existence of which, sir,  
20 you may think was well known and understood by late  
21 1978.

22 **SIR BRIAN LANGSTAFF:** Well, yes, but the expression "viral  
23 hepatitis" is capable of covering both.

24 **MS RICHARDS:** It is undoubtedly capable of covering both.  
25 The question might arise as to how it might be

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1 found negative for hepatitis B Surface Antigen by  
2 radio-immunoassay. Vials from the final dosage form  
3 are examined for quality and safety aspects agreed for  
4 the Armour product [that's a reference to the original  
5 Factorate] which was licensed for supply to hospitals  
6 on 25th March, 1976."

7 Top of the next page, in terms of manufacture:

8 "All plasma is collected in establishments  
9 licensed by the FDA, Bureau of Biologics, and  
10 transferred to Armour under conditions defined in  
11 Title 21 of the Code of Federal Regulations.

12 "Plasma and plasma records are inspected upon  
13 receipt at Armour Pharmaceutical Co, Kankakee,  
14 Illinois ... and if satisfactory, the plasma is  
15 approved for fractionation."

16 Then if we turn to page 27, bottom half of the  
17 page, we can see there the plasma properties are set  
18 out, and point 5 is:

19 "Free of Hepatitis B Surface Antigen as tested  
20 on individual units of plasma by Radioimmune Assay or  
21 other assay meeting requirements of Title 21 ..."

22 Over the page, page 28, the bottom half of the  
23 page, so paragraph 3, there are various requirements  
24 there in relation to information to be included with  
25 shipments of plasma to Armour, so from the collection

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1 understood by those for whom the warnings are  
2 intended, in the context of a discussion about testing  
3 for hepatitis B, and no such test to detect all  
4 potentially infectious plasma donations, would that be  
5 understood by the reasonable reader or reasonable  
6 patient, if they ever saw this, as pointing out  
7 possible risks of transmission of non-A, non-B  
8 hepatitis?

9 Within the same document, we can see at page 12,  
10 at the bottom of the page, "Caution" at the bottom:

11 "The product is prepared from Pooled Human  
12 Plasma. Despite careful selection of donors and  
13 non-reactivity of the reconstituted solution for  
14 hepatitis B antigen by the radio-immuno assay  
15 procedure, freedom from causal agents of viral  
16 hepatitis cannot be assumed."

17 So the same terminology. Then the next page,  
18 last paragraph:

19 "High Potency Factorate is manufactured from  
20 human plasma donations collected at licensed  
21 establishments which are subject to the USA Federal  
22 Law."

23 So here, by this time, it is being said all  
24 collections are from licensed establishments.

25 "Each donation and each product lot has been

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1 centres to Armour's manufacturing plant, and (f) is:

2 "A statement confirming that all units have been  
3 tested and found non-reactive for Hepatitis B Surface  
4 Antigen as defined in Title 21, Code of Federal  
5 Regulations ..."

6 If we go on to page 31, there's a draft data  
7 sheet, and we can see at the top the page, this is  
8 a draft data sheet for the plasma, to be submitted  
9 with each shipment of plasma sent to Armour in  
10 Kankakee. The bottom of the page, you'll see there  
11 "Hepatitis B Surface Antigen", so that's the data  
12 sheet requirement.

13 Then if we go to page 50, we can see this is  
14 part of the quality control materials submitted with  
15 the licence application, similar to what we saw in  
16 relation to the 1975 application, "Hepatitis  
17 Associated Antibody ... Biological Principles of the  
18 Procedure", and then there is a description of the  
19 radioimmunoassay technique that's used in similar  
20 terms to the terms we saw previously.

21 That's the application for the High Potency  
22 Factorate and, as we've seen, the licence was granted  
23 in June 1979. If we turn to ARMO0000046, we can see  
24 a follow-up letter from Armour to the Department of  
25 Health, 21 November 1979. The text of the letter

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1 refers to a request that a copy of any data sheets be  
2 forwarded to the Department:

3 "It is our intention to make this product  
4 available early in 1980 and in connection with this we  
5 have now finalised the data sheet text."

6 If we go to page -- oh, sorry, I should just  
7 continue with the letter, last few lines:

8 "We would like to point out that because of the  
9 specialised nature and use of the product, it is not  
10 our intention to include the text of this data sheet  
11 in the ABPI Compendium."

12 We'll look at what was and was not within the  
13 ABPI Compendium tomorrow.

14 If we go to the third page, we can see the data  
15 sheet being sent to the Licensing Authority and if we  
16 go over two pages, it should be to page 5, we can see,  
17 under the heading "Warning", again, similar  
18 terminology to elsewhere in the documentation:

19 "Factor VIII is prepared from human plasma, each  
20 donation of which has been found negative for  
21 hepatitis B surface antigen ... by the [RIA] method.  
22 In addition, each batch, after reconstitution as  
23 recommended, has been tested and found negative by the  
24 RIA method. However, since no completely reliable  
25 laboratory test is yet available to detect all

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1 page 135, we'll see, as part of the material that was  
2 included within the Irish licence application, is  
3 a letter here from a Dr Lavine, February 1978,  
4 enclosing trial data in relation to the product. Then  
5 if we turn to page 143, we can see under the heading  
6 "Summary of the Trials Reported":

7 "The following information summarises the four  
8 separate evaluations of High Potency Factorate ..."

9 If we go towards the bottom of the page, we can  
10 see that there's a reference under the heading  
11 "Adverse Reactions" to one case of adverse reaction  
12 reported, thought by the clinician to be a case of  
13 short incubation non-A, non-B hepatitis.

14 Over the page, there is what is presumably some  
15 details of how that short incubation hepatitis was  
16 said to have manifested itself.

17 Then if we go to page 146, there is there  
18 a further description about a patient's -- it's about  
19 five lines down, in Study 1, at the top of the page,  
20 one patient developing hepatitis ten days after the  
21 infusion:

22 "... made a prompt and complete recovery and  
23 showed no evidence of liver damage on follow-up one  
24 month later."

