

Friday, 24 September 2021

(9.59 am)

**Presentation by Counsel to the Inquiry on
the Pharmaceutical Companies**

MR HILL: Sir, we're continuing today with our work on Immuno, looking initially at the way that risk was communicated on the product packaging and the product labelling, then we will turn to some of the other issues, a short section on donors, then a short section on other communications between the company and entities within the United Kingdom, before turning to Travenol, and the product in particular there is Hemofil.

So we start with Immuno, the same company that we were dealing with yesterday.

As we heard yesterday, Serological Products Ltd, the UK-based company applied for a product licence for Kryobulin in December 1972, and as part of that application it submitted a set of labels, draft labels, and a draft of the information sheets, sometimes known as the data sheet, that went with the product.

The labels, as I mentioned yesterday, contained the information that the product was prepared from a plasma pool of 1,000 donors who had tested negative

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for hepatitis associated antigens.

The draft direction circular, which we looked at yesterday, but I think it's worth bringing up again, its SHPL0000071_181, please, Soumik.

If we could have page 25, please.

The section entitled "Manufacture and composition", this says:

"Kryobulin is proposed from a pooled plasma of healthy donors and freeze-dried for stabilisation.

All donors whose plasma is used for the production of Kryobulin, are tested at each donation for their GPT level and the absence of AU/SH/HA antigens (Hepatitis Associated Antigen). Any donor who has a history of a pathological transaminase level or a positive AU/SH/HA antigen test, is permanently excluded from the donor programme. Despite these precautions, the risk of transmission of homologous serum hepatitis can only be diminished and not completely eliminated."

A couple of points to pick up from there, sir.

The first is the reference to the GPT level, which I understand to be an alternative phrasing of the ALT level, so a measure of kidney function. And you will hear in some of the evidence that we go on to today that this was a requirement that the German authorities had in place at the time. Immuno, being

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an Austrian company, obviously have the German market, a significant market for blood products, right on its doorstep.

The other point to be raised from there is the other testing, which is, as we discussed yesterday, for the various antigens which are listed there, and then the comment at the end that despite the precautions the risk can only be diminished and not completely eliminated.

If we could go, please, to page 29 of the same document. This is part of the same data sheet which is given with the drug, so you have this section which is about the composition, and then the a little later on you have a section headed "Side effects", and at the bottom of that page you can see:

"Side effects are rarely observed during treatment with Kryobulin ..."

First is an allergic reaction. Then, on to the next page, please, Soumik, point 2:

"Despite the precautions taken in the selection of donors, the risk of transmission of homologous serum hepatitis cannot be entirely excluded when administering human coagulation factors."

That is the hepatitis warning that was in the data sheet.

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Thank you, Soumik, we can take that off the page now.

The product licence was approved in March 1973, as we heard yesterday. The Inquiry have identified no evidence to suggest that the product information was modified as a condition of that licence. So it seems that that draft is what was approved.

There is some criticism that emerges of the warning in 1975, and this is in a series of letters between Dr Dane of the Middlesex Hospital, Mr Berry of Immuno Ltd, the UK company, and the DHSS as well. The chain of correspondence is instructive in a number of regards. It concerns a report from Dr Dane that a child under his care, a 14-month old child, had become infected with hepatitis B following the use of Kryobulin, or a concern that the child might become infected. If we could have the first letter, please, it's MHRA0033321_108.

We can see that that is from the School of Pathology of Middlesex Hospital to Mr Berry, who we referred to yesterday. It says:

"... Mr Berry,

"You recently sent Professor ... Stewart through me, two single dose boxes of Kryobulin for use in the Middlesex Hospital."

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1 The batch numbers are given, sir. As the
2 correspondence develops, there is an error which
3 creeps in about which batch is being referred to. I'm
4 not going to go to that, I don't think it is relevant
5 to the points that are being discussed.
6 "[One of those batches] is now held in reserve.
7 [That batch] was given to a 14 month old haemophiliac
8 child. The diagnosis of haemophilia had been made by
9 Professor Stewart."
10 And the date is given.
11 "One millimetre was held back for HBsAg [that's
12 hepatitis B surface antigen] testing after the
13 Kryobulin had been given. This was positive for HBsAg
14 on duplicate screen test, positive on repeat duplicate
15 screen test, and neutralised completely by immune
16 human, rabbit and horse antiserum, but not by normal
17 human, rabbit and horse serum. Expressed
18 quantitatively in our own units, [the batch] contains
19 approximately 1 MH unit of HBsAg/0.1 ml. We were
20 working well within our limits of detection ..."
21 Go on to the next page, please, Soumik:
22 "As we were unable to detect HBsAg in two
23 previous batches of Kryobulin I was disappointed to
24 find this positive batch. It is not possible to be
25 exactly quantitative in estimating the likelihood of

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1 a donor screened as negative by PHA ..."
2 That's a particular type of test and we will
3 come back to it in the rest of the correspondence.
4 "It is not possible to be exactly quantitative
5 in estimating the likelihood of a donor screened as
6 negative by PHA causing this level of contamination in
7 a pool without knowing details of the manufacture, but
8 I am surprised that we can detect antigen if all
9 original donations have been, as you assured me,
10 tested by PHA.
11 "In view of the recent UK experience with
12 Factor VIII concentrates I do not consider the warning
13 about homologous serum hepatitis on the leaflet to be
14 adequate, particularly when the product has been shown
15 to contain HBsAg.
16 "I will send a copy of this letter to colleagues
17 who may be interested."
18 If we could expand the letter, please, Soumik.
19 We can see that it's copied to Dr Holgate, Dr Craske
20 and Dr Cleghorn. And Dr Holgate is an official within
21 the DHSS.
22 The next piece of correspondence is
23 MHRA0033321_107. This is an internal memorandum from
24 Dr Holgate within the DHSS. It says:
25 "Dr Andrews

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1 "1. Could you thank Dr Dane for this and say we
2 are looking into it.
3 "2. Find out from Dr Magrath the details of
4 this batch. I would hope we can disprove the
5 underlined para -- ie we would not (and have not)
6 release a batch known to be positive then rely on the
7 label warning. I have already told Dr Dane we would
8 never consider this (see previous correspondence).
9 "3. I have talked with Mr Berry and will report
10 to you.
11 "4. Whole matter, when you have the facts,
12 needs reporting. To Mr Mann.
13 "5. I wonder if Mr Taylor should be consulted
14 on the possible libel?"
15 A couple of points to pick out from that,
16 Dr Magrath is somebody whose name came up yesterday.
17 He is somebody who worked for NIBSC, so was involved
18 in testing the products.
19 The possible libel I take to be a reference to
20 the suggestion that the warning was not adequate.
21 **SIR BRIAN LANGSTAFF:** It's very unlike the libel which
22 normally comes before the courts, I have to say.
23 **MR HILL:** I will not try to give my understanding of libel
24 laws, sir, but that was Dr Holgate's concern.
25 If we could have the next document, please,

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1 Soumik, which is MHRA0033321_105.
2 A letter dated 17 July 1975, a couple of days
3 after the previous memorandum, which was 15 July 1975.
4 This is from Mr Berry at Serological Products Ltd, and
5 it is a response to Dr Dane. He says this:
6 "Dear Doctor Dane,
7 "I wish to thank you for your letter dated
8 14 July, 1975, though I and my colleagues in Vienna
9 are very surprised by your results. Their records for
10 batch [the number is given] are on the same level as
11 the earlier batches you have received and upon which
12 you have commented most favourably. They use
13 Austria II in the normal way and routinely repeat
14 after adding HB Ab and in this instance no reduction
15 in values occurred.
16 "The next point in your letter regrettably
17 indicates a misunderstanding between us. This
18 concerns your phrase 'I am surprised that we can
19 detect antigen if all original donations have been, as
20 you assured me, tested by PHA'.
21 "I said that our protocols which we submit to
22 MRC stipulate
23 "1. Donors CEP negative.
24 "2. Donations CEP negative.
25 "3. Pooled plasma CEP & RIA negative.

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1 "4. Final Product RIA negative.
 2 "I added that we were experimenting with PHA
 3 testing and if this was shown to be an improvement
 4 I understood it would be adopted as a routine.
 5 "I regret this misunderstanding and feel it
 6 necessary to put the record straight.
 7 "Since discussing this with you I have now
 8 learned that after 12 months experience with
 9 Haemagglutination Tests, the trial project has been
 10 abandoned as they are dissatisfied with the results.
 11 "Our phrase warning about homologous serum
 12 hepatitis was submitted to and accepted by the
 13 Committee on Safety of Medicines as part of our
 14 Product Licence. This also requires that our material
 15 is not only tested in Vienna but also by the MRC,
 16 where Ausria II is also used. [The batch] was duly
 17 submitted and an Authorisation Notice was received
 18 from the DHSS on 11 June, 1975.
 19 "I have discussed your letter at length with
 20 Dr Holgate and I am making further enquiries.
 21 "Copies of this letter have also been circulated
 22 to those interested and additionally to Dr RD Andrews
 23 who is now the person responsible for Blood Products
 24 at the DHSS Medicines Division and with whom I have
 25 also discussed this matter.

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1 am no longer surprised that we can detect one of your
 2 Kryobulin batches as weakly positive for HBsAg.
 3 "My comment about the warning in your leaflet
 4 was a personal observation, and I am aware that my own
 5 views and those of several of my colleagues do not
 6 coincide with those of the Committee on Safety of
 7 Medicines.
 8 "It does not surprise me if [he gives a batch
 9 number] was found to be HBsAg negative by Ausria II in
 10 Vienna and by MRC. We would expect it to be
 11 borderline or negative. Thus I am not criticising
 12 either the Immuno tests or MRC tests and there is no
 13 disparity between results.
 14 "I should make it clear to you that if Immuno
 15 use CEP screening on original donations then they are
 16 certain to miss a proportion of HBsAg carriers amongst
 17 their donors and that we may then be able to detect
 18 HBsAg in the final product by RIA. Whether we can
 19 detect HBsAg in the final product will depend on the
 20 titre of the HBsAg in the missed positive donor, and
 21 also on whether anti-HBs from other donors has an
 22 opportunity to react at any stage in the processing
 23 with the HBsAg."
 24 He invites him to come and see him if he wishes
 25 to discuss the matter further.

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1 "We are continually looking for improved tests
 2 for quick and accurate donation screening and for more
 3 sensitive final product testing, hence our great
 4 interest in the work you are doing. On this occasion,
 5 however, the great disparity between results is so
 6 noticeable that we wonder if you would consider
 7 a repeat test on a fresh sample of the same batch."
 8 If we can just go to the bottom of that letter,
 9 Soumik, we can see that it is copied to Dr Holgate,
 10 Dr Andrews, Dr Craske and Dr Cleghorn.
 11 If we could go over, please, Soumik to
 12 MHRA0033321_102.
 13 This is Dr Dane's reply to Mr Berry, dated
 14 18 July 1975:
 15 "Dear Mr Berry,
 16 "Please note [and he refers to another letter]
 17 that it was batch [he gives the number] that was used
 18 and ... not [the other batch] which we still hold and
 19 have not tested. In your letter to me you state that
 20 we reported that on [one batch] which is incorrect."
 21 That's the point about which batch was tested.
 22 "There was a misunderstanding about testing of
 23 donors. I made a special note of the time I talked to
 24 you that the original donations were tested by PHA.
 25 However as CEP was used to test original donations I

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1 Copied again to Dr Andrews, Dr Craske and
 2 Dr Cleghorn.
 3 What we take from that final letter, and indeed
 4 the series of correspondence, is that the apparent
 5 discrepancy is resolved by the fact that two different
 6 tests were being used. It was the view of Dr Dane
 7 that the tests that his hospital used were more
 8 sensitive, and would pick up HBsAg infection that the
 9 Immuno test would not pick up.
 10 **SIR BRIAN LANGSTAFF:** Am I right in thinking that the
 11 RIA test, which is radioimmunoassay test, was one
 12 which became, at some stage in the mid-'70s, the test
 13 applied in the UK to screen all blood donations for
 14 the presence -- the potential presence of hepatitis B?
 15 **MR HILL:** That is correct, sir. In October 1975, so a few
 16 months after this --
 17 **SIR BRIAN LANGSTAFF:** So only a couple of months after?
 18 **MR HILL:** Yes.
 19 **SIR BRIAN LANGSTAFF:** So Middlesex were ahead of the game,
 20 or it was in the process of being introduced. And the
 21 CEP test was the previous test and it was known,
 22 I think, in the early '70s that when screening for
 23 hepatitis B was first introduced in '71, '72, that the
 24 tests were imprecise by comparison with those which
 25 followed.

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(3) Pages 9 - 12

1 **MR HILL:** That is my understanding, sir, yes.

2 **SIR BRIAN LANGSTAFF:** So this would be Immuno using the

3 less sensitive test?

4 **MR HILL:** Yes. Whilst, according to Mr Berry's letter,

5 also experimenting on other tests that they could use.

6 **SIR BRIAN LANGSTAFF:** And the difference between them,

7 according to Dr Dane's letter, if I understand this

8 correctly, is that there wasn't enough viral load in

9 the sample to trigger the CEP test to showing

10 positive, but there was enough, at the same level, to

11 trigger the RIA test because it was more sensitive, it

12 picked up smaller quantities.

13 **MR HILL:** That is how I understand the letters, yes, sir.

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

15 **MR HILL:** The only other point I would add to this is that

16 RIA testing itself goes through different generations,

17 so you have a first generation RIA test, and later

18 a second and a third, which become increasingly more

19 sensitive and, if I put it broadly, reliable.

20 **SIR BRIAN LANGSTAFF:** And it may be that RIA tests,

21 because of the radioactivity which it involved and the

22 slight risk that that gave rise to, was, itself,

23 succeeded by a further test in the mid-80s.

24 **MR HILL:** That is my understanding again, sir, yes.

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

13

1 **MR HILL:** The other point that I would draw your attention

2 to from this correspondence, is that it is

3 correspondence not just between the hospital and

4 Mr Berry, but also the DHSS as well.

5 **SIR BRIAN LANGSTAFF:** Yes.

6 **MR HILL:** They have been notified of this incident and are

7 involved in --

8 **SIR BRIAN LANGSTAFF:** And Mr Holgate strikes a defensive

9 tone in his letter. Is that because, or possibly

10 because there was a testing procedure on every batch?

11 **MR HILL:** Yes. So Dr Holgate's response in the

12 memorandum -- we haven't got all of the documents

13 which show how that was followed through -- involves

14 asking Dr Magrath the details of what was done about

15 that batch. And that I understand to be a reference

16 to understanding which tests were done by the British

17 authorities on the batch which came through, and then

18 the detail of what was done is contained in Mr Berry's

19 letter. So presumably he has liaised with the DHSS,

20 and he has indicated to them that the material was not

21 only tested in Vienna, but also by the MRC, that is,

22 the body at the time from the British authorities that

23 was testing it.

24 **SIR BRIAN LANGSTAFF:** Yes.

25 **MR HILL:** And it was duly submitted and authorisation

14

1 notice was received from the DHSS on 11 June 1975.

2 **SIR BRIAN LANGSTAFF:** Yes.

3 **MR HILL:** So between them they have traced through the

4 paperwork to understand what happened to that batch.

5 Both the Immuno test and the Licensing Authority's

6 tests were negative, therefore the product was

7 provided to the hospital.

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

9 **MR HILL:** One final observation from that is specifically

10 about the warning in the leaflet. The criticism which

11 Dr Dane has isn't particularised, as lawyers would

12 say, but in the letter of 18 July 1975, when Dr Dane

13 is aware of the different tests that have been

14 employed, he says that his "comment about the warning

15 in your leaflet was a personal observation", and then

16 he says:

17 "... and I am aware that my own views and those

18 of several of my colleagues do not coincide with those

19 of the Committee on Safety of Medicines."

20 He is not withdrawing his comments and he is

21 associating some of his colleagues with them.

22 **SIR BRIAN LANGSTAFF:** He doesn't, however, say what

23 warning he thought would be adequate.

24 **MR HILL:** No, he doesn't. He doesn't, and we haven't

25 found any document in which he sets that out.

15

1 Soumik, if we could have on screen, please,

2 ABI0000016, page 1 of that document, please --

3 ABPI0000016. Sorry, I think I garbled the reference.

4 **SIR BRIAN LANGSTAFF:** I think you missed out the "P".

5 **MR HILL:** This is taken from a publication called the

6 "Association of the British Pharmaceutical Industry

7 Data Sheet Compendium 1978", there are a number of

8 these publications which aren't necessarily published

9 every year but are published fairly regularly, and

10 they are put together by the Association of the

11 British Pharmaceutical Industry and they contain data

12 sheets for some of the products which were available

13 on the UK market. It was not compulsory, as

14 I understand it, to put your data sheet in there; some

15 companies chose to do so, others did not. Immuno was

16 one of the companies that did.

17 If we could go, please -- you can see on the

18 first page that the first products they're talking

19 about are albumin fractions and protein fraction,

20 Immuno.

21 If we go to page 3, please.

22 This is the entry for Kryobulin. The section on

23 "Presentation" says:

24 "It is prepared from the plasma of donors whose

25 transaminase levels are constantly checked and whose

16

(4) Pages 13 - 16

1 donations are free from HBsAg. Pooled plasma and the
2 final product are also tested for freedom from HBsAg."

3 So a slightly different form of wording to that
4 which was contained in the draft of the product
5 licence, but I don't make any submission as to that
6 being in any way inappropriate. We don't have all of
7 the communication that went between the company and
8 the DHSS.

9 If we go over to the "Contra-indications [and]
10 warnings" section on the next page:

11 "Hepatitis: Despite the precautions taken the
12 selection and testing of donors and donations, the
13 risk of transmitting hepatitis cannot be entirely
14 excluded."

15 That data sheet was in, as I say, the 1978
16 edition of the compendium. The same wording appears
17 in the 1979 to 1980 edition. There is a slight change
18 in the 1981 to 1982 edition, where it is now described
19 as being produced, and I quote "from suitable human
20 donors", and a footnote defines "suitable human
21 donors" by reference to another work, the British
22 Pharmacopoeia, which sets out the certain standards
23 that the pharmaceutical industry should follow.

24 The reference to donors transaminase levels
25 being constantly checked was no longer present by the

17

1 time of the 1981-1982 compendium. But otherwise the
2 entry that we've just looked at was unchanged,
3 including in respect of the hepatitis warning.

4 One point which is slightly surprising, or that
5 we haven't found an explanation for, is that it's not
6 until the 1981 to 1982 compendium that you get the
7 reference to the RIA testing in the data sheet. As we
8 know, that had been approved in October 1975. I'm
9 afraid we simply don't know why it is that it didn't
10 appear at least in that version of the data sheet
11 until the 1981 to 1982 compendium.

12 **SIR BRIAN LANGSTAFF:** So, I mean, can you tell me from any
13 source, it's one thing to test donations made to the
14 general blood supply, for the purpose of transfusions
15 you test those for the presence of hepatitis B
16 indicators, and to do that by RIA from 19 October '75
17 onwards. It may be another thing to test plasma
18 products --

19 **MR HILL:** Yes.

20 **SIR BRIAN LANGSTAFF:** -- which have been prepared abroad,
21 which have not been prepared from British donated
22 blood. Was the testing regime for batch testing: (a)
23 was it still being conducted; and (b) if it was, was
24 that by RIA or was it by some other test? Do you
25 know?

18

1 **MR HILL:** I don't know, sir, but there is that distinction
2 between testing the donors and testing the batch and
3 it's something which comes up regularly across all of
4 these products.

5 If I may just have a moment about the 1981 to
6 '82, the exact words used are:

7 "It is prepared from a plasma of suitable human
8 donors whose transaminase levels are constantly
9 checked and whose donations are shown by RIA to be
10 free from HBsAg. Pooled plasma and the final product
11 are also tested from HBsAg."

12 Now, it doesn't say how that final test is done.

13 I don't know if there is any significance in that,
14 whether or not it was also done by RIA, or by some
15 other test at that time. It's something that we can
16 research. I wouldn't draw any inference from the lack
17 of reference to RIA, it may simply be that it is more
18 easily expressed that way.

19 **SIR BRIAN LANGSTAFF:** But the first time that donors are
20 mentioned as being tested by RIA is in 1981, is it?

21 **MR HILL:** In the data sheets that we have from the
22 compendium, yes, but data -- there are various forms,
23 many, many different forms of the data sheets which
24 fly around. So the one that ends up in the compendium
25 might not be the only that is available in the UK

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1 market at the time. I have seen some information
2 leaflets dating from 1979, where RIA testing is
3 mentioned, that's the -- the reference is
4 SHPL0000665_076, but even then I wouldn't like to say
5 that that was the first time it was mentioned. We
6 have incomplete data from which to draw any
7 conclusion.

