

Wednesday, 29 September 2021

(10.00 am)

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

MS RICHARDS: Sir, before I resume where I left off yesterday afternoon, there are a couple of issues from yesterday afternoon I just want to go back to.

The first relates to the January 1976 ministerial submission. So that was the submission made by the Medicines Division as Licensing Authority to the Minister of State for Health, Dr David Owen, in the context of the Armour application.

If we just go back to that, DHSC003742_078. Soumik, I might have missed out a zero there. I think it should be 0003742_078.

Just a moment, I'll check the reference, DHSC003742_078.

This was the submission, if we go to page 3, paragraph 10, just to pick up a point I meant to come back yesterday and didn't, paragraph 10 talks about the in principle availability of inspection by the FDA, and then the author of the submission expressed doubts as to whether the stringent provisions of US law were in fact fully enforced, and then made reference to a letter from the US Assistant Secretary

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interest."

So these appear to be the facts that the Bureau of Biologics articulated to Granada TV.

"1. All injectable plasma derivatives manufactured in the US or manufactured outside the country and shipped to the US are subject to licensure as biologics and must be made in licensed facilities in compliance with organisational of our standards.

"2. Plasma derivatives made outside the US and not shipped into the US are not subject to the regulation by the Food and Drug Administration, regardless of whether or not the manufacturer is a subsidiary or overseas partner of a US pharmaceutical firm.

"3. Source plasma used in manufacturing licensed plasma derivatives, in the US or overseas, must be collected in facilities with US licences. (Mr Gillard requested a list of the names and addresses of these facilities). Source plasma collected in the US for export to unlicensed overseas fractionators must be collected and processed in facilities with US licences. Source plasma collected outside the US and shipped to overseas consignees manufacturing products not licensed by us are not subject to any US regulations.

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for Health to the Chief Medical Officer at annex B. I had meant to come back to that and didn't.

So if we could go to the document at annex B, which is DHSC0100001_036.

This isn't specifically concerned with the Armour application but it's a rare example of a communication directly from the US to the Chief Medical Officer, then Dr Henry Yellowlees, and so I thought it worth perhaps just bringing up onscreen.

We can see it arises in the context of the Granada Television programme enquiries, and Dr Cooper says to Dr Yellowlees:

"I am writing to apprise you of inquiries which have been directed by a Mr Michael Gillard of Granada Television, London, to members of the staff of our Bureau of Biologics in the Food and Drug Administration regarding US export of plasma derivatives to the United Kingdom, specifically export of Antihemophilic Factor ...

"The general gist of Mr Gillard's inquiries seems to rest on the premise that the American pharmaceutical industry is sending material to the United Kingdom which is so unsafe as to be unacceptable in the US. He was apprised of the following facts, which reflect many of his areas of

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"4. Our hepatitis test requirements, published in 1972 and 1975, apply only to source material. We have not required that final products such as plasma derivatives, which are made from pooled plasma, be tested or be non-reactive for hepatitis B surface antigen ..."

That's what is said to be the Bureau of Biologics' understanding of the position of licensing in the US.

There are then a series of queries set out by Dr Cooper addressed to the CMO, and if we go to the last page, last paragraph, the US Assistant Secretary for Health asks if someone can be identified who could correspond directly with the Bureau of Biologics within the FDA.

If we go back to the first page, we can see there's a handwritten entry. I don't know whose handwriting that is. It seems to be "HG" but it could be "HY", so it could be Dr Yellowlees himself.

"For your early comment please and for any factual answers to queries in the text which may be readily available? Which of you will act as 'contact man'?"

So it seems likely that there will be some further communications or correspondence arising from this, and we'll pick that up when we return to Government decision-making in the spring or at some stage in the

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1 early part of next year. But I just thought I should
 2 flag that up rather than leave it as a loose end.
 3 **SIR BRIAN LANGSTAFF:** The bit in question marks in
 4 handwriting, what does that say?
 5 **MS RICHARDS:** I think it says:
 6 "Which of you would act as 'contact man'?"
 7 **SIR BRIAN LANGSTAFF:** Yes, that's what I thought it
 8 probably said. Thank you.
 9 **MS RICHARDS:** Presumably that's a response to the request
 10 to identify someone on your side to communicate with
 11 the FDA.
 12 **SIR BRIAN LANGSTAFF:** Yes.
 13 **MS RICHARDS:** So we'll see whether there's a further
 14 thread of correspondence and, as I say, pick that up
 15 perhaps when we look at further material relating to
 16 the Chief Medical Officer, Dr Yellowlees, next year.
 17 The second point rising from yesterday, is this --
 18 sorry, sir.
 19 **SIR BRIAN LANGSTAFF:** When it said, in the original
 20 minute, there were grounds for thinking US law had not
 21 been fully enforced, where is the supporting material
 22 for that? Because it says in appendix 2 or something.
 23 **MS RICHARDS:** Well, there isn't. So the reference then is
 24 to annex B, which is to this letter.
 25 **SIR BRIAN LANGSTAFF:** Yes -- that's this letter?

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1 any further material which might cast light on why
 2 Armour occupied a particularly dominant position in
 3 the UK market. We will, when we look at the materials
 4 relating to Bayer, either later today or tomorrow, see
 5 that there are quite a lot of observations in internal
 6 Bayer/Cutter/Miles minutes and memoranda and other
 7 records which look at the position of competitors.
 8 And there's some quite useful information in that.
 9 I'll wait until we get to that with the Bayer
 10 presentation. But in the meantime there are a couple
 11 of letters from 1978 from Armour which might provide
 12 some further explanation.
 13 If we look first of all at BPLL0002161, please.
 14 This is a letter dated 1 July 1978 from Armour
 15 addressed to the consultant haematologist. So it
 16 would appear to be, as it were, a letter that may have
 17 been sent to a number of haematologists. It's
 18 effectively a marketing exercise in relation to
 19 Armour. I don't mean that in an inherently pejorative
 20 sense.
 21 So:
 22 "In view of the increasing number of haemophiliacs
 23 receiving treatment in hospitals other than designated
 24 centres, we feel it important, in case you are not
 25 already attached to a Haemophilia Centre, that you

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1 **MS RICHARDS:** This is annex B.
 2 **SIR BRIAN LANGSTAFF:** So this is the letter which, in the
 3 opinion of the author of the minute, leads me to think
 4 that the US law was not being fully enforced?
 5 **MS RICHARDS:** I'm not sure I would read it in that way.
 6 If we go back to the submission DHSC0003742_078.
 7 **SIR BRIAN LANGSTAFF:** Page 3, paragraph 10?
 8 **MS RICHARDS:** Yes, exactly. I don't read paragraph 10 as
 9 relying upon the annex B letter as that, I read that
 10 as being --
 11 **SIR BRIAN LANGSTAFF:** I see, yes.
 12 **MS RICHARDS:** That's the author's view:
 13 "There are ... grounds for [doubt about] whether
 14 the stringent provisions of US law are in fact ..."
 15 **SIR BRIAN LANGSTAFF:** That doesn't arise from the annex.
 16 **MS RICHARDS:** Exactly.
 17 **SIR BRIAN LANGSTAFF:** That arises independently of the
 18 annex. And the annex is, in effect, the official
 19 response from the United States Government.
 20 **MS RICHARDS:** Yes. And there are other annexes to this
 21 submission but they don't relate to that issue.
 22 **SIR BRIAN LANGSTAFF:** Yes, I follow.
 23 **MS RICHARDS:** We can take those down, thank you.
 24 So the second matter arising out of yesterday
 25 afternoon is this: you asked about whether there was

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1 should be familiar with the latest information
 2 relating to our product, FACTORATE.
 3 "As you probably know FACTORATE was introduced
 4 two years ago in June 1976 and has become firmly
 5 established as a leading conversion concentrate in the
 6 majority of UK centres."
 7 Then this:
 8 "The proven quality of the product, the
 9 flexibility of the presentation, and the economical
 10 price structure outlined below present a good case for
 11 the inclusion of FACTORATE in your routine or
 12 emergency treatment programmes."
 13 Then we can see there's information there set out
 14 about the price, on a sliding scale, depending upon
 15 the quality of units. And it's asserted that:
 16 "The above prices are the lowest on the existing
 17 contract for Factor VIII concentrate by 23-42%."
 18 Then the letter continues to talk about the "New
 19 High Potency Factorate". We looked at the licensing
 20 documents in relation to that yesterday.
 21 If we just look over the page, we can see there
 22 are then various other matters set out which are said
 23 to be relevant to a decision as to whether or not to
 24 buy Factorate, so the shelf life, facility of storage,
 25 and then the new home treatment pack. So a redesigned

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1 kit. If we pick it up about three or four paragraphs
2 from the bottom:

3 "We are confident that this new kit which benefits
4 patient and hospital alike will be just as
5 enthusiastically received as the original version."

6 So matters relating to pricing and then matters
7 relating to, as it were, the usability or the
8 attractiveness of the kit which accompanied the
9 provision of the product are being identified as
10 reasons why the consultant haematologist should buy
11 Factorate from Armour.

12 Then there's a second letter, again from 1978, at
13 OXUH0003868_011.

14 This is -- you'll see it's a letter -- in fact,
15 sorry, it's from November 1977. This is addressed to
16 Dr Biggs at Oxford. And we can see information there
17 set out in relation to the price, and below the table
18 it says:

19 "As in previous years, we have tendered our best
20 prices right from the start of the contract in order
21 to ensure the least disruption to the work of your
22 Centre. It is not our intention to amend these in any
23 way during the period of the contract."

24 If we go over the page, we can see again the issue
25 of price emphasised:

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1 approach that was taken by Armour when he gives his
2 evidence in November.

3 **SIR BRIAN LANGSTAFF:** Could we just go back to the very
4 start of that letter, the heading, the roundel.

5 **MS RICHARDS:** The stamp, yes.

6 **SIR BRIAN LANGSTAFF:** Is that 1540 or 7540?

7 **MS RICHARDS:** 1540 donors, is how I'd read it and that's
8 consistent with the figure we saw in -- we'll come on
9 to it when we look at donors again shortly, I think
10 it's in the response to the Department's queries, but
11 1,540 is certainly a figure which appears elsewhere in
12 the material.

13 **SIR BRIAN LANGSTAFF:** So can you help at all to what that
14 relates?

15 **MS RICHARDS:** I'm going to come on to donors. The
16 information that we have is largely drawn from
17 material provided by Armour. There's no, as it were,
18 independent verification of the material but there are
19 two or three documents which deal with pool sizes and
20 numbers of donors or donations around that time. So
21 I'll come back to that.

22 Soumik, was that the end of the document? Thank
23 you.

24 So those were the two matters I wanted to go back
25 to from yesterday. If I now pick matters up where we

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1 "We are very conscious of the fact that all
2 Centres are working to very tight budgets. We're also
3 fully aware of the implications of the new contract
4 prices in respect of maintaining or increasing current
5 levels of treatment and home therapy programmes within
6 the limits of these budgets.

7 "An analysis of the new terms will reveal the true
8 economic advantage of placing some, if not all, of
9 your commercial concentrate business with Armour.

10 "By purchasing FACTORATE against a given sterling
11 budget, your centre will be able to obtain between 50%
12 and 97.5% more Factor VIII concentrate than other
13 commercial products proved for sale on the DHSS
14 market. By purchasing Factorate there will be no need
15 to reduce your programmes involving the use of
16 commercial concentrate in order to keep expenditure
17 within the confines of your budget for 1978. Coupled
18 with this considerable price differential are the
19 added benefits of our presentation."

20 **SIR BRIAN LANGSTAFF:** The figure of 97.5% there is quite
21 remarkable, if it's effectively saying it's half the
22 price.

23 **MS RICHARDS:** Yes. You'll see, sir, this is a letter from
24 Mr Bishop to Dr Biggs and it may be that Mr Bishop
25 will be able to cast some further light on the

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1 left them at the end of yesterday afternoon, we were
2 looking at Armour's clinical trials certificate
3 relating to the Factorate heat-treated product and
4 just to remind those listening of where we had reached
5 yesterday, we'd looked at the application that was
6 made in August 1983 and we looked at the protocol for
7 the study, which involved the recruitment of mild
8 haemophiliacs and those previously untreated into
9 a study. That application was granted in November
10 1983.

11 In December 1983 -- I'm not going to put the
12 documents up for these purposes -- Armour replied to
13 the Department for permission to extend the study of
14 its heat-treated Factorate include an investigation of
15 the pharmacokinetics. That was also to be carried out
16 by Dr Rizza as the existing investigator. So that was
17 a separate study relating to half life, et cetera, and
18 that involved a small number of severe haemophiliacs,
19 and that extension to the CTX was granted in
20 January 1984.

21 If we just go back to, then, the subsequent
22 product licence variation application, so the
23 application for the licence to cover the heat-treated
24 Factorate that was subsequently made in January 1985
25 at ARMO0000164. We looked at this yesterday. If we

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1 just go back to page 32 of this, we'll see that the
2 half life study was completed, so there's the American
3 study which I referred to briefly yesterday and then
4 the bottom of this page, last paragraph, Dr Rizza's
5 half life study. Those studies were undertaken and
6 completed.

7 However, the study to determine non-A, non-B
8 hepatitis infectivity and whether infectivity was
9 reduced through the heat-treated Factorate was
10 effectively abandoned, and there are a handful of
11 documents that cast a little more light on that.

12 If we start with HCDO0000270_031, these are the
13 minutes of a meeting of the Hepatitis Working Party of
14 UKHCDO, 14 September 1983. Just pausing there, before
15 we look at what it says, you'll recall, sir, from
16 other material that we've looked at that the Armour
17 study of its heat-treated Factorate, to see whether it
18 had made any difference to the transmission of non-A,
19 non-B hepatitis, was not the only study being
20 undertaken around this time in relation to so-called
21 hepatitis reduced products.

22 If we look further down this page we can see
23 there's a discussion. So this is, as I say,
24 September 1983 and there's a discussion at (A) of
25 prospective studies of Factor VIII and IX associated

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1 commercial products in such a clinical trial would,
2 therefore, have to take this into account when
3 considering the best product to use. It was proposed
4 to discuss this problem at the annual meeting of the
5 Haemophilia Centre Directors."

6 So there, at around the time that Armour is
7 seeking approval from the Department of Health for its
8 clinical trial, under the CTX procedure, we can see
9 consideration being given by the Hepatitis Working
10 Party of the possible implications in terms of the
11 chances of transmitting AIDS, and directors -- well,
12 it effectively being said that directors would need to
13 give consideration to that.

14 If we then go to CBLA0001861, this is a letter
15 dated 5 July 1984. If we just go to the second page
16 first of all, we'll see it's from Dr Craske -- if we
17 go back to the first page -- and it's to Dr Smith at
18 the Plasma Fractionation Laboratory in Oxford. It's
19 in the context of a protocol for the study of the
20 BPL/PFL hepatitis-reduced product, and we see from the
21 first paragraph.

22 But then we can see, in the third paragraph what
23 happened in relation to the Armour trial, according to
24 Dr Craske:

"The two patients first treated with Armour heat

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1 hepatitis:

2 "Dr Craske said that after discussions at the
3 Haemophilia Reference Centre Directors meeting in
4 January, he had drawn up a protocol for use in trials
5 of hepatitis reduced factor VIII concentrates as
6 a model for any studies which might be undertaken by
7 Haemophilia Centre Directors. This had been
8 circulated to each Haemophilia Centre Director in
9 March 1983 with a covering note from Dr Craske,
10 Dr Rizza and Professor Bloom."

11 We've looked at that on a number of occasions, and
12 then this:

13 "Products of commercial factor VIII were at
14 present being considered for trials. These were the
15 dry heat treated Travenol Laboratories product and the
16 Armour product. The Travenol product had been granted
17 an exemption from a clinical trial certificate and
18 Armour Laboratories had applied for exemption for
19 their product.

20 "In discussion, it became apparent that there was
21 still considerable concern about the possible
22 transmission of an infection related to [AIDS]. It
23 was not known whether the inactivation procedures used
24 in various products inactivated the putative AIDS
25 related virus. Any director considering using the

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1 treated factor VIII contracted non-A, non-B hepatitis
2 two to three weeks after their first transfusion with
3 this material. One patient has become quite ill,
4 sufficient to require admission to the Local
5 Infectious Diseases Unit, but there is no evidence of
6 hepatic pre-coma. So far as is known, there are no
7 complicating factors which might contribute to the
8 severity of this illness. When the full details of
9 this clinical history are available, I think we should
10 consider whether this trial in its present form should
11 be allowed to continue. It will also be necessary to
12 consider whether this will have any effect on any
13 other trials we are proposing. I do not see that the
14 information at present available suggests that we
15 should not proceed with the study of NHS 'hepatitis
16 reduced' factor VIII, but I thought that you should be
17 aware of the results of the use of the Armour
18 material. This case has been reported to the
19 Medicines Division of the DHSS and the relevant batch
20 of Armour factor VIII has been withdrawn from the
21 trial."

22 So there's an update in relation to two patients
23 treated pursuant to the Armour trial.

24 Then if we go to HCDO0000561, we can see this is
25 the September 15, 1984 meeting of the Hepatitis

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1 Working Party of UKHCDO.
 2 If we go further down the page, we can see in the
 3 paragraph headed "Trials of heat treated factor VIII":
 4 "The results of trials of heat treated commercial
 5 factor VIII were reviewed.
 6 "i) Dry heat. The Hemofil HT trial showed a 63%
 7 incidence of elevated transience in patients who had
 8 previously not received factor VIII concentrate. One
 9 patient had also had CMV infection, though it was not
 10 known if this was related to factor VIII treatment."
 11 Then it turns to Armour:
 12 "The trial of the Armour heat treated product had
 13 been suspended by the Company after the occurrence of
 14 2 cases of symptomatic short incubation, Non-A, non-B
 15 hepatitis in one Haemophilia Centre. The results so
 16 far suggested that 'dry' heat treatment of factor VIII
 17 has little effect (if any) on the incidence of Non-A,
 18 non-B hepatitis in first time treated patients."
 19 So that is what happened to -- that element of the
 20 clinical studies being undertaken by Armour. I don't
 21 have the reference to hand but the application that
 22 was consequently filed for the product licence in
 23 January 1985 made clear that the trial had not
 24 proceeded to completion.

25 In fairness I think, perhaps, to Dr Rizza, there's

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1 not recruited all at once but came in for treatment in
 2 the usual random manner and I think that this should
 3 be remembered. In other words although we may have
 4 a group of 500 mildly affect patients on our books,
 5 only a few of those per year require factor
 6 replacement for surgical procedures. I do not think
 7 it would be ethically justified to give the material
 8 without a good clinical indication."

9 So that was Dr Rizza writing in March of 1983 --
 10 of course, the protocol we looked at post-dates that
 11 by several months -- but it perhaps fleshes out the
 12 picture a little more.

13 We do not, I think, have at the moment a clear
 14 understanding of how many centres actually entered
 15 patients in that trial, or which centres, but we may
 16 be able to find more information out about that.

17 Picking matters up, then, with the product licence
 18 variation application for the heat-treated product,
 19 that was approved by the Licensing Authority in
 20 February of 1985 in principle. Up until that point
 21 the product was being marketed effectively on
 22 a named-patient basis in the United Kingdom by Armour.

23 If we then go to ARMO0000167, we can see a letter
 24 from Dr Duncan at the Department of Health to Armour,
 25 dated 27 February 1985, saying in the second

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1 one other document which I think we should perhaps
 2 look at. We have looked at it before. I think
 3 probably at the time of the Oxford Haemophilia Centre
 4 presentation. But it's about the issue of these types
 5 of trial.