25 Then towards to the bottom of that paragraph, it

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1 potentially infectious plasma donations, the risk of  
2 transmitting viral hepatitis is still present."

3 Then it would appear, if we go to ARMO0000047,  
4 this is an application to vary the High Potency  
5 Factorate licence, the basis of the variation is not  
6 particularly material, but you'll see the date is  
7 February 1980 and if we look at the first paragraph,  
8 last sentence, it says:

9 "It had been our intention to launch the product  
10 in January this year, but to date the product has not  
11 been made commercially available."

12 So there was a period of delay before Armour was  
13 actually marketed in the UK, although, as we'll see  
14 shortly, it did subsequently become available and was  
15 used.

16 There's a product licence application also made  
17 for High Potency Factorate in Ireland by Armour. If  
18 we look at ARMO0000092, and if we go, first of all, to  
19 page 5, we can see at paragraph 12 the heading  
20 "Warning", again, in very similar, potentially  
21 identical, terms to the application that was made to  
22 the UK Licensing Authority.

23 What's interesting in relation to this  
24 application is some of the clinical studies material  
25 that was provided to accompany it. So if we go to

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1 says:

2 "No other adverse effects were observed in any  
3 of the ten patients."

4 It's a short and passing reference to non-A,  
5 non-B hepatitis in the Irish application that was  
6 being made in around the same time -- no, sorry a  
7 little later. The clinical trial data was available  
8 in the late 1970s, but it's a November 1981  
9 application.

10 Then if we turn to ARMO0000116, this is a letter  
11 dated November 1982 to the Department's Medicines  
12 Division. The particular issue is a request for  
13 a shelf life extension for High Potency Factorate, but  
14 we can see by this that, by this time, clearly High  
15 Potency Factorate is being marketed within the  
16 United Kingdom. Third sentence:

17 "This material is required urgently to fulfil  
18 commitments to our customers ..."

19 So the precise date upon which High Potency  
20 Factorate became -- was being supplied within the UK  
21 is unclear but sometime between 1980 and 1982.

22 If we then turn to ARMO0000132, please. We'll  
23 see there, in February 1984, Armour wrote to the  
24 Medicines Division at the Department of Health and  
25 Social Security, you'll see there reference to the two

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1 product licences that we've looked at, and then the  
2 text of the letter says:

3 "Further to today's telephone conversation,  
4 I confirm that the name Factorate shall be changed to  
5 Factorate Heat Treated and the name High Potency  
6 Factorate shall be changed to High Potency Factorate  
7 Heat Treated. Labelling will be amended accordingly."

8 I'll come back to the question of the  
9 heat-treated product shortly. If we just next look at  
10 ARMO0000145, this is a letter, May 1984, in relation  
11 to the High Potency Factorate, from Armour to the  
12 Medicines Division at the Department requiring  
13 a product licence after the expiry date of the  
14 existing licence.

15 If we go over the page, we can see the renewal  
16 application there set out. For reasons that are  
17 unclear, the change of name to Heat Treated Factorate  
18 is not there incorporated. So this appears to be  
19 an application for renewal of the non-heat-treated  
20 High Potency Factorate product licence.

21 If we go to ARMO0000153, we will see that it was  
22 indeed renewed on 13 June 1984. The product licence  
23 for the High Potency Factorate there renewed.

24 Before I look a little further at the question  
25 of the heat-treated product, I just want to show you

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1 themselves: the next largest is, I think, Immuno's  
2 Kryobulin product and then Hyland's Hemofil.

3 The annual returns, I'm not going through  
4 details of annual returns, but we've looked at the  
5 annual returns for some of the bigger centres and some  
6 of the Reference Centres to see if there are any  
7 particular patterns discernible in terms of use of  
8 Armour products. The short answer is that it varies  
9 enormously from centre to centre.

10 We can take that down, thank you. Soumik. So  
11 I'm going to take a handful of examples without  
12 putting up any of the underlying documents, many of  
13 which, in terms of annual returns we've looked at in  
14 the course of evidence and presentation so far.

15 If we take Birmingham Children's Centre, Armour  
16 is first used to a modest extent in 1977. Its usage  
17 increases over the years that follow until, in 1980,  
18 it's around 1 million units of Armour used. By 1981,  
19 Armour was the only commercial concentrate in use at  
20 Birmingham Children's Hospital, with the figures being  
21 around 1.4 million in 1983 and around 1.6 million in  
22 1984.

23 That, you'll recall, is the Centre of which  
24 Dr Hill was the director.

25 A rather different picture emerges in relation

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1 some documents which cast some light on the extent to  
2 which Armour occupied a significant market share  
3 within the United Kingdom. So if we go firstly to  
4 DHSC0003719\_118, this is a table dated 21 December  
5 1976, within the Department's Supply Division,  
6 addressed to Dr Waiter. It's sales figures for  
7 October, together with total figures for the contract  
8 year. We can see there that Armour occupy a fairly  
9 small part of the market at this point in time,  
10 because, of course, Factorate had only been licensed  
11 earlier in 1976. So we can see the total for the 12  
12 months to the end of October 1976 for Armour was  
13 897,308 units; Travenol and Immuno, which had both had  
14 licences for longer by that point in time, much larger  
15 amounts; and Abbott, a smaller amount, 383,624. So  
16 that's the position in the early days.

17 If we then go to PRSE0003437, we will see the  
18 position changes over the following years. This is  
19 a table showing quantities of Factor VIII concentrate  
20 used in UK haemophiliacs breakdown by manufacturer for  
21 the years 1980 and 1981. You'll see from that, that  
22 Armour are by far and away the largest supplier in  
23 terms of quantities. So 1980, 16,576,000  
24 international units, and for 1981, 14,646 -- sorry,  
25 14,646,000 units, and then the figures speak for

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1 to Belfast. Armour's first used in Belfast in 1980 to  
2 a relatively modest extent. Increased usage in 1982,  
3 it was the commercial concentrate used second only to  
4 Kryobulin in terms of volume, but -- and then  
5 a significant usage in 1984. We don't have the  
6 returns for Belfast for 1983.