8 **SIR BRIAN LANGSTAFF:** But you can say, or you are saying,
9 I think, that's the first reference you've found to it
10 in this context?

11 **MR HILL:** It is, yes. But I would add that the -- we have
12 a fairly complete set of data sheets for Kryobulin and
13 Prothromplex from Immuno in the 1980s, far less
14 complete in the 1970s.

15 **SIR BRIAN LANGSTAFF:** Yes.

16 **MR HILL:** The reasons for that we'll see in a second.

17 The 1984 to '85 edition of the compendium of
18 data sheets has the same entry as for 1981 to '82, and
19 then no change in wording for the 1985 to 1986
20 editions. The references for those are ABPI0000037
21 and ABPI0000022. Of note is that neither of those
22 data sheets makes any reference to AIDS, HTLV-III,
23 LAV, HIV.

24 If we could have, please, on the screen, Soumik,
25 ABPI0000022, and page 1. We can see the outside of

20

(5) Pages 17 - 20

1 the book we have the "Data Sheet Compendium", and
2 page 2, please, Soumik. Then page 3, under the
3 section "Date of preparation", it says:

4 "The data sheets included in this Compendium
5 were prepared or reviewed during the final quarter of
6 1984 and the compendium itself was published in
7 July 1985."

8 This is for 1985 to 1986 edition, so we can see
9 that, rather like Beano annuals, they come out
10 covering the year ahead of them. The data sheets
11 themselves were reviewed in the final quarter of 1984.
12 That's fairly typical for these publications. The
13 data sheet that is contained in this compendium, which
14 was reviewed or prepared in the final quarter of 1984,
15 makes no reference to HTLV-III, AIDS, HIV, LAV.

16 **SIR BRIAN LANGSTAFF:** Yes, and if one looks at that
17 document you've got onscreen, and looks to the
18 left-hand side, it says what you told me already, that
19 the data sheets are prepared by the individual
20 companies concerned.

21 **MR HILL:** Yes, that's right.

22 **SIR BRIAN LANGSTAFF:** So they're prepared by Immuno in
23 1984 and they don't refer to AIDS.

24 **MR HILL:** That's right.

25 **SIR BRIAN LANGSTAFF:** Or -- yes, I see.

21

1 risk of transmitting hepatitis cannot be entirely
2 excluded."

3 If we could expand out again, please, Soumik,
4 you can see that the rest of that section also says:

5 "A low incidence of adverse reactions is
6 experienced with Kryobulin, but the following may
7 occur:

8 "Allergic reactions ...

9 "Hepatitis [which is the warning I've just read]

10 "Factor VIII Inhibitors ..."

11 There is a section on the "Treatment of
12 overdosage".

13 Could we have on screen, please, Soumik,
14 SHPL0000066_001. This is a document that we brought
15 up yesterday for a different purpose. We can see that
16 it's dated 20 December 1989, and it comes from Vienna
17 and from Immuno AG and is sent to Mr Coombes of
18 Immuno Ltd. It says:

19 "attached please find a list and copies of all
20 UK specific KRYOBULIN and PROTHROMPLEX [tests] as well
21 as the relevant neutral English texts starting from
22 1980."

23 This from Mrs Diernhofer from the Licensing
24 Department, the head of the Licensing Department.
25 What I understand that to mean is that the 80-odd

23

1 **MR HILL:** As we will see in some of the evidence that we
2 will look at shortly, the data sheets appear to be
3 prepared by Immuno AG, the Vienna-based company, with
4 input and comment from Immuno Ltd, the UK company.
5 We'll come on to that shortly.

6 If we could --

7 **SIR BRIAN LANGSTAFF:** Can you help me, do they continue to
8 refer to the risk of homologous serum hepatitis?

9 **MR HILL:** Yes, the same terms are used in the hepatitis
10 warning as that which we have just looked at.

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

12 **MR HILL:** In fact, let's look at page 22 to 23 of this
13 document, please, Soumik.

14 Kryobulin, you can see the presentation:

15 "It is prepared from the plasma of suitable
16 human donors whose donations are shown by RIA to be
17 free from HBsAg. Pooled plasma and the final product
18 are also tested from freedom from HBsAg."

19 Over to the next page, please, Soumik. The
20 section headed "Contra-indications, warnings,
21 et cetera", if we look -- if we just go up a little,
22 sorry, and a little further -- the right-hand column
23 we get to point 2:

24 "Hepatitis: Despite the precautions taken in the
25 selection and testing of donors and donations, the

22

1 pages that follow contain both texts that were
2 specifically prepared for the UK market, and texts
3 which the company prepared in English and are
4 described as "neutral English texts", which presumably
5 were available for English-speaking markets across the
6 world. It doesn't mean that because something is
7 a neutral English text it wasn't used in the UK
8 market, it just wasn't specifically prepared for that
9 UK market.

10 The date is from 1980, and that goes back to
11 that which I was just saying, that's why we have
12 a good record from 1980. It's more patchy for the
13 1970s.

14 If we could go over to the next page, please,
15 Soumik. This gives a list of the data sheets that
16 follow, and the numbers on the left-hand side are
17 reference numbers which are handwritten onto the
18 sheets that are attached to the letter. The code MWG
19 and VA and FG, and dates that follow, there is
20 a separate document, which I won't take you to now,
21 but I will give the reference so people can check it,
22 it's SHPL0000185, page 4, and that provides the key to
23 that code.

24 MWG is when -- the date on which the text was
25 sent for printing; FG is the date on which the text

24

(6) Pages 21 - 24

1 was released, that is the word that is used in the
2 document; and VA is the date on which the text was
3 withdrawn. By using those codes. We can establish
4 when the documents in question were either sent to the
5 printers, released and/or withdrawn. We can see that
6 the documents cover Kryobulin untreated, the TIM 2
7 heat-treated method and then the heat-treated
8 Kryobulin, which I understand to be the dry
9 heat-treated.

10 The untreated Kryobulin also has a distinction
11 between Kryobulin red and Kryobulin blue, that is
12 a distinction between the European plasma and the
13 American plasma; we will look at that shortly.

14 I'm not going to go through today all of the
15 different data sheets that follow. What I would say
16 is that, having looked at them -- and everybody, of
17 course, is free to do the same -- in the data sheets
18 that I have looked at from this period, there is no
19 reference to the risk of AIDS or HTLV-III in any of
20 the untreated Kryobulin data sheets, the latest --

21 **SIR BRIAN LANGSTAFF:** Or LAV.

22 **MR HILL:** -- or LAV -- the latest of which appears to have
23 been withdrawn in July 1986. I get that date from the
24 right-hand column "VA 11.07.1986". Those sheets there
25 don't contain any warning about HTLV-III, LAV or AIDS.

25

1 Could we have on screen, please, Soumik
2 HSOC0023097. This is a letter from Mr Coombes
3 replying to a letter that he has received from
4 David Watters, the general secretary of
5 The Haemophilia Society. I haven't seen Mr Watters'
6 letter but the tenor of it can be gathered from this
7 reply.

8 Mr Coombes writes this:

9 "Dear David,

10 "Thank you for your letter dated
11 2nd February 1987 concerning the warnings on the use
12 of our blood products during recent years.

13 "We have not issued promotional material on our
14 coagulation concentrates which I assume is your main
15 area of interest and, therefore, our warnings have
16 been mainly restricted to the data sheet and the
17 insert leaflet packed with the product.

18 "As far as our non heat treated products were
19 concerned, the only warning regarding viral
20 inactivation was on hepatitis, as at that time this
21 was thought to be the only problem that could be
22 associated with blood products. I am enclosing a copy
23 of our Kryobulin data sheet for our non heat treated
24 product which was issued in March 1984 and contains
25 our standard statement on hepatitis. This was issued

26

1 from 1973 until the introduction of heat treated
2 products.
3 "As soon as our dry heated product was
4 introduced in March 1985 the statement was changed
5 because of the problem with AIDS and I am enclosing
6 a copy of the data sheet on our heat treated product
7 dated March 1985. This statement is fairly clear in
8 stating that although we have treated the product, the
9 transmission of viral hepatitis or other viral
10 infections cannot be excluded. You will also see on
11 the front of data sheet where it gives details of the
12 heat treatment, it clearly states that this step is
13 carried out to reduce the risk of transmission of
14 infectious agents and not to eliminate them.

15 "I hope this provides you with the information
16 you require, but if I can be of any further help,
17 please do not hesitate to contact me."

18 **SIR BRIAN LANGSTAFF:** Can you just help me with this, it's
19 going back to his phrase which I've just picked up "as
20 at that time this was thought to be the only problem
21 that could be associated with blood products".

22 Dr Eibl was an Immuno official, was he not?

23 **MR HILL:** He was.

24 **SIR BRIAN LANGSTAFF:** He went to a meeting at the
25 Excelsior Hotel at Heathrow on 24 January 1983.

27

1 **MR HILL:** Yes, he did.
2 **SIR BRIAN LANGSTAFF:** At that meeting, Dr Craske presented
3 the details on what was thought to be a real problem
4 with blood products transmitting AIDS.

5 **MR HILL:** I'm going to --

6 **SIR BRIAN LANGSTAFF:** Was he present at that part of the
7 meeting, do you know?

8 **MR HILL:** We don't know, but that is something that I'm
9 going to address you on later. What is certainly the
10 case, from the minutes that we will look at later, is
11 that the question of AIDS was raised when he was
12 present, even if he wasn't present for the subsequent
13 discussion from Dr Craske.

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

15 **MR HILL:** The dates of the Kryobulin sheets that we were
16 looking at a moment as range of being sent to the
17 printers in September 1982, to being released in
18 May 1983, but not withdrawn until July 1986.

19 I won't take you to the data sheet that
20 Mr Coombes attached to the letter. It contains the
21 same wording as those that we've looked at from 1980
22 to '81 and 1984 to '85 compendiums and confirms the
23 point that I made earlier, that there is no reference
24 to AIDS, HIV, LAV, HTLV-III in that data sheet.

25 I will come back to the data sheet which is

28

(7) Pages 25 - 28

1 presented for the heat-treated product shortly but,
 2 before I do, I'm going to look at the blue and red
 3 pack Kryobulin. We know, of course, from yesterday
 4 the distinction between the two being that the
 5 European plasma is in the red pack Kryobulin, the
 6 American is the blue pack.

7 There is a difference in wording in the way that
 8 the product is described in the data sheets that we
 9 have for those. If we could have, please, on screen,
 10 Soumik, SHPL0000066_1, and page 19. This is one of
 11 the data sheets that was sent by Mrs Diernhofer in
 12 December 1989 -- SHPL0000066_001.

13 If we could have, please, page 19. In the top
 14 left-hand corner we can see handwritten on it, "ROT",
 15 which is German for red, this is the European
 16 Kryobulin:

17 "Manufacture and composition
 18 "KRYOBULIN is prepared from the pooled plasma of
 19 suitable human donors who have a GPT activity of less
 20 than 25 [international units per litre]. Each plasma
 21 donation is tested by radioimmunoassay (RIA) for the
 22 absence of HBs-antigen and is only released for the
 23 production of KRYOBULIN if the [HBsAg antigen] test is
 24 negative."

25 That is what is said on the European pack. If

29

1 we could have, please, page 16 of the same document.
 2 Top left-hand corner, "BLAU", German for blue:
 3 "KRYOBULIN is prepared from the pooled plasma of
 4 suitable human donors. Each plasma donation is tested
 5 by radioimmunoassay (RIA) for the absence of
 6 HBs-antigen and is only released for the production of
 7 KRYOBULIN if the HBs-antigen test is negative."

8 The distinction between the two there is the
 9 lack of reference, in the American Kryobulin, to the
 10 test for GPT --

11 **SIR BRIAN LANGSTAFF:** Yes, it's -- the earlier one says
 12 the donors are tested; this one says, effectively,
 13 they're suitable.

14 **MR HILL:** Yes, yes. But there is no specific reference to
 15 the --

16 **SIR BRIAN LANGSTAFF:** It doesn't say what suitability
 17 means?

18 **MR HILL:** The asterisk there is, if we could go down to
 19 the bottom of the page, in extremely small writing:
 20 "Suitable human donors as described in the
 21 British Pharmacopoeia 1980 Vol II under Albumin."
 22 This is a formulation which is used in various
 23 data sheets by Immuno, from memory, I think, by other
 24 companies as well. So it is referring to a standard
 25 textbook for the pharmaceutical industry.

30

1 **SIR BRIAN LANGSTAFF:** How does that British Pharmacopoeia
 2 define "suitability"?

3 **MR HILL:** That, sir, I don't have to hand, but we can
 4 bring that up, I hope today. If not today, then at
 5 the start of the next presentation.

6 What the composition sections don't contain is
 7 any reference to the geographical origin of the
 8 plasma. If we could look at the packaging, if we
 9 could have SHPL0000071_130. This is an example of the
 10 red European packaging. It's not dated, but we can
 11 see that it is said to be distributed by Serological
 12 Products Ltd, which would suggest that it dates from
 13 the early to mid-1970s, before the company changed its
 14 name to Immuno Ltd:

15 "Kryobulin
 16 "Dried Human Antihæmophilic Fraction ...
 17 "Prepared from a plasma pool of 1,000 AU/SH/HAA
 18 negative donors."

19 The product licence is given there. And details
 20 about reconstitution. So that is the original
 21 European product, at the time when only that product
 22 was available, before the American product was
 23 introduced.

24 If we could now please go to MHRA0033321_022.
 25 Just as we are doing so, I note that there is nothing

31

1 on that label, the previous label that we've seen,
 2 which identifies the geographical origin of the
 3 plasma.

4 This is an example of the blue American
 5 Kryobulin.

6 **SIR BRIAN LANGSTAFF:** It's not very clear on the screen.

7 **MR HILL:** I'm afraid this is the best --

8 **SIR BRIAN LANGSTAFF:** You don't have a better copy?

9 **MR HILL:** No, we don't, I'm afraid. We are struggling for
 10 examples of the blue Kryobulin, partly, I'm afraid,
 11 because much of the material that we have is
 12 photocopied, and photocopied in black and white, so
 13 we're unable to tell which is which. What we can see
 14 is that the expiry date is March 1985. You can also
 15 see a couple of lines above that, if you can make it
 16 out, that this is actually a product which is for the
 17 Irish market, because it gives the product licences
 18 for Eire, and it's Irish rather than British. But
 19 what we can tell from this is that there is no
 20 reference here to the geographical origin of the
 21 plasma.

22 It says:
 23 "The preparation is of human origin and cannot
 24 be assumed to be free of hepatitis virus."
 25 No reference to the donor pool size. Then it

32

(8) Pages 29 - 32

1 has information about reconstitution and the
2 administration of the product.
3 Soumik, please could we have on screen
4 SHPL0000071_066. This, I'm afraid again, it's not
5 a great copy, but it is a fax dating from
6 November 1978. It's from Mr Berry and it is sent to
7 Immuno AG. You can see that it's obscured by the
8 redaction, but we can see in the top right-hand corner
9 it's Fr Diernhofer, so Frau Diernhofer, is -- the name
10 that's added there, presumably for her attention.
11 What the fax says is this:
12 "1. We confirm that the factor viii concentrate
13 prepared from american plasma can be called kryobulin.
14 "2. Immuno blue visible the most suitable
15 colour for the pack.
16 "3. There is no mention of plasma source on red
17 kryobulin so there is no need to mention it on the
18 blue packs."
19 That is what Mr Berry wrote at the time.
20 As stated baldly as a proposition there, sir,
21 you may feel that there is some difficulty with that
22 logic. I would only add that Mr Berry is deceased,
23 and you will, of course, in due course, have to take
24 into account the fact that he may have been able to
25 give further evidence about his thinking at the time

33

1 colour, there is, so far as I can tell, nothing on the
2 labelling and nothing in the data sheet that will tell
3 you about it.
4 **SIR BRIAN LANGSTAFF:** So, insofar as any of these packs
5 came into the hands of anyone administering, for
6 instance, the treatment at home, there would be
7 nothing to indicate to the end user -- the patient --
8 where the source material came from.
9 **MR HILL:** No. The only caveat I would add to that is that
10 I am unaware of any other piece of literature or
11 documentation that accompanied the pack. It may be
12 that others can bring that to your attention but, from
13 the material that I have seen and I have presented to
14 you today, the person who was handed a pack of blue
15 Kryobulin would not know that was made from American
16 plasma, unless they knew the significance of the fact
17 that the pack was blue rather than red.
18 **SIR BRIAN LANGSTAFF:** This may be a question you can't
19 answer but maybe others can, but is there any
20 indication that The Haemophilia Society was aware of
21 this particular difference between the red and the
22 blue packs, the cheaper one with the greater risk?
23 **MR HILL:** I'm afraid can't answer that, but we can look
24 into that.
25 One further document that I would draw your

35

1 and what lay behind that expression, and indeed that
2 is the same for all bits of writing or reported speech
3 that we have concerning Mr Berry.
4 **SIR BRIAN LANGSTAFF:** Well, it seems somehow counter
5 intuitive that the regulatory authority has asked for
6 different coloured packaging to distinguish a product
7 which is of European origin, the plasma for which is
8 of European origin, and product for which the origin
9 is essentially American. But there is only
10 a difference in colour on the packs.
11 **MR HILL:** As I understand it, that is the position.
12 **SIR BRIAN LANGSTAFF:** But, equally, it has to be said that
13 the UKHCDO appear to have known that there was
14 a distinction, not least because they were paying less
15 for the blue pack.
16 **MR HILL:** Yes, and as we saw from the price list
17 yesterday, although the price wasn't stated, it was
18 stated very clearly that the blue pack is the European
19 plasma and the red pack is the American plasma. So if
20 you --
21 **SIR BRIAN LANGSTAFF:** Other way around.
22 **MR HILL:** Sorry, the other way around, forgive me: blue is
23 American and red is European. If you know that code,
24 then you know the distinction. If you don't know the
25 difference in -- the significance of the difference in

34

1 attention to, sir, is SHPL0000071_061. I don't think
2 that we need to bring it up. It is an undated fax
3 from the same file that we have just been looking at,
4 this file from Immuno, which does say that in the
5 future the origin of source plasma will be indicated
6 on the accompanying test protocol of samples of the
7 batch released. That would seem to suggest that the
8 plasma origin was sent to those who were conducting
9 the testing in the UK on the batches; where that
10 information went to after that, we don't know.
11 If we could turn now to the dry-heated --
12 heat-treated Kryobulin. As we were discussing
13 yesterday, there was an application for a product
14 licence in February 1985. This is for the original
15 generations of heat-treated Kryobulin, dry
16 heat-treated.
17 That contained various drafts of labels and of
18 data sheets in the same way that we have seen before.
19 I won't bring those up. Instead, I will go to
20 HSOC0023098, please, Soumik, which is the data sheet
21 that Mr Coombes sent in his letter to The Haemophilia
22 Society in 1987.
23 The data sheet is for "Kryobulin Dried
24 Factor VIII, Fraction BP". The "presentation", it
25 says:

36

1 "It is prepared from the plasma of suitable
2 human donors [the same reference is made to the
3 Pharmacopoeia] whose donations are shown by RIA to be
4 free from HBsAg. Pooled plasma and the final product
5 are also tested very for freedom from HBsAg."
6 There is information given about the packaging.
7 If we could expand, please, Soumik. I'm sorry, this
8 is the wrong page, it's page 3 that we should be
9 looking at. This isn't the heat-treated product, this
10 is the non-heat-treated product. Forgive me.
11 This is the heat-treated product. We can see
12 there -- thank you, Soumik -- that it's state d to be
13 Kryobulin heat-treated.
14 The presentation of it says:
15 "It is prepared from the plasma of suitable
16 human donors whose donations are shown by RIA to be
17 free from HBsAg. Pooled plasma and the final product
18 are also tested for freedom from HBsAg.
19 "The product has been heated at 60 °C for
20 10 hours. This step has been introduced to reduce the
21 risk of transmission of infectious agents."
22 You may recall, sir, that a statement about how
23 long the product was heated and at what temperature
24 was a requirement of the product licence. If we could
25 go on to the next page, please, Soumik.