6 It's PRSE0000609. This is a letter from Dr Rizza
 7 to Dr Watt at the Scottish National Blood Transfusion
 8 Service dated 1 March 1983. If we pick it up the --
 9 well, I'll pick it up in the second sentence:

10 "I was glad to hear of the progress you are making
 11 in the preparation of hepatitis reduced risk
 12 factor VIII concentrate specially since 3 drug
 13 companies have been in touch with me in the past 3
 14 weeks pushing strongly to formalise studies of their
 15 different preparations in mildly affected
 16 haemophiliacs. I think it will be necessary to use
 17 infrequently or previously untransfused haemophiliacs,
 18 von Willebrand's patients and carriers of haemophilia
 19 to ascertain to what extent hepatitis risk has been
 20 reduced. I see no ethical problem with this. The
 21 difficulty with this kind of study has been and always
 22 will be I think the small number of previously
 23 untransfused patients who come for treatment. At this
 24 Centre we have managed to collect about 30 suitable
 25 patients over a 2 year period but the patients were

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1 paragraph:

2 "... we cannot accept the proposal that the name
 3 [High Potency Factorate] should remain unchanged. The
 4 Licensing Authority is acting on the advice of the
 5 Nomenclature Sub committee of the British Pharmacopeia
 6 which stipulates that the name of all heat-treated
 7 products should have the suffix 'Heat Treated' or
 8 'HT'. In consequence this condition applies not only
 9 to High Potency Factorate ... but also to Factorate
 10 ..."

11 And you've got the two product licence numbers set
 12 out there.

13 "If you confirm in writing that you accept this
 14 condition the variation of these 2 licences can be
 15 approved without delay."

16 So that was a condition imposed by the Licensing
 17 Authority. I don't think we have the actual product
 18 licence, but no reason to doubt that the licence was
 19 issued.

20 If we then go to ARMO0000181, we can see that in
 21 January of 1986 Armour submitted an application to
 22 vary the product licences for both the Factor VIII
 23 heat treated and the High Potency Factorate
 24 heat treated. And if we turn to page 3, we can see
 25 what the proposed variation was on the right-hand

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1 side. It was the addition of information to the
 2 effect that:
 3 "All units of source plasma are tested for
 4 antibodies to ... (HTLV-III) and found to be
 5 negative."
 6 And the reason given is that this test is now
 7 being carried out routinely on all plasma collected.
 8 So that was the formal variation to the product
 9 licence to reflect HTLV-III screening.
 10 If we go on two pages we can see under the heading
 11 "Presentation", third paragraph down, we can see there
 12 again reference to the particular heat treatment
 13 method that was utilised by Armour. That will become
 14 of greater significance when we look at the issue of
 15 seroconversions from the Armour product in November:
 16 "... heated at 60°C for 30 hours."
 17 Then we can see the next sentence:
 18 "All units of source plasma are tested for
 19 antibodies to human T cell ... (HTLV-III) and are
 20 found to be negative."
 21 And those changes were permitted. We don't have
 22 the precise date, but certainly those changes had been
 23 permitted by July of 1986.
 24 If we then just, in terms of interactions with the
 25 Licensing Authority, go to ARMO0000504, this is an

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1 treatment" there's a discussion of switching to
 2 a different method, a 68 degrees for 72 hours cycle
 3 for future heat treatment of Factorate. Then if we go
 4 to the third paragraph, we can then see reference to
 5 ALT testing. What's said is:
 6 "With regard to ALT testing, please note that all
 7 batches produced since March 1986 have been screened
 8 for ALT, the limit for acceptable donations is not
 9 more than 75/ml."
 10 Then there's reference of chasing up details of
 11 the procedure used by Plasma Alliance, the
 12 organisation which ran the plasmapheresis centres, for
 13 the ALT test, and then a discussion about product
 14 labelling. We'll come back to some aspects of
 15 labelling in due course.
 16 **SIR BRIAN LANGSTAFF:** Just before we leave that highlight,
 17 can we go back to it, please, Soumik. It's the third
 18 paragraph under "Heat treatment", the second sentence:
 19 "Robin James is working out what this means in
 20 terms of our current inventory at Eastbourne."
 21 So what's been said is the batches produced since
 22 March '86 have all been screened for ALT. This is
 23 written four months later. So to work out what it
 24 means in terms of the inventory at Eastbourne, what's
 25 the implication of that? Is it that there is stuff

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1 internal memorandum dated 5 March 1986 from Dr Harris
 2 of Armour. And it says:
 3 "As you know, we discussed the summary data on
 4 this work ..."
 5 We can see from the heading it's "Viral
 6 inactivation data for Factorate and other blood
 7 products":
 8 "The DHSS were superficially happy with the data.
 9 They have, however, requested that we furnish them as
 10 soon as possible with the fullest documentation on
 11 methodology and test results of all our blood
 12 products.
 13 "May I please start to receive these data
 14 urgently, and starting with Factorate generation I."
 15 I'm not going to go into the story of how that
 16 further unfolded. Again, we'll be looking at the
 17 question of what information Armour had about the
 18 success or otherwise of its viral inactivation methods
 19 in 1985 and 1986, what information it provided to the
 20 Department and how the Department responded, when we
 21 come back to that issue in November.
 22 If we then just pick matters up in July 1986 at
 23 ARMO0000557. Again, this is an internal Armour, here
 24 headed "Rorer Health Care Limited", memorandum, this
 25 is to Mr Bishop. We can see under the heading "Heat

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1 stored in the warehouse which is made from the
 2 pre-March unscreened plasma?
 3 **MS RICHARDS:** Certainly, I think the inference is they're
 4 looking to see the extent to which they have stored
 5 material that may not have been tested for ALT.
 6 I don't know the answer as to what was found. Again,
 7 hopefully we can come back to this in November and
 8 tell you if we have an answer or not.
 9 **SIR BRIAN LANGSTAFF:** We may find out more, we may not?
 10 **MS RICHARDS:** We may.
 11 Then just to complete the picture in these very
 12 outlined terms, in relation to the heat-treated
 13 product and its licensing, if we go to ARMO0000602, we
 14 can see that on 7 October 1986, in relation to
 15 Factorate, Armour -- or Rorer -- wrote to Dr Duncan
 16 Thomas at the National Institute for Biological
 17 Standards and Control saying:
 18 "I refer to our telephone conversation today, in
 19 which I informed you of the withdrawal of FACTORATE
 20 from the UK market.
 21 "I enclose for your files, a copy of the recall
 22 letter and the press release."
 23 Then if we go to the third page we can see
 24 a letter dated 7 October 1986, which refers -- sorry,
 25 if we just look at the heading, you'll see it refers

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1 to both product licences, so the Factorate IP, that's
2 the intermediate purity, and the Factorate High
3 Potency:
4 "With immediate effect, Armour Pharmaceutical
5 Company Limited is withdrawing from the UK market the
6 Factorate products detailed above. The Company has
7 relinquished the relevant product licences. This
8 action follows consultation with the DHSS after
9 notification by a UK physician of two cases of HIV
10 antibody sero-conversion associated with the use of
11 Factorate.

12 "Armour is not yet in possession of the complete
13 clinical profile concerning these two
14 sero-conversions. However, the decision to withdraw
15 Factorate was made even though the material used in
16 these two cases is not that currently on the market.
17 In view of the decision taken yesterday we advise that
18 no further administration of Factorate should be
19 given. You should return all Armour Factorate in
20 inventory to Armour Pharmaceutical Company Limited,
21 [Eastbourne]. "

22 As I say, the detailed steps which led up to that
23 decision will be examined in November.

24 Then just deal very briefly with two other Armour
25 products. Monoclate-P, if we go to ARMO0000212.

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1 view of the transmission of HIV by a previous Armour
2 product with an identical heat treatment schedule
3 [presumably Factorate Heat Treated], an efficacious
4 virucidal procedure against HIV would be applied to
5 the product. Dry heat at 60°C for 30 hours was
6 inadequate."

7 Then there were a number of concerns expressed by
8 other authorities, under the heading "Safety" and,
9 indeed, a number of concerns raised in relation,
10 I think, to quality, as well, in terms of the method
11 of preparation.

12 Ultimately, I think there is evidence to suggest
13 that, towards the end of 1989, these issues may have
14 been resolved and a product licence for Monoclate-P
15 was granted but I don't think we need to go into the
16 detail of that. There was also a subsequent Factor IX
17 product called Mononine licensed by the UK in,
18 I think, February 1993.

19 That's the overview, sir, of matters relating to
20 licensing applications for Armour products. I'm going
21 to turn now, then, to the issue of donors. So if we
22 start just by quickly returning to ARMO0000005. This
23 is a letter we looked at yesterday afternoon when we
24 were looking at the licensing application process in
25 relation to the Factor VIII product. So it's a letter

27

1 You'll see this is a later letter, July 1988, to
2 Armour, and it's headed "Application through the
3 Community Concertation Procedure. Monoclate
4 Lyophilised Powder".

5 I'm not going into this in any great detail.
6 Monoclate-P was a product derived from monoclonal
7 antibodies, dry heated at 60 degrees for 36 hours.

8 There was an application by Armour which was
9 unsuccessful, various concerns being raised by the
10 Department, and then a product licence application for
11 the product was made in February 1988, and there were
12 objections raised to the application.

13 Then we can pick up the picture in 1988 with this
14 letter, and it's really not so much because of the
15 need to investigate what happened with Monoclate but
16 just to show how it might be said that the degree of
17 rigour with which product licence applications were
18 scrutinised by the Licensing Authority may be thought
19 to have changed over the years.

20 Here we have a number of concerns being expressed
21 by the Department. We'll see in the first paragraph:

22 "Acting as the [UK] rapporteur for the Committee
23 for Proprietary Medicine Products ..."

24 We can see under the heading "Safety":

25 "There was insufficient evidence of safety. In

26

1 from Armour, 2 February 1976.

2 If we go towards the bottom of the page, we can
3 see there, sir, the figure of 1,540, which you asked
4 about earlier this morning, when we looked at that
5 letter to Dr Biggs. So:

6 "The number of donations is approximately 1,540
7 per batch to give a pooled plasma of approximately
8 1,000 litres."

9 So that's the information as at 1976 in terms of
10 pool size.

11 **SIR BRIAN LANGSTAFF:** Just pausing there for a moment, the
12 roundel that we looked at earlier spoke of donors, did
13 it, rather than donations?

14 **MS RICHARDS:** Yes, I think it did, sir. Sorry, I don't
15 have a --

16 **SIR BRIAN LANGSTAFF:** If we just go back to that for
17 a moment.

18 **MS RICHARDS:** Soumik it was OXUH0003868_011. Yes.

19 **SIR BRIAN LANGSTAFF:** Yes.

20 **MS RICHARDS:** Yes, you're right.

21 **SIR BRIAN LANGSTAFF:** So this is now donations rather than
22 donors in this?

23 **MS RICHARDS:** Yes. So the letter at ARMO0000005, which
24 pre-dates the letter to Dr Biggs by about 18 months,
25 talks about 1,540 donations per batch.

28

1 **SIR BRIAN LANGSTAFF:** Yes.

2 **MS RICHARDS:** But you're absolutely right, sir, the later

3 letter then seems to have translated that into 1,540

4 donors. In any event, that's the pool size

5 information given to the Licensing Authority at the

6 time of the product application. Then if we go over

7 the page, in terms of the source of plasma, and again

8 we looked at this yesterday, this just a reminder,

9 (f):

10 "We confirm that the plasma will only be from

11 donor centres in the USA, and from USA sources."

12 We discussed yesterday, sir, the slight ambiguity

13 in that latter phrase.

14 We then pick up the picture in terms of

15 information about the plasma supply from

16 PJON0000055_001. Sir, you'll recall looking at this

17 earlier with Mr Hill. This is Dr Jones's note

18 referring to a Paris trip in September 1979 and

19 a meeting with Robert Taub and Wolfgang Marguerre.

20 I think, sir, you queried, if we look at the second

21 paragraph, what the recently purchased company

22 covering Germany might be, and I'm afraid we don't, at

23 the moment, know the answer to that, or whether it's

24 accurate.

25 Mr Taub was subsequently involved with Octapharma

1 on, or understanding of, the organisation of the

2 Revlon Health Care Group:

3 "Headquarters of Armour are in Phoenix, Arizona.

4 Plasma phoresis headquarters is in Phoenix with the

5 biggest centre in Knoxville, Tennessee.

6 "Fractionation is carried out at Kankakee ...

7 which is 100 miles south of Chicago. The plasma

8 phoresis centres cover a block of mid States from

9 Chicago to Tennessee. One million litres of plasma

10 are drawn within a year from centres under the direct

11 control of Armour ..."

12 That's the relevant point in terms of plasma

13 supply. What is being described here are centres that

14 are effectively part of the Armour group:

15 "... this being 20% of the US production. It is

16 claimed by Marguerre, who says he has figures to

17 support it, that no outside source plasma is necessary

18 for the Armour products."

19 There's then a discussion about other companies

20 that I don't think we need look at. Then if we go to

21 the next paragraph, it says:

22 "On Monday, 17th September, 1979 in session with

23 Marguerre and Taub the following points -- in addition

24 to those already mentioned -- emerged."

25 The first point is about Hyland. Then the second

1 but my understanding of Octapharma is that it was set

2 up in 1983, so some four years later, and in

3 Switzerland not Germany. So precisely what that

4 refers to, we're currently unclear. It may not matter

5 in any event. In any event, we can skip over the

6 paragraph that deals with Travenol, because Mr Hill's

7 already dealt with that, and go to the bottom of the

8 page where we can pick up a discussion about Armour

9 and Factorate:

10 "It was suggested by Marguerre that the true cost

11 of plasma was presently around 12p/factor VIII unit

12 and that this cost did not take into account any

13 research and development. To his knowledge no

14 research and development was intended in any company

15 other than Armour. The cost of Factorate in the [UK]

16 would be increased in December, and it was expected

17 that Koate would follow. An increase in costs within

18 the [UK] would then allow for some research and

19 development. The price is likely to be 10.5p/unit."

20 If we go over the page -- sorry, and I should say

21 that, although I'm looking at the question of donors

22 as a theme, this document covers a number of different

23 issues but I don't want to keep coming back to it so

24 we'll look at the whole document.

25 So we then see Dr Jones's reflections or thoughts

1 is this:

2 "Marguerre and his colleagues were highly critical

3 of the management of plasma sales from Armour,

4 particularly with regard to the [UK]. They had

5 successfully taken over half the market by using

6 unrealistic price structure [which again may reflect

7 issues of cost being responsible for the success of

8 the Armour product in the UK market] which allowed for

9 no service commitment or research or development. It

10 was the intention to change this image, but this could

11 only be done by increasing price.

12 "Specifically, there emerge two objectives.

13 "The first is to try and validate the Bonn

14 approach, this almost certainly being connected with a

15 recent acquisition of the company for Taub in Germany.

16 "The second ..."

17 And again, this is the relevant point in terms of

18 considering the issue of donors:

19 "The second was to throw open the whole of the

20 plasma collection and marketing in the United States

21 to independent scrutiny. The attitude to the other

22 companies if this were done, would be that there was

23 no intention of attacking them, but nor was there any

24 intention of supporting the introduction of plasma

25 from developing countries.

1 "In order to achieve these two objectives and
2 later hazily sketched ideas to develop a major
3 commitment to funding national and international
4 meetings, symposia and research and development in the
5 clinical sector, it was proposed that PJ
6 [Dr Peter Jones] became a 'consultant' with direct
7 access to Marguerre and Taub and with authority to
8 approach any physician or scientist he wished in order
9 to set up programmes."

10 There's then a discussion about what was said to
11 be the first objective, and some work being undertaken
12 in Germany. We don't, I think, need to look at that.

13 If we go to the last paragraph on this page:

14 "With regard to the second objective, it was
15 suggested that within the coming weeks a gradual
16 dialogue be established between PJ and
17 Revlon Health Care and that this should culminate in
18 a visit to the facilities in the United States. It
19 was stated that PJ could invite anybody from the
20 scientific field (Arthur Bloom in particular being
21 mentioned) to accompany him on this trip, the purpose
22 of which would be to validate the company claims of
23 collection and fractionation independence. It was
24 also mentioned that Revlon presently put 9% of their
25 profit into research."

33

1 So that's what I think appears to be a record made
2 by Dr Jones for his own purposes. There's no evidence
3 of this document being shared with or sent to others.
4 We can then pick matters up by looking at the report
5 of the trip that Dr Jones then subsequently undertook.
6 And that is at PJON0000040_001. So it's headed
7 "Confidential. Revlon Health Care Group. A Report on
8 Plasmapheresis in the United States".

9 If we go to the next page we can see it's said
10 that:

11 "This report is confidential to Mr W Marguerre,
12 Vice President, Biological Products, Revlon Health
13 Care Group ..."

14 Then we can see, if we go on to page 4, the
15 "Introduction", which says this:

16 "In 1979 Mr W Marguerre, on behalf of the Revlon
17 Health Care Group, invited Dr Jones to visit Group
18 facilities for the collection of blood products in the
19 United States.

20 "Revlon's interests in the medical field had been
21 strengthened by the acquisition of Armour
22 International, and by the creation, in late 1978, of
23 an organisation for the plasmapheresis of donors
24 within the Group. It was Group policy to achieve
25 self-sufficiency in source plasma, and to this end

35

1 So we have here the genesis of the idea that
2 Dr Jones would undertake an inspection of some of the
3 fractionation -- sorry, some of the plasma collection
4 centres from which the plasma for fractionation by
5 Armour was obtained.

6 If we just go over the page:

7 "PJ stated that he would go along with the project
8 with the provisos that it was fully understood that
9 there were no strings attached, that he remained in
10 Newcastle, and that any commitment made by either the
11 company or himself was known to his colleagues. This
12 was agreed."

13 Then there's a reference to a need to look into
14 possible long-term side effects of intensive
15 transfusion therapy.

16 If we go to the conclusion:

17 "No finances discussed, apart from statement of
18 full financial support for studies conducted through
19 PJ with complete expenses and reimbursement for
20 personal time".

21 And then in capitals and speech marks:

22 "WE INTEND TO UTILISE YOUR BRAIN."

23 Which is presumably the message which Dr Jones was
24 given, or his understanding of why he was being
25 approached by Armour.

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1 Armour Pharmaceuticals had acquired the company Plasma
2 Alliance, operating in the United States of America."

3 Just pausing there, we've obviously seen a lot of
4 material about the objective of self-sufficiency as
5 a governmental objective for the United Kingdom. Here
6 is self-sufficiency being articulated in 1979 and 1980
7 as a discrete policy of Armour, that it will be able
8 to fractionate and create its products from plasma
9 collected under its control.

10 And then -- sorry, it could be thought that
11 saying, "It was Group policy to achieve
12 self-sufficiency in source plasma", might suggest that
13 that objective hadn't yet been achieved. But it's not
14 clear.

15 "Dr Jones' brief was to visit a number of
16 plasmapheresis centres managed by Plasma Alliance, to
17 talk with management, staff and donors and to report
18 his findings to Mr Marguerre. It was an essential
19 understanding within this agreement that 'there was
20 nothing to hide', and that the open nature of the
21 visit was designed to demonstrate that Plasma Alliance
22 were a sound, healthy and ethical organisation. On
23 his part, Dr Jones agreed to report back, in
24 confidence, directly to Mr Marguerre.