7 Cardiff, by way of contrast, which of course is  
8 the centre at which Professor Bloom was the director,  
9 shows, for the most part, fairly limited usage over  
10 a number of years in the late 1970s of Armour and,  
11 until around 1982 when it's used to a greater extent  
12 but amongst a range of commercial concentrates there  
13 used, and then barely used at all in 1983 and 1984.

14 Interestingly, if we look at one of the other  
15 children's hospitals, so Glasgow Children's Hospital,  
16 it is apparent that Armour was the commercial product  
17 of choice for the then director, Dr Willoughby. It's  
18 very substantially used from 1978 through to 1982.

19 But the picture essentially varies very much  
20 from centre to centre, so there's no obvious pattern  
21 in terms of usage, other than as the overall figures  
22 show, it, if not dominated, the market, was a very  
23 significant player in the market by 1980.

24 **SIR BRIAN LANGSTAFF:** And the reason for that?

25 **MS RICHARDS:** There is no obvious reason that we can

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1 detect, I'm afraid. There was the issue relating to  
2 price that we saw referred to earlier in the 1970s, in  
3 the departmental material we looked at before the  
4 break. The extent to which that price differential  
5 was maintained over the following years and the extent  
6 to which that, in turn, influenced individual Centre  
7 Directors is unclear.

8 Unfortunately, for many of the centres, we don't  
9 have the relevant director alive to ask.

10 **SIR BRIAN LANGSTAFF:** No, we do have, I suppose,  
11 a division, do we, in the -- one of those figures you  
12 showed me earlier, was it the 1976 table? That's  
13 probably --

14 **MS RICHARDS:** DHSC000 --

15 **SIR BRIAN LANGSTAFF:** 118.

16 **MS RICHARDS:** -- 719 --

17 **SIR BRIAN LANGSTAFF:** C719\_118.

18 **MS RICHARDS:** That's the one.

19 **SIR BRIAN LANGSTAFF:** We've only got the price there, and  
20 Armour is obviously selling for a fair bit less than  
21 both Travenol and Immuno. It's easy to work it out  
22 because if one reads across to the figure on the  
23 right-hand side, having divided by 10, both Travenol  
24 and Immuno are charging more per unit than Armour is.  
25 Armour is charging less than 10p a unit.

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1 concentrates used, and about three times as much as  
2 its nearest rivals. It may be price. That's the only  
3 factor that we can identify as a possible, and it's  
4 only a possible factor.

5 **MS RICHARDS:** Yes. And it's the reason why I went back to  
6 some of the annual returns for the reference centres  
7 or bigger centres to see if there was any discernible  
8 pattern. But there wasn't. So, as I say, one sees  
9 there are some directors for whom Armour was plainly  
10 the commercial concentrate of choice, and Dr Hill at  
11 Birmingham Children, Dr Willoughby at Glasgow Children  
12 are two examples of that. But when we look at some of  
13 the other big reference centres, Cardiff, Newcastle,  
14 there isn't an obvious pattern that emerges in terms  
15 of an overwhelming preference for Armour or, indeed,  
16 any particular concentrate, year after year.

17 **SIR BRIAN LANGSTAFF:** Yes. Thank you.

18 **MS RICHARDS:** If we then just pick the picture up in 1983,  
19 in terms of usage, DHSC0002229\_055.

20 This is a minute -- I think we probably looked at  
21 it when Dr Walford gave her evidence, but for present  
22 purposes it's the table on the second page that is of  
23 interest.

24 It says:

25 "The following companies import coagulation

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1 **MS RICHARDS:** Yes, and we saw that being a feature that  
2 apparently attracted itself to the Department's Supply  
3 Division when the licence applications were being  
4 considered.

5 What I don't know, sir, is whether  
6 that -- (overspeaking) --

7 **SIR BRIAN LANGSTAFF:** Whether it was maintained.

8 **MS RICHARDS:** -- it was maintained.

9 **SIR BRIAN LANGSTAFF:** We don't have any other documents  
10 with values written on them?

11 **MS RICHARDS:** Not off the top of my head. We might do.  
12 We can certainly see if we can find out any more about  
13 that.

14 **SIR BRIAN LANGSTAFF:** Okay.

15 **MS RICHARDS:** There may be a range of reasons, of course,  
16 why directors choose particular products. We'll get  
17 a sense, I think, when we look at Bayer perhaps, of  
18 some of the marketing techniques that were used and it  
19 may be that Mr Bishop will be able to cast some light  
20 on the issue as well, in terms of his interactions  
21 with Haemophilia Centre Directors.

22 **SIR BRIAN LANGSTAFF:** So at the moment we don't know why  
23 it is that Armour began to conquer the market to the  
24 extent that -- in the figure you've shown me from 1980  
25 or '81, it was very nearly half of all the commercial

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1 factor concentrates into the UK from the USA."

2 Then we've got the companies listed, and then  
3 annual sales. And you'll see the figures in relation  
4 to Factorate: 15 to 20 million international units,  
5 then the High Potency Factorate: 1-1.5 million  
6 international units. Alpha's Profilate is 5 million,  
7 Travenol's Hemofil is 8-9 million. Immuno's  
8 Kryobulin, there are the various different figures,  
9 we've got the red pack, 0.9 million, the blue, 4.1,  
10 and then the Prothromplex and the FEIBA. And then  
11 Miles' Koate, which we look at when we look at Bayer,  
12 8 million.