37

1 very quickly go to the heat-treated labels.
2 SHPL0000067_044, please, Soumik.
3 SHPL0000067_044, and page 4, please.
4 This is the draft label that was provided as
5 part of the product licence, and we can see that it is
6 for the heat-treated product:
7 "The preparation is of human origin and cannot
8 be assumed to be free of [viral hepatitis]."
9 That's the warning had is given on the
10 packaging.
11 You'll note, sir, that the reference to the
12 donor pool of 1,000 donors is no longer present.
13 **SIR BRIAN LANGSTAFF:** When did that cease to be used?
14 **MR HILL:** We cannot put a precise date on it. What we can
15 say is that this is February 1985, and it's not
16 present there. I can work through the other data
17 sheets and the code that we have and see if we --
18 **SIR BRIAN LANGSTAFF:** Well, it would be quite useful.
19 I mean, the implication might be that the general pool
20 had got larger and larger.
21 **MR HILL:** It might be, sir. There is a document that
22 I will show you later today which might weigh the
23 other way.
24 **SIR BRIAN LANGSTAFF:** Yes.
25 **MR HILL:** But --

39

1 We can see at the bottom right quarter:
2 "contra-indications, warnings, etc ..."
3 The same phrase is used:
4 "A low incidence of adverse reactions is
5 experienced with Kryobulin, but the following may
6 occur ..."
7 Point 2:
8 "Despite the measures taken to reduce the risk,
9 the transmission of viral hepatitis or other viral
10 infections cannot be ruled out."
11 That is the data sheet that accompanied the
12 heat-treated product. Mr Coombes, in the letter that
13 I showed you a short while ago, wrote that he thought
14 that it was, and I quote:
15 "... fairly clear that although we have treated
16 the product, the transmission of viral hepatitis or
17 other viral infections cannot be excluded."
18 The 1986 to 1987 editions of the compendium had
19 a data sheet which has equivalent information to that,
20 there are slight tweaks of wording but I needn't
21 trouble you with those. That is the same for 1988 to
22 1989, and the references for those are ABPI0000030,
23 ABPI0000031, ABPI0000024.
24 The steam and vapour-heated Kryobulin -- I'm
25 sorry, before we turn to those, actually, we can just

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1 **SIR BRIAN LANGSTAFF:** That's why I'm asking.
2 **MR HILL:** Yes.
3 So steam or vapour heated Kryobulin, as we heard
4 yesterday the first application was made in March 1986
5 for method 2 steam treatment. I won't take you to the
6 label, but it includes the following words that --
7 quotes:
8 "To inactivate potentially present viral agents,
9 the manufacture of Kryobulin includes steam treatment.
10 The treatment reduces the virus titre in
11 HTLV-III spiked samples of the product by 10 to the
12 power of 4 infectious units per millilitre. The
13 HTLV-III titre was determined after incubation with
14 hTh9 cells and subsequent measurement of reverse
15 transcriptase activity in the clarified cell
16 supernatant."
17 So a rather more technical description than the
18 ones we have seen before. In terms of side effects it
19 says:
20 "By careful selection of donors and plasma and
21 the steam treatment process, the transmission of
22 HTLV-III can be excluded. The above measures will
23 certainly reduce the risk of transmission of viral
24 hepatitis, but this cannot be entirely ruled out."
25 The reference is SHPL0000065_031. That is for

40

(10) Pages 37 - 40

1 the method 2 steam treatment.

2 A somewhat more cautious wording was contained

3 in a further data sheet, and we can tell from the code

4 that we looked at earlier that this was released on

5 1 October 1985, withdrawn on 27 March 1986. It's

6 SHPL0000066_001. It says that:

7 "The risk of viral hepatitis is reduced by

8 careful donor and plasma selection and

9 product-specific steam treatment. In all probability

10 the risk of HIV transmission can be excluded by the

11 above measures, nevertheless a potential risk of HIV

12 or other known viruses being transmitted remains."

13 There was a further application -- the

14 application for method 2 steam treatment was

15 unsuccessful, and so a further application was made in

16 December 1986 for method 3, a vapour heated product.

17 Perhaps we can have on screen, please, Soumik,

18 MHRA0033320_007. This is, we believe, part of the

19 application that was made and it's part of the draft

20 of the data sheet that would be provided with the

21 product were the licence to be permitted. It says:

22 "A low incidence of adverse reactions is

23 experienced with Kryobulin, but the following may

24 occur ..."

25 Then if we go down, please, Soumik, to the bit

41

1 on to specify precisely why it is unacceptable.

2 There is a document that we have which records

3 discussions between representatives of Immuno Ltd and

4 Beecham, another pharmaceutical firm, from

5 October 1987.

6 If we could that on screen, please, Soumik, it's

7 SHPL0000008_108.

8 The context of this is that Immuno and Beecham

9 were working together on some products, and they had

10 a shared mutual interest in approving the efficacy of

11 the steam treatment that was being used by Immuno on

12 their products. We can see that the date of the

13 covering letter is 3 November 1987, the meeting took

14 place on 13 October 1987.

15 If we could go, please, to pages 3 and 4,

16 Soumik, of the document.

17 At the bottom of the page, the section on the

18 "Department of Health and Social Security" says that:

19 "The DHSS is now regarded as one of the most

20 stringent licensing authorities for blood products.

21 In the case of blood products per se, these are

22 referred to the blood product group headed by

23 Mrs Sylvester. One of her staff (Mr Sloggem) has

24 special responsibility for vetting any heat treatment

25 procedures and he is reported to be very thorough in

43

1 which is in a slightly different font:

2 "The careful selection of donors and plasma and

3 the vapour heat treat process which has been shown

4 capable of reducing artificially introduced HTLV-III

5 by 6 log steps suggests that in the light of present

6 knowledge the transmission of HTLV-III can be

7 excluded.

8 "The above measures will certainly reduce the

9 risk of transmission of viral hepatitis. This has

10 been demonstrated by the fact that upwards of 20 naive

11 patients have been followed up by ALT tests for

12 4 months and have not acquired NANB infection but.

13 Transmission of Hepatitis cannot be entirely ruled

14 out."

15 December 1986 is, we believe, the time that this

16 was used as part of the application.

17 That product didn't receive a licence, and so

18 it's unclear if the information sheet was ever used in

19 the UK market. One of the reasons given by the DHSS

20 officials for the refusal of the licence during

21 a meeting in August 1987 was that, and I quote:

22 "The statement on hepatitis and HIV risk in the

23 pack insert is not acceptable."

24 The reference is SHPL0000141_136. That's

25 a document that we looked at yesterday. We don't go

42

1 assessing data."

2 We go on to the next page, please:

3 "As a result of the increased number of abridged

4 applications which have been submitted recently to

5 avoid the new requirements for expertise statements,

6 the blood products group now has so many abridged

7 applications pending that it has claimed that it could

8 be 15 months after submission before any new abridged

9 applications will start to be examined."

10 This chimes with the evidence in the Evans and

11 Cunliffe report that we looked at yesterday.

12 Give me one second, sir.

13 At the bottom of that page, Soumik.

14 The section on "Data sheets/insert [labels]"

15 says:

16 "The DHSS has also raised a number of issues

17 relating to Immuno's data sheets ... It was noted that

18 statements on inactivation were often much more

19 positive in continental Europe than would be accepted

20 by the DHSS who for blood products, per se, require

21 statements indicating that although such products have

22 been treated to minimise virus transmission they

23 cannot be guaranteed to be virus free."

24 Thank you, Soumik, we can take that off the

25 screen, please.

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(11) Pages 41 - 44

1 If we could go now, please, to SHPL0000141_233.
 2 The previous document was provided to give some
 3 general context of the approach of the DHSS, or at
 4 least how that approach was viewed by Immuno Ltd at
 5 the time. What I'm going to take you to now is
 6 correspondence between Immuno Ltd and Immuno AG,
 7 showing a discussion taking place in and around
 8 October 1986 about the wording of the statement on
 9 HTLV-III inactivation that was used for the method 3
 10 vapour heated Kryobulin.

11 This correspondence is likely to have been
 12 prompted by concerns at that time about the Armour
 13 product, Factor VIII, which had been withdrawn from
 14 the market.

15 On 30 October 1986, Mr Nicholson, in this fax to
 16 Ms Henninger at Immuno AG, proposes that the statement
 17 be changed to the following terms:

18 "... 'by careful selection of donors and plasma
 19 the vapour heat treatment process, the transmission of
 20 htlviii can probably be excluded.

21 "the above measures will certainly reduce the
 22 risk of transmission of viral hepatitis but this
 23 cannot be entirely ruled out'."

24 That is the proposal that is coming from
 25 Immuno Ltd. The reply is at SHPL0000141_231. This

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1 comes from Mrs Diernhofer, the head of the licensing
 2 department. It says this:
 3 "We have discussed your proposal with Dr Kaeser
 4 and Dr Schwarz. Both of them do not agree to use
 5 a statement which diverges essentially from the
 6 wording generally adopted by our company world-wide.
 7 The statement agreed upon during our May meeting is
 8 already a commitment on our part, since we generally
 9 state that the transmission of HTLV-III will be
 10 prevented.

11 "We do not see any connection with the Armour
 12 product which was heat-treated and prepared from
 13 unscreened material and caused sero-conversion. Our
 14 product is vapour heated and produced from HTLV-III
 15 negative plasma donations, and we have provided data
 16 for HTLV-III inactivation in our preclinical study
 17 which shows 10⁶ reduction of HTLV-III already after
 18 3 hours.

19 "If we used a weaker statement such as proposed
 20 by IMMUNO Ltd we might also run into difficulties at
 21 a later date, should it become necessary or
 22 appropriate to use a stronger statement. We will then
 23 not be able to provide further data on HTLV-III
 24 inactivation.

25 "For the above reasons both Dr Schwarz and

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1 Dr Kaeser are of the opinion that we should leave the
 2 respective statements as agreed upon during our May
 3 meeting.

4 "The statement should therefore read as follows:

5 "By careful selection of donors and plasma and
 6 the vapour heat treatment process, the transmission of
 7 HTLV-III can be excluded.

8 "The above measures will certainly reduce the
 9 risk of transmission of viral hepatitis but this
 10 cannot be entirely ruled out."

11 You can see the distinction between the more
 12 definite statement of Immuno AG and the one that was
 13 preferred by Immuno Ltd. The terms of the letter from
 14 Mrs Diernhofer, you may feel, sir, are an instruction
 15 as to what should be done, rather than advice.

16 If we could have on screen, please, Soumik
 17 SHPL00000661_001, page 28, please.

18 SHPL0000066_001. This is a data sheet which is
 19 dated November 1987 -- forgive me, this one is from
 20 July 1989; the same form of words was used in
 21 November 1987 and in April 1988. If we look at the
 22 section under "Side effects", the penultimate
 23 paragraph there:

24 "The state of the art suggests that it cannot be
 25 precluded with certainty that both known or unknown

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1 viruses, which may occur in plasma, are transmitted
 2 through factor concentrates.

3 "In all probability the risk of transmission of
 4 hepatitis viruses is eliminated by careful donor and
 5 plasma selection and product-specific steam treatment.

6 "The product is safe with respect to
 7 transmission of HIV (HTLV III/LAV)."

8 This is a data sheet that was described as
 9 a neutral English data sheet, so it's not specific to
 10 the UK market, but it's one of those that was sent by
 11 Mrs Diernhofer in her letter from December 1989. As
 12 I say, that one dates from July 1989; same wording
 13 November 1987 and April 1988, pages 28, 30 and 32 of
 14 that same document.

15 In November 1987, Mr Coombes wrote to Immuno AG
 16 expressing his concern about that form of words and if
 17 we could have on screen, please, Soumik
 18 SHPL000008_097. -- sorry, SHPL000008_097.

19 "Dear Mrs Diernhofer

20 "Thank you for the information which you
 21 recently sent to us concerning the registration
 22 queries. ...

23 "I am, however [this is the second paragraph],
 24 concerned about the statements you have given under
 25 the heading 'Side Effects'. In the first paragraph

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(12) Pages 45 - 48

1 you suggest that it cannot be guaranteed that both
2 known and unknown viruses will not be transmitted
3 through factor concentrate and in the final paragraph
4 you contradict this statement by saying that the
5 product is 'safe' in regard to the transmission of
6 HIV.

7 "Apart from that contradiction I feel that the
8 final paragraph would certainly not be acceptable for
9 the Authorities in the UK. Irrespective of the
10 evidence that is available. It is always very unwise
11 for a pharmaceutical company to use the word 'safe'
12 and most companies would avoid this as a safeguard
13 against legal action in case for any reason the
14 product was found to transmit HIV in the future.

15 "I would appreciate your views on my comment s."

16 That, sir, seems to us to be a direct reference
17 to the warning that I have just shown you. We don't
18 have a response, or at least we have not found
19 a response, from Mrs Diernhofer to this letter, but I
20 would point out that the same form of words remained
21 in data sheets that were issued in April 1988 and
22 July 1989 in the neutral English form.

23 All of the neutral English text that I've shown
24 you about method 2 and method 3 steam treatment, and
25 indeed all of the others that are contained in that

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1 "micro organisms can be exposed to moist heat by
2 using hot water, boiling water, steam at atmospheric
3 pressure (steaming) or steam under pressure
4 (autoclaving).

5 "2. sensible heat
6 "the heat required to raise the temperature of
7 water from freezing to boiling point.

8 "3. latent heat.
9 "the additional heat needed to convert water at
10 its boiling point to steam at the same temperature.

11 "by inference, therefore, our inactivation
12 process cannot with scientific accuracy be called
13 steam treated, as definition 3 has not been met."

14 That is the "latent heat" definition:
15 "one us company, alpha, uses the phrase 'wet
16 heat' and is currently enjoying virtually all the
17 commercial factor viii business available.

18 "in our view, we should use the official
19 description:
20 "moist heat treated"
21 "if you agree, we will change over immediately
22 to this description and use the following titles for
23 kryobulin."

24 He lists those titles. The response is at
25 SHPL0000065_037. I say "the response", it's not

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1 file which I haven't shown you, use the phrase "steam
2 treated" and, indeed, that phrase is given prominence
3 because it's part of the title of the product.

4 The description, as we saw yesterday, was
5 considered by the Committee on Safety of Medicines
6 Subcommittee on Biologicals to be, and I quote,
7 "a misnomer and unacceptable", the reference is
8 MHRA0033320_044.

9 Internal Immuno correspondence shows, once
10 again, the concerns were raised on this point by
11 Immuno Ltd and were communicated to Immuno AG. If we
12 could have on screen, please, Soumik SHPL0000065_038;
13 it's tab 405.

14 This is dated -- it's not always clear whether
15 this is the 2 May or 5 February 1986.

16 **SIR BRIAN LANGSTAFF:** It looks like 5 February.
17 **MR HILL:** We think it is probably 5 February.

18 This is written by Mr Berry to Dr Schwarz of
19 Immuno AG. He says this:
20 "as requested by you, i have looked further into
21 the phrases 'vapour heated' and 'steam treated'.
22 "cooper and gunn's classical text book
23 'dispensing for pharmaceutical students' makes the
24 following definitions:
25 "1. moist heat

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1 necessarily clear that this is the response, it is
2 a consequent fax from later in the month and, again,
3 it comes from Mr Berry. It refers to a recent visit
4 that he has undertaken to Immuno AG, and in the
5 section headed "general" -- sorry it's dated
6 24 February 1986. In the section "general", it is
7 said:
8 "agreement that we adopt the scientifically
9 accurate phrase 'moist heat treatment'."

10 So it is Mr Berry recording his understanding of
11 what he has agreed with Immuno AG that his suggestion
12 has been accepted.

13 However, if we look at SHPL0000065036, we have
14 a fax which is sent by Mrs Diernhofer, the head of the
15 licensing department. It refers back to the telex, or
16 a telex, of 24 February 1986. What it says is this:
17 "1. Following the discussion with Dr Schwarz we
18 would like to inform you that we intend to stick to
19 the term 'steam treatment' instead of 'moist heat
20 treatment' to avoid further confusion as to the
21 denomination of our method of virus inactivation. We
22 are using this term in all English-speaking countries
23 with the exception of the USA where the authorities
24 have insisted on the use of 'vapour heat treatment'."

25 The subsequent application that was made for

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1 a product licence did refer to vapour heat treatment,
 2 but as we have seen, the data sheets that were sent by
 3 Mrs Diernhofer in December 1998, all refer to steam
 4 heat treatment.
 5 I'm about to move on from Kryobulin to the other
 6 products produced by Immuno, sir, and I note the time .
 7 **SIR BRIAN LANGSTAFF:** Yes. Well, we'll take a break now
 8 until 11.55. 11.55.
 9 **(11.23 am)**
 10 **(A short break)**
 11 **(11.55 am)**
 12 **MR HILL:** Sir, I'm turning to the other products that
 13 Immuno supplied to the UK market, both Prothromplex
 14 and FEIBA. I'm not going to go through in the same
 15 level of detail. For Prothromplex, we have the data
 16 sheets from the 1980s under the reference SHPL0000185.
 17 We've seen the letter from Mrs Diernhofer which
 18 attached those. People can look at them and see how
 19 the warnings changed during the period.
 20 I'm just going to point out a couple of matters
 21 to you from those. The first is, if we could have on
 22 screen, please, ABPI0000036. This is the other source
 23 that we have. The data sheet compendiums is one, and,
 24 again, Prothromplex can be found within those.
 25 This is from 1981 to 1982, so it would have been

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1 published in 1981, drawing on data sheets from the
 2 tail-end of 1980. At pages 4 to 5, please, Soumik.
 3 We can see, and I'm afraid it's slightly twisted
 4 over, but this is for the original form of
 5 Prothromplex, the non-heat-treated form. The data
 6 sheets contains the following. It says:
 7 "It is prepared from the plasma of suitable
 8 human donors whose transaminase levels are constantly
 9 checked and whose donations are shown by RIA to be
 10 free from HBsAg. Pooled plasma and the final product
 11 are tested by RIA for freedom from HBsAg.
 12 Prothromplex is also tested to discount the likelihood
 13 of ..."
 14 I think it's:
 15 "... disseminated intravascular coagulation."
 16 Which is a form of complication concerning
 17 clotting. We can see there that the tests, the RIA
 18 tests, are for both donations and for the final
 19 product.
 20 The other point that I would like to draw your
 21 attention to from this sheet is at the very bottom of
 22 page 477. This is in the "Contra-indications and
 23 warnings: "
 24 "2. Despite the precautions taken in the
 25 checking of donors, donations and the final

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1 product ..."
 2 **SIR BRIAN LANGSTAFF:** We're still not there. There we
 3 are.
 4 **MR HILL:** There we are:
 5 "... donors, donations and the final product,
 6 the transmission of hepatitis cannot be entirely
 7 excluded following the administration of coagulation
 8 factors. This should be taken into account before
 9 using Prothromplex to control haemorrhage in non-life
 10 threatening situations in liver disease patients and
 11 those undergoing anticoagulant therapy."
 12 So that final sentence is one that was not
 13 present in the data sheets for Kryobulin but has been
 14 included in this data sheet for Prothromplex, dating
 15 from circa 1980 to 1981.
 16 The other data sheets from the 1980s for the
 17 un-heat-treated Prothromplex do not contain any
 18 references to HTLV-III, HIV, et cetera, et cetera.
 19 One other document relating to Prothromplex, if
 20 we could have on screen, please, Soumik,
 21 SHPL0000168_025.
 22 This is a draft product label dating from 1984.
 23 You can see there that the date is 29 November 1984.
 24 If we could go, please, to page 8.
 25 We can see, about halfway down that page:

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1 "Prepared from a plasma pool of 1,000 HBsAg
 2 negative donors."
 3 This goes to the point you were making earlier,
 4 sir, in November 1984, at least in respect of
 5 Prothromplex, that is still maintained on the draft
 6 label.
 7 Thank you, Soumik.
 8 There are, as well as the leaflets for the
 9 un-heat-treated products, the same reference that
 10 I gave earlier contains leaflets for the heat-treated
 11 and the steam or vapour heat-treated product as well.
 12 I won't go through those now, sir.
 13 I turn then to FEIBA. If we could have
 14 onscreen, please, Soumik, CBLA0008057.
 15 This is a letter dated 18 August 1975, and it
 16 concerns a product that was then called Fraction R,
 17 but we can see from other documents that that is
 18 an early name for the blood product that becomes known
 19 as FEIBA. It's informing doctors about this product
 20 and its use for patients with Factor VIII inhibitors.
 21 I won't go through the whole of the document; it
 22 is enough to say that there is no reference in it to
 23 any risk of hepatitis.
 24 We can see on the next page -- please, Soumik --
 25 that there is a section headed "Warning", which refers

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1 to the risk of the clotting disorder that I mentioned
2 earlier, DIC, and gives advice about how to minimise
3 that risk.

4 If we could expand again, please. There is
5 a reference to "Side effects", which refers to
6 allergic and anaphylactic reactions. No reference to
7 hepatitis risk from this product.

8 There was a product licence application for
9 FEIBA in March 1977, and there is what appears to be
10 the proposed product leaflet. It is at
11 SHPL0000086_055. I won't go to it now, but, again, it
12 contains a similar warning to that which was contained
13 in the letter, no reference to a hepatitis risk.