25 "It is the purpose of this report to set out the

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1 results of the United States visit."
 2 The report is signed by Dr Jones and dated
 3 June 1980.
 4 If we go to the next page, we can see the centres
 5 that were visited by Dr Jones, and I think it's six
 6 centres in total. So there's a Knoxville Centre,
 7 there's then a visit to the Plasma Alliance
 8 Laboratories and Offices.
 9 Then we can see the Chattanooga Centre and the
 10 Atlanta Centre, then the St Paul's Centre, the
 11 Minneapolis Downtown Centre and University Centre, and
 12 then the final visit is to the Kankakee Plant, which
 13 is not, obviously, a plasma collection centre but was
 14 where the fractionation was undertaken.
 15 If we then turn to page 9, we can see Dr Jones's
 16 general description of Plasma Alliance's centres:
 17 "Plasma Alliance employ 888 staff (full and
 18 part-time) for the collection, testing and shipping of
 19 plasma obtained from paid donors in 22 Centres. Of
 20 these, 75 are '40 hour' employees. Total donor beds
 21 is presently 1,037, with an average Centre size of
 22 40-45 beds. Bed occupancy runs at about 60 per cent.
 23 Each Centre has a Manager and an Assistant Manager, a
 24 Donor Room Supervisor, a member of staff with specific
 25 responsibility for quality control and a Physician,

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1 What's meant by that is, I'm afraid, unclear.
 2 "In all cases all operating procedures were
 3 strictly observed, and the standard of professional
 4 expertise and donor care was impressive.
 5 "Of special merit were firstly, the safety checks
 6 used by Plasma Alliance to guarantee donor safety and
 7 plasma/red cell identification, and the institution of
 8 the NABSAF coded system in addition to donor details
 9 and signature and bed number is applauded. Secondly,
 10 the standards of the donor room staff were
 11 exceptionally high."
 12 Then he talks about his impression at the bottom
 13 of the page:
 14 "A first class organisation with a sound
 15 commitment to quality control. The recommendations
 16 made at the end of this report are made in the light
 17 of this overall judgment. Donors questioned ... had
 18 no complaints about the procedures and most seemed to
 19 enjoy the experience of taking a rest during
 20 plasmapheresis. This impression is not in accord with
 21 the reportedly low rate of reattendance."
 22 Over the page, there's a heading, "A Note about
 23 Reactions", and Dr Jones says this:
 24 "Reactions had been noted in each Centre, and from
 25 the Recommendations in this report, it will be seen

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1 who is not necessarily in attendance throughout
 2 opening hours. When the Physician is not in
 3 attendance, arrangements exist with a local hospital
 4 for cover ..."
 5 So you'll see from that, sir, there are
 6 22 collection centres run by Plasma Alliance, and, as
 7 I say, it appears to be I think five or six centres
 8 that were visited by Dr Jones.
 9 If we carry on down the page it is said that:
 10 "Donors are looked after by Registered or Licensed
 11 Practical Nurses or their equivalent in terms of
 12 training.
 13 "In each Centre an Immunisation Programme was
 14 used; details of this were not available, nor were
 15 they in the brief of the visits.
 16 "All Centres were administered under FDA rules.
 17 An in-house Standard Operating Manual ... was
 18 available in each Centre visited."
 19 If we go to page 11, we then see Dr Jones's
 20 description of the plasmapheresis procedures.
 21 "The regulations for the acceptance, screening,
 22 medical examination and plasmapheresis of donors is
 23 laid down in the [standard operating manual] SOM, and
 24 was followed through in detail in Knoxville, and in
 25 a curtailed form in the other Centres visited."

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1 that these were of special concern to the author.
 2 This is because any organisation which relies on
 3 blood/plasma donation must ensure the safety of its
 4 donors."
 5 Then there's a reference to emergency equipment
 6 and the like.
 7 Then this:
 8 "It is not unusual for donors to lie to questions,
 9 and the SOM and the staff are to be commended for the
 10 instructions about recognising fraud and how to deal
 11 with it. However, in one Centre it was admitted that
 12 two epileptics had not been spotted during the
 13 screening procedures. People like this, and those who
 14 experience reactions (on average twice a week in the
 15 Centres visited) should be covered in planning
 16 emergency procedures."
 17 Then if we go over to page 14, Dr Jones is, we
 18 will see from there, in general terms complimentary
 19 about the centres, and general standards were, he
 20 said, "excellent".
 21 There's then a visit on the next page to Kankakee,
 22 which is the fractionation plant. Although there's
 23 a particular criticism there about "the number of
 24 outdated Red Cross and Community Blood Bank whole
 25 blood packs lying around", which might suggest that

40

1 Kankakee was not only receiving blood from Plasma
2 Alliance, but there's no further illumination of that
3 issue in this document.

4 If we turn on to page 19, we can see Dr Jones
5 saying:

6 "It would appear that the FDA ruling 640.62 is not
7 always followed. This regulation states:

8 "Medical Supervision

9 "A qualified licensed physician shall be on the
10 premises when donor suitability is being determined,
11 immunisations are being made, whole blood is being
12 collected, and red cells are being returned to the
13 Donor."

14 So, for present purposes, considering issues of
15 the donor suitability, the requirement is for the
16 attendance of a qualified licensed physician at the
17 premises.

18 Then Dr Jones says:

19 "To my knowledge the careful requirements for
20 nearby hospital staff to be 'on call' in the event-off
21 an emergency ... laid down in the Plasma Alliance SOM,
22 are not in accord with this regulation.

23 "In general, the absence of a Physician from some
24 Centres during plasmapheresis worried me. I realise
25 that the practices in the USA are different from those

1 bounds of necessary industrial security) and suggest
2 that:

3 "- an article on plasmapheresis by Plasma Alliance
4 be approved by Revlon and submitted to the medical
5 press for publication."

6 And there is a subsequent publication which we
7 will look at. Secondly:

8 "- the occasion of the World Fair in Knoxville in
9 1981 be used to teach the public and the medical
10 professions about the ethical standards maintained by
11 industry."

12 If we go over the page next to the heading "Source
13 Plasma", Dr Jones says this:

14 "It is imperative that the Revlon Health Care
15 Group become totally self-sufficient in terms of
16 source plasma. Whilst the need for buying in plasma
17 from other organisations exists -- even when these are
18 FDA approved and of impeccable character -- there will
19 be doubt within the medical profession."

20 Again, an inference that may be drawn from that is
21 that at the time of Dr Jones's visit or report, his
22 understanding may have been that Revlon/Armour had not
23 achieved total self-sufficiency in terms of source
24 plasma and were therefore still reliant upon other
25 sources. That's an inference that can be drawn from

1 employed in the UK, with which I am more familiar, but
2 I think serious consideration should be given to
3 continuous medical supervision."

4 Then if we go over to the next page, we can see at
5 the top of the next page:

6 "In addition the SOM lays down at least 16
7 occasions when a Physician's judgment is required.
8 Continuous supervision by well-motivated medical staff
9 should save waiting timetable for 'problem' donors,
10 expose more of the community to the knowledge that it
11 is company policy to ensure donor health, and may well
12 have a 'spin-off' effect in increasing the average
13 number of times a donor attends from the present 4-5."

14 So there are some concerns expressed by Dr Jones
15 about the apparent absence, in non-compliance with the
16 FDA regulation, of a physician.

17 We can then, I think, skip over the next few pages
18 and go to page 25. "Company Image" is the heading:

19 "The 'bad' image associated with procedures
20 involving paid donors has not been helped in any way
21 by secrecy. The organisation managed by
22 Revlon Health Care and Plasma Alliance Inc, is, in my
23 opinion, of so high a standard that it lends itself to
24 a more open attitude. I strongly recommend that
25 consideration be given to more exposure (within the

1 this document. But we'll see what's said elsewhere
2 about that.

3 That, I think, is all we need to look at within
4 Dr Jones's report of his visit.

5 We can then go to ARMO0000229 for a subsequent
6 publication, which is dated July 1981. It's called
7 Plasma Perspectives. And we can see -- well, it's
8 perhaps worth, I think, reading the introduction under
9 "A New Interface" because it will help you place this
10 document in context.

11 It says this:

12 "It is clearly outside the scope of standard
13 product literature to examine current and
14 controversial issues relating to the supply and use of
15 blood products. However, it is important that the
16 views of both manufacturers and medical profession
17 should have the opportunity of being voiced. Indeed,
18 one of the recommendations contained in the
19 International Federation Pharmaceutical Manufacturers
20 Association's ... 1980 report on blood products was
21 that although 'care should be taken to avoid
22 over-promotion of the various products made from human
23 blood, full information on such products should
24 continue to be made fully available'. It is the
25 intention of Plasma Perspectives to be the vehicle of

1 these views and to form an interface where the
2 opinions of both producers and users can be seen.
3 Clearly for such a publication to be of real value it
4 has to be seen to take an objective and impartial
5 view. Much of this objectivity will be dependent on
6 the contributions, correspondence and reports which
7 are received from those with a special interest in the
8 administration of blood products. The newsletter will
9 be published by the Plasma Division of the Armour
10 Pharmaceutical Company and ..."

11 So it's an Armour publication, although the
12 aspiration appears to be that it will be something
13 that provides objectivity and impartiality.

14 And we can see at the bottom of that column:
15 "It will be distributed on request free of charge
16 to members of the medical and allied professions.

17 "The first issue of Plasma Perspectives is, for
18 the most part, based on a report by Dr Peter Jones,
19 Director of the Haemophilia Centre at Newcastle,
20 following an invitation to visit some of Armour's
21 plasmapheresis centres and their Fractionation plant
22 in the USA. We believe that this impartial report
23 will go a long way to correct many of the
24 misapprehensions and misunderstandings which have
25 arisen in relation to the collection and distribution

1 Armour has rationalised the network into one highly
2 organised subsidiary, Plasma Alliance Incorporated,
3 which now coordinates the activities in 22 centres,
4 all of which are located in North America."

5 Go to the next paragraph:

6 "Plasma Alliance's 22 centres are responsible for
7 collecting from approximately 22,000 donors registered
8 at any one time, records for whom are centrally
9 controlled by computer at the Company's principal
10 plasmapheresis laboratories in Knoxville Tennessee
11 which are among the largest of their kind with over
12 9,000 donors per month."

13 So that's the core information about Plasma
14 Alliance. If we then turn to -- sorry, still on this
15 page -- the right-hand column, you'll see a heading
16 partway down, "Armour In-House Standard Operating
17 Procedures Conform to FDA Regulations" is the heading:

18 "Embodied in the above is a rigid and
19 sophisticated record control which, for example,
20 covers the following critical areas ..."

21 Then the first heading is "Processing of Source
22 Plasma Donors", and a number of points set out:
23 records, general criteria, identity, age, weight,
24 appearance, health criteria. And then this is, as we
25 understand it, what's said to be the screening process

1 of plasma from commercial sources within the USA."

2 Then we can, I think, for present purposes pick
3 matters up on page 2, under the heading "Armour -
4 Plasma Collection and Control". What is said, if we
5 just go to the top of the page, left-hand column:

6 "Plasma collected for the production of Armour's
7 Factorate both, Standard and High Purity, is SOURCE
8 PLASMA which is a Federally defined and regulated
9 product in the USA."

10 Then we can skip over the rest of that paragraph
11 and go to the next one, where it says this:

12 "The practice of collecting plasma from Third
13 World countries where blood products are already in
14 short supply and where, in some cases, hepatitis B is
15 endogenous has been severely criticised."

16 Then this is the claim made by Armour:

17 "All of Armour's SOURCE PLASMA is collected from
18 Federally regulated plasmapheresis centres on the USA
19 mainland."

20 So this is what is said by Armour in 1981.

21 "In 1975, in order to help achieve
22 self-sufficiency and total control of its operations,
23 Armour purchased Blood Plasma Services which
24 maintained 12 centres in 11 cities. Since that date,
25 other plasmapheresis centres have been acquired and

1 in relation to donors:

2 "Questionnaire on medical history especially
3 transmissible diseases."

4 Then this:

5 "Frequency and volume criteria, addictions,
6 previous donation history. Heart, lung, liver, kidney
7 performance."

8 Now, quite what it was said was undertaken by
9 reference to these criteria, what tests, examinations,
10 questions, is not clear from this material.

11 Then at the top of the next page it continues by
12 reference to haematological and medical examination.

13 Then I think if we go down towards the bottom of
14 that column, that left-hand column, we see a heading
15 then, "The Major Concern is testing for Hepatitis B
16 Surface Antigen":

17 "There is still no, completely reliable laboratory
18 test available to detect all potentially infectious
19 plasma donations."

20 Then there is an explanation that Armour uses the
21 radioimmunoassay, and if we look at the last sentence
22 in that section, it says:

23 "The test is carried out on each donation and pool
24 as well as the finished product."

25 We then have a heading "Absolute Traceability to

1 the Individual Donor is Achieved", and we can see it's
2 said this:

3 "If a donation, when first tested, gives
4 a positive result the test is repeated and if
5 a further sample from the donation is positive and
6 this is confirmed by a neutral isolation test, then
7 the donor is classified as positive and excluded
8 permanently from donating.

9 "No unit is shipped if a positive result is
10 obtained even if the positive is shown to be false."

11 Then if we pick it up towards the bottom of the
12 page, we then come back to the question of pool sizes.
13 So it's said:

14 "Small Factorate Batch Sizes Facilitate Control.

15 "All batches offer pooled plasma from which
16 Factorate ... is produced comprise donations from [and
17 then the word 'only', whether that's an accurate
18 description will be a matter for your judgment] only
19 approximately 2,000 donors. Should the need ever
20 arise, under the foregoing system and control,
21 location of the finished product and traceability back
22 to donor is quick, simple and efficient."

23 So how the 2,000 -- or said to be approximately
24 2,000 fits with the 1,540 is unclear. Of course this
25 is a couple of years further on. This is July 1981,

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1 controlled by trained, qualified, Armour personnel as
2 are the distribution, fractionating, processing,
3 control and research facilities. This self
4 sufficiency, control and long term commitment to the
5 field of plasma fractionation has an important bearing
6 upon the quality, reliability of and confidence in the
7 products produced."

8 If we go over the page -- and I'll finish this
9 document before we break, if I may -- we can see, if
10 we go to the bottom of the page, there's a heading,
11 "Dr Peter Jones, Director of the Haemophilia Centre at
12 Newcastle comments as follows", and then there are
13 various quotes from the report that we have looked at
14 a few minutes ago.

15 If we go to the next page, the bottom of the page,
16 the quotes continue, and then in the right-hand column
17 it reverts to the text of the Plasma Perspectives
18 publication, and says this:

19 "Armour's participation in human plasma
20 fractionation has grown into one of the largest
21 fractionation facilities in the world today."

22 Then there's a description of investment in a new
23 plasma fractionation and sterile filling facility at
24 the Kankakee location, et cetera.

25 Then if we turn to page 8, we can see the heading

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1 so the pool sizes may have increased.

2 Then it's asserted, bottom of that column:

3 "Difficulties associated with tracing donors from
4 large pools containing many thousands of donations
5 obtained from plasma brokers and independent
6 collection centres do not arise under the system
7 operated by the wholly owned and controlled Armour
8 Plasmapheresis Centres."

9 Then we can see there's then a heading "Non-A
10 Non-B Hepatitis", and it's explained four lines down:

11 "Specific laboratory tests for the identification
12 of this most recently recognised type of hepatitis are
13 not yet available so that diagnosis can only be made
14 by exclusion of hepatitis A and B."

15 Then if we go further down, it's said in the last
16 paragraph:

17 "When reliable serological markers for non-A,
18 non-B hepatitis are available, Armour will be ideally
19 positioned to take the initiative. Meanwhile research
20 and development is an ongoing activity aimed at
21 providing increasingly safe therapeutic blood
22 products."

23 Then we have the heading "Confidence is
24 Important":

25 "All Armour Plasmapheresis Centres are fully

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1 "Armour follow 'nothing to hide' policy":

2 "To allay the emotive and unsubstantiated
3 allegations which have been made in connection with
4 the supply of blood derivatives from commercial
5 sources, Armour opened its doors to Dr Peter Jones ...
6 Dr Jones's brief was to visit a number of Armour
7 Plasmapheresis Centres to talk with management, staff
8 and donors to report his findings."

9 At the bottom of the page:

10 "In general, he found 'a first class organisation
11 with a sound commitment to quality control' ..."

12 Then we can see recommendations from the report
13 set out in -- of which one is the need for closer
14 liaison between the Director of Medical Services and
15 the physicians working in the centres.

16 Then if we go to the right-hand column:

17 "The recommendations made by Dr Jones have been
18 implemented wherever possible in order to maintain the
19 highest standards throughout the Plasma Alliance
20 Group.

21 "The Publication of Dr Jones' comments on what he
22 saw follows his own recommendation, couched in the
23 following terms ..."

24 Then we see the reference that we saw from
25 Dr Jones's report to the organisation being of such

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1 a high standard that it lends itself to a more open
 2 attitude.
 3 The last reference I just draw attention to is
 4 page 23. So there are a number of photos and other
 5 materials. Here there's a section headed "The Plasma
 6 Alliance donor", described as:
 7 "A normal, healthy individual who is carefully
 8 screened, selected and monitored."
 9 What's said is this:
 10 "The quality of the Plasma Alliance product is
 11 largely due to the quality of the donor. In each of
 12 our centres nationwide, special care is given to the
 13 screening of each individual before he is allowed to
 14 join the plasmapheresis program. An initial physical
 15 examination is conducted by a Plasma Alliance
 16 physician ..."
 17 Pausing there, you'll recall that one of
 18 Dr Jones's comments had been that not all centres had
 19 a physician on site:
 20 "... followed by a check-up each time he comes in
 21 to donate. In fact, a regular Plasma Alliance donor
 22 is checked and tested more often than the regular
 23 population.
 24 "To make certain the prospective donor has not
 25 been rejected for any reason in the past, current

1 sizes, by Armour, in this publication in July 1981.
 2 Sir, that's probably a convenient point at which
 3 to take the morning break.
 4 **SIR BRIAN LANGSTAFF:** Yes, well, we will take a break
 5 until quarter to 12. Quarter to 12.
 6 **(11.18 am)**
 7 **(A short break)**
 8 **(11.45 am)**
 9 **MS RICHARDS:** Sir, we next pick up documents which provide
 10 information about pool sizes and donor procedures.
 11 In 1983 -- if we go to ARMO0000243 -- this is
 12 a Revlon Health Care Group inter-office memorandum
 13 dated 27 April 1983. And we can see the subject is
 14 "Trip Report - Plasma Alliance Reviews".
 15 And what -- it's from SH Mueller, and it records
 16 as follows in the first paragraph:
 17 "On April 20-22, 1983, I visited five Plasma
 18 Alliance Centers in Indiana and Ohio ... Each center
 19 was toured physically, and basic operating and
 20 documentation systems were reviewed at each. Plasma
 21 Alliance's current program for screening donors who
 22 are at high risk re AIDS was discussed with the Center
 23 Managers."
 24 Then we see the centres visited were West
 25 Lafayette, Indianapolis, Columbus, Akron and

1 files and extensive cross-referenced microfiche
 2 records are checked daily.
 3 "Once a donor is approved, the entire plasma
 4 collection procedure is thoroughly explained. Since
 5 plasmapheresis is unique in that a donor must be
 6 reinfused with his own red cells, the donor must be
 7 completely familiar with the process. During
 8 donation, Plasma Alliance nurses and technicians check
 9 and double check each donor frequently to insure his
 10 safety, and thus, the safety of our product.
 11 "For Plasma Alliance and for the many people
 12 needing the products derived from plasma, a donor is
 13 a valuable asset to his community and to the quality
 14 of our product."
 15 So that, I think, is all I need to show you --
 16 **SIR BRIAN LANGSTAFF:** I think if we get the same idea, if
 17 we look at what's underneath the photograph on the
 18 left.
 19 **MS RICHARDS:** Yes:
 20 "We're looking with the kinds of donors who are
 21 healthy young people who are local, repeatable donors.
 22 We are not looking for people who are in the hard
 23 roads of life", is what is said.
 24 So that's what is set out about the approach to
 25 donor selection and donor screening and, indeed, pool

1 Cleveland.
 2 "Overview: Each of the centers we visited was
 3 clean, well-organised and quite professional in
 4 appearance. The personnel I met were knowledgeable
 5 and aware of current regulatory issues. The centers'
 6 operations conform to current regulatory requirements.
 7 Appropriate controls are in place to assure donor
 8 safety and product quality, screen out inappropriate
 9 potential donors, prevent overly-frequent donations,
 10 and to limit overbleeding."
 11 So that's the overall assessment, what's said to
 12 be a satisfactory picture.
 13 Then if we look at the next paragraph, it refers
 14 to the Plasma Alliance centres being -- and this is
 15 the fourth line, "regularly audited by Knoxville QA".
 16 Then the last sentence of that paragraph:
 17 "It is certainly worth noting that PA's [Plasma
 18 Alliance] FDA inspectional track record recently has
 19 been excellent."
 20 "Facilities/Equipment: The centers we visited
 21 [you'll recall there were five of them] are located
 22 either adjacent to university campuses or in
 23 near-downtown areas. All of the locations appeared to
 24 be acceptable, ie, the neighborhoods seemed relatively
 25 stable and did not evidence adverse street