13 So again, Armour, as at June 1983, which is the  
14 date of this document -- so the figures may, for  
15 example, go up -- I don't know whether they go up into  
16 '83 or whether they stop at '82, but Armour continued  
17 to dominate the market. But again, I'm afraid, that  
18 data doesn't explain the reason why.

19 Then to pick up the picture in relation to the  
20 licensing process for the heat-treated Factor VIII, if  
21 we go to SHPL0000067\_028, this is a letter to Immuno  
22 but we know from another letter that it was sent in  
23 similar or identical form to Armour. So it's  
24 26 November 1984 from M Duncan to -- this is to  
25 Immuno, but it says:

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1 "Following our recent telephone conversation may  
2 I confirm that the licensing authority wishes to  
3 encourage all companies involved in the production of  
4 Factor VIII to use a dry heat treatment process in the  
5 course of manufacture.

6 "We are inviting each company to consider this  
7 proposal and, hopefully to make early (abridged)  
8 application for a new product licence."

9 Then if we go to ARMO0000156, we can see  
10 a letter from Armour, 4 January 1985:

11 "Application for Variations to ..."  
12 Both product licences.

13 And then the letter begins with reference to the  
14 letter from ME Duncan dated November 26, so clearly  
15 a letter in identical form or similar form went to  
16 Armour.

17 "... we enclose applications" -- sorry, let me  
18 read the whole thing.

19 "With reference to the letter from Dr ME Duncan  
20 dated November 26, 1984, and the undersigned's  
21 [that's Mr or Ms Collins, regulatory affairs manager  
22 for Armour] meeting with her on December 19th, 1984,  
23 we enclose applications (two copies of each file) to  
24 vary the above Product Licences. The variation  
25 relates to the inclusion of a heat treatment stage in

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1 seroconversion through the heat-treated concentrates  
2 in November.

3 The application for the variation for the  
4 heat-treated Factorate is ARMO0000164.

5 We can see it's dated January of 1985.

6 And if we go to page 5, we'll see there the  
7 heading "Reason for change/background statement":

8 "For some years work has been progressing at  
9 a number of centres particularly in the USA on the  
10 development of Factor 8 products with reduced risk of  
11 the transmission of hepatitis. Work at Armour  
12 Pharmaceutical Company, Kankakee, Illinois, resulted  
13 in the development of a heat treatment stage  
14 incorporated as the final part of the process in the  
15 current production of intermediate potency Factorate  
16 ... and High Potency Factorate. Initial studies  
17 revealed that heat treatment, a commonly accepted  
18 concept in the destruction of heat-labile viruses, was  
19 insufficient alone to prevent the transformation of  
20 Hepatitis B, although evidence existed to suggest that  
21 non-A non-B viruses might be removed by this process.

22 "The process was approved by the FDA for the  
23 US market and by the BGA for the German market.  
24 A Product Licence application was submitted  
25 16 February 1984 for the High Potency Heat Treated

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1 the processing of the products. Much of the  
2 information presented has already been assessed by the  
3 DHSS in relation to our CTX [clinical trial exemption]  
4 and PL applications relating to [non-A, non-B]  
5 hepatitis ...

6 "It is understood that such applications as  
7 these are being considered a priority by the licensing  
8 authority in view of the general situation relating to  
9 AIDS in the UK."

10 So that's the application for variation for  
11 heat treatment being submitted by Armour in  
12 January 1985. If we go to ARMO0000157, we can see the  
13 application for the variation. This is in relation to  
14 the High Potency Factorate, and the proposed  
15 variation, we'll see from the right-hand side, under  
16 the heading "Proposed":

17 "The method of manufacture will be as currently  
18 undertaken but with an additional step in respect of  
19 having heat treatment. The finished lyophilised vials  
20 from the current process will be subjected to a heat  
21 treatment in a water bath at an attained temperature  
22 of 60°C +/- 1°C for a period of 30 hours."

23 The significance of that particular heat  
24 treatment method as opposed to others will become  
25 apparent when we look in more detail at the issue of

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1 Factorate ... Earlier a CTX application was submitted  
2 for the intermediate purity product Factorate Heat  
3 Treated ... on 11th August, 1983 in order to undertake  
4 a definitive study at UK Haemophilia Centres over an  
5 extended period of time in previously untreated  
6 patients to determine if infectivity of the product  
7 had been eliminated."

8 Pausing there, we will look at some documents  
9 relating to that Armour study of its heat-treated  
10 material either this afternoon or tomorrow morning.

11 "Subsequent events indicated strongly that while  
12 the products were clinically effective, the heat  
13 treatment process employed did not achieve the desired  
14 objective in relation to [non-A, non-B] hepatitis, and  
15 the Product Licence application was withdrawn and the  
16 CTX surrendered in November 1984.

17 "During 1984 concern among UK physicians  
18 continued to grow over the AIDS situation."

19 Then reference is made to isolation of the  
20 causative virus and to the development of tests with  
21 the virus.

22 If we then pick it up in the next paragraph:

23 "The heat treatment process developed for  
24 Factorate and High Potency Factorate products in  
25 relation to NANB hepatitis looked as though it may be

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1 sufficient to destroy the LAV HTLV III virus.  
 2 A programme of work to assess the situation in  
 3 relation to a number of heat-treatment processes and  
 4 products has been undertaken by the US Centre for  
 5 Diseases Control (CDC) in conjunction with the FDA  
 6 Bureau of Biologies (BOB). It would appear that the  
 7 in vitro situation 60°C for 4 minutes will inactivate  
 8 the virus in certain conditions ..."

9 Then over the page, there's then further  
 10 information about the proposed heat treatment process,  
 11 which was 60 degrees centigrade for 30 hours. It's  
 12 asserted that all the indications are that this  
 13 process is effective in the destruction of the virus.