14 A further reference, SHPL0000086_028, to another
15 section of the application, which deals with contra
16 indication, precautions and warnings. Again, no
17 reference to a hepatitis risk. That application, as
18 we heard yesterday, was unsuccessful, so we don't know
19 what form the data sheet took when the product was
20 provided on an unlicensed basis.

21 A new application for a UK licence was made on
22 25 September 1981. If we could have onscreen, please,
23 Soumik, SHPL0000091_007.

24 This is the proposed package insert from the
25 1981 application, and we can see, under the

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1 "Characteristics and Composition" section it states
2 that:

3 "FEIBA IMMUNO is prepared from the plasma of
4 donors meeting the requirements of the British
5 Pharmacopoeia ..."

6 Same rubric that has been used before:

7 "Donors who are HBsAg positive by
8 radioimmunoassay are permanently excluded from the
9 programme."

10 If we could go to page 5 of this document,
11 please -- sorry, page 4, first, just so that we can see
12 see the subheading, "Side Effects", then on to page 5.
13 The third paragraph down:

14 "Despite continuous donor tests it is impossible
15 to completely exclude the risk of transmission of
16 viral hepatitis in the use of human coagulation -factor
17 preparations."

18 So we do have now a hepatitis warning.
19 September 1981, that is the first reference to
20 a hepatitis warning that your team has found in
21 respect of FEIBA.

22 As I mentioned yesterday, included in the
23 application was information that, in nine cases, the
24 transmission of hepatitis as a result of FEIBA
25 treatment could not be excluded. The reference for

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1 that is SHPL0000209, page 6.

2 Turning to the dry-heat treated FEIBA, I'm not
3 going together through all of the different licence
4 sheets, but there is one point of interest which
5 emerges from them.

6 First, if we could have onscreen, please,
7 SHPL0000068_074.

8 We can see, dated 29 November 1984, and this is
9 an application for an amendment of the FEIBA licence
10 to allow for the heat-treated product. If we go to
11 page 16, please, Soumik.

12 There's a particular form of words used here:

13 "To decrease the potential risk of transmission
14 of viral hepatitis and other viral infections the
15 following steps are taken:

16 "1. Donor and Plasma Selection:

17 "All donations and pools of plasma used in the
18 manufacture of FEIBA IMMUNO TIM 4 and the final
19 product were tested for HBs-antigen by Radio Immune
20 Assay (RIA) and found non-reactive.

21 "2. Thermoinactivation by Method TIM 4:

22 "FEIBA IMMUNO TIM 4 is subjected to a model
23 virus controlled product specific thermoinactivation.

24 Tests on FEIBA IMMUNO TIM 4 also include absence of
25 pyrogens, sterility, and innocuity."

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1 So that is what is said, and it's the reference
2 to viral hepatitis in that first line:

3 "To decrease the potential risk of transmission
4 of viral hepatitis and other viral infections ..."

5 That is of interest here.

6 If we go, please, to SHPL0000067_056.. This is
7 a fax sent by Mr Nicholson of Immuno Ltd, which draws
8 attention to a concern that he has about that
9 reference. We can see point 2 -- the date is
10 19 December 1984:

11 "feiba tim 4.

12 "we think it would be preferable to have a uk
13 only 'neutral english' pack insert with the claim for
14 reduction in hepatitis transmission deleted."

15 So he is suggesting to get rid of the specific
16 reference to hepatitis, and we can see, during the
17 correspondence, why that is.

18 We go now, please, to SHPL0000067_055 **. This
19 is the response which comes from Mrs Diernhofer.

20 Mrs Diernhofer says:

21 "we have again discussed the issue of printing
22 a uk only 'neutral english' pack insert, and think
23 that the possibility of claims that may be made by one
24 or the other doctor would not justify the additional
25 costs arising from the printing of 2 different neutral

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1 english pack inserts. Besides we hope that the
2 product licence will be granted within soon and we
3 will then have to prepare a uk pack insert anyway.
4 Since we are free to use any pack insert as long the
5 product is only sold on a doctor/named patient basis
6 we would prefer to use our standard neutral english
7 pack insert for the time being."

8 If we go now to SHPL0000067_053.

9 **SIR BRIAN LANGSTAFF:** It would appear to follow, would it,
10 that so far as selling to a doctor on a named patient
11 basis, Immuno could describe their product as they
12 liked, in ways which would not be acceptable to the
13 Licensing Authority if the product were licensed?

14 **MR HILL:** Yes, while bound by other legislation as to how
15 you make representations about a particular product.

16 **SIR BRIAN LANGSTAFF:** Yes. So the question would then be:
17 to what extent would there be other controls over the
18 description applied? And the "possibility of claims",
19 that must be legal claims, would it? In paragraph 2.

20 **MR HILL:** I would suspect the claims that may be made by
21 one or the other doctor, we haven't been able to trace
22 what means. What it may mean is that there have been
23 some concerns raised by doctors, possibly doctors
24 within the DHSS, with whom this has been discussed, to
25 the effect -- and we can see this from the other

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1 correspondence -- that the heat inactivation treatment
2 step has not been shown to have any effect on
3 hepatitis. Therefore, you should not be saying it is
4 used to treat viral hepatitis. Although, out of
5 fairness to the company, it should be noted that what
6 the warning said was that, in order to reduce viral
7 hepatitis and other viruses, the "following steps are
8 taken". One is the testing --

9 **SIR BRIAN LANGSTAFF:** I follow.

10 **MR HILL:** -- and the other is for heat treatment. But we
11 can see from Mr Nicholson's reply that he wasn't
12 content with the answer that he'd got from
13 Mrs Diernhofer.

14 **SIR BRIAN LANGSTAFF:** Yes.

15 **MR HILL:** That is SHPL0000067_053. 21 December 1984, what
16 he says in the second paragraph is this:

17 "In principle our view is the same -- if there
18 is evidence to show that there is a reduction in post
19 transfusion hepatitis rates with kryobulin tim 2
20 prothromplex tim 4 and feiba tim 4 then the statement
21 concerning hepatitis transmission is acceptable
22 without amendment. However, because we thought this
23 evidence was not present in the data for submission to
24 the dhss, we suggested the phrase should be amended
25 and dr schwarz agreed.

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1 "we realise that initially leaflets were
2 prepared, including the reduced hepatitis with claims
3 that were however done before we had a chance to
4 evaluate the data and discuss modifications with you.

5 "whether or not the product is licensed is we
6 feel irrelevant. All claims for products whether
7 licensed or not should be capable of full
8 substantiation as otherwise the company is open to
9 criticism for making incorrect claims and possibly
10 even legal action in serious cases.

11 "we therefore would prefer uk leaflets not to
12 claim reduction in hepatitis risk."

13 We can see there that although the issue has
14 arisen specifically about FEIBA, it also relates to
15 other data sheets for other products which are
16 heat-treated in similar ways.

17 **SIR BRIAN LANGSTAFF:** Mm.

18 **MR HILL:** SHPL0000067_052 **, please, Soumik.

19 This is a fax to Mr Nicholson from
20 Mrs Diernhofer, responding to his fax of 21 December,
21 and this one is 17 January.

22 Mrs Diernhofer says:

23 "we have reconsidered your above telex and want
24 to stress that dr schwarz has agreed to your request
25 to delete the reference to the reduction of the

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1 hepatitis risk in the leaflets for heat treated
2 kryobulin, prothromplex and feiba in order not to
3 complicate the licensing of these products.

4 "the respective leaflets are under print for
5 kryobulin tim 2 and prothromplex tim 4.

6 "since feiba is not a registered product and you
7 have received all supplies in 'neutral english'
8 packaging elements so far, we intend to use our
9 respective 'neutral english' leaflet and packaging
10 elements also for the heat-treated product prior to
11 the registration of the product.

12 "in our 'neutral english' feiba leaflet we do
13 not make any claims as to the degree of the reduction
14 of the risk of transmission of hepatitis and therefore
15 need not be afraid of any criticism or legal action in
16 this connection.

17 "as soon as feiba tim 4 will be licensed we will
18 of course immediately print the leaflet submitted to
19 and approved by the authorities."

20 Now, counsel to the Inquiry analysis of this set
21 of correspondence is that Immuno AG continued to use
22 a leaflet claiming that testing and heating steps were
23 intend to decrease the risk of hepatitis transmission
24 for unlicensed FEIBA, as no claim was made for their
25 success in achieving that intention.

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1 This was despite opposition from Mr Nicholson,
2 who did not consider the claim to be evidenced.
3 Immuno AG did, however, agree to remove the reference
4 to hepatitis risk from other leaflets that were being
5 reprinted at that time.

6 It also seems to have accepted that the claim
7 could not be made in the licensing application. Once
8 the product was licensed, the reference to the
9 reduction of hepatitis risk was removed from the FEIBA
10 leaflet, which instead referred to efforts made to
11 reduce the risk of transmission of infectious agents.
12 So the words "hepatitis" or the word "hepatitis" is
13 removed.

14 The reference to that is a series of references
15 I can give, which I won't bring up: SHPL0000114_012,
16 and also data sheets contained in the ABPI compendium
17 at ABPI0000024, ABPI0000031. One further reference as
18 well is SHPL0000067_051, which shows that the new
19 Kryobulin TIM 2 leaflet that was sent to Mr Nicholson
20 on 22 January 1985, so the one that was being
21 reprinted at the time of the correspondence, refers
22 to, and I quote:

23 "... decrease the potential risk of transmission
24 of viral infections."

25 So the word "hepatitis" is removed.

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1 obliquely, is at PRSE0003071 -- please, Soumik --
2 which may point the other way.

3 This, as we can see, are the draft minutes of
4 a meeting that was held on the infectious hazards of
5 blood products at NIBSC on February 9, 1984.

6 This is a document to which we will return to at
7 length in the November hearings, when we're dealing
8 with the response to risk. I won't go into the detail
9 behind this meeting now, all I will do is turn to
10 page 3 of the document, please, Soumik.

11 Those at this meeting included US officials,
12 UK officials and representatives of fractionators, and
13 although the minutes are marked to be "draft", there
14 is a series of correspondence which shows that there
15 was broad agreement that they were accurate.

16 This section is the one that I draw your
17 attention to now:

18 "In the discussions that followed, it was
19 pointed out that the pool sizes used by the commercial
20 fractionators ranged from 1,000 to 10,000 litres of
21 plasma, though sometimes the pools were combined at
22 the cryoprecipitate stage, giving a possible maximum
23 of 20,000 litres of plasma equivalent. The average
24 volume collected from plasmapheresis donors was
25 680 ml, with a minimum pool size of around

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1 I won't take you to any of the leaflets for the
2 steam or vapour-treated FEIBA. I will provide two
3 references for the transcripts so that the document
4 can be identified for those who wish to see them:
5 SHPL0000106_150 and SHPL0000490_005.

6 That concludes, sir, all I intend to say on the
7 topic of communication of risk for Immuno products.
8 There are a couple of sweep-up points, as it were, on
9 the donors and on communication to others that I will
10 now turn to.

11 On donors I don't intend to say very much,
12 because, as we have gone through, we have picked up
13 the relevant pieces of information that we have about
14 them, and we have discussed the inclusion of the
15 reference of the pool size of 1,000 donors on various
16 product labels, and indeed, in the initial
17 application, Dr Thomas, in his report that we
18 discussed yesterday, referred to the pool size being
19 1,000 donors between the ages of 18 and 65, with
20 plasmapheresis centres in Austria and Germany.

21 As we have seen, the reference to 1,000 donors
22 disappears from the labels, and that may indicate that
23 that is no longer an accurate statement to be made
24 about the pool size.

25 But the document to which I referred earlier,

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1 1,500 donors and a maximum of around 30,000 donors.
2 The maximum pool size used by the NHS producers is
3 1,000 kilograms of [what was originally written as
4 cryoprecipitate but has been changed to] plasma,
5 incorporating material from about 5,000 donors."

6 That is, of course, expressed in general terms,
7 without reference to specific companies. But I do
8 note that the lower end of the range for commercial
9 producers is stated to be 1,000 litres of plasma.

10 **SIR BRIAN LANGSTAFF:** 1,500 donations.

11 **MR HILL:** From 1,500 donations.

12 **SIR BRIAN LANGSTAFF:** Or donors, in fact, rather than
13 donations.

14 **MR HILL:** There is evidence that we will go on to at hear
15 shortly that perhaps "donations" is the more accurate
16 description, because a plasma pool may contain more
17 than one donation from a particular donor. So
18 1,500 donations creates a 1,000-litre pool of plasma.
19 That doesn't necessarily mean that 1,500 donors have
20 been used.

21 **SIR BRIAN LANGSTAFF:** Well, it depends on how one
22 interprets the second from last sentence in the top
23 paragraph. Because, as it stands, what it is saying
24 is the average volume collected from plasmapheresis
25 donors is 680 ml; it doesn't say the average donation

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1 was 680 ml.
 2 **MR HILL:** That's true, sir, but --
 3 **SIR BRIAN LANGSTAFF:** If that's right, and if it was it
 4 saying is meant to be -- and I'm not sure that it is,
 5 these are minutes after all, so donors, donations, may
 6 slip one into the other -- but if it is what it says
 7 literally, then although a donor may repeat donations,
 8 the -- if the average per donor is 680 ml, then the
 9 minimum pool size of 1,500 donors would follow from
 10 1,000 litres.
 11 **MR HILL:** Yes, sir, the evidence that I had in mind is
 12 evidence that we will come on to hear from Dr Kingden .
 13 ^name
 14 **SIR BRIAN LANGSTAFF:** Yes.
 15 **MR HILL:** It is his point that, as a general principle,
 16 the fact that a pool contains 1,500 donations doesn't
 17 mean that they necessarily came from 1,500 individual
 18 donors. This is a different document which is saying
 19 something different, whether or not -- how precise the
 20 wording was intended to be in these minutes, as you
 21 say, sir, is unclear.
 22 **SIR BRIAN LANGSTAFF:** I mean, if one is taking this
 23 literally, then it would follow, 680 ml is actually
 24 over a pint, isn't it?
 25 **MR HILL:** I'll defer to you on that, sir.

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1 that this is hearsay evidence and we haven't been able
 2 to find anything to support it at this stage or to
 3 show that it is incorrect, but with that caveat, could
 4 we have on screen PJON0000055_001. This is
 5 a memorandum that was written by Dr Jones. We'll come
 6 back to it when we're dealing with other companies.
 7 It is about a meeting that he had with Robert
 8 Taub and Wolfgang Marguerre, who are with the Revlon
 9 Health Care Group and who have recently taken over
 10 Armour. The presentation that you'll hear on Armour
 11 will deal with this in more detail.
 12 The point about Immuno is the last
 13 paragraph that we can see on that page. What Dr Jones
 14 has recorded in this memo, based on what he has
 15 discussed with Dr Taub and Dr Marguerre is:
 16 "With regard to Immuno it was confirmed that the
 17 low priced blue packet is made from plasma bought from
 18 [America] ..."
 19 **SIR BRIAN LANGSTAFF:** "From Armour".
 20 **MR HILL:** Sorry, "from Armour".
 21 "... and that the more expensive red pack which
 22 is 'made' in Europe in fact contains plasma bought
 23 from the United States."
 24 Dr Jones is recording that. As I say, we have
 25 no documents that I have seen that helps us one way or

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1 **SIR BRIAN LANGSTAFF:** I think you'll find a litre is
 2 1.8 pints, so 500 ml is 0.9 of a pint, 550, therefore,
 3 is about a pint. So this is more than a pint. It's
 4 an awful lot of plasma.
 5 **MR HILL:** Yes, sir.
 6 **SIR BRIAN LANGSTAFF:** If one thinks of the usual blood
 7 donation as being a pint of blood, in our
 8 measurements, then half of that, roughly 55 per cent
 9 of it, is going to be plasma. So it's not
 10 inconceivable that it was talking about donors rather
 11 than donations but we just don't know, really, do we?
 12 **MR HILL:** I think that's right, sir, I think that's right.
 13 The point I was drawing to your attention about Immuno
 14 is that the lower end of that range is 1,000 litres of
 15 plasma and, although that would require more than
 16 1,000 donations, it may be that that figure relates to
 17 Immuno. I have to say I don't know of any other
 18 commercial company that was running pools of
 19 1,000 litres at that time.
 20 **SIR BRIAN LANGSTAFF:** Yes.
 21 **MR HILL:** But, again, we have what we have from the
 22 minutes and that is an inference, and it may be right
 23 and it may be wrong.
 24 One other document to which I will draw your
 25 attention, and it comes with a very significant caveat

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1 another as to whether or not that is correct. I raise
 2 it as a matter that we will continue to investigate.
 3 Thank you. If we could take --
 4 **SIR BRIAN LANGSTAFF:** Who is confirming it?
 5 **MR HILL:** My reading of the memorandum is that Dr Jones
 6 has -- or the topic has been raised between Dr Jones
 7 and Dr Taub and Dr Marguerre and it is either Dr Taub
 8 or Dr Marguerre, or a combination of the two of them,
 9 who have confirmed that position.
 10 **SIR BRIAN LANGSTAFF:** Just give me a moment.
 11 Do you know what recently-purchased company that
 12 was?
 13 **MR HILL:** My understanding sir, and it's something that
 14 will be explored more next week, is that this is --
 15 Revlon had recently acquired Armour --
 16 **SIR BRIAN LANGSTAFF:** Yes.
 17 **MR HILL:** -- and the memorandum goes on to describe
 18 Dr Taub and Dr Marguerre's views and plans, and their
 19 ideas for Dr Jones's involvement.
 20 **SIR BRIAN LANGSTAFF:** So this amounts to Dr Jones
 21 reporting a conversation. Who is the memorandum to?
 22 **MR HILL:** We don't know. If we could go to the final
 23 page, please, Soumik.
 24 There is nothing there. One possibility is that
 25 it was an internal memorandum that Dr Jones wrote for

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1 his own benefit to record the conversation. But, at
 2 present, I can't assist as to why -- as to who this
 3 was shared with, if anyone.

4 **SIR BRIAN LANGSTAFF:** Go back to page 1.

5 **MR HILL:** Page 1, please.

6 **SIR BRIAN LANGSTAFF:** It's unlikely to be a memo to
 7 himself, given the expression "strictly confidential".

8 **MR HILL:** I don't know, sir. It may be that he marked the
 9 document in that way to ensure that anybody who saw it
 10 realised that it was strictly confidential. But we
 11 simply don't know at present to whom this was -- or
 12 the intended audience, if any, of this memorandum.

13 **SIR BRIAN LANGSTAFF:** Yes. It's talking about Travenol,
 14 which is not Armour, knowing or suggesting that their
 15 supplies come from Belize, that must be and Lesotho,
 16 and this is Armour saying that they sold plasma to
 17 Immuno, but then purporting to know that that's the
 18 plasma used for the blue packet. Yes, I see, there
 19 must be a big question mark over the reliability of
 20 the information in this.

21 **MR HILL:** Yes.

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

23 **MR HILL:** I'm going to briefly, sir, refer to some of the
 24 other communications and contacts that Immuno and
 25 representatives of Immuno had with individuals and

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1 reported to us.

2 "Five similar reactions have been reported from
 3 other batches used in Europe and on checking back it
 4 has become clear that rapid infusion has been a common
 5 factor.

6 "In consequence we have decided to amend our
 7 directions so that more specific guidance is given
 8 concerning the rate of injection and we suggest 10 ml
 9 in 3 minutes.

10 "We enclose a copy of a letter we have sent to
 11 all Kryobulin purchasers and we have notified the
 12 Medicines Commission of our action."

13 So the document is showing the way in which the
 14 company responded to an adverse incident that was
 15 reported to them. For the record, the other documents
 16 relevant to this are MHRA0033322_003, and the same
 17 stem, _004.

18 There are other documents which also show the
 19 company responding to adverse reactions. I don't
 20 think I need to take you to them.

21 SHPL0000271_088, please, Soumik. This is
 22 a letter dated 15 September 1975. We can see from the
 23 initials that it was sent by Mr Berry, it was sent to
 24 Dr Andrews at the Department of Health and Social
 25 Security Medicines Division. He says in the first

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1 institutions within the UK. This is certainly not
 2 intended to be comprehensive, but there are a couple
 3 of documents which may assist you in understanding
 4 some of the issues.

5 One that I will begin with is an example of how
 6 adverse events were reported, involving Immuno. If we
 7 could have MHRA0033322_001.

8 We can see that this is a letter copied to
 9 Dr Thomas, sent to Dr Winfield, and if we could just
 10 expand out, please, Soumik. We can see that it is
 11 sent by the managing director of Serological Products,
 12 that's Mr Berry at this time, 2 October 1974. It
 13 says:

14 "Immediately following the receipt of your
 15 letters dated 30th August, 1974 and 9th September,
 16 1974 I reported the reaction to the Medicines
 17 Commission and at the same time made enquiries from
 18 our Principals."