1 activities."
 2 The top of the next page says:
 3 "The donors we saw were both students and
 4 neighborhood residents ..."
 5 Then if we go down to the bottom of the page, we
 6 can see under the heading "Operations/Documentation":
 7 "All of the centers visited were using uniform
 8 procedures in compliance with PA policies and SOP's
 9 [standard operator procedures]. New donors are
 10 photographed after presenting adequate identification,
 11 and receive a pre-donation physical exam, at which
 12 time informed consent is obtained. Repeat donors are
 13 identified via their filed photos. In locations where
 14 other plasmapheresis operations exist nearby, centers
 15 exchange information concerning permanently-rejected
 16 donors, and also use a UV-florescent finger stain to
 17 detect and prevent overly-frequent multi-center
 18 donations. All donors are screened on each visit, for
 19 blood pressure, pulse, weight, temperature,
 20 hematocrit, evidence of drug abuse, and symptoms of
 21 hepatitis or other diseases which would affect ability
 22 to donate. Long term donors receive annual physical
 23 examinations."
 24 Pausing there, of course this is describing
 25 procedures as at April 1983, when, as is clear from

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1 cards now include a screening question to determine
 2 whether a donor is in a high risk group. Also, each
 3 donor is being asked to sign a questionnaire verifying
 4 that they have read the AIDS fact sheet and that they
 5 do not belong to a high risk group. The signed
 6 questionnaire is being kept in the donor record
 7 folder.
 8 "Each of the Center Managers I spoke with thought
 9 that the program was working reasonably well. Each
 10 reported that some donors have voluntarily eliminated
 11 themselves from the program. The screening
 12 questionnaire has not caused any adverse donor
 13 response, and in fact, apparently has engendered some
 14 serious conversations about AIDS among donors and
 15 potential donors. Center Managers advise that in some
 16 cases they personally spoke to donors who they
 17 suspected of being in a high risk group (after the
 18 donor signed the questionnaire to the contrary), and
 19 these donors also voluntarily withdrew. I was quite
 20 impressed by the sensitive fashion in which Center
 21 Managers are approaching this task ..."
 22 Again, we'll look in more detail at some of the
 23 ways in which the risk of AIDS was responded to by
 24 pharmaceutical companies, but you'll note that this is
 25 what is being described by April 1983, and you may

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1 this document, they are alive to the issue of AIDS, so
 2 it isn't necessarily a reflection of the procedures
 3 that might have adopted in previous years. I don't
 4 think we know one way or the other.
 5 And in relation to the passage we just looked at,
 6 what we don't get from this, perhaps unsurprisingly as
 7 it is just a trip report, is a description of how this
 8 screening is undertaken. So we're told, for example,
 9 that donors are screened for evidence of drug abuse or
 10 symptoms of hepatitis, but it doesn't tell us how that
 11 screening is undertaken.
 12 Third paragraph on that page then refers to the
 13 documentation system, and it's said that:
 14 "The documentation system employed by PA is
 15 excellent, and the centers demonstrated uniform
 16 adherence."
 17 And further details given in relation to that.
 18 Two paragraphs further down records that:
 19 "Each center was found to maintain a daily log of
 20 rejected donors ..."
 21 Then we have a heading "AIDS":
 22 "Plasma Alliance has implemented a program to
 23 screen out high risk donors, per current FDA
 24 requirements. A factsheet concerning AIDS has been
 25 posted in each of the screening booths. Donor product

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1 wish to consider in comparison what was happening in
 2 the United Kingdom at that stage in transfusion
 3 centres. We know that the leaflet, for example, was
 4 not -- the first leaflet was not in operation at this
 5 point in time, not for some months, until
 6 1 September 1983, so it may provide a degree of
 7 contrast in that respect.
 8 So that's that 1983 report. If we then pick
 9 matters up with BART0000863. This is a letter dated
 10 19 May 1983 from Armour "To All Haemophilia Centre
 11 Directors", and we can see it's said in the first
 12 paragraph:
 13 "The Armour Pharmaceutical Company is acutely
 14 aware of the current concern of the Medical world
 15 regarding ... (AIDS) and its possible implication to
 16 Haemophilia care and treatment.
 17 "Despite the fact that there is a little evidence
 18 to associate plasma component therapy with the
 19 transmission of AIDS [you may wish to consider in due
 20 course, sir, whether you think that's an accurate
 21 characterisation of the state of knowledge as at May
 22 of 1983], Armour, through its affiliate organisation,
 23 Plasma Alliance, has had programmes in operation for
 24 several months, which have been designed to help
 25 prevent the utilisation of plasma obtained from

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1 members of high risk groups associated with AIDS in
2 the production of clotting factor concentrates."
3 **SIR BRIAN LANGSTAFF:** Just pausing there, if in truth
4 there is little evidence, there was nonetheless, it
5 would appear, enough to persuade Armour that it should
6 take that action.

7 **MS RICHARDS:** Yes, indeed.

8 And if we go over the page, we can pick matters up
9 in the second paragraph, which refers to.

10 "Data reported by CDC in May, 1983, indicate that
11 since the initial cases were reported, approximately
12 1,500 cases of AIDS have occurred. Of even more
13 alarming nature is the increased rate of incidence of
14 reporting; an accession rate of 100 patients per month
15 appears to be current. Approximately 40% of the
16 reported AIDS patients have died ..."

17 So acknowledgement there of the high mortality
18 rate.

19 We can then pick issues up relating to Armour's
20 plasma collection processes in the bottom paragraph of
21 the page, where it says this:

22 "Of additional concern to Armour Pharmaceutical
23 Company and to others in the health care field is the
24 indication, from data generated by the CDC, that AIDS
25 is being seen in recipients of blood, blood

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1 subsidiary, Plasma Alliance, operates 16 centres
2 located in the Midwest and Southeast portions of the
3 United States."

4 I'm not entirely sure why we've gone from 22 to
5 16 centres over the preceding couple of years.

6 "None of these centres are located in the AIDS
7 high incidence areas of the country (New York City,
8 Miami, San Francisco Los Angeles) mentioned earlier,
9 nor is plasma used in the manufacture of clotting
10 factor products obtained from facilities located in
11 these areas. Furthermore, no plasma is obtained from
12 collection facilities located outside of the
13 United States. Nevertheless, the AIDS issue cannot be
14 treated solely on the basis of geography, since
15 incidence of the syndrome is scattered over a wide
16 area."

17 Then we see set out the steps that Armour is
18 telling the Haemophilia Centre Directors it's been
19 taking.

20 "Taking the first of several steps designed to
21 avoid collecting plasma from members of groups shown
22 to be at high risk for contracting AIDS, informational
23 posters were displayed at our centres in
24 December, 1982. These posters advised potential
25 donors about AIDS and its possible impact on the

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1 components, and blood derivatives. In a summary
2 presentation made in May, 1983, the CDC stated that
3 14 haemophiliacs have apparently contracted AIDS, and
4 that an as yet unidentified number of non-haemophilic
5 recipients of blood and blood components also have
6 developed the syndrome. The CDC is investigating the
7 possible relationship between AIDS and the use of
8 blood and blood derivatives, and is attempting to
9 determine whether transmission of AIDS via transfusion
10 is indeed occurring."

11 Then if we go to the next page, we can see what's
12 said about identification of high risk groups:
13 homosexual or bisexual males, drug abusers, immigrants
14 from Haiti.

15 Then there's a discussion of those groups having a
16 high incidence of hepatitis B infection. And you'll
17 see in the second paragraph -- again, these are issues
18 we will be returning to -- there's reference to the
19 possibility of testing for laboratory markers of
20 hepatitis B, which wasn't at this point in time being
21 implemented.

22 If we pick matters up then at the bottom of the
23 page, under the heading "Plasma Collection and
24 Utilisation by Armour Pharmaceutical Company USA":

25 "Armour Pharmaceutical Company USA, through its

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1 treatment of haemophilia, and requested donors in any
2 of these groups to defer themselves from plasma
3 donation."

4 That's said to be the first step.

5 We then see the next step in the following
6 paragraph:

7 "In February 1983, a more aggressive programme was
8 initiated, following discussions with organisations
9 such as the US [FDA], Office of Biologics, the
10 National Haemophilia Foundation, the Centres for
11 Disease Control, and other commercial manufacturers of
12 clotting factor concentrates. This programme included
13 direct communication with each donor in the form of
14 written and oral information and questions, designed
15 to defer from the donor population individuals at risk
16 for contracting AIDS. Each donor is presented a fact
17 sheet describing the high risk groups thus far
18 identified with AIDS, the seriousness of the syndrome,
19 and the possible link to the treatment of haemophilia.
20 Furthermore, all donors are questioned by trained
21 processors as to their being members of high risk
22 groups and as to the presence of any signs (night
23 sweats, diarrhoea, chills, etc) that might be
24 indicative of AIDS. Donors are required to affirm in
25 writing that they are not members of the several high

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1 risk groups involved, without having to reveal any
2 facet of their personal and private lives. Periodic
3 physical examinations performed by plasma centre
4 attending physicians also include evaluations for
5 possible signs and symptoms of AIDS.

6 "We will continue to move forward, in cooperation
7 with other responsible segments of the health care
8 team, both governmental and non-governmental, to
9 implement additional plasma collection activities and
10 programmes deemed to be effective and appropriate."

11 Then if we look at the bottom of the page, it says
12 this:

13 "The plasma collection actions described earlier
14 in this statement are designed to prevent the use of
15 plasma obtained from individuals in one or more of
16 several high risk groups in the production of clotting
17 factor concentrates. They are predicated on the
18 possibility that AIDS may be transmitted through blood
19 and certain blood derivatives, although it must be
20 re-emphasised that no agent responsible for
21 transmission has yet been identified. However, one
22 must consider that an infectious organism may be
23 involved, and that the appearance of AIDS is prevalent
24 in groups with high incidence of Hepatitis."

25 There is then reference to heat treatment in the

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1 present but we can start, I think, at ARMO0000260.
2 This a telex dated 16 June 1983, the date is at the
3 very bottom of the document, from the Department of
4 Health, Health Services Division, to Armour
5 Pharmaceuticals, and we can see it starts by saying:

6 "Re telecon of 15 June 1983 ..."

7 So there had been some form of telephone
8 discussion:

9 "Please supply following information urgently by
10 return telex if possible."

11 Then there are a series of questions:

12 "1. Does your company manufacture coagulation
13 factor concentrates for use in the UK? If yes, name
14 the products and state how much of each is supplied
15 annually.

16 "2. From which country or countries is the source
17 plasma obtained?

18 "3. If from the USA, is all plasma collected at
19 FDA-licensed plasma collection centres? Please give
20 the names of the centres and their locations.

21 "4. If non-USA plasma is used, name the countries
22 involved and state whether the plasma collection
23 centres in these countries are licensed by the
24 national regulatory authorities.

25 "5. Are you able to identify the origin of the

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1 following paragraph.

2 Then the last paragraph says:

3 "The Revlon Health Care Group, of which Armour
4 Pharmaceutical Company is a member, is firmly
5 committed to providing safe and effective products to
6 the medical community, and will continue to devote
7 considerable time and attention to the problems
8 associated with AIDS and haemophilia treatment, and to
9 efforts undertaken to resolve them. We believe that,
10 given the level of today's knowledge regarding AIDS
11 and its transmission, the programmes in place at our
12 plasma collection centres provide an effective way to
13 reduce the potential for use of plasma obtained from
14 high risk groups."

15 And as we saw from the first page of this letter,
16 it was sent to all Haemophilia Centre Directors, and
17 was, you may infer, designed to provide a degree of
18 reassurance in the hope that Haemophilia Centre
19 Directors would continue to use Armour products.

20 It's around this time that there are a series of
21 requests for information from the Department of Health
22 to Armour, and indeed to other pharmaceutical
23 companies, about issues relating to donors and donor
24 selection procedures, and indeed plasma supply.

25 We don't have a complete set of documents at

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1 plasma included in each batch of final product and the
2 date on which it was collected?

3 "6. Is the plasma from each selection centre
4 fractionated separately or is the plasma from several
5 collection centres pooled prior to processing?

6 "7. If the plasma is of USA origin are you able
7 to supply final products which do not contain plasma
8 from the major 'epidemic' areas for AIDS eg New York,
9 San Francisco, Los Angeles, Miami?

10 "8. Can you confirm that all plasma of USA origin
11 in your products is being collected in conformity with
12 the FDA Directive of 23 March 1983?

13 "9. Did your company institute, in advance of the
14 FDA requirements, any special precautions to be taken
15 by plasma collection centres in respect of AIDS? If
16 so, what were these precautions and when were they
17 introduced?

18 "10. If USA plasma is used, are you able to
19 confirm that all future supplies of coagulation factor
20 concentrates to be sold in the UK will be manufactured
21 from plasma collected in accordance with the FDA
22 Directive of 23 March 1983 (or in accordance with the
23 special precautions, if any, instituted by your
24 company at an earlier date)?

25 "11. If the answer to (10) is no, from what date

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1 can you meet this requirement?"
 2 So those were the questions posed by the
 3 Department of Health. I'm just going to go through
 4 the correspondence in chronological order. If we go
 5 next to ARMO0000264, this is from Mr Tarbit of Armour
 6 to Dr Rodell, so from Armour UK to Armour in the US.
 7 It's dated 20 June 1983, and it says:
 8 "Thank you for your comprehensive telex responding
 9 to the questions raised by our DHSS."
 10 We don't, unfortunately at the moment, have or
 11 haven't been able to locate that telex. But, in any
 12 event, this a request for some further bits and pieces
 13 of information. So Mr Tarbit continues:
 14 "We would appreciate your comment on the following
 15 points arising from these responses, together with
 16 certain other additional queries which we have now
 17 received from the Supplies Division of the DHSS ...
 18 "1. Should we assume that all haemophiliacs
 19 developing AIDS have received Factorate as well as
 20 other products.
 21 "2. Your telex indicates that new procedures were
 22 implemented in February which conflicts with earlier
 23 information we had received stating that these started
 24 in October/November 1982, could you please clarify.
 25 3. With respect to the donor identified in your

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1 **MS RICHARDS:** I don't know. Go to the second page. It's
 2 quite difficult to --
 3 **SIR BRIAN LANGSTAFF:** It looks as though it is, yes.
 4 Curious.
 5 **MS RICHARDS:** It is curious.
 6 **SIR BRIAN LANGSTAFF:** Anyway. Somebody else has written
 7 that on. So that may be why, I think.
 8 **MS RICHARDS:** Yes, HL Shaw was based in Armour in
 9 Eastbourne, so with Armour Pharmaceutical Company in
 10 the UK, as I understand it. As you say, someone else
 11 has written that on. So this is 21 June 1983, and
 12 then we can see -- well, it says:
 13 "Thank you for your telex of 16 June on the above
 14 subject."
 15 So it's a response to the DHSS queries.
 16 "Certain of the specific questions you ask require
 17 responses in more detail than the information we have
 18 available and these have been referred to our
 19 associate company in the USA for more comprehensive
 20 responses. These latter will be transmitted to you as
 21 soon as they are available to us.
 22 "In the interim our responses to the points you
 23 raised are as follows:
 24 "1. Our company manufacturers Factor VIII
 25 concentrate (trade names Factorate and High Potency

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1 telex, it is not clear whether this donor is now no
 2 longer giving plasma. (We would like to know whether
 3 any of the batches identified have been supplied to
 4 our market.)
 5 4. We understand that plasma may be sourced from
 6 centres other than those of our Plasma Alliance Group
 7 and would like further information on these
 8 particularly with reference to their frequency of use,
 9 name and location in respect of recognised high risk
 10 areas. We assume that any such centres would be FDA
 11 approved and subject to corporate audit periodically.
 12 5. We would be interested in information on the
 13 effect the more stringent screening procedures have
 14 had on the donor panel in terms of the deferment and
 15 if known the comparable effect on donors of other
 16 manufacturers.
 17 "In view of the situation we would be grateful to
 18 receive urgent responses to these queries."
 19 Then the next letter, or the next telex, is
 20 21 June. It's ARMO0000266. We can see the date,
 21 21 June, this is from HL Shaw, and -- at least I think
 22 that who it's from -- yeah. It says this:
 23 "Thank you for" --
 24 **SIR BRIAN LANGSTAFF:** Well, if it's from HL Shaw, why is
 25 it copied to HL Shaw?

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1 Factorate) in the USA and these products are imported
 2 and sold in the UK. Approximate annual sales of these
 3 products are follows ..."
 4 We can see the figures set out, 15 to 20 million
 5 international units of Factorate; 1 to 1.5 million
 6 international units of High Potency Factorate.
 7 "2. Source plasma is of USA origin and processing
 8 of this to the finished product also takes place in
 9 the USA.
 10 "3. All plasma is collected at FDA licensed
 11 centres. Routinely all plasma used is collected at
 12 plasmapheresis centres owned by Plasma Alliance, which
 13 as with Armour Pharmaceuticals is a subsidiary of the
 14 Revlon Health Care Group. These centres are focused
 15 as follows ..."
 16 Then we have a list of them: Akron, Atlanta,
 17 Chattanooga, Cleveland, Colombo --
 18 **SIR BRIAN LANGSTAFF:** Colombos.
 19 **MS RICHARDS:** -- Colombos, sorry -- Dayton, Knoxville,
 20 Lexington, Louisville, Nashville, Oklahoma, Omaha,
 21 West Lafayette, University of Minnesota and St Paul.
 22 "On occasions plasma has also been obtained from
 23 other FDA-licensed centres."
 24 So it does appear that Armour was not entirely
 25 self-sufficient in the sense of receiving plasma only

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1 from its Plasma Alliance centres, at least according
 2 to this document.
 3 "We are seeking further information on the names
 4 and locations of these centres from the USA."
 5 Then if we go over the page:
 6 "4. Only USA plasma is used.
 7 "5. We believe that the comprehensive labelling
 8 and record requirements of the FDA Code of Federal
 9 Regulations and the additional corporate in-house
 10 requirements per MIT identification of the origin of
 11 plasma included in this batch to specific donor level
 12 as well as centre. Confirmation of this is awaited
 13 from the USA.
 14 "6. Plasmapherised plasma is collected from the
 15 Plasma Alliance centres and processed at Armour
 16 Pharmaceutical Company, Kankakee, Illinois. We
 17 believe that plasma from several centres is used in
 18 the production of a batch of material.
 19 "7. None of the Plasma Alliance centres are
 20 located in any of the areas associated with high risk
 21 of AIDS transmission. We believe this to be also the
 22 case with other centres used by the company. Thus our
 23 Factorate products will not contain material derived
 24 from plasma collected in these areas.
 25 "8. We confirm that all plasma used in the

1 6/20/83
 2 "1. Information furnished by the Centers for
 3 Disease Control indicates that those haemophiliacs
 4 diagnosed as having contracted AIDS have received
 5 multiple products, including cryo, from multiple
 6 sources. There does not appear to be any instance in
 7 which a haemophiliac patient received one product
 8 exclusively. We are not certain as to whether each of
 9 them indeed received one product inclusively. We are
 10 not certain as to whether each of them indeed received
 11 Factorate concentrate as part of haemophilia
 12 treatment, but assumed such a likelihood.
 13 "2. I cannot comment on information given to you
 14 earlier as to when procedures were implemented in
 15 Plasma Alliance centers. The centers in December ..."
 16 I think there might be a word missing sorry
 17 I think after "Plasma Alliance centers".
 18 **SIR BRIAN LANGSTAFF:** There's something there and it
 19 doesn't read on easily.
 20 **MS RICHARDS:** Yes:
 21 "... the centers in December, 1982 and that more
 22 formal steps were taken in February, 1983, are correct
 23 to the best of my knowledge."
 24 That would be consistent with what was set out in
 25 that letter to Haemophilia Centre Directors in

1 production of our blood products is now collected in
 2 conformity with the FDA Directive of March 23, 1983.
 3 "9. We believe that a full programme of special
 4 precautions regarding screening procedures and
 5 dissemination of information to donors was initiated
 6 in our Plasma Alliance centres in February of this
 7 year. Before that time information on the risk of
 8 AIDS had been relayed to donors by means of posters
 9 displayed in the collection centres since
 10 October/November 1982 although the revised screener
 11 procedures had not been finalised and implemented.
 12 Confirmation of this is being sought from the USA.
 13 "10. We believe that all future supplies of our
 14 products, Factorate and High Potency Factorate, sold
 15 in the UK will have been processed from plasma
 16 collected under the new procedures."
 17 So that's the response to the DHSS questions and
 18 then, if we go to ARMO0000263, this is a further
 19 telex. I think the date of this is 23 June 1983.
 20 There's certainly a stamp to that effect in the top
 21 right-hand corner. It's not entirely clear but, in
 22 any event, it's a response to the further questions in
 23 the telex of 20 June, and I think it would appear to
 24 be from Dr Rodell:
 25 "The following is in response to [your telex] of

1 May 1983, which said posters in December 1982, and
 2 then screening procedures in February.
 3 "[Please] bear in mind that industry discussions
 4 as to action steps did not begin until December, 1982.
 5 "3. The donor discussed in my earlier telex has
 6 not participated in our plasmapheresis programs since
 7 late February, 1983. Factorate concentrate derived
 8 from pools containing units of plasma from this
 9 individual have been distributed domestically and have
 10 been exported, some of this material did go to the UK.
 11 "4. Armour Pharmaceutical Company uses only
 12 plasma collected by the Plasma Alliance centers in the
 13 manufacture of Factorate concentrate. To that extent,
 14 we are unique among all other manufacturers, who rely
 15 upon outside source material quite heavily."
 16 So it appears to be being asserted here by
 17 Dr Rodell or by Armour in the US that, in fact, Plasma
 18 Alliance does supply the entirety of the plasma.
 19 "5. Within our own organization over
 20 150 individuals have deferred themselves since the
 21 AIDS program was initiated in February, 1983. I must
 22 point out that Plasma Alliance centers are not located
 23 in any of the 'hot spots' associated with AIDS, ie
 24 New York, Florida, California. Alpha Therapeutic
 25 Corporation has stated that over 400 individuals have

1 deferred themselves. I have no data from other
2 manufacturers."