14 Then if we pick it up a few lines down in that  
 15 first paragraph:

16 "There have been unprecedented number of 'named  
 17 patient/requests and the situation with regard to such  
 18 supply on the scale sought is totally unsatisfactory.  
 19 It is clear that Haemophilia Centre Directors believe  
 20 that a heat treated product, even though not proven  
 21 over time to eliminate the AIDS risk virus is  
 22 preferable to a non-heat-treated product."

23 Then the next paragraph explains that studies  
 24 are continuing:

25 "However, we believe the products with the heat

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1 conducted by Dr C Rizza at Oxford Haemophilia Centre  
 2 on the material used under the CTX 0231/0070A."

3 Then it goes on to set out a conclusion in  
 4 relation to the half life of both heat-treated and  
 5 conventional Factor VIII.

6 We'll come back to elements of the study, but if  
 7 we then go to, I think it's page 166. No, I don't  
 8 want to conflate the US and the Oxford studies.

9 I can pick up the Oxford study by reference to  
 10 the CTX material and because that may be a reference  
 11 to -- oh, no, this is the Oxford one, I think. Sorry.

12 "Revlon Health Care (UK) Limited supplied the  
 13 investigator with sufficient supplies of the following  
 14 to allow for completion of the study."

15 And there's reference to "Heat Treated  
 16 Factorate" lots.

17 "Standard commercially available Factorate  
 18 Lot Y73903 was taken from the stock at the Oxford  
 19 Haemophilia Centre."

20 Then there's a reference to four patients being  
 21 entered into the study. If we go to the next page  
 22 you'll see, under the heading "Informed Consent", it's  
 23 said:

24 "Written informed consent was obtained from all  
 25 participating patients."

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1 treatment process as proposed are safe and effective.  
 2 Furthermore we believe the heat treatment process  
 3 proposed will render the existing products obsolete  
 4 and thus apply for a variation to the existing  
 5 Licences."

6 Then there is, again, a large amount of material  
 7 which is provided. I don't think we need to look at  
 8 most of it, but if we go to page 32, we can see some  
 9 information about studies in humans of the  
 10 heat-treated product.

11 "Heat treated Factorate proposed for  
 12 introduction onto the UK market has been and is  
 13 currently on the US and German markets. Hence there  
 14 is already considerable exposure of patients to this  
 15 product. Furthermore, the product is being used in  
 16 the UK on a 'named-patient' basis and has been used in  
 17 the abortive clinical study (CTX 0231/0070A).  
 18 Additionally a half life study has been conducted in  
 19 the UK by Dr Rizza, Consultant Haematologist at the  
 20 Oxford Haemophilia Centre."

21 Then there is reference to a half-life study in  
 22 the US that was conducted. Then if we go towards the  
 23 bottom of the page, we can pick up the reference to  
 24 Dr Rizza's study:

25 "The second study, as mentioned above, was

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1 Then the results over the page, page 168, are  
 2 there set out.

3 So that, I think, is really just an indication  
 4 of one of the studies that was undertaken domestically  
 5 in relation to heat-treated Factorate prior to it  
 6 being licensed, the half-life study. There's  
 7 a further study that we will come on to.

8 Before we do that, if we go to ARMO0000301.  
 9 You'll see that this is a letter from  
 10 Revlon Health Care/Armour Pharmaceutical Company  
 11 Limited, 2 November 1983, to Dr Preston in Sheffield.  
 12 "... I confirm that we have now been granted our  
 13 Clinical Trial Exemption Certificate by the  
 14 [Department] and can proceed with trials to evaluate  
 15 our Heat Treated Factorate to the protocol left with  
 16 you for information."

17 Then there's a reference to the study underway  
 18 at Oxford. So we have a study in Oxford and a study  
 19 in Sheffield ongoing essentially from 1983 in relation  
 20 to the heat-treated Factorate.

21 Then, if we go to ARMO0000121, this is the  
 22 application, the CTX application. If we turn to  
 23 page 3, we'll see there that it's an application under  
 24 the clinical trials order 1981.

25 If we go over the page to page 4 we can see the

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1 date of it, which is 18 August 1983.  
 2 If we go to page 5, we can see a section  
 3 "Particulars of Medicinal Product and Trial" and, if  
 4 we go over the page, we are told the full details of  
 5 the proposed trial are that the investigator is  
 6 Dr Rizza at Oxford, the duration of the trial is one  
 7 year.  
 8 "number of patients involved:  
 9 "Approximately 25 depending upon availability of  
 10 patients fulfilling inclusion criteria."  
 11 Then if we go to page 12, we can see the  
 12 protocol for this study. It's dated May 1983, the  
 13 date is in the bottom left-hand corner. And if we go  
 14 to the next page, we get some background information  
 15 about the trial:  
 16 "One of the primary concerns in the use of  
 17 coagulation factors in the haemophilic patient who  
 18 has mild to moderate disease which requires infrequent  
 19 treatment or in the newly diagnosed patient, is the  
 20 knowledge that each exposure presents a risk of  
 21 causing hepatitis."  
 22 Then under the heading "Objective", further down  
 23 the page:  
 24 "It is the purpose of this study to use our  
 25 especially prepared Factorate product exclusively for

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1 use only the trial Factorate. Any break in this rule  
 2 will end the study for that subject at the time the  
 3 non-study product is used. Patients will be entered  
 4 into the study as they require Factorate HT [heat  
 5 treated].  
 6 "The end point of the study will be the presence  
 7 or absence of hepatitis as measured by hepatitis  
 8 markers and liver chemistries taken serially over the  
 9 one year period of study."  
 10 Top of the next page:  
 11 "All patients or their guardians will have the  
 12 purpose of the study carefully explained and will sign  
 13 an Informed Consent. They will understand and agree  
 14 to the use of study Factorate exclusively for the one  
 15 year period of the study. However, in the best  
 16 interests of their patients, the physicians may  
 17 prescribe any treatment considered necessary. If this  
 18 includes Factor VIII other than the study material the  
 19 patients will continue to be followed but not included  
 20 in the analysis."  
 21 Then if we just go over to the next page and  
 22 pick it up under "Study Design", towards the bottom of  
 23 the page, this is the penultimate paragraph:  
 24 "The patients will be mild haemophiliacs and  
 25 therefore not on home treatment. Any intercurrent