19 I pause there to say that this -- both reports
 20 were about a severe reaction to an injection of
 21 Kryobulin, which involved tachycardia and vomiting.
 22 This is the response that Mr Berry is giving:

23 "I have now learned that all of [the] batch [the
 24 batch number is given] was sent to the UK and we are
 25 able to confirm that no other reactions have been

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1 paragraph:

2 "Since we first started selling Factor VIII and
 3 Factor IX Concentrate in 1973 you will, I am sure
 4 [you] agree, that our products have gained a good
 5 reputation for freedom from adverse reactions
 6 especially Serum Hepatitis. This view is supported by
 7 the greatly increased demand.

8 "This good track record has undoubtedly been due
 9 to the use of donors from low incidence areas, and the
 10 checking of their individual donations, pooled plasma
 11 and final product for absence of Australian Antigen."

12 I won't go through the rest of the letter, sir,
 13 but you can see the point that is being made there by
 14 Mr Berry in September 1975.

15 On a different theme, I don't ask for this to be
 16 brought up but the reference is DHSC0003743_132. It
 17 is a minute of a meeting that took place in August --

18 **SIR BRIAN LANGSTAFF:** Just pause for a moment. I want to
 19 check something. Can you just remind me of the date
 20 that you used earlier for the discussion which
 21 arose -- the confusion that arose with Dr Dane in
 22 respect of the use of the CEP test and the RIA test?

23 **MR HILL:** July 1975.

24 **SIR BRIAN LANGSTAFF:** What's puzzling me at the moment is
 25 that here what appears to be said is that RIA is used

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1 to test the pooled plasma, and it's before October.
 2 **MR HILL:** It is. So the application to change the licence
 3 to say that it's been tested by RIA or to change the
 4 information that goes out with the product to say RIA
 5 is in October.
 6 **SIR BRIAN LANGSTAFF:** I see.
 7 **MR HILL:** This seems to be a suggestion that that is being
 8 done --
 9 **SIR BRIAN LANGSTAFF:** Done before then?
 10 **MR HILL:** -- before then. Whether or not it was done in
 11 time to have been used on the batches that Dr Dane was
 12 concerned about is a --
 13 **SIR BRIAN LANGSTAFF:** Well, they may have been made
 14 earlier.
 15 **MR HILL:** Exactly.
 16 **SIR BRIAN LANGSTAFF:** I see. Yes, thank you.
 17 **MR HILL:** This is 1975, obviously, when the reference made
 18 to the areas of donor selection, the importance of
 19 donor selection is before the application was made to
 20 start using American plasma.
 21 August 1979, the document to which I referred
 22 a moment ago, Mr Berry met with Mr Harley of the DHSS,
 23 and the document shows that there was a suggestion
 24 from Mr Berry that Immuno were considering the
 25 possibility of investing in both a plasmapheresis

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1 of the discussion held at that meeting.
 2 If we could go to the next page, please, Soumik.
 3 We can see that it's Professor Bloom in the
 4 chair and the meeting begins with Mr Berry welcoming
 5 all present, so Immuno Ltd welcoming all present, and
 6 then Dr Eibl explaining two methods of viral
 7 inactivation that were being studied, and it goes on
 8 to give some detail about those methods. They appear
 9 to be chemical methods of viral inactivation, rather
 10 than heat treatment. So, although Professor Bloom is
 11 in the chair, it appears that this part of the meeting
 12 is the representatives of Immuno Ltd and Immuno AG
 13 introducing various clinicians to a viral inactivation
 14 technique that they were intending to deploy, and
 15 they're also seeking to try and generate interest in
 16 clinical trials of the product that results.
 17 As we know from previously looking at this
 18 document, the only reference to AIDS in this Immuno
 19 note is -- comes a little later in the document.
 20 I don't ask for it to be shown. It's in response to
 21 what seems to be questions from the clinicians, when
 22 it was said that it wasn't known whether the new viral
 23 techniques would reduce the risk of AIDS and, in any
 24 event "it was not known if AIDS is caused by a virus
 25 or an attacker inimical to T-cells".

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1 centre or centres for paid donors, and a fractionation
 2 plant in the United Kingdom. The company was also
 3 prepared to process plasma obtained from NHS voluntary
 4 donors.

5 Mr Harley said that he would take account of
 6 this proposal when preparing the forthcoming paper for
 7 Ministers. The document also records that Immuno
 8 offered him a trip to Vienna at their expense to see
 9 how things were done there, and Mr Harley recorded
 10 that he merely noted this offer in his minute. He
 11 included the account of that offer in the minute that
 12 was circulated to all of his colleagues.

13 You will recognise, sir, that this in the period
 14 of time when there was consideration being given to
 15 the possibility of private involvement in
 16 fractionation in the United Kingdom. Ultimately, that
 17 came to nothing.

18 The final two documents that I will take you to
 19 in respect of Immuno concern the Heathrow meeting of
 20 24 January 1983, to which you made reference earlier,
 21 sir. The first is RFLT0000050, please, Soumik. We've
 22 seen this document before and I, as a result, won't go
 23 through it in great detail. But it is being sent from
 24 Immuno Ltd to Dr Kernoff, one of the attendees at the
 25 meeting. It was sent on 16 March, and it is a summary

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1 So there is reference to AIDS and the risk of
 2 AIDS through blood products in the Immuno note, but
 3 what there isn't is the extended discussion led by
 4 Dr Craske which we can see from the other version of
 5 the minutes of that meeting, which are at PRSE0002647,
 6 if I could ask for those to be brought up, please,
 7 Soumik.

8 These are notes of the meeting. We can see
 9 topic "Hepatitis Reduced factor VIII and Factor IX
 10 Concentrates for Haemophilia Therapy", so that seems
 11 to be the reason that the meeting was called. We then
 12 have an account of what Dr Eibl said about their new
 13 viral inactivation techniques. If we could expand
 14 that page, please, Soumik.

15 Then we go over to the next page, please. Quite
 16 a lot of technical detail given about the inactivation
 17 techniques. Then a discussion of clinical trials
 18 design, and over to the next page, as well, please,
 19 Soumik.

20 Then we have a new heading, which is "Acquired
 21 Immunodeficiency Syndrome". The first line of the
 22 note says:

23 "This was discussed in the after lunch period.
 24 Dr Craske summarised the current position."

25 I won't go through it, we've looked at this

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1 document before.
2 One possibility is that the meeting was convened
3 by Immuno Ltd and Immuno AG in order to discuss with
4 the clinicians their new viral inactivation techniques
5 and to, as I say, try to get interest in a clinical
6 trial. That presentation, as it were, took place in
7 the morning, then there was lunch, and then, after
8 lunch, AIDS was discussed and the discussion was led
9 by Dr Craske.

10 It is notable that there is no reference in the
11 Immuno note to Dr Craske's discussion. It is also
12 notable that in Dr Craske's discussion, there is no
13 evidence of any participation specifically by Dr Eibl
14 or anything reflecting Immuno's position on AIDS, as
15 it were.

16 So the possibility is that, following the
17 presentation in the morning, the Immuno
18 representatives either left or took on a purely
19 observing position. The clinicians took advantage of
20 the fact that they were all there to then have their
21 own discussion about AIDS. That is an inference from
22 the documents. Other inferences, sir, can also be
23 drawn.

24 One other point about the January meeting, and
25 this came up in Dr Walford's evidence in July. There

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1 is a DHSS minute dated 31 December 1982.
2 Soumik, perhaps if we can have this onscreen,
3 please. It's DHSC0002223_065.
4 It's a minute from Dr Fowler to Dr Walford,
5 heading "[Factor VIII] concentrate with reduced
6 hepatitis risk". This minute refers to discussions
7 that are ongoing with Travenol, and then it says:
8 "This, however, is pre-empted by Immuno's recent
9 meeting with haemophilia centre directors and the
10 directors of BPL and PFC, the outcome of which is, we
11 are led to believe, a multi centre clinical trial of
12 the product in named patients. I have not heard that
13 Travenol proposed to hold a symposium, although it
14 would be very much in character were they to do so.
15 The Immuno meeting is said to have been quite
16 an expensive exercise at Heathrow. I was not invited,
17 but my information comes indirectly via John Holgate
18 from one of the participants."

19 The possibility raised by Dr Walford, for
20 perfectly understandable reasons, is that there was
21 another meeting that was held in December because this
22 refers to it in the past tense. We haven't been able
23 to find any documents relating to such a meeting, and,
24 again, raised as a possibility is the fact that this
25 is a slightly garbled recollection of what has been

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1 said by others. I don't mean that with any criticism
2 of the author. But the message has been lost
3 somewhere and what this is actually referring to is
4 the forthcoming meeting which is going to take place
5 in January, rather than a meeting that has already
6 taken place, because the description of what that
7 meeting is, taking place at Heathrow, discussing with
8 Haemophilia Centre Directors the viral inactivation
9 and an attempt to get a multi-centre clinical trial up
10 and running, all of that ties in with the January
11 note. So we can't be confident that this is the case,
12 but it may be that this minute actually refers to
13 a meeting that is due to take place, rather than one
14 that has taken place.

15 The product that was discussed at the Heathrow
16 meeting, the chemically inactivated product, is one
17 that may have been raised elsewhere. There is some
18 evidence that it was -- formed part of a presentation
19 or a stall that Immuno held at the Stockholm
20 conference in June and July 1983. The reference is
21 BAYP0004722.

22 However, we have seen no evidence that the
23 product that was being discussed ever made it to the
24 UK market.

25 A further reference that I will put on the

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1 transcript is BPLL0001351_119. I don't ask for this
2 to be put up, but it's a letter on 20 June 1983 from
3 Mr Berry to Professor Bloom, providing an update on
4 what he described as the virus inactivated
5 concentrates that were discussed at the Heathrow
6 meeting. He said that the testing procedures were
7 prolonged and that, while Immuno were continuing to
8 pursue the ideas, they were being designated as
9 "generation 2 inactivated products", to use the
10 terminology that Mr Berry used, and he added that
11 Immuno were also working on first generation
12 heat-treated product, where progress was more rapid.

13 So it appears that what was being discussed at
14 Heathrow in January goes on to the back-burner, as it
15 were, and that heat treatment becomes the preferred
16 initial method of viral inactivation, but the chemical
17 method is designated as a generation 2 procedure.

18 That, sir, is all that I intend to say about
19 Immuno, and I will turn to the next product, in
20 particular Hemofil, and the companies involved with
21 it, Baxter and Travenol, either now or after lunch,
22 depending on your preference.

23 **SIR BRIAN LANGSTAFF:** Well, let's take a break now, so we
24 have Travenol all in one piece, unless you think that
25 there is any introductory material that you want to

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1 give us?

2 **MR HILL:** I'm happy to take the break now, sir. I think

3 it may be easier to do that and come back --

4 **SIR BRIAN LANGSTAFF:** Well, let's do that so we can have

5 Travenol Hemofil all in one go, as it were, and we'll

6 take a break now until 1.50. 1.50.

7 **(12.51 pm)**

8 (The luncheon adjournment)

9 **(1.54 pm)**

10 **MR HILL:** Sir, before we move to Travenol, you raised this

11 morning the question of the British Pharmacopoeia

12 definition of a suitable donor.

13 If we could have on screen, please, Soumik,

14 SHPL0000245_005.

15 This is the British Pharmacopoeia of 1980,

16 volume 2, and it is this volume that is referred to in

17 some of the data sheets that we looked at this

18 morning. The first reference that I can find to it is

19 from the data sheet from the 1981 to 1982 compendium.

20 The reference, not that we need to bring it up, is

21 ABPI0000036, and it's about Kryobulin. That data

22 sheet would have dated from sometime in 1980.

23 The definition of the donor is contained, if we

24 can find page -- the fifth page of this electronic

25 document and, it's page 845 of the printed copy.

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1 Perhaps if we could go to the second page,

2 and -- yes, for some reason I have a different

3 reference. Yes.

4 But this is the entry for "Albumin". It says:

5 "Albumin is a solution in a water of human

6 albumin containing a low proportion of salt."

7 This the relevant passage for our purposes:

8 "It is prepared from pooled liquid plasma

9 obtained from blood from human subjects (a) who as,

10 are far as can be ascertained by a registered medical

11 practitioner after simple clinical examination and

12 consideration of their medical history, free from

13 disease transmissible by blood transfusion, (b) whose

14 blood has been tested with negative results for

15 evidence of syphilitic infection, (c) whose blood has

16 been tested with negative results for the presence of

17 hepatitis B antigen by a method not less sensitive

18 than reversed passive ..."

19 Sorry, I've lost all --

20 **SIR BRIAN LANGSTAFF:** Haemagglutination.

21 **MR HILL:** Haemagglutination, thank you.

22 "... and (d), the haemoglobin value of whose

23 blood in terms of the Cyanmethaemoglobin Solution for

24 Haemoglobinometry (British Standard 3985:1966) is not

25 less than 12.5 per cent w/v (female donors)" --

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1 **SIR BRIAN LANGSTAFF:** Weight to volume.

2 **MR HILL:** Weight to volume.

3 "... (female donors) or not less than

4 13.3 per cent [of weight to volume] (male donors)."

5 So that was the definition to which reference

6 was made in the data sheets. I note that there are

7 previous volumes of the British Pharmacopoeia. We

8 will look into whether the definition of

9 "suitable donors" changed in those previous volumes.

10 **SIR BRIAN LANGSTAFF:** So this would appear to mean that

11 a suitable donor, there has to be a medical

12 examination by somebody who is actually a doctor, and

13 he sees no sign of a transmissible disease, there has

14 actually been a blood test for syphilis, and/or

15 hepatitis B antigen, and he's got quite a bit of

16 haemoglobin.

17 **MR HILL:** Yes.

18 **SIR BRIAN LANGSTAFF:** Yes. So this is prepared from

19 plasma from the blood of the people who have gone

20 through these various different tests.

21 **MR HILL:** Yes.

22 **SIR BRIAN LANGSTAFF:** Yes. So one would expect to see

23 some record of these tests and their results in any

24 centre accepting plasma for plasmapheresis.

25 **MR HILL:** Yes, one would expect that. It's not expressly

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1 stated as a requirement, as a recordkeeping

2 requirement in the Pharmacopoeia, but it's hard to see

3 how the tests can be done effectively without records.

4 **SIR BRIAN LANGSTAFF:** Well, it's one thing to have

5 a definition, it's another to make sure it will be

6 able to -- or to be able to rely upon it.

7 **MR HILL:** Yes.

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

9 **MR HILL:** I will turn then now to the next company, and,

10 as I say, although this section has been timetabled as

11 being Hyland, Travenol and Immuno, in the 1970s and

12 the 1980s, Immuno was a separate up company from

13 Hyland, to Travenol, and indeed was a competitor

14 of it. A very brief outline of the company structure

15 for Hyland, Travenol and Baxter.

16 The US company was Baxter International Inc,

17 founded in 1931 as the Don Baxter Intravenous Products

18 Company and headquartered in Illinois, near Chicago.

19 We will see later something from the 1975 World in

20 Action documentary which includes some footage from

21 outside the headquarters in Illinois and an interview

22 with the senior vice-president for medical affairs of

23 Baxter.

24 Travenol Laboratories was founded in or

25 around 1948 or 1949, and it was a specialist

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1 pharmaceutical division within Baxter.
 2 Hyland Laboratories was acquired by Baxter --
 3 Baxter Inc this is -- in 1952, and Hyland were based
 4 in Glendale in California. As a result of this, we
 5 often see reference to the Hyland division of Travenol
 6 Laboratories, and that is part of the wider Baxter Inc
 7 group. That is the US company.
 8 The UK company was incorporated on
 9 18 November 1948, as Wallerstein Co Ltd. The name was
 10 changed on 14 February 1972 to Travenol Laboratories
 11 Ltd. The name was changed again on 1 February 1988,
 12 to Baxter Healthcare Ltd. The UK company again is not
 13 a manufacturer, but it is involved in importing and
 14 selling US blood products in the UK in the 1970s and
 15 the 1980s.
 16 For completeness, sir, I point out that Baxter
 17 Healthcare Ltd spun off the bioscience element of the
 18 business to a company called Baxalta UK Ltd in 2015.
 19 Again, I make no submission on the current
 20 company structure or on the liabilities or
 21 culpabilities that arise from it.
 22 The witness statement of Bo Tarras-Wahlberg at
 23 WITN3805001 provides further details.
 24 For those following the evidence, again it is
 25 helpful to keep in mind that whenever there is

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1 a reference to Travenol Ltd, then that is to the
 2 UK company, as opposed to Travenol Laboratories or
 3 Baxter Inc or Hyland, which is a reference to the
 4 manufacturers in the United States. The key names for
 5 the UK companies are Travenol Laboratories Ltd, from
 6 1972 to 1988, and then Baxter Healthcare Ltd from
 7 1988.
 8 The principal product with which we're
 9 interested for the Baxter-Travenol group is Hemofil,
 10 Factor VIII concentrate. An overview of Hemofil, and
 11 indeed of other products, is contained in a draft
 12 witness statement prepared by and on behalf of
 13 Henry Kingdon in 1990. If we could have onscreen,
 14 please, CBLA0000011_005.
 15 Dr Kingdon was at that time the vice-president
 16 and general manager of the Hyland division of the
 17 Baxter Healthcare Corporation, having previously been
 18 its medical director. That information can be found
 19 out CBLA0000011_076.
 20 He was approached by the legal team representing
 21 BPL in the UK HIV litigation to provide a witness
 22 statement in those proceedings.
 23 The relevant correspondence can be found at
 24 BPLL0016042_021, and CBLA0000069_074.
 25 The statement was never finalised, as the

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1 litigation settled in December 1990, subject to
 2 negotiation over the terms of that settlement.
 3 The version which we're going to look at now is
 4 that of 8 November 1990. We can see the date in the
 5 top right-hand corner expressed in the American style.
 6 It is a first draft that was prepared by
 7 lawyers, on which Dr Kingdon wrote "Comments for
 8 inclusion and information". The other correspondence,
 9 the references to which I have referred you earlier,
 10 indicates that those lawyers had met with Dr Kingdon
 11 in order to speak to him and help him to draft up the
 12 statement.
 13 On the covering note, Dr Kingdon wrote, and you
 14 can see here:
 15 "I did my editing in blue (or black)."
 16 In blue:
 17 "These are changes that should be incorporated
 18 into your next draft. I [have] made explanatory
 19 comments.
 20 "In this pink or magenta color -- these are just
 21 explanatory and not intended to be incorporated."
 22 And he says:
 23 "Thanks -- good first draft!"
 24 So we can see that obviously Dr Kingdon has had
 25 input into considering the draft and was the source of

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1 the information that is contained in it, but it is not
 2 a finalised draft.
 3 It's not always possible, looking at the draft,
 4 to identify when Dr Kingdon is talking about a
 5 practice that stood as of 1990, and when he is talking
 6 about a practice that was in place at an earlier
 7 period. Sometimes it is made clear; sometimes it is
 8 not so clear. As we go through, that is something
 9 which is worth keeping in mind.
 10 With those caveats in place, the statement
 11 provides an overview of Baxter's approach and of the
 12 products that it produced, and as a result we'll start
 13 here.
 14 Hyland Laboratories produced a Factor VIII
 15 concentrate named Hemofil from at least 1968. That is
 16 at paragraph 28.
 17 Hyland was the first manufacturer to obtain
 18 a licence for and market a Factor VIII concentrate in
 19 the United States, and Dr Kingdon recalls, from his
 20 time as a physician, treating a patient with Hemofil
 21 in 1968, at the University of Chicago.
 22 This is paragraph 28.
 23 Hyland introduced a Factor IX product, Proplex,
 24 in August 1970.
 25 That's paragraph 32.