3 So that's the further information supplied to
4 Armour UK by Armour in the US.

5 There is then, if we move to later in 1983,
6 a telex at ARMO0000302. The date of this is
7 4 November 1983. It's to Mr Bishop, so it's addressed
8 to Armour in the UK. It's from, it looks like,
9 I Regier. I'm afraid I don't know off the top of my
10 head who that is.

11 It refers, in the first part of it, to a recall of
12 products by Cutter:

13 "Cutter recalled 16 AHF lots ... distributed to
14 33 countries, including Japan. Several other lots are
15 on hold. One of Cutter's plasma donors recently died
16 because of AIDS. The man donated about 5 liters of
17 plasma over the time, but apparently failed to
18 indicate any information about his disease during that
19 time. We will probably have to expect very detailed
20 questions regarding donor screening/selection of
21 donors during the BGA hearing at ..."

22 I'm not quite sure what that next word is.

23 **SIR BRIAN LANGSTAFF:** Berlin, is it?

24 **MS RICHARDS:** It probably is. That would make sense.

25 **SIR BRIAN LANGSTAFF:** That would stand with BGA.

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1 excellent quality and highest standards. Although it
2 is obvious that it is actually not know how to avoid
3 [it should be 'not known'] transmission of AIDS, it
4 should also be emphasized that we have recently
5 introduced Factorate HT [heat treated] to improve the
6 safety of our product.

7 "We will keep you informed on this matter and
8 would appreciate any feedback."

9 So that's November '83. Then if we go to
10 CGRA0000319. This a Cutter internal memorandum, dated
11 13 March 1984, and it refers to a meeting held on
12 6 March. You'll see that there were attendees from
13 a number of different pharmaceutical companies
14 including in relation to Armour, Dr Mike Rodell.
15 You'll see under the heading "In Summary" that, for
16 discussion at the meeting, was the question of
17 beginning hepatitis B core antibody testing of source
18 plasma donors.

19 It says:

20 "... following 5 [hours] of discussion, a vote was
21 taken [three are identified as voting in favour]. All
22 others [with the exception of one who abstained] were
23 not in favour."

24 If we go to the bottom of the page and I'm really
25 going to pick up what was said by Dr Rodell,

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1 **MS RICHARDS:** It would, indeed, which is effectively the
2 German regulatory or licensing body.

3 "I am also concerned about suggestions that paid
4 donors are less likely to be truthful when asked
5 questions which would disqualify them as donors.
6 "Under the circumstances I suggest that we have
7 a meeting ..."

8 Then a suggested date is given, prior to what's
9 described as the BPI meeting:

10 "At the hotel Kempinski. The Cutter incident is
11 under investigation now and Dr Rodell will have
12 detailed information available for our meeting.

13 "We regret the unfortunate circumstances of the
14 Cutter incident. However, the possibility of
15 something like that happening to any plasma
16 manufacturer cannot be included. It should be to our
17 advantage to remind our customers in an appropriate
18 form, that Armour processes plasma from our wholly
19 owned and fully controller plasma pheresis centers."

20 **SIR BRIAN LANGSTAFF:** It must be 'fully controlled',
21 I think.

22 **MS RICHARDS:** Yes, I think there are a handful of
23 typographical errors in the telex. I think that must
24 be what was intended.

25 "Plasma Alliances has a worldwide reputation for

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1 reflecting his role with Armour. It says:

2 "Immediately prior to the conclusion of our
3 meeting it was recommended that the Industry should
4 refrain from starting anti-HBc testing. Carr was
5 adamant that Alpha would not begin, Rodell said Armour
6 would not use the test unless a competitor was using
7 it to competitive advantage."

8 Then it continues in relation to representatives
9 of other companies.

10 If we go to the third page -- sorry, actually, if
11 we pick it up at the top of the second page, first of
12 all, my apologies. Under the heading "General
13 comments", it says:

14 "After an introductory/background statement,
15 Rodell asked that each of us give comments and
16 thoughts on anti-HBc testing. Both the original
17 statement and subsequent comments by each attendee, in
18 the order presented, are summarized."

19 Then we have contributions again from various
20 different individuals. If we go to the bottom of the
21 third page, we will see what was recorded in this
22 Cutter memorandum as being said by Dr Rodell:

23 "... questions if anti-HBc test is sufficiently
24 specific to be effective. It would exclude only 50%
25 of donors with AIDS prodrom. Provided figures showing

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1 anti-HBc testing and rejection of positive donors
 2 should cost several million [dollars] per year. 14 to
 3 15 Plasma Alliance centers collecting about
 4 850,000 liters per year. Armour currently derives all
 5 plasma from Plasma Alliance, no contract centers."

6 So obviously the last two sentences pick up upon
 7 the question of what the sources of plasma were used
 8 by Armour, and it appears to be said it's entirely
 9 Plasma Alliance centres.

10 Dr Rodell's opposition to or hesitancy in relation
 11 to introducing hepatitis B core antibody testing
 12 appears to be twofold. One, it's said it would
 13 exclude only 50% of donors with AIDS prodrom and,
 14 secondly, it talks about the costs.

15 There's a further document on the issue of the
 16 introduction of hepatitis B core antibody testing, and
 17 that is at ARMO000138. So this is a letter of
 18 15 March 1984 from Dr Rodell to Dr Duncan Thomas at
 19 the National Institute for Biological Standards and
 20 Control in London, and he says this:

21 "Dear Dr Thomas:

22 "As a result of the December, 1983 meeting of the
 23 FDA's Blood Products Advisory Committee, a study Group
 24 was formed to consider the appropriateness of testing
 25 potential blood and/or plasma donors for core antibody

1 associated with [AIDS]. Although a full report of the
 2 Study Group's deliberations and conclusions will be
 3 furnished to the [FDA] in the near future, it was felt
 4 that an interim statement should be made available at
 5 this time.

6 "The Study Group was divided in its position on
 7 testing for Anti-HBc as a means of identifying AIDS
 8 high risk group members, with the majority believing
 9 that such testing was not appropriate for that
 10 purpose. However, members of the majority group
 11 indicated that they would likely be compelled to
 12 follow suit if any of the organizations represented
 13 initiated Anti-HBc testing programs."

14 Then there are various further matters set out,
 15 including in the last paragraph a suggestion for some
 16 pilot studies.

17 I think we can pick up consideration of matters
 18 relating to donor screening at ARMO000425. This is
 19 a letter dated 14 August 1985 from Dr Rodell, to
 20 Dr Peter Jones, and it's part of the bigger saga of
 21 seroconversions in relation to treatment with
 22 heat-treated Factorate and we can see Dr Rodell
 23 saying:

24 "I have been requested ... to respond to your
 25 letter ..."

1 to hepatitis B ... as an additional means of
 2 identifying members of high risk groups associated
 3 with AIDS.

4 "The Study Group met on March 6, 1984, at which
 5 time each member presented views, information, and
 6 data relative to the issue."

7 So that's presumably a reference to the meeting
 8 that was discussed in the Cutter memorandum.

9 "We felt it appropriate to issue a summary
 10 statement regarding our findings and conclusions in
 11 advance of a full report to be prepared in the near
 12 future.

13 "I am enclosing a copy of the Study Group's
 14 Interim Summary Statement, and hope it will be helpful
 15 to you."

16 If we go over the page we can see the summary
 17 statement is authored by Dr Rodell. The first
 18 paragraph refers to the meeting at which the issue of
 19 testing blood or donors for core antibody to
 20 hepatitis B was discussed.

21 Paragraph 2 says:

22 "The purpose of the meeting was to review all
 23 aspects and ramifications of the use of testing for
 24 Anti-HBc as an additional means of determining whether
 25 potential donors were members of high risk groups

1 We'll look at all the underlying correspondence in
 2 November.

3 Dr Rodell says:

4 "In my capacity as designated Responsible Head of
 5 Armour Pharmaceutical Company to the USA FDA, I am
 6 directly involved in issues associated with the plasma
 7 collection and processing ..."

8 If we go over the page, we can see in the top
 9 paragraph, Dr Rodell saying this, picking it up in the
 10 fifth line:

11 "Although testing for Anti-HTLV-III is not
 12 mandatory in the US, our Plasma Alliance subsidiary
 13 implemented system-wide testing of each donation of
 14 plasma very shortly after the availability of the
 15 test. Units of plasma found to be positive for
 16 Anti-HTLV-III are not used in the manufacture of
 17 clotting factor concentrates, and donors of these
 18 units are permanently deferred from further
 19 participation in our plasma programs. In addition,
 20 the donor education programs that we implemented in
 21 1982 [presumably a reference to the posters in
 22 December 1982 and then the subsequent February 1983
 23 procedures], designed to discourage members of high
 24 risk groups from participating in plasma donation
 25 programs, have been augmented and are still in place."

1 It's not clear what's meant by reference to them
2 being augmented, either in terms of how they were
3 augmented or the date of augmentation.

4 And then we can see if we pick it up in the third
5 paragraph, Dr Rodell says:

6 "In your letter to Mr Miller, you requested
7 specific information on the movement of plasma and
8 plasma products internationally. Armour
9 Pharmaceutical Company has never utilised plasma
10 collected outside the continental United States in the
11 production of clotting factor concentrates, nor do we
12 intend to in the future.

13 "Additionally, for the manufacture of clotting
14 factor concentrates, Armour has not used plasma
15 collected from cities in the [US] designated by the
16 CDC as 'high risk AIDS areas'. A listing of the
17 center location of our subsidiary Plasma Alliance is
18 attached."

19 Then there's a reference to the conference that we
20 know Dr Jones was organising in relation to AIDS in
21 February 1986, and an offer is made by Dr Rodell that
22 information could be provided, and then it's said at
23 bottom of the page:

24 "Equally, Mr C Bishop from our [UK] operation
25 would be pleased to help you with the organisation of

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1 an industry position in relation to AIDS.

2 "The following was agreed to ..."

3 Various matters set out that I don't need to
4 trouble you with. But if we go to the second page
5 there is a reference to issues of batch sizes, as it's
6 described in the second paragraph:

7 "Any attempt to reduce batch sizes of AHF was
8 considered ineffective because Haemophiliacs received
9 product representing hundreds of thousands of donors
10 during the year regardless of batch size. Also so
11 little is known regarding the effect of dilution that
12 a batch size reduction could conceivably have
13 a detrimental effect. Finally, batch size reduction
14 could have serious negative repercussion on productive
15 availability an, most especially, on cost.

16 "Cryoprecipitate which is the ultimate in batch
17 size reduction is felt to be at best a delaying action
18 since it can so substantially alter the lifestyle of
19 Haemophiliacs."

20 Again, that's a discussion that we'll need to come
21 back to. There's a reference there in the context of
22 developing an industry position.

23 Then if we go to ARMO0000242, this a short telex
24 from Mr Bishop, so Armour UK, dated 27 April 1983, to
25 a number of -- well, it's addressed to Anita Bessler

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1 the Congress."

2 The Plasma Alliance centres locations are then
3 listed on the following page. I'm not going to read
4 them out. Sorry, the page after that. We can see
5 them there set out.

6 Well, sir, there's obviously a lot more to the
7 involvement of Dr Jones in the context of bringing to
8 the fore the issue of seroconversions from
9 heat-treated Factor VIII, but we'll explore that in
10 more detail in November.

11 Can I just then pick up some references to pool
12 sizes. So we saw the figures from 1976, we saw the
13 figure in July 1981 in that publication of
14 approximately 2,000 donors described, I think,
15 effectively as a small pool.

16 If we then go to BAYP0004375. This now January of
17 1983. It's a letter dated 21 January 1983 from
18 a senior vice president at Alpha, to Cutter. And it
19 refers to a meeting which was held on 14 January 1983,
20 and there's a list of those in attendance at the
21 meeting. It includes Bob Johnson, Armour, but you'll
22 see representatives of the major pharmaceutical
23 companies all involved.

24 We can see it's said:

25 "The purpose of the meeting was to develop

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1 but then there are a number of people copied into it,
2 and its subject is "AIDS - Armour Policy", and it says
3 this:

4 "Further to our telecon 26th April I would confirm
5 that the circulars sent by Travenol and Cutter to the
6 UK Haemophilia Centre Directors are on their way to
7 you, and that sent by Alpha will be following shortly,
8 under separate cover.

9 "I would like to emphasise the urgency of
10 a similar definitive statement from our own operation,
11 along similar lines, together with a more simplified
12 statement, which can be passed on to the increasing
13 number of UK haemophiliacs who are beginning to ask
14 questions of their individual centres."

15 Then this:

16 "I understand that Ingo Regier will be discussing
17 this with you in detail. I should like to receive
18 your recommended circular, painting as positive
19 a picture as possible and emphasising our small
20 batch/donor pool sizes."

21 That appears to be -- and again, it's a document
22 we can ask Mr Bishop about in due course --
23 a characterisation of the Armour pool size as being
24 small. Whether that's by way of comparison with
25 others or not is unclear from the document.

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1 We then, in terms of discussion of pool sizes,
2 move to 1986, and ARMO0000501. This a document dated
3 5 March 1986. It's an inter office memorandum from
4 Mr Christie to Dr Harris, and it refers to a "Meeting
5 with [the Department of Health] on Factorate Heat
6 Treated, 3 March 1986".

7 This is, again, part of the series of
8 communications between the Department and Armour
9 concerning possible seroconversions from heat-treated
10 Factorate.

11 For present purposes, the salient paragraph is the
12 second paragraph under the heading "Manufacturing
13 Process", where it says this:

14 "We were asked the size of our donor pool which
15 was defined as between 5,000 and 20,000 donors."

16 Then there is a suggested calculation in relation
17 to what's described as the "maximum virus challenge".

18 Now, why those figures appear in circumstances
19 where very much smaller figures have earlier been used
20 is currently unclear.

21 **SIR BRIAN LANGSTAFF:** There may be a question about the
22 use of the word "pool". I can see -- it's
23 a possibility, I'm not passing any comment on it --
24 that "donor pool" may refer to the number of repeat
25 donors who are, if you like, on the books. The pool

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1 areas of low risk for AIDS and all the centres being
2 Armour's own centres.

3 **SIR BRIAN LANGSTAFF:** On the question of pool again,
4 there's a paragraph above that.

5 **MS RICHARDS:** Yes.

6 **SIR BRIAN LANGSTAFF:** "... the risk of potential positive
7 donations to a pool ..."

8 And that must be a pool of plasma from which
9 manufacture is made.

10 **MS RICHARDS:** That would appear logically and
11 linguistically to be correct, sir.

12 **SIR BRIAN LANGSTAFF:** So unless there's actual positive
13 evidence that "donor pool" means the number of donors,
14 I'm inclined, but I'm open to submission on it in due
15 course, to think that it is referring to the
16 manufacturing plasma pool.

17 **MS RICHARDS:** Yes. The only other reference to "pool"
18 that I can see is the top of page 3, but that's
19 looking at a specific pool of plasma which contained a
20 donation from an individual who subsequently developed
21 AIDS.

22 **SIR BRIAN LANGSTAFF:** Yes.

23 **MS RICHARDS:** And the issue of that particular infected
24 batch and what was done in relation to it is an issue
25 we're going to be looking at in more detail in

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1 of donors, as opposed to the way in which we have been
2 interpreting this, as the pool of plasma from which
3 the product is then made. It's a possibility.

4 **MS RICHARDS:** Yes, it is. Unfortunately, I don't think
5 any of the individuals who were present at the meeting
6 are individuals that we're going to be able to ask
7 about this issue, so I don't think we can cast any
8 further light on it, other than bringing it to your
9 attention.

10 **SIR BRIAN LANGSTAFF:** Well, although I can see that
11 possibility, it may perhaps be the less likely of the
12 two in the context, because the context goes on to
13 talk about "pool" in the last sentence. And there the
14 pool really only makes sense if it is the pool of
15 plasma from which product is made.

16 **MS RICHARDS:** Yes.

17 **SIR BRIAN LANGSTAFF:** So it's difficult to think that the
18 author would switch from one meaning of "pool", pool
19 of donors, to another meaning, of pool of donation,
20 donated plasma, in the same paragraph.

21 **MS RICHARDS:** Yes. I'm just looking to see whether
22 there's anything further in this document which casts
23 light on it, but I don't think there is.

24 There is then, towards the bottom of the page,
25 a repetition of all plasmapheresis centres being in

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1 November.

2 **SIR BRIAN LANGSTAFF:** But if it's 5-20,000 donors feeding
3 into a pool, it's a large pool.

4 **MS RICHARDS:** Yes.

5 **SIR BRIAN LANGSTAFF:** Much larger than the earlier
6 references.

7 **MS RICHARDS:** Yes. Certainly we've not, I think,
8 uncovered any other documentation which suggests that
9 the pool sizes were of that magnitude for Armour.
10 Having said that, all the documentation upon which
11 we're relying is, I think -- it's all Armour-generated
12 documentation, so I don't think we have anything
13 which, outside of Armour's own publications, addresses
14 the issue of pool sizes, at least not
15 contemporaneously.

16 If I can then just deal very briefly with the
17 question of the collection of plasma from prisons,
18 I think the document here is CGRA0000545.

19 Again, this is a Cutter document. It's described
20 in terms of its subject as referring to a
21 "Fractionator Meeting, April 12, 1985".

22 If we go to the second page, we can see the
23 heading "Prison Plasma". It says this:

24 "This subject [elicits] even more diverse
25 viewpoints. Cutter and Alpha believe that science has

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1 progressed to the point that we can screen this plasma
2 through testing (HTLV-III etc) and we now heat treat
3 the products. Hyland says they have no current prison
4 plasma sources (!) and Armour states they will never
5 have any."