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1 an extended period of time in a number of previously  
 2 untreated patients or in those who have received  
 3 minimal treatment to determine if infectivity of the  
 4 product has been eliminated."  
 5 So this was a proposed PUP study, effectively.  
 6 "Minimal treatment is defined as having received  
 7 no Concentrate or cryoprecipitate during the preceding  
 8 six (6) months and not having undergone major surgery  
 9 [et cetera] and having no history of hepatitis, yellow  
 10 jaundice, sub-clinical hepatitis or any abnormal liver  
 11 function tests."  
 12 If we go over the page, we see the "Study  
 13 Design":  
 14 "Selected study sites will be haemophilia  
 15 centres run by recognised experts in haemophilia care,  
 16 who have an adequate number of patients to assure the  
 17 recruitment of at least five (5) untreated subjects  
 18 each over a one (1) year study period. In addition,  
 19 these centres will be asked to recruit an equal number  
 20 of patients who have had infrequent treatment and are  
 21 free of hepatitis markers."  
 22 Next paragraph:  
 23 "It will be essential for the centres recruited  
 24 to have close control over their patients to ensure  
 25 that those entered into the study have access to and

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1 illness will be recorded with date and time of such  
 2 illness."  
 3 Then at the bottom of the page:  
 4 "The patient records or duplicates will be  
 5 segregated at the treating institution to ensure that  
 6 the investigator or staff will be notified at any time  
 7 the patient enters the institution either as  
 8 an out-patient or in-patient."  
 9 At the top of the next page:  
 10 "In the absence of transfusion hepatitis  
 11 patients will be followed for 1 year following  
 12 treatment with heat treated Factorate."  
 13 Then it explains about undertaking of liver  
 14 function tests and other tests, collection of blood,  
 15 et cetera, et cetera.  
 16 "This study will continue for twelve months. A  
 17 complete physical examination will be repeated at the  
 18 twelve month visit.  
 19 "Those patients whose liver function tests  
 20 remain elevated for one year after the attack of  
 21 non-A, non-B hepatitis or become carriers of  
 22 hepatitis B virus will be referred to the local liver  
 23 clinic for investigation of chronic liver disease.  
 24 Liver biopsy will only be carried out if clinically  
 25 indicated."

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1 Then one final reference is at page 21. Now  
2 this is not part of the protocol for the study that  
3 we've just been looking at. But this appears to be  
4 part of the same material that was submitted to the  
5 Licensing Authority in relation to the CTX  
6 application. So an application under the Medicines  
7 Exemption from Licences (Clinical Trials) Order 1981,  
8 Factorate heat-treated product. We can see the first  
9 paragraph talks about the time spent on trying to  
10 develop a Factor VIII with a reduced risk of  
11 transmission of hepatitis. Then if we go, however, to  
12 the penultimate paragraph, it says this:

13 "In addition, the recent upsurge in incidence of  
14 Acquired Immune Deficiency Syndrome ... has  
15 highlighted the problem of possible transmission of  
16 illness through blood products. The nature of the  
17 AIDS syndrome and lack of knowledge of the background  
18 aetiology are such that it is impossible to determine  
19 whether procedures such as heat treatment might afford  
20 protection. Nevertheless there is a growing body of  
21 opinion that heat treatment of material could maximise  
22 safety without detriment to the product or its  
23 clinical efficacy.

24 "The present study is proposed to assess the  
25 value of heat-treatment on transmission of non-A non-B

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1 heat-treated Factorate in prevention of transmission  
2 of non-A non-B hepatitis."

3 So the purpose of going to that in some detail  
4 is really to illuminate the protocol drawn up by  
5 Armour together with, it would appear, Haemophilia  
6 Centre Directors, Dr Rizza being identified as the  
7 investigator, and contemplated in 1983 with the  
8 knowledge of the risk of AIDS one sees referenced in  
9 the page we just looked at, the use of Heat Treated  
10 Factorate in patients with mild haemophilia.

11 **SIR BRIAN LANGSTAFF:** Yes, patients who had not previously  
12 needed treatment with any factor concentrate?

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** So if they were to be enrolled in  
15 the study, assuming it -- well, I don't think one can  
16 assume it to be ethical, given what our ethicists have  
17 said about the need for therapeutic benefit for  
18 a patient. But if it were, they'd have to be told  
19 about the risk, potential risk of AIDS, as well as the  
20 potential risk of hepatitis, coming from the treatment  
21 they'd never had before.

22 **MS RICHARDS:** Yes. Yes, the ethical questions to which  
23 the protocol and the study give rise are multiple and  
24 fairly evident.

25 **SIR BRIAN LANGSTAFF:** Yes. Is there any material -- since

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1 hepatitis. The discovery of common interests led to  
2 an approach to the UK Haemophilia Centre Directors  
3 Working Party on Hepatitis with resultant  
4 collaboration on the design of the study."

5 Top of the next page:

6 "The Haemophilia Centre Directors expressed  
7 a wish that the study be conducted with Factorate,  
8 rather than High Potency Factorate as, for economic  
9 reasons [that may be the answer, sir, to your  
10 question] this is the product most commonly used in  
11 the UK."

12 **SIR BRIAN LANGSTAFF:** Well, it may only be the difference  
13 between the people choosing the cheaper of those two,  
14 as opposed to Armour as against the rest.

15 **MS RICHARDS:** Yes, and the next paragraph:

16 "This situation has been discussed informally  
17 with DHSS professional staff and it was agreed that  
18 this present application could be supported with  
19 development data on the High Potency Factorate product  
20 [et cetera].