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1 I take that to mean that it was introduced into
2 the American market at that time.
3 Hemofil and Proplex were produced from large
4 pools comprised of plasma obtained from paid donors
5 using plasmapheresis.
6 That is at paragraph 12.
7 Dr Kingdon referred to plasma pools of
8 15,000 donations per pool, but it not clear whether
9 the size of pool varied over time. There is some
10 other that we'll come to which suggests that they did.
11 At paragraph 22, Dr Kingdon makes the point that
12 we discussed earlier, that there might be more than
13 one donation from a single donor in that pool.
14 By the 1980s, plasma donations were obtained
15 from plasmapheresis centres owned and operated by
16 Hyland, or independent centres that contracted with
17 Hyland in compliance with their standards.
18 I think it's helpful to go to the actual text
19 now, to see what Dr Kingdon says about that.
20 Could we have on screen, please, Soumik, page 5
21 of CBLA0000011_005. We'll take it from paragraph 12:
22 "The industrial manufacturers fractionate plasma
23 collected from plasmapheresis centres around the
24 United States. Hyland processes plasma collected from
25 plasmapheresis centres owned and operated by Hyland

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1 procedures in the collection centres including donor
2 selection, labelling of donations and testing. Prior
3 to the direction that source plasma be licensed [this
4 is the corrected version], a certain amount of plasma
5 was imported for the production of concentrates."
6 The uncorrected version read:
7 "... a number of manufacturers in the United
8 States imported plasma from countries such as Haiti
9 and certain countries in Africa ..."
10 I'm afraid I can't quite make out the next --
11 "for use", I think it is.
12 **SIR BRIAN LANGSTAFF:** "... for use in the production of
13 concentrates."
14 Yes.
15 **MR HILL:** So that is the uncorrected version. The
16 corrected version, as we can see, makes a more generic
17 statement:
18 "All importation stopped following the FDA
19 direction that source plasma and the centres producing
20 source plasma be licensed; the FDA would not inspect
21 offshore sites which meant that imported plasma would
22 not be approved plasma and therefore could no longer
23 be used in the manufacture of blood products. As
24 a result, since approximately 1978, all plasma used
25 for the production of concentrates in the United

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1 throughout the United States and in addition,
2 a number of independent contractors collect and
3 process plasma under contract in compliance with
4 standards set by Hyland. Hyland also custom
5 fractionates all fresh frozen plasma collected by the
6 American Red Cross under a plasma fractionation
7 contract."
8 He goes on to describe some details of that
9 contract which I won't trouble you with.
10 "The plasmapheresis industry the United States
11 developed in the mid 1970s ..."
12 **SIR BRIAN LANGSTAFF:** Where are we now?
13 **MR HILL:** Sorry, paragraph 13, we go to.
14 **SIR BRIAN LANGSTAFF:** Thank you.
15 **MR HILL:** "The plasmapheresis industry the United States
16 developed in the mid 1970s and is widely used by the
17 manufacturers. Plasmapheresis enables each donor to
18 give up to 32 donations in 8 weeks as compared with
19 a single donation in 8 weeks by conventional
20 collection methods.
21 "In the mid 1970s the FDA mandated source plasma
22 as a licensed product. In order to obtain a licence
23 for the production of source plasma every collection
24 centre must be inspected annually. Annual inspections
25 are carried the out by the FDA who look closely at all

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1 States has been obtained from donors in the United
2 States."
3 That is a proposition, sir, that we will test by
4 some other material in due course.
5 Dr Kingdon goes on to discuss blood collection
6 at Hyland centres. This is paragraph 15:
7 "Hyland collects plasma by way of plasmapheresis
8 at donor centres owned and operated by Hyland
9 throughout the country. In addition, Hyland
10 fractionates plasma collected at a number of
11 independent centres who collects plasma under contract
12 with Hyland. All donors are paid a small fee per
13 donation. Plasmapheresis donors may make up to 32
14 donations per 8 weeks with two donations taken per
15 sitting.
16 "Plasma collection centres tend to be located
17 near areas where there is likely to be a population
18 willing to spend 2-3 hours donating plasma for a small
19 payment. For example, centres are often located close
20 to universities, in order to attract the student
21 population, near army bases and in the lower
22 socio-economic sections of a city. Donor selection is
23 rigorous and donors are given physical examinations to
24 check for needle tracks and signs of alcohol abuse.
25 "Every donation is coded immediately following

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the donation. The coding information contains the donor's bleed number, the date of the donation and the donor's social security number. Each bottle of plasma obtained during a bleed is labelled with this information. After each donation, a plasma sample from the donation, labelled in the same manner as the donation, is sent to the Hyland centralised testing laboratory where it is tested for antibodies to HBV, HIV and ALT. Testing for HIV was introduced in April 1985. ALT testing was introduced at around the same time. The ALT test is a marker for active liver cell injury and is used as a surrogate test for NANBH. ALT testing was introduced following a mandate by the BGA (Bundesgesundheitsamt), the German regulatory authority. Hyland sell Factor VIII and Factor IX concentrates in Germany and introduced ALT testing in order to comply with the German regulatory requirements. Testing for HCV has not been introduced at Hyland donor centres.

"Testing of all donations is carried out at the Hyland centralised testing laboratory with the results sent to both the donor centre and to a manufacturing facility in Los Angeles. Hyland operates only one testing site and all plasma collected by or on behalf of Hyland in the US is sent to the laboratory for

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testing. Each donor centre holds all donations until clearance to ship is received from the testing laboratory. Any donation which fails any aspect of the testing procedure is destroyed by the blood centre which collected it for donation and the who retain records verifying that this has been done. Donors who test positive for HIV are blacklisted and are unable to make any further donations at any Hyland Centre or any centre affiliated with Hyland. Records are computerised with donors identified by their social security numbers.

"The turnaround time for testing and the subsequent shipment of all cleared plasma is 7-10 days. Shipment to the manufacturing facility may take up to one week thereafter depending on where the plasma is being shipped from. Once the plasma arrives at the plant the manufacturing process and all subsequent steps such as quality control procedures and release by the FDA takes some months. And it may be six months to one year before a donation given at any of the blood centres appears in the form of a licensed concentrate.

"All plasma used in the manufacture of [Factor VIII] or [Factor IX] concentrate is fractionated at the Hyland manufacturing plant in Los

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Angeles although in the past, some of the concentrate produced for sale in Europe was manufactured at Lessines [in] Belgium, the first heat-treated concentrate, Hemofil-T, was originally heat-treated in Lessines. Material received at the manufacturing plant is put into quarantine for a period which varies depending on the amount of product in stock. Prior to fractionation the bar codes on the bottles of plasma are read to determine whether there have been any human shipping errors. Any donations which are picked out during this process are destroyed. In addition this process removes any donations from donors who have subsequently been identified as sero-positive. While the laboratory test will identify sero-positive donors thus enabling the donation which is the subject of the test to be destroyed, the bar code reading of the manufacturing plant will identify, with reference to the donor's social security number, any earlier negative donations by that donor which have not been processed.

"The computer inspection line was introduced in 1984-5. Prior to this the same procedures were undertaken manually."

Removed from the draft by Dr Kingdon is the following clause:

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"... although under the manual procedure, donations, from donors who had sero-converted between one donation and another were unable to be removed."

That has been struck through by Dr Kingdon.

A couple of further points picked up elsewhere in the statement about donors: at paragraph 34, Dr Kingdon comments that, regardless of the FDA measures that were introduced in the mid-'70s it was his view that fractionators would not have continued to use imported plasma, as much of it was infected by hepatitis B virus and was therefore unable to be used in the manufacture of concentrates. That's at paragraph 34.

In terms of the time lag between a test being conducted or a step introduced and that step taking effect in the product which is available, if we could bring up, please, Soumik, paragraph 138, at page 45 of the document. This is specifically about the HIV testing that was introduced in April 1985. What Dr Kingdon says is:

"Even though testing was introduced by Hyland in April 1985 it took approximately 6 months from that time for the manufacturing pipeline to be cleared of untested plasma as plasma in stock but untested at the time testing was introduced was put through the

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1 manufacturing process. As a result, even after the
2 introduction of testing, some concentrates made from
3 untested plasma and with a shelf life of 2 years
4 remained on the market."

5 **SIR BRIAN LANGSTAFF:** Now, the shelf life, is that once
6 the product has been made?

7 **MR HILL:** Unfortunately, sir, we have those words, and
8 I can't interpret them any further.

9 **SIR BRIAN LANGSTAFF:** So there is no further help as to
10 whether the six months to a year in quarantine before
11 manufacture is in addition to this, or not?

12 **MR HILL:** Not in this statement. We may be able to find
13 something elsewhere but I'm afraid that is a question
14 that we would have liked to ask Dr Kingdon, but
15 obviously --

16 **SIR BRIAN LANGSTAFF:** I suspect another question you may
17 like to ask him, but I'm asking you because you can
18 tell me if there's anything in his statement to say
19 anything about it, is that the tenor of what he
20 appears to be saying is that if a donation is shown ,
21 after it has been taken, to have come from someone who
22 has a sero-conversion, it's removed?

23 **MR HILL:** Yes.

24 **SIR BRIAN LANGSTAFF:** At what stage does he say the
25 donation is pooled with other donations?

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1 Dr Kingdon joined Hyland in 1981, a point which
2 is generally relevant to his statement as well, so
3 before 1981 he is not speaking from personal
4 experience or knowledge. When he joined Hyland in
5 1981 a heat-treated version of Hemofil, called
6 Hemofil-T, had already been developed and was awaiting
7 clinical trials. That's at paragraph 45.

8 The product was heated in a dried state at
9 60 degrees for 72 hours -- that's paragraph 54 -- and
10 it had been developed with the intention of
11 inactivating hepatitis B virus. That is at
12 paragraph 52.

13 1981, sir, is significantly earlier than the
14 period of heat treatment that we were talking about
15 with Immuno.

16 **SIR BRIAN LANGSTAFF:** Yes. When in '81 did he join
17 Hyland?

18 **MR HILL:** April 1981, paragraph 45.

19 **SIR BRIAN LANGSTAFF:** So this is -- before April 1981,
20 Hemofil-T was already developed?

21 **MR HILL:** Yes, and awaiting clinical trials.

22 One of the clinical trials involved saw
23 a preparation of Hemofil-T from a 300-donor pool,
24 which had undergone extensive screening for
25 hepatitis B surface antigen, anti-hepatitis B surface

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1 **MR HILL:** That, I can't answer, I will go back to the
2 statement and see if I can get any further clarity
3 from it.

4 **SIR BRIAN LANGSTAFF:** Because a consequence would be that
5 it might be very difficult to remove one donation
6 without dumping the whole pool.

7 **MR HILL:** Yes. I will go back to the statement and see if
8 I can find more precision on that point.

9 **SIR BRIAN LANGSTAFF:** I mean, I suspect he may not have
10 said anything about it all, but it might be
11 interesting to know.

12 **MR HILL:** Yes.

13 I will turn -- Dr Kingdon says a number of other
14 things in his statement and I'm sure, sir, that you
15 will consider his whole statement in due course. He
16 expresses opinions about how Hyland's system of
17 checking donors compared with the voluntary donors in
18 the United States, and he makes a number of other
19 points as well, and I will leave that to another day .

20 I will turn, instead, to his account of the
21 development of heat treatment for factor concentrates
22 and the difficulties involved in it, and it's at
23 paragraph 36 and following of the statement. I'm not
24 going to ask for all of this to be shown, I will
25 summarise some of it and I will read other parts .

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1 antigen, anti-hepatitis B core antigen, and it had
2 been screened for ALT levels as well. Half of the
3 pool was spiked with hepatitis B virus prior to it
4 being freeze dried and then put through the
5 heat-treatment process, with the other half left as
6 a control.

7 The trial was reported in August 1984 as having
8 delayed the onset of hepatitis B virus in chimpanzees
9 from six weeks to six to nine months, and as of
10 showing no transmission of non-A, non-B hepatitis.
11 That is at paragraph 48 of the statement, and the
12 relevant publication is CBLA0000061_002, which is
13 Hollinger et al, *Reduction in risk of hepatitis*
14 *transmission by heat-treatment of a human Factor VIII*
15 *concentrate*, in the Journal of Infectious Diseases
16 1984, volume 150, pages 250 to 262. The authors there
17 commented that the heat-treatment method employed:
18 "... has the potential for reducing and possibly
19 eliminating the risk of hepatitis transmission by
20 these products."

21 It is important to note in this and indeed in
22 the other studies, that the date at which the trial is
23 published is some time after the initial results are
24 beginning to come through.

25 A clinical trial, led by Professor Mannucci

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1 using Hemofil-T manufactured from a plasma pool
2 screened only for hepatitis B surface antigen, showed
3 that non-A, non-B occurred in 84 per cent of the
4 patients in the trial.

5 The reference is paragraph 49 to 50 in the
6 statement.

7 The results of that clinical trial were
8 published in the Lancet in July 1985. Our reference
9 for that is HSOC0001563. It is Colombo, Mannucci, et
10 al, Transmission of non-A, non-B hepatitis by
11 heat-treated factor VIII concentrate, Lancet,
12 6 July 1985, volume 2, pages 1 to 4.

13 Again, the point is that, although that was
14 published in July 1985, there is evidence that
15 Professor Mannucci was already telling people about
16 the results that he was finding of non-A, non-B
17 infections at a much earlier stage, and in another
18 article that he wrote retrospectively,
19 Professor Mannucci said that in September 1983 he
20 informed:

21 "... a large number of haemophilia treaters that
22 early patients in his trial had developed hepatitis."

23 And the reference to that is PRSE0002333.

24 In a memorandum dated 24 March 1984,
25 Professor Bloom, Dr Craske and Dr Rizza informed

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1 Haemophilia Centre Directors that trials were showing
2 a 63 per cent attack rate of non-A, non-B on first
3 exposure for previously untreated patients. That is
4 CBLA0001831.

5 The point here, sir, is that the initial hopes
6 that came from the laboratory trial that Hemofil-T
7 might inactivate non-A, non-B hepatitis proved to be
8 illusory, and that was done through the use of
9 a clinical trial, and information about that clinical
10 trial begins to be shared from about September 1983.
11 But the trial itself is not reported until some time
12 afterwards.

13 Dr Kingdon in his statement, at paragraph 50,
14 talks about why these different results were achieved,
15 and he attributes the difference to the fact that the
16 laboratory trial was done on a product which was
17 created from a pool which had undergone extensive
18 screening, presumably in order to try to eradicate the
19 possibility that hepatitis B was already in it because
20 they were going to spike it with hepatitis B to see
21 the effect. Dr Kingdon thinks that it is that
22 extensive screening of the pool which meant that when
23 the heat treatment was applied to it, the heat
24 treatment was effective against hepatitis, but when
25 the product was created, as it were, in the usual way,

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1 with just hepatitis B surface antigen screened out,
2 then the heat treatment did not prove effective, and
3 that is why non-A, non-B hepatitis is still
4 transmitted.

5 That is Dr Kingdon's view, I express no comment
6 on it.

7 Hemofil-T was, however, according to Dr Kingdon,
8 found to inactivate HIV. And if we go, please, to
9 page 20, Soumik, of the document, it's paragraph 57,
10 Dr Kingdon says this:

11 "In 1984 after it became apparent that
12 Dr L. Montagnier had developed a test for anti-LAV we
13 conducted an experiment in conjunction with him to
14 determine whether the virus was heat labile and
15 whether, if so, Hemofil-T was AIDS-free. Frozen
16 samples taken from the patients who formed part of the
17 study being carried out by Mannucci were sent to
18 Montagnier who performed assays to determine whether
19 any of the patients had HIV. As controls, we used
20 samples taken from patients who were as comparable as
21 possible (similar age, similar treatment intensity)
22 and who had been treated at roughly the same time and
23 over the same period as those used in the Hemofil-T
24 study. The assays performed by Montagnier showed that
25 while Hemofil-T did not transmit HIV the other

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1 concentrates used in the study did. Montagnier's
2 findings, which were reported in the Lancet in
3 February 1985 ... provided the first evidence that the
4 HIV virus was heat labile. Although I was verbally
5 informed of the results of the assays in
6 September 1984 they were not formally reported in the
7 medical press until February 1985."

8 The Lancet article can be found at
9 SHPL0000371_036. It's The Lancet, 2 February 1985,
10 pages 271 to 272.

11 I note there, sir, that Dr Kingdon expresses
12 this as the first evidence that HIV was heat labile.

13 I see you shaking your head, and you're on the
14 same page as a Clifford Chance lawyer in the 1980s,
15 because exactly the point that I anticipate you're
16 about to raise was raised in the draft with
17 Dr Kingdon. If we could go, please, to page 24.

18 The comments in bold from the lawyer, which
19 again concerns this point about it being the first
20 evidence that it was heat labile is:

21 "Are you sure this is correct? I understand
22 that the Cutter also reported in or around
23 October 1984 that they had conducted studies showing
24 that their product was heat labile. This was referred
25 into the MMWR on 26 October 1984."

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1 Dr Kingdon's response, which was an internal
2 response, not to be put into the statement, was:
3 "Yes, I am sure that this is correct."
4 He says, and I quote:
5 "The Cutter study was a laboratory study done in
6 collaboration with CDC, and (1) was flawed by moisture
7 in the dried product (2) had no clinical proof of HIV
8 kill."

9 So that is the reason why Dr Kingdon made the
10 comment that he did. Again, the distinction is drawn
11 between a study which is done in laboratory
12 circumstances, rather than a study that is done on the
13 product as manufactured.

14 **SIR BRIAN LANGSTAFF:** Yes.

15 **MR HILL:** Dr Kingdon goes on to say that a heat-treated
16 version of Proplex, Proplex-T, was also introduced by
17 Hyland, although it was later found that
18 non-heat-treated Proplex inactivated HIV due to the
19 use of ethanol in the manufacturing process. That's
20 paragraphs 58 to 61.

21 Hyland subsequently moved away from heat-treated
22 products and instead used a solvent detergent method
23 of viral inactivation. This was licensed from
24 a technique patented by the New York Blood Center.
25 The resulting Factor VIII product was Hemofil-M, and

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1 the process was adopted in order to inactivate non-A,
2 non-B hepatitis.

3 That's at paragraph 41.

4 I won't go through any more of Dr Kingdon's
5 statement now, sir, but I'm sure it is a document to
6 which we will return at some later stage.

7 Turning then to the UK situation. Travenol Ltd,
8 so the UK company, applied for a UK product licence
9 for Hemofil on 3 November 1972. The reference for
10 that is DHSC0003741_104. There is, however, evidence
11 that Hemofil had been available in the United Kingdom
12 before that licence application.

13 Can we have on screen, please, Soumik,
14 SHPL0000276_181.

15 This, as you will see, is a letter from the
16 Department of Health and Social Security to Travenol
17 Laboratories Ltd. It is dated 12 October 1972, and it
18 comes and its signed from an MC Laut (?). It is
19 marked "For the attention of BL Steer". It says this:

20 "1. I am writing with regard to your
21 application for a licence under Part 1 of the
22 Therapeutic Substances Act 1956 to enable you to
23 import HEMOFIL (Factor VIII) and the visit by
24 inspectors of the licensing authority to your premises
25 at Bowles House on 29 July. As you are aware the

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1 visit was made as a result of promotional literature
2 relating to hemofil (a copy of which is enclosed)
3 coming into the possession of the licensing authority
4 which implied that the product was available in this
5 country.

6 "2. The inspectors on the occasion of their
7 visit ascertained that a consignment of hemofil had
8 been imported recently, that stocks of hemofil were in
9 your possession and that quantities had been sold and
10 supplied to a number of doctors.

11 "3. You should know that:-

12 "(a) under section 3 of the Therapeutic
13 Substances Act 1956 the importation of a substance
14 controlled under Part 1 of the Act is prohibited
15 unless the substance is consigned to a person licensed
16 by the licensing authority to import it;

17 "(b) under section C of the [Therapeutic]" --

18 **SIR BRIAN LANGSTAFF:** Section 6, I think.

19 **MR HILL:** Sorry.

20 "... under section 6 of the [Therapeutic
21 Substances] Act it is an offence for a person (i) to
22 sell or have in his possession for sale a controlled
23 substance knowing it to have been manufactured or
24 imported in contravention of Part 1 of the Act or the
25 regulations made thereunder; (ii) to fail to comply

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1 with the provisions of any regulation made under
2 Part 1 of the Act;.

3 "(c) under section 45(1) of the Medicines Act it
4 is an offence for any person to import any medicinal
5 product except in accordance with a product licence,
6 as also is the possession of that product for the
7 purpose of selling or supplying;

8 "(d) under section 96(5) of the Medicines Act it
9 is an offence for a commercially interested party to
10 send or deliver to a doctor advising material relating
11 to a medicinal product without an accompanying data
12 sheet or in advance of such a data sheet being sent or
13 delivered to doctors ..."

14 If we go over the page:

15 "(e) under section 124(1) of the Medicines Act
16 where an offence under the Act which is committed by
17 a body corporate is proved to have been committed with
18 the consent and connivance of, or to be attributable
19 to any neglect on the part of, any director, manager,
20 secretary or similar officer of the body corporate, or
21 any person who was purporting to act in such
22 a capacity, he, as well as the body corporate, shall
23 be guilty of that offence and shall be liable to be
24 proceeded against and punished accordingly.

25 "The Department takes a most serious view of

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1 this matter but have noted the undertaking given by
2 Mr Steer on behalf of the company that there would be
3 no further distribution of hemofil without authority.

4 "I understand you are in the process of
5 preparing an application for a product licence under
6 the Medicines Act for hemofil and I should like to be
7 advised as to when you expect to be in a position to
8 submit the application to the licensing authority.
9 Your application for an import licence under the
10 Therapeutic Substances Act has been received and is
11 under consideration."