6 And then it goes -- well, I'll read the whole
7 paragraph out, although that's the only reference to
8 Armour.

9 "Reilly is perpetually gloomy on the subject, and
10 feels we are destined to fail. Nevertheless, we
11 agreed to hang together for a try with the FDA. We
12 will propose to begin using prison plasma cryo and
13 abandon our 'Gentlemen's agreement' unless the FDA
14 takes issue and threatens regulatory action. We will
15 further agree to do whatever testing the FDA deems
16 necessary to answer any academic concerns."

17 Picking it up in the penultimate sentence:

18 "The argument for using prison plasma is the
19 additional testing (HTLV-III) and heat treatment which
20 provides product safety."

21 In any event, what's said there to be Armour's
22 position is they will never have any. It's not
23 terribly illuminating, but --

24 **SIR BRIAN LANGSTAFF:** I think the "will" sounds more like
25 an expression of determination --

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1 **SIR BRIAN LANGSTAFF:** But words which I thought, when
2 I saw them, would suggest that any prison donations
3 would be excluded on that basis, if it is accurate.

4 **MS RICHARDS:** Yes. I think the only -- and "question
5 mark" is probably putting it too high -- the only
6 slight gap in information is the question of whether,
7 at all times -- at least from the late 1970s onwards,
8 once Armour had acquired Plasma Alliance -- they were
9 able to obtain all the plasma they required for
10 fractionation from the Plasma Alliance centres, which
11 don't appear to have included any prison locations, or
12 whether there were ever occasions in which they drew
13 or obtained plasma from non-Plasma Alliance centres,
14 which, although US-based and FDA licensed, might not
15 have precluded collection of prison plasma.

16 But there is no -- I should put it this way,
17 I think: there is no positive evidence that we have
18 seen which suggests prison plasma being used by Armour
19 in the period of time with which the documents are
20 concerned.

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

22 **MS RICHARDS:** The last issue just in relation to donors
23 and the screening of donations is -- if I can just
24 touch on, and again, then, defer for more detailed
25 consideration in November -- the issue of screening

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1 **MS RICHARDS:** Yes.

2 **SIR BRIAN LANGSTAFF:** -- than a prediction.

3 **MS RICHARDS:** Yes. Whether it is intended as
4 a comprehensive account of the past is impossible to
5 say from the document. This is a meeting that was
6 looking at whether prison plasma should now be used as
7 at 1985, given the availability of testing. So it
8 probably doesn't help in any understanding as to the
9 past position.

10 I should say we've not seen any contemporaneous
11 documents or any primary source documents to
12 demonstrate Armour collecting or using plasma
13 collected in prisons.

14 So I have drawn this to your attention, sir,
15 because it's a passing reference to prison plasma.

16 **SIR BRIAN LANGSTAFF:** And in the Plasma News or whatever
17 the title of the document was you showed us earlier,
18 the objective presentation -- or presentation which
19 aimed to be objective, written by or on behalf of
20 Armour, which exhibited Peter Jones's comments on his
21 visit, the photograph on the top left-hand side which
22 I drew your attention to, that, I think, says that: we
23 don't take plasma from people who -- circumstances
24 show a hard life. Or words to that effect.

25 **MS RICHARDS:** Yes.

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1 donors for HTLV-III. So there are just, I think,
2 three or four documents from 1986 that I'll briefly
3 refer to.

4 If we start at ARMO0000496, this is described as
5 a "Report of a meeting held in Fort Washington to
6 discuss Factorate on 27.2.86". A number of people
7 present, including, we'll see, Dr Rodell.

8 And then the document at the bottom is dated
9 28 February 1986. It's I think probably from
10 Dr Harris, and it's copied to Dr Christie and
11 Mr Bishop, so it's sent to Armour UK, although it's
12 a meeting that takes place in the States.

13 Then we can see in the first main paragraph:

14 "The meeting then reviewed on a case by case basis
15 every instance of sero-conversion that has been
16 reported anywhere in the world ..."

17 Again, that's the issue we'll come back to. And
18 if we pick it up about five lines down, six lines
19 down:

20 "The net result of these discussions was that, in
21 the opinion of everyone at the meeting, there is no
22 problem with Factorate drawn from unscreened donors."

23 So that's donors not screened for HTLV-III.

24 "However, it was felt that, just as with any
25 ongoing improvements which have been made with

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1 Factorate, adding the screening to the donor pool is
2 an improvement to the product, and we should, first of
3 all, withhold from distribution all non-screened
4 product, under one stipulation. This is that,
5 withholding that non-screened product does not result
6 in patients being unable to obtain a product or the
7 potency they want when they order, or hospitals or
8 physicians not being able to have access to the
9 particular product that they have designated for the
10 use of the specific patients."

11 "In other words, the meeting felt that there
12 [were] no reason to believe there was a problem with
13 non-screened product but, at least in theory, by
14 screening, we will improve the product even more and
15 we should do as much as we can to implement those
16 improvements as quickly as possible."

17 Then the last paragraph -- actually I should read
18 the whole document.

19 "In the meantime, it was considered there was no
20 reason to cause any problems in terms of the normal
21 day to day delivery of Factorate to our customers,
22 etc, based on all the information available to date.
23 In terms of the US and UK and everybody else who has
24 non-screened product in inventory, we will continue to
25 withhold the distribution of that product as long as,

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1 Dr Harris, who is Armour UK, but I might be wrong, but
2 I can't remember -- I'm not sure I know who the
3 initials "LEW" stand for.

4 So it appears to be an internal document and it is
5 being provided, amongst others, perhaps only, to
6 Mr Christie and Mr Bishop, to inform them of what has
7 been discussed in the States.

8 **SIR BRIAN LANGSTAFF:** The curiosity of it is that it's
9 proposing to introduce a screening, which is bound to
10 be expensive, it's proposing to not -- effectively to
11 recall or withhold batches which have not been
12 screened, which is going to be expensive and lead to
13 the loss of product already manufactured, all on the
14 basis that there is no evidence that it has any effect
15 at all, which is -- just makes me curious about the
16 document.

17 **MS RICHARDS:** Yes. Well, it may be that Mr Bishop will be
18 able to assist us with it, although of course he is
19 not the author of the document itself and was not
20 a participant in the meeting.

21 Then there is, of course, a proviso or
22 stipulation, which is that withholding that
23 non-screened product does not result in patients being
24 unable to obtain the product, or hospital or
25 physicians not being able to have access to the

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1 or unless, we only have that type of product to
2 distribute within the market. In other words, it is
3 a voluntary withholding and not a withdrawal from the
4 market."

5 Then the next paragraph:

6 "The meeting agreed that it was very important to
7 gear up production in Kankakee and to, as rapidly as
8 possible, be in the position where not only will we
9 not be distributing product from non-screened donors
10 but that we will reach a point that where, without
11 interrupting the supply to the patient, we can
12 exchange un-screened product with material that has
13 already been screened."

14 So it's a slightly torturous account of the
15 discussion. I don't mean that in a critical sense.

16 **SIR BRIAN LANGSTAFF:** Who is this addressed to?

17 **MS RICHARDS:** Um ... I am not sure, I'm afraid, sir. It's
18 an internal document. The very top of the page refers
19 to a "Telephone conversation PAG/CB/Anita Bessler",
20 dated 28 February, and then it's "Report of a meeting
21 held in Fort Washington to discuss Factorate on
22 27.2.86", and we see those who attended.

23 At the bottom of the page it is CC'd to
24 Mr Christie and Mr Bishop, who are Armour UK. I'm not
25 sure whether -- "PAH" I had assumed was probably

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1 particular product, so it contemplates, I think, the
2 possibility that there might be circumstances in which
3 the unscreened product might --

4 **SIR BRIAN LANGSTAFF:** Well, it does, but the overriding
5 message is: we're going to carry out something which
6 is going to be expensive in more than one way, which
7 we have no reason to believe will make any
8 improvement.

9 **MS RICHARDS:** Yes.

10 **SIR BRIAN LANGSTAFF:** Apart from the show of it.

11 **MS RICHARDS:** There are then a handful of other documents
12 on the same topic, so if we go in chronological order
13 to 13 March 1986, so the following month,
14 PJON0000034_022.

15 This is a letter dated 13 March 1986. It is from
16 Dr P Harris, medical and technical director at Armour
17 Pharmaceutical Company Limited. This is a version
18 addressed to Dr Jones but we have also a version which
19 suggests that it was sent more widely to Haemophilia
20 Centre Directors.

21 I think we can pick it up -- it deals in large
22 measure with issues about viral inactivation, but we
23 can pick it up in the last paragraph on that page
24 where it is said:

25 "As you may already know, all our plasma

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1 collection centres are situated in the American
2 mid-west away from the known areas of high risk for
3 AIDS. Our typical donor is a multiple visitor and
4 undergoes thorough medical examination and follow-up
5 at each attendance. Each donation is now specifically
6 screened for HTLV-III antibody and all product being
7 supplied is donor tested."

8 The top of the next page:

9 "Before donor testing it was estimated that the
10 risk of including an HTLV-III contaminated donation in
11 a plasma pool was from 0.25-0.3%. By introduction of
12 our donor testing, it may be assumed that this risk
13 has been minimised.

14 "However, it should not be overlooked that there
15 may be material in centres, or in the home that is not
16 derived from donors tested for anti-HTLV-III. We do
17 appreciate that this information would aggravate the
18 potential for distress to the haemophiliac, because of
19 the patient's inference that non-donor tested material
20 may be less safe with regard to the AIDS risk.
21 Further, we recognise that any decision to give
22 a patient this information rests with you as the unit
23 director."

24 Then the last paragraph explains:

25 "I am sending this letter to UK Haemophilia Centre

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1 this:

2 "I wrote on 13th March to all UK Haemophilia
3 Centre Directors who were considered likely to have
4 used Factorate Heat Treated during the preceding
5 12 months ..."

6 That's the letter we have already looked at.

7 Then the next paragraph:

8 "On the 23rd June 1986 however, our American
9 parent company wrote to all US based Blood Bank
10 Directors and/or Haemophilia Treatment Co-ordinators
11 recommending to them the return for exchange of any
12 non-donor tested material. In line with our corporate
13 policy, and having obtained the agreement of the DHSS,
14 I am now recommending the return of all non-donor
15 tested Factorate so we can exchange this for material
16 manufactured from screened donations.

17 "Would you please review your stocks of Heat
18 Treated Factorate, including that issued for home
19 treatment, and if you have any from the batched listed
20 overleaf, please return these to Armour Pharmaceutical
21 Company Limited ... These will be exchanged for
22 donor-screened product. All Armour material supplied
23 in the UK since January 1986 has been donor-screened."

24 So that's what is said in July 1986. Again, it's
25 an issue we'll need to come back to but you'll see

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1 Directors who are likely to have used 'Factorate' in
2 the preceding 12 months."

3 There's then a letter from Dr Jones, not to Armour
4 but to a fellow haematologist in Manchester Children's
5 Hospital. That's at ARMO0000517 -- I'm sorry, Soumik,
6 can I give you a different reference?
7 HCDO0000271_075.

8 As I say, it's from Dr Jones to Dr Evans at the
9 Royal Manchester Children's Hospital. Again, it's
10 part of the bigger issue of seroconversions from
11 heat-treated Factor VIII, but on the issue of
12 individual donor testing, in the second paragraph,
13 Dr Jones says this, picking it up in the second line:

14 "The really worrying thing to me is that there is
15 evidence that there are still concentrates being used
16 which have been derived from plasma which has not been
17 individually donor tested. This I know to be true of
18 the Armour product but I suspect that it might also be
19 true of other commercial concentrates as well."

20 Then it goes on to discuss a range of other
21 matters.

22 Then, if we go to ARMO0000554, we can see a letter
23 dated 11 July 1986, again this is from Dr Harris of
24 Armour Pharmaceutical Limited in the UK, to
25 a Dr Mustafa at a hospital in Darlington, and it says

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1 there the statement that's made of "All Armour
2 material supplied to the UK since January 1986 being
3 donor-screened", but the meeting which was the first
4 meeting we looked at in relation to this issue was
5 a meeting 27 February 1986.

6 **SIR BRIAN LANGSTAFF:** The Fort Washington meeting?

7 **MS RICHARDS:** The Fort Washington meeting. That doesn't
8 mean that the statement that "All Armour materials
9 supplied in the UK since January 1986 has been
10 donor-screened" is incorrect or inaccurate, but we
11 will need to come back to this to see whether we can
12 bottom out in more detail the correct factual
13 position.

14 The final document that I just wanted to draw to
15 your attention on the issue of donors is CGRA0000570.
16 So the date of this is 25 July 1986, and it's a memo
17 from Dr Harris, and we've got the heading now "Rorer
18 Health Care Limited" to Mr Thomas, copied to various
19 people, including Mr Bishop and Mr Christie and
20 Dr Rodell.

21 Again, what's set out in this first page is
22 something we'll be coming back to, but if we go to the
23 second page, we can see a paper headed "Review of
24 Factor VIII products with respect to possible freedom
25 from viral contamination. Factorate Heat Treated --

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1 Armour". Then we've got the heat treatment method,
2 60 degrees centigrade for 30 hours.

3 Then some additional observations:
4 "(a) our own collection centres away from known
5 high risk areas.

6 "(b) Donor education.

7 "(c) Pre-donation screen by questioning and
8 physical examination."

9 Then this:

10 "Unfortunately, experience has shown that
11 prospective donors do not always tell the truth."

12 So that's an observation worth flagging up.

13 There is then a more detailed discussion in this
14 document about seroconversions from heat-treated
15 concentrates. If we go to -- no, in fact there is
16 nothing which casts any particular further light on
17 the position in relation to donors. I think we'll
18 pick up the rest of this document in November.

19 So, sir, that completes the theme in relation to
20 donors. The next issue in relation to Armour that
21 I want to pick up is issues about communication of
22 risk, and looking at some of the product labels and
23 data sheets, and we can perhaps do that at
24 two o'clock.

25 **SIR BRIAN LANGSTAFF:** Yes. Well, let's take a break now

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1 I would draw to your attention.

2 **SIR BRIAN LANGSTAFF:** If I may just comment for one
3 moment, one of the documents you showed me this
4 morning described telling others and users, it said,
5 of certain features about the product. By "users", it
6 was quite clear from the context it meant doctors.

7 **MS RICHARDS:** Yes, absolutely.

8 With that general observation in mind, we'll then
9 turn to some of the specific materials relating to the
10 Armour Factorate product.

11 If we start with ARMO0000002.

12 This is from the 1975 application for the product
13 licence for Factorate, much of which we looked at
14 yesterday. If we go to page 60, please, we can see
15 some of the materials -- the warning in other
16 materials that accompanied the application, or at
17 least formed part of the file containing the
18 application, and we can see there "Caution", so those
19 are the last three lines:

20 "This product is prepared from pooled human
21 plasma. Despite careful selection of donors, it may
22 contain causative agents of viral hepatitis."

23 Then within the same document if we go to page 66,
24 this is described as a "Revised package insert
25 leaflet", and again, it appears in -- as part of

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1 until 2 o'clock. 2 o'clock.

2 (12.57 pm)

3 (The Short Adjournment)

4 (2.00 pm)

5 **MS RICHARDS:** Sir, I'm going to turn to consider questions
6 of the communication of risk by Armour, largely in
7 terms of product labelling, data sheets and the like.
8 But before we look at any specific documents, I'll
9 just set out an observation which has been made to me
10 by a representative of Core Participants -- not
11 specific, I should say, to Armour but on the question
12 of warning labels and data sheets and so on more
13 generally -- and that's to just point out there may be
14 a question mark as to the extent to which those are
15 written materials that would have been seen by
16 patients, or at least seen by certain cohorts of
17 patients.

18 Leaving aside the question of whether what's in
19 a product label or product insert can ever be
20 a substitution for the clinician's discussion of risk,
21 there will be some cohorts of patients who will never
22 have seen that in any event: children, those treated
23 in hospital, not at home, and the like.

24 So that was just an observation made to me on
25 behalf of a number of Core Participants that I said

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1 a file, which suggests it was being put forward as
2 part of the application. And we can see there the
3 heading "Warning" on the right-hand side:

4 "Antithaemophilic Factor (Human) - FACTORATE is
5 prepared from human plasma, each donation of which has
6 been found negative for Hepatitis B Surface Antigen
7 ... by the ... (RIA) method. In addition, this lot,
8 after reconstitution as directed in this insert, has
9 been tested and found negative by the RIA method.
10 However, since no completely reliable laboratory test
11 is yet available to detect all potentially infectious
12 plasma donations, the risk of transmitting viral
13 hepatitis is still present."

14 So that was material at the time of the licence
15 application for Factorate.

16 If we go on to ARMO0000006, this is a letter,
17 17 May 1976, from Armour to the DHSS Medicines
18 Division, and we can see it refers to the data
19 sheet -- this is in the last paragraph of the letter:

20 "The data sheet for Factorate are now in draft
21 form. I enclose a copy for your attention."

22 Then if we go to page 3, top of the right-hand
23 side, we'll see year after year the terminology and
24 language used is almost always the same, so we see
25 here the warning:

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1 "Factor VIII is prepared from human plasma ..."
2 There's reference to the testing of donations for
3 hepatitis B surface antigen, there's reference to
4 testing the batch, and by the RIA method as well, and
5 then the same general statement: the risk of
6 transmitting viral hepatitis is still present.

7 If we move to 1977, ARMO0000017, the date is in
8 the bottom left-hand corner, October 1977, and the
9 product licence holder is identified as Armour
10 Pharmaceutical Company Limited, Eastbourne.

11 We can see it's a data sheet for Factorate, and if
12 we turn to the second page, top right-hand corner,
13 we've got the warning again. The language used has
14 not changed from the draft submitted in 1976.

15 If we then go to 1978 and the High Potency
16 Factorate, it's at ARMO0000023.

17 If we turn to page 10, we can see here -- and this
18 is part of the draft package insert -- "Warning".
19 Again, essentially the same points being made: testing
20 of the donations for hepatitis B surface antigen,
21 testing of the batch, but "no completely reliable
22 laboratory test", so the "risk of transmitting viral
23 hepatitis is still present".

24 If we go on to page 12, in terms of packaging,
25 bottom of the page there's the heading "Caution:

1 right-hand column, Factorate, as in the Armour product
2 Factorate, the trademark product, is not listed in the
3 index.

4 If we go to page 14 -- no, if we go to
5 ABPI0000039, sorry, Soumik, and go to page 14. Other
6 Armour products are included in the 1980-81 ABPI
7 Compendium but not Factorate.

8 If we then move on to 1981, ARMO0000091, and if we
9 go to the bottom of page 2, we'll see the date. This
10 is described -- sorry, Soumik, top of the page first
11 of all, my apologies -- this is described as an
12 application for a product authorisation for Factorate
13 double fill presentation. Some form of variation,
14 essentially.

15 September 1981 is the date at the bottom of the
16 page.

17 If we go to page 5, we will see, under the heading
18 "Warnings", paragraph 12 -- again, this is the draft
19 package insert submitted with the application -- as at
20 September of 1981 it's essentially the same
21 terminology as was used consistently, really, from the
22 late seventies onwards:

23 "Factor VIII is prepared from human plasma, each
24 donation of which has been found negative for
25 hepatitis B surface antigen ... by the ... (RIA)

1 "The product is prepared from Pooled Human Plasma.
2 Despite careful selection of donors and non-reactivity
3 of the reconstituted solution for hepatitis B antigen
4 by the radio-immuno assay procedure, freedom from
5 causal agents of hepatitis cannot be assumed."

6 So put in a slightly different way there and the
7 reference to "selection of donors", but the same
8 essential method it might be thought.

9 If we go next to ARMO0000035, I'm not going to go
10 to the details of it, sir, I'll just ask you to note
11 we're now in June 1979, and we have a draft package
12 insert, a further version, being sent, but it has the
13 same terminology, and you'll see that -- I don't think
14 we need to go to it -- from pages 5 and 7, exactly the
15 same language used as that which was enclosed with the
16 original product licence application for High Potency
17 Factorate.