21 "We believe that this study, performed under the  
22 auspices of the country's leading haemophilia  
23 specialists, studying in depth a group of highly  
24 investigated patients is the definitive course to  
25 follow at this time in order to prove the efficacy of

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1 we're on that particular tack, is there any material  
2 that you spotted in the protocol which suggested there  
3 would have been treatment in any event with a non-heat  
4 treated Factor product?

5 **MS RICHARDS:** There was one passing sentence, is all I can  
6 recall, which if we go back to page 14 of the document  
7 we had up, ARMO000121, and if we look at the second  
8 paragraph under "Study Design", it would be reading  
9 a lot into the use of one short sentence, it is the  
10 last sentence:

11 "Patients will be entered into the study as they  
12 require Factorate HT."

13 It could be said that the inference to draw from  
14 that is that they're only treated if they require the  
15 product. But I don't recall there being anything else  
16 which addresses that issue. I'll re-read it again  
17 overnight.

18 **SIR BRIAN LANGSTAFF:** That may be of some importance.  
19 I mean, that could indicate that, although one starts  
20 off with a recruitment of 20-odd patients who'd never  
21 been treated before, there will be an occasion or so  
22 when one of them needs to have an agent to stop  
23 bleeding, and assume that DDAVP won't work, if it is  
24 one of those cases, or cryoprecipitate is thought  
25 insufficient, that they might then have used whatever

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1 Factor product was available.  
2 **MS RICHARDS:** Yes. There are quite a lot of assumptions  
3 that one has to build into that one sentence, and it's  
4 perhaps instructive to note the date of this protocol  
5 is May 1983.  
6 **SIR BRIAN LANGSTAFF:** Yes.  
7 **MS RICHARDS:** One need only think of the consideration  
8 that was being given by the Haemophilia Reference  
9 Centre Directors at their special meeting in May 1983,  
10 resulting in that letter from June of 1983, which  
11 talked about the position of those who were previously  
12 untreated patients.  
13 **SIR BRIAN LANGSTAFF:** Yes.  
14 **MS RICHARDS:** That, sir, is probably an appropriate note  
15 on which to end for today.  
16 **SIR BRIAN LANGSTAFF:** Yes. Yes, thank you.  
17 **MS RICHARDS:** I should say it's possible that I may finish  
18 the Armour documents in the course of tomorrow because  
19 there is so much more of the Armour story that we're  
20 going to be telling in November. If I do, then we may  
21 go on to Bayer at some point in the course of tomorrow  
22 afternoon. Of course, you know that the time  
23 estimates from counsel are hopelessly unreliable, so  
24 it may not turn out to be the case, but it's  
25 a possibility we might start Bayer tomorrow afternoon