12 Sir, I won't take you to the therapeutic
13 substances --

14 **SIR BRIAN LANGSTAFF:** Can you just go back to the heading
15 on the first page, just so we can see what -- it comes
16 from the DHSS Medicines Division.

17 **MR HILL:** Yes, it does.

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

19 **MR HILL:** It is unclear from the documents that the
20 Inquiry has reviewed how much Hemofil had been
21 provided to and used by doctors in the United Kingdom
22 at that time. The Hemofil product licence -- sorry,
23 the application for the Hemofil product licence noted
24 that while no organised clinical trials of the product
25 had been carried out, it had been, and I quote,

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1 "The Availability of Factor VIII concentrates
2 represents a major advance in the care of patients
3 with classical haemophilia. Such concentrates have
4 enabled corrective orthopaedic procedures to be
5 carried out, and for the first time there is
6 a prospect of domiciliary treatment. The major
7 disadvantage of currently available commercial
8 preparations, such as Hemofil, is that they are
9 prepared from very large plasma pools, and carry the
10 risk of transmitting hepatitis virus. Hyland screen
11 all their donors for hepatitis-associated antigen,
12 which reduces but does not eliminate this risk.
13 However, no attempt is made to disguise the risk of
14 hepatitis, and it may be considered that the decision
15 to use this material could be left to the individual
16 clinician who can balance the potential hazard against
17 the anticipated therapeutic benefit to the patient.

18 "It is recommended that a product licence be
19 granted."

20 That is Dr Thomas' comment.

21 The reference to "no attempt [being] made to
22 disguise the risk" is a reference to some of the data
23 sheets and packaging that we will come on to later.

24 Dr Thomas also provided the subcommittee with
25 his summary of a report that had been produced

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1 "administered to two patients in an emergency
2 situation at St Thomas' Hospital". The results of
3 this applications of Hemofil were described as
4 "successful treatments" and they were included in the
5 application itself.

6 The reference for that is SHPL0000275_029.

7 The Hemofil application was considered by the
8 Committee on the Safety of Medicines Subcommittee on
9 Toxicity and Clinical Trials and the Subcommittee on
10 Biologicals in December 1972 and January 1973
11 respectively.

12 Dr Thomas -- this is Duncan Thomas, who we came
13 across yesterday as well -- prepared a report for the
14 subcommittees. Could we have on screen, please,
15 Soumik. It is DHSC0105593_006.

16 We can see on the top right corner, "Report
17 by: Dr Thomas". The subcommittees are listed just
18 underneath that, and the dates of the meetings are
19 given the box there.

20 It is stated to be an application under the
21 1968 Act for a product licence.

22 If we could turn, please, to page 14 of this
23 document. This is for "Medical Comment". It comes
24 from Dr Thomas. So this is a summary of what he has
25 found in the rest of his report:

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1 following an inspection of Hyland Laboratories in
2 California and a blood bank in San Francisco owned by
3 Hyland. This inspection had taken place in
4 October 1972.

5 Could we have, please, DHSC0105593_006.

6 I'm sorry; page 15 of the document.

7 In the bottom right-hand corner we can see the
8 initial DPT, which are Dr Thomas' initials. At the
9 top we can see that is a summary of the inspection
10 report. I don't have the full report for you, sir.

11 We will continue to see if we can find it.

12 This is the summary.

13 "Hyland Laboratories, Costa Mesa, California,
14 were inspected on October 24th, 1972. In addition,
15 a commercial blood bank in downtown Los Angeles, owned
16 and operated by Hyland, was also inspected.

17 "The blood bank performed plasmapheresis on
18 between 200-300 people daily. 1000 ml blood was
19 collected from the donors (in two steps) and the cells
20 returned. This was done twice weekly on the 'regular
21 customers', who constituted about 50% of the total
22 number of donors. The donors were all men, mostly
23 middle-aged, and predominantly of Mexican origin.
24 They were euphemistically described to me as 'people
25 who need \$5', which is the amount they were paid for

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1 each donation of blood. From what I saw, they were
 2 certainly not affluent, although they could not fairly
 3 be described as down-and-out alcoholics. Neither did
 4 they seem to be youthful hippies, for the most part.
 5 However, the medical screening of the donors was
 6 rudimentary: a microhaematocrit determination of ear
 7 lobe capillary blood, blood pressure and temperature,
 8 and that was about all. Probably the most important
 9 screening carried out was routine testing for
 10 hepatitis-associated antigen, using Hyland's own
 11 counterelectrophoresis kit. This testing is carried
 12 out on all blood that is collected, on every visit,
 13 and before the plasma leaves for the blood bank.
 14 Several aspects of the whole operation do not meet
 15 TS Regulations [I take that to mean therapeutic
 16 substances]. For example, the transfusion needle is
 17 not inserted by a doctor, the donors are not screened
 18 for syphilis, more than 420 ml blood is removed at one
 19 session, and a haematocrit and not a haemoglobin
 20 determination is made. However, it is hoped that the
 21 sub-committee will advise the licensing authority on
 22 the relevance of some of these requirements in the
 23 present context.

24 "At the factory, plasma is pooled, and the pools
 25 contain plasma from as many as 6,000 donors. The

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1 fractionation process is carried out under excellent
 2 conditions in a modern, well-equipped plant. The
 3 personnel seemed highly competent and well-informed.
 4 My only criticism was that the aseptic filling area
 5 was small and overcrowded, and they placed too much
 6 reliance on laminar flow cabinets. However, a new
 7 filling area was due to be built within a matter of
 8 weeks.

9 "Standardisation of the Factor VIII concentrate
 10 is carried out using a house standard, and not the
 11 International Standard. They promised to mend their
 12 ways, but I am doubtful if they will, unless required
 13 to do so.

14 "In conclusion, obviously the main problem with
 15 this product is the hepatitis hazard. The donors do
 16 not inspire confidence, and Factor VIII concentrate is
 17 prepared from very large plasma pools. Despite the
 18 HAA testing, the risk of hepatitis must still be
 19 considered to be present. However, the firm make no
 20 attempt to disguise this potential hazard."

21 That was the summary of the inspection report
 22 and it was included in the documents that was sent by
 23 Dr Thomas to the subcommittees for their consideration
 24 as part of the licence application.

25 Dr Maycock wrote to Dr Thomas on 4 January 1973.

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1 That is the letter that we looked at yesterday. He
 2 expressed the same view in respect of Hemofil as he
 3 did with Kryobulin. The reference is DHSC0100026_163.
 4 In short, he generally supported Dr Thomas' report,
 5 but he suggested that initially the licence, if it is
 6 to be granted, be restricted to just a few haemophilia
 7 centres so that efficacy can be assessed.

8 The problem that we have, sir, is that we have
 9 little documentation about what happened next in the
 10 licensing process. In particular, we haven't yet
 11 identified whether or not any conditions were attached
 12 to a licence which was granted.

13 The DHSS informed Travenol on 19 February 1973
 14 that the Licensing Authority proposed to grant
 15 a product licence. The reference for that is
 16 DHSC0003741_104. The licence itself was issued on
 17 10 September 1973, SHPL0000276_159.

18 **SIR BRIAN LANGSTAFF:** So as from 19 February it was
 19 effectively licensed?

20 **MR HILL:** Yes.

21 **SIR BRIAN LANGSTAFF:** In the same way as Kryobulin was
 22 from 22 March?

23 **MR HILL:** Yes. Let me just check that, sir. If we go to
 24 DHSC0003741_104, we can see the letter is
 25 19 February 1973, and it refers to the application

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1 dated 3 November. But then it says:

2 "As amended by your letters dated 3 and 5
 3 January and 5 February 1973, the Licensing Authority
 4 proposes to grant a product licence for ..."

5 Then Hemofil is given and then there are some
 6 conditions attached to the potency of the unit being
 7 expressed in international units:

8 "The supply of the product will be restricted to
 9 hospitals and haemophilia centres and the provisions
 10 set out in regulations 4(g), (h) and (i) of the
 11 Therapeutic Substances Manufacture and Importation
 12 General Regulations 1963 shall apply."

13 So those are the conditions that are expressly
 14 attached there.

15 It goes in the next page to say:

16 "The product licence will also include
 17 a provision that the number of the licence shall
 18 appear on all containers or packages in which the
 19 product is packed and on any package inserts or
 20 accompanying literature.

21 "The formal documents relating to the issue of
 22 the licence are being prepared and will be sent to you
 23 in due course.

24 "Please let me know the date on which the
 25 product is introduced on to the market."

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1 In terms of Kryobulin, there is an express
2 reference to the fact that this letter of intent can
3 be used as a full product licence until the full
4 product licence is received. There is no such
5 expression in this letter --
6 **SIR BRIAN LANGSTAFF:** Well, it seems to almost to follow
7 from the expression "the formal documents relating to
8 the issue of licence".
9 **MR HILL:** Precisely.
10 **SIR BRIAN LANGSTAFF:** So the intention looks to be
11 precisely the same.
12 **MR HILL:** I think that is a fair inference from the
13 document, sir.
14 **SIR BRIAN LANGSTAFF:** So, as from February of '73, the --
15 Hemofil was on the market --
16 **MR HILL:** Yes.
17 **SIR BRIAN LANGSTAFF:** -- officially?
18 **MR HILL:** Officially. A further point that I would make
19 there is that there are references to the letters of
20 3 and 5 January and 5 February 1973. We haven't yet
21 been able to identify those. It is likely and,
22 indeed, I'll go as far as probable, that those letters
23 concern some amendments or some undertakings that the
24 company have made in respect of the licensing process
25 in order to get the licence through. Unfortunately,

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1 the product had to have a non-reactive test result
2 before it could be released for sale. The variation
3 application was accepted in June 1975."
4 The reference is SHPL0000276_185. That is
5 30 May 1975.
6 We have got, sir, to the section, or the part of
7 the chronology where the World in Action documentary,
8 Blood Money, arises. This was broadcast on
9 1 December 1975, the second part was broadcast on
10 8 December 1975. But it is the first part in which
11 Hyland's facilities are -- form the basis of the
12 investigation that took place there.
13 It is my intention to share about 20 minutes of
14 that documentary, which shows what was actually
15 happening in and around the donor centres that Hyland
16 were using. Are you content for me to do that now,
17 sir?
18 **SIR BRIAN LANGSTAFF:** Do you need time to set it up at
19 all?
20 **MR HILL:** It has been set up, so it --
21 **SIR BRIAN LANGSTAFF:** Well, let's see it now, shall we?
22 **MR HILL:** The reference, sir, is MDIA0000113, and it's
23 from about six minutes and four seconds into it.
24 (Video played)
25 **MR HILL:** We won't go any further onto the World in Action

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1 we don't have them or at least we haven't found them
2 yet.
3 The licence itself, the formal licence was
4 issued on 10 September 1973, that's SHPL0000276_159.
5 Again, as with Kryobulin, despite Dr Maycock's
6 proposal, there wasn't an initial restriction to just
7 a few haemophilia centres.
8 Travenol were also granted an import licence
9 under the Therapeutic Substances Act on 15 March 1973.
10 The reference to that is SHPL0000276_167.
11 As we saw yesterday, Travenol were included as
12 one of the parties to the central contract with the
13 DHSS, which ran from 1 November 1973. The other party
14 was Serological Products Ltd, so that's Kryobulin and
15 Hemofil and, as we heard yesterday, certainly at one
16 stage the intention was for 5 million international
17 units of each.
18 Travenol Ltd submitted an application to vary
19 the product licence for Hemofil on 30 May 1975, and
20 that is to include a reference to the use of RIA
21 testing for hepatitis B. It was set out as part of
22 that application: **
23 "Each unit of plasma was tested for HBsAg by
24 counterelectrophoresis and the final product was then
25 tested for HBsAG using the Ausria II kit. Each lot of

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1 documentary, as they move back to the United Kingdom
2 after that, sir. I'm conscious of the time, sir.
3 **SIR BRIAN LANGSTAFF:** Yes. We'll take a break, shall we,
4 until 3.45.
5 **MR HILL:** Thank you, sir.
6 (3.17 pm)
7 (A short break)
8 (3.45 pm)
9 **SIR BRIAN LANGSTAFF:** Just before you start again,
10 Mr Hill, let me just say something to those who may
11 have been watching or should I say, hoping to watch on
12 YouTube. I'm very sorry that it seems that your
13 transmission was shut off. Let me explain why.
14 The YouTube systems detected, so I'm told, that
15 something which they thought was copyright was being
16 displayed, and their systems are such that it
17 instantly shut down the transmission. It was
18 copyright; of course we had the right to play it, but
19 that was why you didn't see what you may already have
20 picked up from other sources, which is the
21 transmission of 1 December 1975 from World in Action.
22 We're back online now, if you haven't been
23 discouraged from continuing to watch. I'm sorry, once
24 again, for that, but I hope that's a sufficient
25 explanation. It's what I've been told. And we're

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1 ready to begin.

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

3 Before we return to the narrative for Travenol

4 and Hemofil, I'm just going to refer back to some

5 evidence that we heard about Immuno, and in particular

6 about Mr Berry and what he said in 1979 about the

7 difference between American plasma Kryobulin and

8 European plasma.

9 **SIR BRIAN LANGSTAFF:** What he was reported as saying?

10 **MR HILL:** What he was reported to have said, precisely,

11 sir.

12 So if we could, please, on the screen, Soumik

13 HCDO0000403.

14 This is at page 3 of the minutes of the

15 Haemophilia Reference Centre Directors meeting of

16 6 April 1979. The document that we looked at

17 yesterday. The relevant section in particular being:

18 "Professor Ingram has been in contact with

19 Mr Berry photograph Immuno who has said that their

20 action was aimed at making available to clinicians

21 material which may carry less risk of transmitting

22 hepatitis."

23 If we could also have onscreen, please, a split

24 screen, LOTH0000012_136.

25 I should say that I'm grateful to Ms Gollop for

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1 respect of that is that the reference to "the Company"

2 is -- it is unclear whether that is intended to refer

3 to Immuno Ltd, the UK company, or Immuno AG, the

4 Austrian company, or both. And this record was in

5 1979. The document that we looked at, the internal

6 Immuno AG document that we looked at yesterday, in

7 which reference was made to the hepatitis risk of the

8 two products, that was from 1976.

9 **SIR BRIAN LANGSTAFF:** Thank you very much for that.

10 It's important that that should be there to

11 stand beside the evidence that we've thus far heard.

12 Is there any evidence to show that Mr Berry was aware

13 of the way in which the discussion at Immuno AG was

14 recorded, where Immuno AG recorded a view which

15 essentially meant that they would seek to licence

16 American product?

17 **MR HILL:** I have no evidence that Mr Berry was aware of

18 that discussion.

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

20 **MR HILL:** Another point that you raised, sir -- thank you,

21 Soumik, we can take that off the screen. Can we have

22 instead CBLA0000011_005, page 9. I'm grateful to

23 Mr Cummins for this -- you asked about when it was

24 that donations were pooled as per the description that

25 had been given by Dr Kingdon of Hyland's processes.

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1 bringing this to my attention. This is a letter

2 written on 8 August 1979 by Professor Ingram to

3 Dr Rizza, who had, as we understand it, prepared those

4 minutes. What Professor Ingram says is:

5 "Thank you for sending me the Minutes of the

6 Eighth Meeting of Haemophilia Reference Centre

7 Directors. At the top of page 3, I would like to ask

8 you to expand the record of my reported conversation

9 with Mr Berry of Immuno. Would you please replace the

10 latter part of that sentence with ..."

11 And I quote now; and I understand this to follow

12 on from the section where it said:

13 "Professor Ingram has been in contact with

14 Mr Berry of Immuno ..."

15 The new version is:

16 "... who had said that the American ('blue')

17 material was offered for those who wished to take

18 advantage of the lower American price, where as the

19 European ('red') material was still available for

20 those who felt that it carried a lower risk of

21 conveying hepatitis, although the Company regarded

22 both products as equally safe."

23 That is Professor Ingram correcting the minute

24 which purported to record what Mr Berry had told him.

25 The only additional points I would make in

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1 The answer comes in paragraph 22 of his statement,

2 which follows on from the section that I read, which

3 says that:

4 "Once the computerised inspection is completed

5 the donations are combined into a start pool."

6 The context of that is that the donation has by

7 that stage already been tested at Hyland's testing

8 centre, and has also been transported to Hyland's

9 manufacturing centre, and there has been a period in

10 which it has sat in quarantine at the manufacturing

11 centre. It has then been processed on a -- at least

12 by 1990, when this statement was written, it had been

13 inspected via a computerised line, which had been

14 introduced in 1984-85, and it wasn't only after that

15 inspection that the different donations then get

16 pulled together.

17 **SIR BRIAN LANGSTAFF:** There is some reference, which you

18 showed me earlier, about the greater difficulty of

19 doing something manually. What --

20 **MR HILL:** If we could go, please, Soumik, to the previous

21 page, page 8. It's actually the previous paragraph,

22 paragraph 21. This is the section that we read

23 earlier.

24 **SIR BRIAN LANGSTAFF:** Yes.

25 **MR HILL:** The computerised inspection line was introduced

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1 in 1984-5. Prior to this the same procedures were
 2 undertaken manually."
 3 That is where the revised statement ends. The
 4 first draft, prior to Dr Kingdon's revision, went to
 5 complete that sentence by saying:
 6 "... although under the manual procedure,
 7 donations from donors who had sero-converted between
 8 one donation and other were unable to be removed."
 9 **SIR BRIAN LANGSTAFF:** So in other words, if that had
 10 stood, it would be saying that until the computerised
 11 line was introduced, then the material was liable to
 12 be pooled without a donation -- the fact that
 13 a donation was infected, or potentially infected, and
 14 having the result of the donation itself being
 15 withdrawn. Is that what it's saying?
 16 **MR HILL:** What I understood this to mean is that the
 17 computerised system allows the operator to run a bar
 18 code, and if the bar code flags up that that person
 19 has now tested positive for HIV, then previous
 20 donations can be pulled from the line if they still
 21 exist.
 22 **SIR BRIAN LANGSTAFF:** Yes.
 23 **MR HILL:** Under the manual system, that stage wasn't
 24 possible.
 25 **SIR BRIAN LANGSTAFF:** I see.

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1 **MR HILL:** But it may be that you could still pull that
 2 donation, but you just couldn't identify the other
 3 ones.
 4 **SIR BRIAN LANGSTAFF:** So it may be previous donations
 5 which hadn't yet got to the stage of being pooled,
 6 but -- or may have been pooled?
 7 **MR HILL:** Yes. I stress that is my interpretation of the
 8 statement, others may be available.
 9 **SIR BRIAN LANGSTAFF:** Well, it's not clear. The true
 10 meaning may be a matter of submission in due course.
 11 **MR HILL:** Yes. And as you said, sir, we don't know why
 12 that was struck through by --
 13 **SIR BRIAN LANGSTAFF:** No, but plainly he didn't wish it to
 14 be in for whatever reason.
 15 **MR HILL:** Yes.
 16 Soumik, can we have on screen, please,
 17 MHRA0004180.
 18 We're returning now, sir, to the narrative.
 19 We can see that this document this entitled
 20 "Note of a Meeting of the Divisional Management Group
 21 held on 9 December 1975". This is a DHSS group. We
 22 can see Dr Holgate's name there, amongst a number of
 23 other people who were involved in that meeting.
 24 If we could go to page 3, please, Soumik, under
 25 "Any Other Business". 9 December, the day after the

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1 second of the World in Action documentaries had been
 2 broadcast, and eight days after the first.
 3 "Any Other Business."
 4 "4.1. Blood Coagulation Factors for Haemophilia
 5 "Mr Tringham reported that a television 'World
 6 in Action' film had made criticisms of Travenol's
 7 production of 'Factor VIII' in the USA. The
 8 criticisms were in conformity with an inspection
 9 report carried out on behalf of the Division. The
 10 Minister of State had been briefed and was concerned
 11 about the supply of the Factor and about the hazards
 12 of using it."
 13 I pause there to say that the Minister of State
 14 at the time was Dr Owen:
 15 "A similar product manufactured by Armour had
 16 recently been cleared by the Committee on Safety of
 17 Medicines; Supply Division were anxious that it should
 18 be licensed as it would be available at a lower price
 19 than the Travenol product. There was some doubt as to
 20 whether the collection of blood products for either
 21 product was satisfactory. Dr Holgate said that he
 22 doubted whether inspection of the American collection
 23 centres would be useful. What was needed was to
 24 strengthen the requirements in the product licence,
 25 and to insist on returns from each collecting centre,

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1 including the rate of rejection of donors or
 2 donations.
 3 "The story of the television film was that
 4 Britain could be self-sufficient in factors for
 5 haemophilia within a few years. The Department in
 6 1972 had allocated £500,000 and had bought the
 7 equipment needed for production. However, there was
 8 some difficulties. Neither of the production units
 9 had applied for product licences. The SHHD [that is
 10 the Scottish Home and Health Division] had written to
 11 the factory at Liberton, and Medicines Division
 12 reminded HS2 Division that although the Lister
 13 Institute of Preventative Medicine (Elstree) had
 14 a contract with the Department, this did not give them
 15 exemption from the requirement to hold a product
 16 licence. Mr Tringham emphasised that his concern was
 17 to regularise the situation, not to stop production.
 18 The haemophiliac patients' group were protesting at
 19 the delays in commissioning plant. Supply Division
 20 were concerned that in the meantime doctors might
 21 develop brand preferences for the imported products.
 22 Dr Holgate said that doctors would prefer the British
 23 products as being safer. Indeed, once a pure supply
 24 is available, doctors will want to use the product in
 25 situations in which the currently available Factors

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1 would be too great a risk."