18 That brings us then, therefore, to 1979. If
19 I then just pick matters up by reference to the ABPI
20 Compendium of data sheets, for 1980 to '81, if we go
21 to ABPI0000040. And I hope I've got the right page
22 reference here because I've only got the individual
23 sheets. Page 5 I'm hoping will be the right one.
24 Yes.

25 So the point here, if we look at the bottom

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

8 So the language is, as we will see from that,
9 unchanged.

10 And if we go to page 8, and if we can zoom in to
11 the top part of the page, we've got the warning there,
12 top left-hand corner. It's essentially the same
13 language on that label.

14 I don't think I need show you the 1981-1982 ABPI
15 Compendium of data sheets. I'll give you the
16 reference. It's ABPI0000042. Again, although Armour
17 participated in the sense that there are other Armour
18 products listed in the Compendium, Factorate still
19 doesn't feature in the ABPI Compendium of data sheets.

20 If we go, however, to the 1983-84 Compendium,
21 which is ABPI0000045, and go first of all to page 2,
22 we can see the heading "New Products", and the
23 italicised sentence at the top:

24 "The following names appear in the index to this
25 issue of the Compendium but not appear in the 1981-82

1 edition. It does not necessarily follow that they're
2 recently introduced products".

3 And of course Factorate wasn't.

4 Then if we go down towards the bottom of the page
5 left side, the index for F, we can see that Factorate
6 is there listed.

7 Then if we go to ABPI0000046, page ... try
8 page 14, would you, Soumik? Yes.

9 If we just zoom in there, we've got there
10 "Factorate" set out.

11 If we go to the next page, halfway down the page,
12 we've got "Contra-indications, warnings, etc":

13 "Warning: Factor VIII is prepared from human
14 plasma, each donation of which has been found negative
15 for hepatitis B surface antigen ... In addition, each
16 batch, after reconstitution as recommended, has been
17 tested and found negative by the RIA method."

18 Then the same terminology:

19 "... the risk of transmitting viral hepatitis is
20 still present."

21 This Compendium was, I think, published in January
22 of 1983. I can double check that. I mention that
23 because you'll see, of course, that there is no
24 reference there to HIV, HTLV-III or AIDS.

25 If we go to the right-hand column we see there

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1 as I'm aware, in this any reference to AIDS.

2 And the same is true, I think, in relation to the
3 High Potency Factorate, which starts at the bottom of
4 the page. If we go over to what should I think be
5 page 16, the contra-indications/warnings, halfway down
6 the right-hand column, are in identical form to that
7 for Factorate itself.

8 If we then leave the ABPI and go back to the
9 licence application documentation, ARMO0000145, sir,
10 we'll see this is the application submitted in
11 May 1984. It's essentially for renewal of the product
12 licence for High Potency Factorate. And if we turn to
13 page 11 we can see "Warnings and Adverse Effects",
14 again in largely the same language. There's a slight
15 modification, so it reads:

16 "Factor VIII is prepared from human plasma, each
17 donation of which has been found negative for
18 hepatitis B surface antigen ... by the RIA method. In
19 addition, each batch [et cetera, et cetera] has been
20 tested and found negative. However, since no
21 completely reliable laboratory test is yet available
22 to detect all potentially infectious plasma donations,
23 the risk of transmitting viral hepatitis to patients
24 is still present and personnel administering and
25 handling this material should also exercise

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1 "High Potency Factorate" is also listed in the
2 Compendium, and if we turn over the page, we'll see at
3 the very bottom of the left-hand column, under the
4 heading "Contra-indications, warnings, etc", the same
5 terminology is used. So it's the same language for
6 High Potency Factorate and Factor VIII. I don't think
7 I need read it out.

8 Sticking with the ABPI, if we go to ABPI0000050,
9 this is the ABPI Data Sheet Compendium for 1984-85.
10 If we try page 3, Soumik. Yes.

11 So if we look at the heading "Date of
12 preparation", halfway down on the right-hand side, it
13 says:

14 "The data sheets included in this Compendium were
15 prepared or reviewed during the final quarter of 1983
16 and the compendium itself was published in
17 April 1984."

18 Then if we go to page 14, we see the entry at the
19 bottom right-hand column for Factorate, and then the
20 warnings are on the following page, top half of the
21 page, right-hand column.

22 So the contraindication/warning there, again, is
23 in relation to the testing for hepatitis B surface
24 antigen, and the fact that the risk of transmitting
25 viral hepatitis is still present. There isn't, as far

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1 appropriate caution."

2 So there's that slight refinement, and I think
3 that's the only reference in this document. So that's
4 as at May 1984. If we then turn to 1985, ARMO0000165.
5 This is a letter dated 13 February 1985 from Armour to
6 the Medicines Division at the Department of Health,
7 and it refers to enclosing label texts for the above
8 products, which are Factorate and High Potency
9 Factorate.

10 If we go over the page, to page 2, we can see
11 the -- so it's "Important: see leaflet for complete
12 information". Then the "Caution":

13 "This solution is of human origin, despite careful
14 selection of donors and processing, it cannot be
15 assumed to be free of hepatitis virus."

16 Then bottom of the page, the "Caution" in the
17 left-hand -- thank you:

18 "The product is prepared from Pooled Human Plasma.
19 Despite careful selection of donors and non-reactivity
20 of the reconstituted solution for hepatitis B antigen,
21 and the radio-immunoassay procedure, freedom from
22 causal agents from viral hepatitis cannot be assumed."

23 Then if we go to the next page, just turn it
24 round. I think we've got the same language there, and
25 then the bottom of the page, left-hand corner, yes.

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1 So the same terminology used.
 2 So no reference -- sorry, if we just go over the
 3 page. I'm not quite sure, sir, whether these are just
 4 multiple copies of the same labels or there's
 5 a difference between the labels. It may be there's
 6 a difference in terms of sizes, I'm not sure. Again,
 7 we've got similar caution, the solution is of human
 8 origin, despite careful selection of donors and
 9 processing it cannot be assumed to be free of
 10 hepatitis virus.
 11 So the terminology there is all relating to the
 12 hepatitis virus, so you'll see no reference there to
 13 HIV or to HTLV-III or AIDS.
 14 If we go to page 5, we can see the proposed data
 15 sheet test for High Potency Factorate here set out,
 16 and if we turn on to page 7, under the heading
 17 "Contra-indications, warnings", the warning is in the
 18 same terminology as we've seen really from the late
 19 1970s onwards, with the risk of transmitting viral
 20 hepatitis being identified as still being present.
 21 That's as at February 1985, when this material is
 22 being sent to the Department of Health and Social
 23 Security, Medicines Division. No reference there,
 24 you'll see, to HIV or AIDS.
 25 There is actually a document at ARMO0000366, which

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1 the same terminology, the same language used in
 2 relation to testing for hepatitis B surface antigen
 3 and the risk of transmitting viral hepatitis still
 4 being present.
 5 So no reference there to, again, HTLV-III or AIDS.
 6 The same is true for the High Potency Factorate. Yes,
 7 I should say that compendium was published in
 8 July 1985, the introduction to it explains that it's
 9 prepared, or the data sheets have been prepared for
 10 reviewed during the last quarter of 1984.
 11 **SIR BRIAN LANGSTAFF:** Just go back to it for a moment.
 12 The side effects, bottom right-hand side.
 13 **MS RICHARDS:** "Products of this type are known to cause
 14 mild chills, nausea or stinging at the infusion site."
 15 **SIR BRIAN LANGSTAFF:** Yes.
 16 **MS RICHARDS:** Yes, I should have said a lot of the labels
 17 over the years contain a similar description of side
 18 effects, but yes, it's mild side effects there being
 19 described, and nothing associated with HTLV-III or
 20 AIDS.
 21 If we then pick it up with a further application
 22 to vary the product licence at ARMO0000181, this is
 23 9 January 1986, an application by Armour to the DHSS
 24 enclosing applications to vary the above product
 25 licence.

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1 shows that the Department did pick up upon an issue
 2 relating to the content of the data sheet and package
 3 insert, but it's not -- in terms of the language of
 4 the warning, what's said is:
 5 "... the DHSS have insisted that we, as for all
 6 other manufacturers/suppliers of such products,
 7 include the temperature and time of the heat-treatment
 8 in the data sheet (and package insert) ..."
 9 And:
 10 "Additionally, we have had some minor 'autocation'
 11 [I think that should be alteration] with them over
 12 the names of the products in that they require the
 13 words 'heat treated' in the product name whereas we
 14 wanted these words prominently on the label but with
 15 the product name intact."
 16 So the Medicines Division pick up on aspects of
 17 the contents of the sheets and the labels but not in
 18 terms of the warning.
 19 If we then turn to the next ABPI Compendium for
 20 1985 to 1986, should be at ABPI0000022. If we turn to
 21 page 15, bottom right-hand corner, we have the entry
 22 for Factorate. If we turn over the page, halfway down
 23 the page on the right-hand side, again under the
 24 heading "Contraindications, warnings", it says
 25 "Factor VIII is prepared from human plasma", and it's

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1 We looked at this earlier, if we go to page 3 we
 2 see what the proposed variation was on the right-hand
 3 side, under the heading "Proposed". It was the
 4 inclusion of the fact that units of source plasma were
 5 tested for HTLV-III, and it says, "Proposed data sheet
 6 text attached".
 7 If we go on to page 5, we can see what I think is
 8 the proposed data sheet as at January 1986. So under
 9 the heading "Presentation", and we looked at this
 10 previously, there is reference there to HTLV-III, it's
 11 the fourth paragraph under "Presentation", in the
 12 context of their having been tested, and the units of
 13 source plasma having been found to be negative.
 14 If we turn to page 7, the "Contra-indications,
 15 warnings, etc", at the bottom of the page, the
 16 language is unaltered. So it still refers to
 17 hepatitis B surface antigen testing, in terms of both
 18 the plasma and the batches of reconstituted product.
 19 It refers to the risk of transmitting viral hepatitis,
 20 and then has the same terminology in relation to side
 21 effects that you pointed out, sir:
 22 "Products of this type known to cause mild chills,
 23 nausea or stinging at the infusion site."
 24 So no inclusion as a warning or side effect of the
 25 possible transmission of HTLV-III.

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1 Then we can see, if we go to ARMO0000531, this is
2 May 1986. So we can see active consideration being
3 given to the content of the data sheet and leaflet.
4 It says:

5 "The Factorate data sheet has recently been
6 amended to include details of heat treatment and
7 testing for antibodies to HTLV III virus."

8 Which is essentially what we saw under the heading
9 "Presentation" in the earlier document:

10 "Therefore, please arrange to update the leaflet
11 to include the following statements at the end of the
12 section of composition and standardisation:

13 "This product has been heated at 60°C for 30
14 hours. This step has been introduced in order to
15 reduce the risk of transmission of infectious agents.

16 "All units of source plasma are test for
17 antibodies to [HTLV-III] and found to be negative."

18 Again, in terms of where it appears in the data
19 sheet and in the leaflet, it's not in any headings on
20 warnings or any side effects that that reference is
21 there set out.

22 Then I think we can see that, if we go to
23 ARMO0000192, this is 9 June Armour submitting copies
24 of applications for variations to the product licences
25 for the heat-treated Factorate and heat-treated High

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1 relation to both the warning and the side effects is
2 as set out in the previous documents that we have
3 looked at.

4 **SIR BRIAN LANGSTAFF:** Do we know why the language is "all
5 units", as opposed to "All donations"? It depends
6 what units is what units covers.

7 **MS RICHARDS:** I'm sorry, sir, where?

8 **SIR BRIAN LANGSTAFF:** This is "All units are tested for",
9 whatever it is, ALT, in one case.

10 **MS RICHARDS:** Oh, sorry.

11 **SIR BRIAN LANGSTAFF:** Yes, it's referring to units, which
12 I've taken to be individual donations but I may be
13 wrong. Because it could be a larger unit.

14 **MS RICHARDS:** I'm afraid I don't know the answer to that,
15 sir. We can look at it further and see whether we can
16 work out whether there's a significance to be attached
17 to that wording or not.

18 **SIR BRIAN LANGSTAFF:** It's yet another different word --

19 **MS RICHARDS:** It is.

20 **SIR BRIAN LANGSTAFF:** -- donations, donors, units. They
21 may all mean the same thing, pretty much, but they
22 might not.

23 **MS RICHARDS:** No.

24 If we then just have a look at ARMO0000534, this
25 is a letter or memo, 10 June 1986, from Mr Bishop to

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1 Potency Factorate. If we go to the second page, if we
2 look at the bottom half of the page, typed in, there's
3 a cross in the box "Other ... Additional information
4 on data sheet".

5 So the variation to the product licence is because
6 they're going to include additional information on the
7 data sheet, and then, if we go to the right-hand
8 side -- sorry, if we go to the next page. We can see
9 the proposed change, which is:

10 "As at present but additionally the following
11 information to be included ..."

12 We're now in relation to ALT testing:

13 "In addition all units are tested for ALT ... and
14 found to be less than twice the established upper
15 normal value for the test kit."

16 Then, if we go over the page, we see -- no, in
17 fact those are the present changes not the proposed
18 changes. If we go to page 8, we'll see what's said to
19 be a proposed change. But I think that's the same
20 terminology we've already seen, so again it's
21 explaining that the units of source plasma have been
22 tested for HTLV-III, rather than anything additional
23 by way of text.

24 Yes, if we go to page 14, under the heading
25 "Contra-indications, warnings", the language in

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1 somebody else within the company. It says:

2 "Further to our previous correspondence, I enclose
3 a copy of Cutter's packaging (one of our competitors),
4 from which you can see they are now adopting the
5 suggested labelling.

6 "Please advise whether there is any progress with
7 regard to our own labelling."

8 Then if we go -- sorry, let me read the whole of
9 that. Go back to the letter, my apologies, Soumik.

10 "If necessary, and to save time, I suggest a label
11 be produced just for the outers containing the 10
12 vials, although ideally each individual vial should be
13 so labelled."

14 And the Cutter leaflet to which reference is made
15 is on the next page -- sorry, not the leaflet, it's
16 the packaging. We can see the bottom -- if we look at
17 the left-hand side:

18 "Warning: Koate HT is a purified dried fraction of
19 pooled plasma obtained from many donors. The presence
20 of hepatitis viruses should be assumed and the hazard
21 of administering Koate HT should be weighed against
22 the medical consequence of withholding it particularly
23 in persons with few previous transfusions of blood or
24 blood products."

25 We'll look tomorrow in more detail at the various

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1 Koate labels and data sheets used from time to time
2 and we'll see if there's any difference there in the
3 way that's described and the Armour labels. But
4 I think it's the -- however, the strip of white and
5 the language there that Mr Bishop was probably
6 referring to, although again I doubt he'll be able to
7 clarify that for us, where it says, "Each individual
8 unit of plasma has been tested for antibody to
9 HTLV-III by an FDA approved method and found
10 nonreactive".

11 Now, of course, that's still not a warning, but
12 it's a piece of information that it would seem Cutter
13 was placing on Koate HT.

14 **SIR BRIAN LANGSTAFF:** It's almost an opposite to warning,
15 isn't it?

16 **MS RICHARDS:** Reassurance.

17 **SIR BRIAN LANGSTAFF:** Yes, it's basically saying: We're
18 aware of this risk, we've excluded it by testing. Or
19 at least it might be read that way.

20 **MS RICHARDS:** Yes.

21 Then if we go to ARMO0000556, we've got a memo
22 from 14 July 1986 to Mr Bishop from AS Clark about
23 "Factorate labelling":

24 "We now have approval from the Department of
25 Health and Social Security for the use of a label

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1 **SIR BRIAN LANGSTAFF:** Yes.

2 **MS RICHARDS:** If we go back to ARMO0000556, it would
3 appear that what's been done, whether for reasons of
4 speed or for some other reason I don't know, is the
5 label is going to be on the outers as opposed, one
6 assumes, to the individual vial. Then it says the
7 wording is as per that on the data sheet.

8 The next page of the document is actually
9 a licensing authority response to a request. So it's
10 presumably the Department of Health's approval of what
11 Ms Clark is describing to Mr Bishop, and we can see --
12 sorry, if we just go back and look on the left side,
13 "Present" it says:

14 "On the outer, containing 10 vials, labelling as
15 per attached sheet."

16 Then:

17 "As at present but additionally a sticker with the
18 following wording:

19 "All units of source plasma are tested for
20 antibodies to human T cell lymphotropic virus type III
21 (HTLV-III) and found to be negative.'

22 "This wording has previously been approved for use
23 on the data sheet."

24 I should just perhaps make that point, it's
25 probably obvious from everything we've looked at, but

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1 relating to HTLV-III antibody testing on Factorate
2 outers."

3 So this would appear to be the response to
4 Mr Bishop's communication.

5 "The wording is as per that on the data sheet.

6 "We still await approval from the National Drugs
7 Advisory Board."

8 And then go over the page.

9 **SIR BRIAN LANGSTAFF:** Just -- you may not be able to
10 answer this, I suspect you might not, but the
11 Factorate outers, there's only reference to vials,
12 individual vials, being labelled.

13 **MS RICHARDS:** Yes.

14 **SIR BRIAN LANGSTAFF:** So the issue might be whether the
15 outer is the label on the vial, which sounds less
16 likely, than it is on the packet, where -- rather if
17 one goes to an off-licence and buys a 12 pack, it may
18 come in -- if you do -- it may come in cardboard, with
19 labelling on it.

20 **MS RICHARDS:** Yes. I'd certainly read it that way. If we
21 go back to the way in which Mr Bishop expressed his
22 communication at ARMO0000534, he draws a distinction
23 between the outers containing the 10 vials as compared
24 to each individual vial. So, yes, I'd read that as
25 the pharmaceutical equivalent of the 12 pack.

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1 the various forms of wording that we've looked at on
2 the data sheets and the like are all material that is
3 submitted to the licensing authority. So it's not the
4 pharmaceutical companies such as Armour simply going
5 it alone. They've submitted their wording to the
6 licensing authority and we've seen from time to time
7 the licensing authority raises issues, but there's no
8 evidence of any issue being raised about the absence
9 of any warning about HTLV-III or AIDS.

10 So that's where we get to as at the middle of
11 1986. If we go to ARMO0000566, there's a further
12 communication in 1986 in relation to labels, and it
13 just says:

14 "... in order to get more definitive information
15 on the rationale for the statement it has been
16 proposed to make on Factorate labels, we have obtained
17 a copy of the test procedure used by Plasma Alliance."

18 Then we can see reference there to the ALT
19 testing:

20 "Plasma donations having an ALT titre above
21 70 units per ml at 30 degrees C are excluded from
22 plasma pools for Factorate production. This is
23 consistent with the label text proposed ..."

24 So this appears to be a label text amendment in
25 relation to adding some form of information about ALT

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1 testing.
 2 Lastly, the 1986-1987 ABPI Data Sheet Compendium,
 3 which is, I hope, at ABPI0000024. So if we go to
 4 page 13, bottom right-hand corner, we have here the
 5 entry for "Factorate Heat Treated". If we go over to
 6 the next page, we see in the top left-hand corner,
 7 second paragraph down, the reference there to the heat
 8 treatment method. "This product has been heated at
 9 60°C for 30 hours. This step has been introduced in
 10 order to reduce the risk of transmission of infectious
 11 agents."

12 So there is explanation as to why there is heat
 13 treatment.

14 There is then reference in the next paragraph to
 15 the units of source plasma being tested for antibodies
 16 to HTLV-III and found to be negative.

17 If we then, on the same page, to bottom right-hand
 18 corner, we've got there "Contra-indications, warnings,
 19 etc", and we have the same terminology in relation to
 20 warnings so -- sorry, the same terminology as we've
 21 seen over the years: the reference to testing for
 22 hepatitis B surface antigen, the possible present risk
 23 of transmitting viral hepatitis, and then the side
 24 effects of mild chills, nausea or stinging. But
 25 nothing further. And the same is -- in this

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1 the Krever report. We haven't found any specific
 2 documents which show the addition of warnings about
 3 the risk of AIDS in the United Kingdom. So it's
 4 possible that the Krever report leaves open the
 5 possibility that there may be material that we haven't
 6 found. But what I've shown you, sir, is what was
 7 submitted to the licensing authority and what was
 8 included in the ABPI Compendium.