1 at some point.  
2 **SIR BRIAN LANGSTAFF:** Yes, thank you.  
3 **(4.34 pm)**  
4 **(The hearing adjourned until 10.00 am the following day)**  
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185/6 185/13 185/16 186/2</p> <p>'<b>81 [1]</b> 166/25 '<b>82 [2]</b> 69/16 168/16 '<b>83 [2]</b> 41/16 168/16 '<b>83 or [1]</b> 168/16 '<b>87 [1]</b> 51/15 '<b>Armour [1]</b> 4/1 '<b>brokered [2]</b> 50/24 52/8 '<b>Dr [1]</b> 122/12 '<b>Dr Holgate [1]</b> 122/12 '<b>Factor [1]</b> 123/3 '<b>Factor VIII [1]</b> 123/3 '<b>high [2]</b> 48/16 49/3 '<b>M [1]</b> 3/21 '<b>named [4]</b> 3/9 3/21</p>	<p>173/16 174/16 '<b>NANB [1]</b> 81/17 '<b>non [1]</b> 81/17 '<b>non-A [1]</b> 81/17 '<b>very [1]</b> 126/15 '<b>Will [1]</b> 10/1 '<b>World [1]</b> 123/1</p> <p><b>0</b></p> <p><b>0.9 million [1]</b> 168/9 <b>001 [4]</b> 16/10 56/19 83/24 86/3 <b>002 [3]</b> 24/13 32/20 119/6 <b>003 [1]</b> 24/5 <b>0038 [2]</b> 107/18 145/6 <b>004 [1]</b> 23/20 <b>0044 [1]</b> 151/2 <b>005 [3]</b> 22/12 53/13 120/12 <b>006 [1]</b> 65/3 <b>0070A [2]</b> 174/17 175/2 <b>008 [1]</b> 85/3 <b>010 [1]</b> 93/12 <b>012 [2]</b> 29/7 93/17 <b>013 [1]</b> 18/6 <b>018 [1]</b> 32/5 <b>023 [1]</b> 20/20 <b>0231/0038 [1]</b> 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[1]</b> 2/19 <b>10.08 [1]</b> 2/21 <b>100 [1]</b> 86/20 <b>1002 [1]</b> 32/23 <b>103 [1]</b> 17/1 <b>10p [1]</b> 140/4 <b>10th [1]</b> 83/18 <b>10th June [1]</b> 84/4 <b>11 [1]</b> 114/22 <b>11 May 1976 [1]</b> 30/22 <b>11.29 [1]</b> 53/4 <b>11.55 [1]</b> 53/6 <b>118 [3]</b> 162/4 165/15 165/17 <b>11th August, 1983 [1]</b> 172/3 <b>12 [9]</b> 3/17 5/25 53/3 53/18 113/10 154/9 158/19 162/11 177/11 <b>12 February 1976 [1]</b> 95/11 <b>12 November 1975 [1]</b> 119/9 <b>12 years [2]</b> 113/12 117/14 <b>12p [1]</b> 140/4 <b>13 [1]</b> 135/4 <b>13 February 1980 [1]</b> 93/23 <b>13 June 1979 [2]</b> 150/24 151/4 <b>13 June 1984 [1]</b> 161/22 <b>131 [1]</b> 89/23 <b>135 [1]</b> 159/1 <b>138 [1]</b> 87/18 <b>14 [2]</b> 23/16 184/6 <b>14 November 1989 [1]</b> 6/19 <b>14,646 [1]</b> 162/24 <b>14,646,000 [1]</b> 162/25 <b>140 [1]</b> 87/25 <b>141 [3]</b> 2/16 6/25 87/1 <b>142 [1]</b> 9/8 <b>143 [1]</b> 159/5 <b>146 [1]</b> 159/17 <b>149 [2]</b> 6/1 6/10 <b>149,000 [1]</b> 17/4 <b>15 [2]</b> 36/21 168/4 <b>15 December 1975 [1]</b> 31/16</p>	<p><b>15 October 1976 [1]</b> 16/10 <b>15 September '82 [1]</b> 69/16 <b>15,000 [2]</b> 27/20 28/15 <b>15,000 donations [1]</b> 28/1 <b>16 [2]</b> 109/18 135/20 <b>16 February 1984 [1]</b> 171/25 <b>16 January 1976 [1]</b> 125/14 <b>16 October [1]</b> 118/3 <b>16 October 1975 [1]</b> 116/7 <b>16 smaller [1]</b> 31/24 <b>16,576,000 [1]</b> 162/23 <b>166 [1]</b> 175/7 <b>168 [1]</b> 176/1 <b>17 November [1]</b> 87/15 <b>18 [3]</b> 36/24 136/14 138/1 <b>18 August 1983 [1]</b> 177/1 <b>18 January 1977 [1]</b> 32/8 <b>18 months [1]</b> 5/25 <b>182 [1]</b> 6/11 <b>19 [2]</b> 37/2 132/14 <b>19 March 1979 [1]</b> 92/13 <b>191 [1]</b> 5/21 <b>1951 [2]</b> 99/8 100/10 <b>1959 [1]</b> 101/24 <b>1965 [1]</b> 42/21 <b>1968 [2]</b> 9/19 127/11 <b>1970 [1]</b> 100/12 <b>1970s [9]</b> 25/17 38/17 42/17 81/4 98/10 103/23 160/8 164/10 165/2 <b>1972 [3]</b> 18/1 20/9 124/13 <b>1973 [3]</b> 20/15 110/9 112/1 <b>1974 [2]</b> 13/20 83/9 <b>1975 [34]</b> 14/1 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<b>1</b> 1987... [10] 3/15 3/19 4/11 4/13 4/18 5/5 5/17 10/11 24/1 46/1 1988 [3] 5/20 10/10 23/18 1989 [3] 5/25 6/16 6/19 1990 [13] 7/1 9/9 9/10 27/25 29/1 53/16 53/18 55/9 55/11 55/22 56/5 101/8 103/17 1990s [2] 55/8 101/11 1992 [1] 101/2 1993 [1] 107/10 1994 [3] 6/7 6/16 23/25 19th [1] 169/22	<b>21 November [1]</b> 156/25 <b>22 June 1976 [1]</b> 26/15 <b>22 plasma [1]</b> 104/11 <b>23 August [1]</b> 65/8 <b>23 May 1975 [1]</b> 82/17 <b>23rd [1]</b> 66/12 <b>24 [2]</b> 22/13 110/5 <b>24 March '83 [1]</b> 41/16 <b>25 [2]</b> 29/12 177/9 <b>25 March 1975 [1]</b> 29/20 <b>25 March 1976 [2]</b> 145/13 149/1 <b>25 March 1981 [1]</b> 149/2 <b>25 November 1975 [1]</b> 87/5 <b>25th [1]</b> 155/6 <b>26 [2]</b> 169/14 169/20 <b>26 November 1984 [1]</b> 168/24 <b>27 [1]</b> 155/16 <b>27 February 1985 [1]</b> 23/13 <b>27 January 1976 [1]</b> 141/11 <b>28 [2]</b> 138/5 155/22 <b>28 August 1987 [1]</b> 2/25 <b>28 September 2021</b> <b>[1]</b> 1/1 <b>29 [2]</b> 23/11 37/10 <b>29 January 1976 [1]</b> 15/10 <b>29 January 1979 [1]</b> 90/1 <b>29 October 1976 [1]</b> 31/17 <b>2c [1]</b> 33/22	42/22 43/3 <b>30 such [1]</b> 86/18 <b>31 [2]</b> 114/16 156/6 <b>31 July 1984 [1]</b> 149/4 <b>32 [1]</b> 174/8 <b>340 [1]</b> 64/11 <b>383,624 [1]</b> 162/15	<b>4</b> <b>4 December 1975 [2]</b> 87/19 88/5 <b>4 January 1985 [1]</b> 169/10 <b>4 minutes [1]</b> 173/7 <b>4.1 [1]</b> 168/9 <b>4.34 [1]</b> 186/3 <b>40 [1]</b> 23/8 <b>409 [2]</b> 1/23 1/25 <b>42 states [1]</b> 64/12 <b>43 [1]</b> 43/8 <b>464 [1]</b> 6/11	<b>5</b> <b>5 million [1]</b> 168/6 <b>50 [2]</b> 133/20 156/13 <b>500,000 [1]</b> 124/13 <b>58 [1]</b> 83/2	<b>6</b> <b>6 October 1976 [1]</b> 32/10 <b>6,000 [6]</b> 26/13 26/19 27/23 27/23 28/12 64/12 <b>6,000 litres [3]</b> 26/25 27/3 28/14 <b>60 [2]</b> 170/22 173/7 <b>60 degrees [1]</b> 173/11 <b>600 [1]</b> 111/22 <b>600-odd [1]</b> 27/7 <b>6000 litres [1]</b> 15/18 <b>630 [1]</b> 13/25 <b>673 [1]</b> 9/24	<b>7</b> <b>7 December 1987 [2]</b> 4/11 5/17 <b>7.2 [1]</b> 117/16 <b>7.3 [1]</b> 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