2 That is the end of that discussion. The

3 reference to the Armour application is one that will

4 be picked up next week in the presentation on Armour.

5 Soumik, DHSC0003719118, please.

6 This is a document that we looked at yesterday,

7 sir, and it's designed to show how much Hemofil was

8 being used as of this time, which is 21 December 1976.

9 So we've moved on another year down the line.

10 The October sales, in 1976, for the Travenol

11 product, which we take to be Hemofil, were 865,680

12 international units, and overall, for the 12 months to

13 31 October 1976, a little over 5.2 million

14 international units, at a value of £627,738.

15 It is, as we can see there, the most used

16 commercial product at that time.

17 On 26 August 1977 -- so, again, a leap forward

18 of almost a year -- Travenol submitted an application

19 to vary the product licence in order to add the

20 facility at Lessines in Belgium as a manufacturer, and

21 to include a correction to the test method used for

22 screening each plasma donation for hepatitis B surface

23 antigen. And the correction was that each plasma

24 donation was tested using solid phase radioimmunoassay

25 procedure rather than counter-electrophoresis. The

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1 variation application was withdrawn on

2 30 January 1978, and instead it was said that the

3 changes would be included in the renewal application

4 for the licence.

5 That's SHPL0000276_106, and the same stem, _081.

6 The product licence was renewed on

7 19 February 1978, SHPL0000283_005.

8 We have looked at the 1980 annual returns

9 before. I won't bring them up. I will simply remind

10 people of the figures. As of 1980, the Royal Free

11 Hospital treated patients with approximately

12 31,500 units of Hemofil, making it the least used of

13 their commercial concentrates, other than a Speywood

14 product.

15 By contrast, the Royal Free used more than

16 2 million units of Factor VIII -- forgive me, I've

17 gone on to the wrong product there.

18 So Royal Free, 31,500 units of Hemofil.

19 Royal Victoria Infirmary in Newcastle, 54,400 units of

20 Hemofil. Again, the lowest of all of its

21 concentrates.

22 Northern Ireland recorded more than 520,000

23 units of Hemofil, which made it second after

24 Kryobulin. As we saw yesterday, Hemofil in

25 Northern Ireland was used for in-patients, and

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1 patients with Factor VIII antibodies, whereas

2 Kryobulin tended to be used in the home treatment.

3 In 1979, Hyland and Travenol introduced

4 a variant of Hemofil, which was called Hemofil 2. We

5 haven't identified many documents about Hemofil 2.

6 Those which we have identified show that it was on the

7 market until November 1982, when it was taken off for

8 commercial reasons. It was said to be unprofitable in

9 light of currency variations in particular. The

10 original Hemofil was classed as a high purity product.

11 Hemofil 2 was an intermediate purity product and was

12 intended to be sold at a lower price. But ultimately

13 that didn't prove economic for the company, and that's

14 why it was taken off the market.

15 The reference is DHSC0002223_055, and then the

16 same stem, _056, the same stem, _058.

17 The Inquiry hasn't identified any documents

18 indicating that Hemofil 2 received a product licence.

19 There is then a twist in the story, which we,

20 frankly, haven't got to the bottom of yet. On

21 16 December 1982 -- so we've moved forward several

22 years and we're getting towards the end of the

23 five-year period under which the then active licence

24 ran -- on 16 December 1982, Travenol submitted

25 a renewed application or -- sorry a renewal

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1 application for Hemofil, and they did it on

2 a particular form. As per a request by the DHSS they

3 then resubmitted it under a different form, and it was

4 called the "Review/renewal of expiry licence form".

5 That was done on 26 October 1983.

6 Renewal documents were never sent back to

7 Travenol, Travenol Ltd, this is, and we can see from

8 the correspondence that they assumed that the

9 Department had renewed the product licence under that

10 new scheme. By late November 1984, however,

11 Travenol Ltd had been informed that the blood products

12 were not covered by this scheme. So even though the

13 DHSS had told them to reapply under that scheme,

14 actually it didn't cover blood products. The Hemofil

15 product licence expired on 19 March 1983. So there is

16 then this period between 19 March 1983 and

17 November 1984, where there is a legal issue,

18 I suppose, as to the status of Hemofil as to whether

19 it was a licensed product or not. The references are

20 MHRA0009345, SHPL0000283_005.

21 There is confusion there, and I don't seek now

22 to pretend that we have got to the bottom of that or

23 to attribute any responsibility for where that

24 confusion lay.

25 The document from 28 June 1983 that we looked at

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yesterday, which is the table that the DHSS compiled showing the answers that they had got to Dr Walford's questionnaire, showed that Hemofil had an annual sale of 8 to 9 million international units, making it one of the most-used Factor VIII products, but some way behind the alleging product at that time, which was Factorate, which was somewhere in the region of 15 to 20 million international units.

We have now reached the part of the narrative where we get on to the heat-treated product. As we know from Dr Kingdon's statement, the American company had been pursuing heat treatment for some time, by this stage. The first clinical trials had taken place in France in 1982; in March 1983, the FDA granted a licence for Hemofil-T in the United States; in April 1983, the West German authorities granted a licence for Hemofil; and by the time that the UK application came to be made, which is what we will look at in a second, Hemofil-T had also been licensed for sale in Canada, Spain, Sweden, Belgium and Ireland.

Reference for that is SHPL0000283_005 and also paragraph 51 and 46 of Dr Kingdon's statement.

In April 1983, Travenol Ltd met with Dr Fowler and Dr Purves of the Medicines Division of the DHSS to

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discuss Hyland products in general and regulatory issues, and it's in this context that they raised the heat treatment of Hemofil. Could we have on screen, please, Soumik SHPL0000233_058.

This is an internal Travenol Ltd document, it's a British company and we can see its address in Norfolk in the top right-hand corner. We can see it is from Mr Cameron to Mr Chard, copied to various others, dated 25 April 1983 the subject "Meeting at DHSS with Drs Fowler and Purves". If we could expand that, please, a little. Thank you very much, Soumik.

The minute records:

"C Chard and A Cameron met [Dr Fowler] and [Dr Purves] of the Medicines Division of the DHSS to discuss issues relating to the Hyland Therapeutic Ranges and several other Regulatory areas."

The first thing they discuss are plasma protein fractions and Buminat, I won't trouble you with that. Second Hemofil-T, at the bottom of that page:

"Drs Fowler and Purves had previously received details of this study and stated that they could not really comment on this product and we should submit the file and wait for the response. The Final Product Licence Application would have to be seen at Committee level and, although product costs should not come into

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the discussion, the overall cost/benefit would be examined."

I can't assist as to what was meant by that comment. If we could go on to the next page, please, Soumik:

"One issue that would have to be included in the final submission would be a quantification of hepatitis risk reduction on heating."

We can see there, sir, another example of how the licensing process works: there are meetings between DHSS officials and the companies, and the DHSS officials tell them the kind of things that would expect to see in a licence application.

"Overall Conclusions

"The meeting proved very useful and Drs Fowler and Purves made many constructive suggestions as to future Regulatory approaches for new products."

Over onto the next page, please, Soumik:

"One point that was raised by Dr Fowler was the increasing use of 'Release on Prescription Only' as a means of marketing products without a Product Licence. This issue has been raised at a very high level (Secretary of State for Health) and has occurred because of large figures appearing on Health Authority budgets for products which are not licensed. The DHSS

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considers that the 'Prescription Only' system of release is being misused by several companies -- as an alternative to obtaining a Product Licence. There is a considerable likelihood of the system being 'tightened-up' to prevent continued abuse by large companies."

That takes us back, sir, to a commentary made yesterday about why it was that the 1984 order was made, and the motivation behind that. This document, perhaps, gives us some insight into that, and why the system was -- why it was felt needed to tighten the system up.

In May 1983, Travenol submitted a variation to the product licence for Hemofil to incorporate a dry heat treatment step at 60 degrees for 72 hours in the final stages of manufacture. So that is Hemofil-T. The CSM Subcommittee on Biologicals assessed the application in September 1983, assisted by a report prepared by Dr Fowler and Dr Purves. If we could have on screen, please, DHSC0105556_028.

We can see the names of Drs Fowler and Purves there, the same people who had met with representatives of Travenol Ltd in that previous document that we looked at. The application was received in May 1983, to be considered at the

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1 September 1983 meeting of the Committee on Safety of
2 Medicines.

3 If we could now go to page 5 of this document,
4 please. This is part of the report that was produced
5 for consideration at those meetings and this is from
6 the pharmacist providing a pharmaceutical comment. If
7 we go down to point v, there are various technical
8 observations about the application, and it says that
9 it is noteworthy that, point v:

10 "no reasons have been given for the inclusion of
11 the heat-treatment step. This must raise questions
12 about the justification of such a treatment in view of
13 the fact that up to 20% of the activity of the product
14 may be lost by virtue of its inclusion. This could
15 lead to the product containing up to 20% of
16 degradation products.

17 "NOTE: If it has been included to reduce the
18 chance of transmission of viral infections, one would
19 have expected to see some work with the product spiked
20 with known viruses.

21 "Anecdotal information indicates this step has
22 been included to minimise the chance of transmission
23 of AIDS: but, this assumes that AIDS is a viral
24 mediated infection. There is no evidence to confirm
25 this."

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1 seriously lacking in experimental and clinical detail.

2 "Numbers are small in all the in vivo studies,
3 both animal and human, so even if a full, detailed
4 description of the work had been provided, it might
5 still have been thought insufficient to support this
6 Variation.

7 "Medical recommendation

8 "That this Variation be refused on the grounds
9 that the evidence of safety and efficacy was
10 inadequate.

11 "Remark

12 "The Committee may feel that on the evidence of
13 the two letters sent by Travenol to Transfusion and
14 Haemophilia specialists, that the company are already
15 promoting heat treated Hemofil as being less likely to
16 transmit viral infection, with particular reference to
17 hepatitis B, non-A non-B hepatitis and possibly AIDS."

18 The Inquiry, sir, hasn't identified all of the
19 appendices to which reference is made there. But we
20 have found one. PRSE0004496, please, Soumik. This is
21 a letter dated 9 May 1983, which was sent to the
22 Department of Health and Social Security. It is -- it
23 says "Dear", and then a name has either been removed
24 or was not included, and it is possible that this was
25 a circular that was sent to others as well and that's

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1 If we could then go on, please, to page 7, to
2 the medical comment. This says:

3 "The company applied to vary their product
4 licence for a conventional [Factor VIII] concentrate,
5 by the addition to the manufacturing process of a heat
6 treatment step. No reason is given for this but it
7 may be assumed that they have a reason, because the
8 proposed treatment destroys about 20% of the coagulant
9 activity yield. Two letters sent by the company to
10 Regional Transfusion Directors and specialists in
11 haemophilia, together with the reprint from Hospital
12 Infection Control for May 1983, provide the answer.
13 See APPENDICES 5, 6 & 7.

14 "This application concentrates on the coagulant
15 properties remaining of a product after the heat
16 treatment and skates over the toxic potential of
17 degradation products associated with the loss of 20%
18 of the coagulant activity.

19 "The brief summaries of results obtained from
20 animal and human studies are inadequate for the
21 purposes of assessing this Variation. It will be seen
22 that the reports from in vivo animal studies are
23 conclusions rather than results; there are no data.
24 Although the reports of studies in humans are more
25 forthcoming with regard to data, they are still

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1 certainly the impression one gets from the medical
2 comment that was made. The letter says this:

3 "I want to advise you of important developments
4 and actions being taken by Hyland Therapeutics and
5 Travenol Laboratories in connection with the risks of
6 Acquired Immune Deficiency Syndrome. (AIDS). While
7 the causative agent of this disease remains to be
8 identified, some evidence suggests that it is caused
9 by a virus that can be transmitted by blood and
10 certain blood products."

11 The letter goes on to describe some of the steps
12 that Hyland had taken in response. It also describes
13 how a donor had been identified, although not finally
14 diagnosed, as having been a possible victim of AIDS,
15 and the steps that Hyland in the United States had
16 taken in response to that. It was stressed that no
17 therapeutic products fractionated from plasma pools
18 that contained this donor's plasma had been shipped to
19 any customers in Europe.

20 If we go over to the next page, please, Soumik.
21 Hyland has described the screening procedures that
22 they have put in place. Then they say this in the
23 second paragraph:

24 "In addition to screening procedures to
25 eliminate high risk donor groups, and placing in

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1 quarantine all products made from plasma pools
 2 affected by this donor, Hyland is taking a third major
 3 action it believes could contribute to the safety of
 4 the Haemophilic. Hyland will, as expeditiously as
 5 possible, convert both its European and US facilities
 6 to manufacture only heat treated Factor VIII product.
 7 "This new heat treated product (Hemofil-T) which
 8 Hyland Therapeutics has recently introduced, has equal
 9 potency and effectiveness as normal Hemofil ... but
 10 has been subjected, during manufacture, to
 11 an additional heat treating step designed to reduce
 12 active viral content. This new product is being
 13 offered at only a small price premium over the regular
 14 non-heated product.
 15 "Since the causative agent for AIDS has not been
 16 identified, and since the effects of the heat treating
 17 process on all viruses have been not determined,
 18 Hyland Therapeutics cannot, at present, give assurance
 19 that the heat treated product eliminates the risk of
 20 transmission of AIDS. However, Hyland Therapeutics
 21 believes that administration of the heat treated
 22 product, designed to reduce active viral content, may
 23 increase patient and centre personnel safety."
 24 I won't read the rest of the letter, sir, but
 25 that is one of the letters that have been identified

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1 as being problematic by those who were assessing the
 2 Hemofil-T application.
 3 The Committee on Safety of Medicines Biologicals
 4 Subcommittee concluded that they could not recommend
 5 that the licence be granted or be varied.
 6 Could we have on screen, please, Soumik
 7 DHSC0003951_006. These are the minutes of that
 8 meeting as they referred to Hemofil. They are, as
 9 most such minutes, relatively short. The
 10 recommendation is that:
 11 "On the evidence before them, the Sub-Committee
 12 on grounds of safety, quality and efficacy was unable
 13 to recommend that the Product Licence should be varied
 14 as indicated.
 15 "The Sub-Committee considered that
 16 "1. Justification should be provided for the
 17 inclusion and choice of the heat treatment step.
 18 "2. The heat-treated product was inadequately
 19 characterised.
 20 "3. Inadequate evidence of safety and efficacy
 21 was provided.
 22 "4. In the event of a grant of a variation to
 23 the licence, labels and data sheets should be modified
 24 to the satisfaction of the secretariat."
 25 If you could expand. The "Remarks":

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1 "1. Promotional letters making unjustified
 2 claims on improved safety margins in respect of
 3 infection and AIDS were seen by the Sub-Committee and
 4 strongly deprecated.
 5 "2. Evidence of the long-term safety in
 6 haemophilic patients of treated products such as this
 7 is regarded as an important prerequisite of
 8 licensing."
 9 Travenol were notified on 14 October 1983, that
 10 the variation application had been refused by the
 11 Committee on Safety of Medicines on the grounds that
 12 were listed above as SHPL0000283_005.
 13 Travenol Ltd submitted an additional variation
 14 application for Hemofil in September 1984, to include
 15 a heat treatment step. In November -- and so --
 16 sorry, before I move on to 1984, sorry, I'll just make
 17 the point that this was all taking place in
 18 October 1983. Yesterday when we were discussing
 19 Immuno and the documents that we saw encouraging
 20 companies to apply for heat-treated licences, that was
 21 taking place in the autumn of 1984. So a year later.
 22 It is in that context that we move on to
 23 September 1984, when Travenol Ltd submitted a further
 24 variation application for Hemofil again to add the
 25 heat treatment step.

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1 That is SHPL0000283_005.
 2 In November, the DHSS requested that Travenol
 3 instead submit an abridged licence application for
 4 Hemofil-T, SHPL0000283_005.
 5 As we know, by that time the DHSS were
 6 encouraging all companies to put forward such
 7 applications.
 8 On 30 November 1984, Travenol submitted an
 9 application for the abridged blood product licence.
 10 That's SHPL0000283_005.
 11 I will show one page from that application. Can
 12 we have that on screen, please, Soumik, on page 10 of
 13 that document.
 14 This is part of the application, and this is, as
 15 people will no doubt recognise now, part of the
 16 warning section of the data sheet that would be put
 17 forward. It says:
 18 "Warnings
 19 "This concentrate is prepared from large pools
 20 of fresh human plasma which may contain causative
 21 agents of viral hepatitis. However, each unit of
 22 plasma used in the manufacture of this product has
 23 been found to be non-reactive for hepatitis B surface
 24 antigen ... when tested with licensed third
 25 generations reagents. In addition, this product has

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1 been subjected to a heating procedure during its
 2 manufacturing process designed to reduce the risk of
 3 transmission of hepatitis. Although these testing and
 4 heating steps reduce the risk of hepatitis
 5 transmission, the possibility of such transmission
 6 should be considered in use of the product."
 7 There is, as you will see, sir, no reference to
 8 HTLV-III or LAV or AIDS as part of that warning
 9 section.
 10 A study was submitted with the application.
 11 This can be found under the same reference. That
 12 study was one of the studies referred into
 13 Dr Kingdon's summary, and it's the one that was
 14 carried out across 10 haemophilia centres in five
 15 countries in Europe, including in the UK, under
 16 Dr Savidge and Dr Aronstam. At that stage the study
 17 was reporting 55 per cent of patients had developed
 18 post-transfusion hepatitis. As we know, the figures
 19 change as the results continue to come in.
 20 In each case it was classified as moderate,
 21 non-A, non-B hepatitis. The application also reported
 22 eight adverse reactions to the use of the product,
 23 some of which related to non-A, non-B hepatitis, four
 24 in fact. The company placed this in the context of an
 25 estimated 4,000-plus patients having been treated with

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1 the product, and more than 190 million international
 2 units having been sold. That's a worldwide figure at
 3 that stage, and we've seen that its licensed in other
 4 countries.
 5 The company argued, and I quote, the "reported
 6 rate of adverse reaction is low", and also argued that
 7 "non-A, non-B hepatitis is a common condition in
 8 haemophiliac patients on Factor VIII therapy".
 9 The Licensing Authority granted Hemofil-T
 10 a product licence on 27 February 1985. The reference
 11 for that is CBLA0000006_023.
 12 So that's February 1985. In June 1985,
 13 Travenol Inc withdrew non-heat-treated Hemofil, and
 14 non-heat-treated Proplex from the US market and
 15 replaced unused units with heat-treated units.
 16 That's CGRA0000472.
 17 That's the US market. We are still
 18 investigating what happened in the UK market, and we
 19 will come back to that in November.
 20 There is a further variation application on
 21 13 February 1987 to include a specification that the
 22 product was manufactured exclusively from individual
 23 plasma donations screened for HTLV-III antibodies as
 24 well for hepatitis B surface antigen, and that the
 25 plasma was obtained only from donors with normal ALT

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1 levels. SHPL0000282_004.
 2 I note, again, and similar points were made
 3 earlier, although that application is coming in on
 4 13 February 1987, some of those steps, at least, have
 5 been taken some time before that.
 6 I'm about to move on, sir, to the next
 7 generations of Hemofil, which is Hemofil-M,
 8 a monoclonal purification method. I note the time,
 9 sir, and I wonder if that is a convenient moment.
 10 **SIR BRIAN LANGSTAFF:** So when are we going to complete the
 11 story of Travenol and Hemofil?
 12 **MR HILL:** On Tuesday.
 13 **SIR BRIAN LANGSTAFF:** On Tuesday? Starting at 10?
 14 **MR HILL:** I'm in your hands on that, sir.
 15 **SIR BRIAN LANGSTAFF:** Well, we'll start at 10.
 16 So 10 o'clock on Tuesday, and that's our next
 17 sitting.
 18 **(4.30 pm)**
 19 **(The hearing adjourned until 10 am on Tuesday,**
 20 **28 September 2021)**
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