9 **SIR BRIAN LANGSTAFF:** If he's accurate in what he says,
 10 then the warnings that were given in the USA were not
 11 given in the UK.

12 **MS RICHARDS:** That's an inference -- the obvious inference
 13 to draw from what's said, combined with the absence of
 14 any material that we've --

15 **SIR BRIAN LANGSTAFF:** But the parent company involved is
 16 exactly the same.

17 **MS RICHARDS:** Yes.

18 **SIR BRIAN LANGSTAFF:** And the products are made in the
 19 same place in --

20 **MS RICHARDS:** In Kankakee, Illinois.

21 **SIR BRIAN LANGSTAFF:** -- Kankakee, yes.

22 **MS RICHARDS:** Yes. So it may be that there is material
 23 that we have not found, and it's for that reason
 24 that I wanted to draw your attention to what was said
 25 in the Krever report.

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1 compendium, it's the same information, I think, for
 2 the high potency heat treated Factorate.

3 So those are the documents that we presently have
 4 in relation to product labelling, package inserts,
 5 data sheets, in the period up until 1986. I should
 6 just, if I may, read a very short paragraph from the
 7 Krever report. I don't have it available to display
 8 on screen.

9 It's chapter 14 of the Krever report, which
 10 obviously was the Canadian inquiry into blood
 11 contamination. It's page 399 of that report.

12 It says this:

13 "When fractionators prepared their vials of factor
 14 concentrate in packages for shipping, they included
 15 printed information about the concentrates, their
 16 proper use, and possible risks in using them. In the
 17 autumn of 1983 and in early 1984, US fractionators
 18 added warnings about the risk of AIDS to the
 19 information in the product inserts. Armour for its
 20 Factor VIII concentrate in October 1983, Cutter for
 21 its commercial Factor VIII concentrate in
 22 January 1984, and Hyland for its Factor VIII
 23 concentrate in March 1984."

24 We haven't found sir, those -- there are no
 25 specific documents cited in support of that passage in

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

2 **MS RICHARDS:** In the interests of trying to be as fair and
 3 comprehensive as possible.

4 Sir, that's it in terms of data sheets, package
 5 inserts, product labels. I just want to turn to a few
 6 other aspects of what might be called communication of
 7 risk. The first is to draw your attention to a
 8 document which we may come back to at a later stage.

9 It's at BAYP0005366. This is a letter dated
 10 August 14, 1984. It's addressed to Cutter, and it
 11 describes in the first paragraph a meeting in
 12 Los Angeles between Cutter, Hyland representatives,
 13 and the organisational body which is sending this
 14 letter, the name of which, at the top left-hand
 15 corner, is not entirely clear. It looks like
 16 "Hill+Knowlton", not 100 per cent sure.

17 In any event we can see if we look in the first
 18 paragraph it says:

19 "We regret that we were able to meet also with
 20 people from Alpha and Armour, as we believe the four
 21 companies -- along with perhaps the Red Cross -- have
 22 a common need for a good, honest, straightforward
 23 education programme."

24 Then it goes on to talk about communication of
 25 information to patients, and to the public.

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1 Now I'm not going to go through the detail of this
2 letter, not least because it's directed to Cutter
3 rather than to Armour. But if we go to page 5, what
4 we see here is the text of what's said to be a public
5 relations proposal by a public relations firm,
6 Burson-Marsteller, I think, August 13, 1984. It's
7 described as a:

8 "Public relations proposal for Hyland
9 Therapeutics, Armour Pharmaceuticals, Cutter
10 Biological, Alpha Therapeutics."

11 It may be that this is a document that never got
12 to Armour, and so it may be, absent any further
13 information that we find, that there are no particular
14 conclusions that can be drawn, in relation at least to
15 Armour or Alpha, who were not apparently at the
16 meeting in Los Angeles.

17 But if we go to the next page, we see what's said
18 under the heading "Situation":

19 "Four companies -- Hyland Therapeutics, Armour
20 Pharmaceuticals, Cutter Biological and Alpha
21 Therapeutics -- comprise an industry that provides an
22 antihæmophilic factor to approximately 20,000
23 hæmophiliacs nationwide."

24 That's obviously talking about the US.

25 "Last year it is estimated that 40 hæmophiliacs

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1 But it is perhaps more telling in a broader sense,
2 in terms of the pharmaceutical industry, and if we go
3 to the next page, the objectives of this public
4 relations proposal are set out:

5 "To increase the awareness among hæmophiliacs of
6 the dangers of reducing infusion rates, ie there is
7 more risks involved of long-term complications from
8 not conducting the infusions than in getting AIDS."

9 Then:

10 "To improve communications between hæmophiliacs,
11 their physicians, the hæmophilia associations and the
12 supplying companies."

13 Then it goes on to outline various suggested
14 strategies, which I'm not going to necessarily go
15 through.

16 Well, perhaps if we just go to page 12, there are
17 various what's described as communication tactics that
18 are identified on this page and then we go to the
19 following page, which include the production of
20 results in newsletters, producing booklets, having an
21 advisory panel and various other things.

22 So, as I say, it may be of more general interest
23 in terms of understanding at least what a public
24 relations firm thought the pharmaceutical industry
25 might want rather than assessing any action on the

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1 contracted and died of ... (AIDS) after receiving an
2 infusion of an antihæmophilic factor that was
3 contaminated with the virus. Subsequently,
4 hæmophiliacs nationwide have reduced the frequency of
5 their infusions because of the fear of contracting
6 AIDS, even though their physicians in the hæmophilic
7 associations have urged them to maintain normal
8 infusion rates.

9 "Consequently, sales for the anti-hæmophilic
10 factor have declined 15 to 20 percent in the last
11 year.

12 "Alpha, Cutter, Armour and Hyland have asked
13 Burson-Marsteller to develop a public relations
14 proposal to address the problem of decreasing infusion
15 rates of the anti-hæmophilic factor among
16 hæmophiliacs."

17 Now, that refers to this firm being asked by the
18 four companies. Whether that was a statement of fact
19 or whether this was a proposal reflecting the
20 anticipation that all four companies would approach
21 the firm is unclear, and that's why I want to be
22 careful to say that it's not a thing possible to
23 deduce from the information that is in this material,
24 that this is something which Armour, or indeed Alpha,
25 had signed up to.

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1 part of any individual pharmaceutical firm.

2 The other aspect of communication of risk I just
3 wanted to briefly explore is the response within
4 Armour to various media reports of risks associated
5 with the use of their products.

6 Sir, if we look, for example, at ARMO0000483, we
7 can see here a report in the New Scientist,
8 February 1986, "Blood treatment may not kill AIDS
9 virus". This raised the concern that there was still
10 seroconversions taking place with heat-treated
11 products, and it's an article -- we've looked at it
12 before and we'll certainly, I think, be looking at it
13 again -- it refers to the allegations being made by
14 Dr Jones of seroconversion and a case in the
15 Netherlands.

16 It expressly refers to the Armour product, as well
17 as a number of other products in the course of the
18 article.

19 There's a second article at ARMO0000472 at around
20 the same time. This is a publication in The Guardian
21 so it's the left-hand side. Doesn't refer to Armour
22 by name, but it talks about four men in the
23 Netherlands and the US developing AIDS after taking
24 heat-treated Factor VIII. You will note in here there
25 is ascribed to Dr Donald Acheson, as we know the Chief

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1 Medical Officer at the time, what's said to be
2 criticism of Dr Jones for making this information
3 public.

4 In any event, there are two media publications in
5 February 1986, and we know that there came to be, in
6 the course of 1986, this critical issue about the
7 possibility of people receiving heat-treated Factorate
8 being infected with HIV.

9 I just want to look at a few internal Armour
10 documents which record discussions about how they
11 might respond to such reports. We can pick it up at
12 ARMO0000526. This is from Mr Bishop to Dr Harris,
13 25 April 1986, so it's an internal communication.
14 Again, we can perhaps ask Mr Bishop about it in due
15 course.

16 So it would appear Mr Bishop is requesting action
17 to be taken in response to the New Scientist article
18 and we can perhaps just look at the last sentence of
19 Mr Bishop's memo:

20 "On the basis of the foregoing, I would again
21 recommend that we write to the New Scientist and also
22 to Dr Richard Lane to get an official statement from
23 them [presumably BPL] that they do not consider their
24 product any safer than ours in terms of inactivation
25 of the HTLV-III virus."

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1 products."

2 I'm not going to go through the detail of those
3 cases, sir.

4 If we go to the bottom of the next page, having
5 set out various matters in relation to ostensibly
6 those two cases, the suggested summary is in the
7 penultimate paragraph:

8 "... no sero-conversion on any other 'clean
9 virgin' not otherwise at risk for AIDS has been
10 reported and live virus has never [underlined] been
11 isolated from Armour's heat treated FACTORATE.

12 "The above is subject to final ratification and
13 updated communications."

14 So it would appear to be being deliberated within
15 Armour whether there should be a robust response by
16 way of what was described as a "defence statement" to
17 the articles that were being published in The Lancet.

18 If we go over to the next page, page 4, we can see
19 what I think is Mr Bishop's PS:

20 "There was a meeting held in Newcastle by the
21 Reference Centre AIDS Committee at which the main
22 topic of conversation was the double standards being
23 applied by the industry with fully screened product,
24 and the NHS who were still supplying unscreened
25 product. Unfortunately, there are rumours going about

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1 We can see then, if we go to ARMO0000548, this is
2 a memo now again, I think an internal memorandum from
3 Mr Bishop, dated 4th July 1986, and on the topic of
4 seroconversion to HTLV-III. This is now referring to
5 an article in The Lancet -- the Lancet, 31 May,
6 picking it up in the second paragraph -- sorry, it's
7 two articles in The Lancet, 14 June, 31 May:

8 "Both these articles, besides attempting to
9 clarify their own heat-treating procedure [I think
10 that is a reference to Cutter] identify ours as being
11 implicated in the cases quoted.

12 "The decision has been taken to respond to The
13 Lancet within the next 2-3 weeks with a carefully
14 prepared 'defence' statement setting the facts
15 straight. As soon as this document is prepared,
16 copies will be forwarded to you together with
17 a Technical Bulletin from Robert Christie."

18 Then reference is made to enclosing certain
19 documents and publications.

20 If we go over the page, there's what I understand
21 to be the suggested information for inclusion within
22 the defence statement. So the heading "Introduction":

23 "The suggested implication of Armour heat-treated
24 FACTORATE ... is based on two cases, both of which
25 received prior treatment with non-heat treated

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1 that Armour are supplying unscreened material and this
2 is probably originating from competitor sources and
3 you must please leave everybody in no doubt that all
4 Armour material being sold is sourced from donor
5 material which has been screened and tested for
6 antibodies to HTLV-III."

7 So Mr Bishop appearing to hold clear views as to
8 the way in which the company should respond. As
9 I say, we can no doubt ask him about that.

10 If we then move on to CGRA0000527, this is again
11 from Mr Bishop, 16 July 1986. The heading is
12 "Proposed UK defence document", and we can see in
13 brackets:

14 "(To: Lancet + Technical Bulletin to Sales Force
15 and Review to Swedish Health Authorities)."

16 Not entirely clear what that meant, other than it
17 seems to be a suggestion that there should be
18 a response to The Lancet and then to some other
19 publications.

20 "In light of the US refusal to originate a Defence
21 Document as discussed, I propose the following to form
22 a basis for a UK originated document ..."

23 Pausing there, the inference that seems likely
24 from this is the American company, parent company, has
25 decided it's not going to produce a defence statement

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1 but Mr Bishop seems to be of the view that this should
2 be a UK-based one:

3 "Objective:

4 "1. To nullify negative impact of the published
5 'sero-conversion' stories.

6 "2. To restore/confirm confidence in our heat
7 treating process regarding HIV inactivation.

8 "3. To demonstrate our faith in our own product.

9 "Thus,

10 "4. To stop any further deterioration in sales --
11 UK + Scandinavia."

12 Then the "Suggested Format" for this UK-originated
13 document is:

14 "a. Refer to the ... Cutter letters in The Lancet
15 ... and correct the misleading nature of the article

16 ...

17 "b. Defend the 60°C for 30 hours referred to by
18 the Editor in the June 14th Lancet article by citing
19 the Armour experience, both in vitro and in vivo.

20 "c. Summarise as per penultimate paragraph
21 [that's referring to his earlier document that we
22 looked at] and emphasise importance of comprehensive
23 analysis of all data published and unpublished in the
24 interest of the patient.

25 "I would emphasise that this document is essential

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1 discredited. This would appear to be the case from
2 discussions both Mike Cross and myself have had to
3 date with leading Directors.

4 "Nevertheless, I will just elaborate on various
5 points made in the article starting with the New
6 Scientist ..."

7 I'm not going through the details of Mr Bishop's
8 comments. We can then perhaps explore that with
9 Mr Bishop in due course. If we go to the third page,
10 third paragraph, Mr Bishop says this:

11 "It is our feeling, and that of our advisers, (who
12 include members of the UK Haemophilia Centre
13 fraternity) that these are close be treated with the
14 contempt they deserve and, therefore, we propose to
15 take no further action other than discussion by you
16 with individual Doctors who may express some concern
17 which you are in a position to discuss on a sensible
18 level.

19 "Unfortunately, the mention of Dr Michael Rodell's
20 statement that we are reviewing our heat treatment
21 process now prevents us from preparing an official
22 'defence document/article' to The Lancet, which would
23 not be totally misconstrued by those wishing to cast
24 dispersions on the Armour operation. We can not on
25 the one hand defend our existing treatment and then

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1 for the maintenance of FACTORATE business in our
2 markets."

3 Then ARMO0000562. There's a further document from
4 Mr Bishop dated a couple of days later, 18 July 1986.
5 It's described as a house message from Armour
6 Pharmaceutical Company Limited. The subject is
7 "Factorate recall -- media response".

8 We can see in the first paragraph he refers to:

9 "... copies of the New Scientist and Guardian
10 articles of the 17th July on the above mentioned
11 subject", which presumably is the recall.

12 "I have it from an extremely reliable source that
13 both articles were initiated by the actions of
14 Peter Jones and, certainly in the case of the New
15 Scientist, this took the form of him providing them
16 with a copy of our recall/exchange letter together
17 with his comments. This is obvious from the last
18 paragraph of both articles which forms the 'pay-off'
19 and is, in my opinion, an attempt to justify his
20 previous outburst out the Newcastle AIDS conference in
21 February which, you will remember, caused so much
22 consternation to Doctors and patients alike.

23 "It may well be, and it is to be hoped, that the
24 majority of Doctors will view the articles in the
25 light of this objective and the contents immediately

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1 immediately introduce a new one, although the reasons
2 for introducing the new process are primarily to
3 attack the [non-A non-B] problem.

4 "However, you are in possession of all the facts
5 which we, obviously, will continue to update you on
6 and we will rely on you to relay the correct factual
7 information to all of your contacts."

8 Now, as I've said repeatedly, we will be looking
9 at the heat-treated seroconversion issue in November.
10 I have drawn attention to these documents now, partly
11 because they may help place in context some of the
12 issues that we will want to explore with Mr Bishop in
13 November but also because it is perhaps useful to see
14 what was being said internally within Armour to public
15 discussions about risks from their products.

16 Sir, that, I think, is probably -- actually,
17 sorry, no, one further document on the same theme.
18 ARMO0000568.

19 **SIR BRIAN LANGSTAFF:** 568?

20 **MS RICHARDS:** 568, yes. This Mr Bishop, I think, to the
21 same recipients of the communication we looked at
22 a moment ago, 7 August 1986, and again, it's in part
23 on the issue of public discussions in relation to
24 risk. He says in the first paragraph:

25 "I know enquiries to you regarding a review of our

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1 heat treating procedure have been increasing lately,
2 especially with the announcement in the press recently
3 (Guardian/New Scientist) wherein Dr Michael Rodell
4 declared this intent from the States.

5 "In order to help you tackle these questions with
6 some degree of credibility, the following should be
7 the lines upon which your official response is made."

8 Then there is set out a suggested line to take, in
9 terms of constant review of product range, in order to
10 upgrade and refine the products. If we look further
11 down the page, so the last two paragraphs, this is,
12 again, still part, I think, of the suggested line to
13 take:

14 "We would emphasise again that this move does not
15 imply any lack in confidence in our current procedure
16 ... in terms of HIV elimination/inactivation, but is
17 designed to improve still further the safety factor in
18 the product in terms of total viral inactivation
19 without the need for the addition of stabilisers ..."

20 Then he says this:

21 "Naturally, we have a considerable quantity of
22 existing material in inventory and the last thing we
23 need is for people to hold off ordering until the new
24 product comes through".

25 Over the page:

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1 HHFT0001201_003.

2 So here we have a communication between Armour and
3 Dr Jones, December 1980, and it refers to:

4 "... a Protocol, revised according to our
5 discussion in Alton on 1st December ...

6 "In addition to the modification to the protocol,
7 we also discussed and agreed the following points:

8 "The two centres taking part will be Newcastle and
9 Alton.

10 "Although each centre will recruit a minimum
11 number of 6 cases, we would allow 10 sets of treatment
12 of each product at each centre."

13 The study was said to start in January 1981.

14 There is then a cost estimate put forward, which gives
15 a total, I'm not sure whether it's per centre or for
16 the two centres, of £6,840.

17 Over the page:

18 "You agreed that these costs will be met from
19 Research Funds initially, and we will then reimburse
20 you on receipt of your invoice.

21 "We agreed that the Hemofil 2 would be obtained
22 and provided by us. We therefore need to know as
23 a matter of urgency the quantities which you and
24 Dr Aronstam calculate to be necessary."

25 So there is some funding proposed by Armour for

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1 "We would emphasise, therefore, that it will be
2 a phasing-in process and not an overnight change and
3 customers should understand this.

4 "If there are any queries resulting from this
5 information, please let me know upon my return from
6 holiday but, hopefully, this statement will enable you
7 to 'scotch' any rumours as to our motives branded
8 about by negative Directors or competition."

9 We know, of course, that exactly two months later
10 Armour withdrew Factorate and High Potency Factorate
11 from the market, the communication of 7 October 1986,
12 and you may wish in due course to consider those
13 discussions in light of that subsequent event.

14 So that's the material on communication of risk.
15 There are then just a handful of documents I wanted to
16 show you, sir, in terms of some of Armour's
17 interactions with other Haemophilia Centres and
18 Haemophilia Centre Directors.

19 This is in terms of some of the studies that were
20 undertaken as between Armour and Haemophilia Centres,
21 in addition to the ones that we've already looked at,
22 and some of the financial assistance or support that
23 was, from time to time, made available by Armour to
24 Haemophilia Centres, so there's just a few documents
25 in that regard to show you, starting with

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1 the study at Newcastle and Alton. We've looked,
2 I think, at the details of that study -- there are so
3 many it's difficult to remember sometimes -- when we
4 looked at Treloar's.

5 Indeed, I think we've seen it discussed in various
6 minutes of the UKHCDO and the Hepatitis Working Party.

7 So that's some degree of sponsorship by Armour of
8 the study at Newcastle and Alton in 1980. Then if we
9 move to 1981 and Oxford, OXUH0001624_004, we can see
10 a letter dated 6 August 1981 from Mr Bishop to
11 Dr Rizza at Oxford. It appears from the first
12 sentence that someone from Armour has made a recent
13 visit to the unit. There's a discussion about
14 a paper, in the second paragraph, and Mr Bishop says:

15 "As I have indicated in the past, please let us
16 help in any way we can regarding the preparation of
17 this paper."

18 That was a paper on inhibitor treatment.

19 Then there's a discussion about possible future
20 sponsorships. Mr Bishop says:

21 "[We will await] the outcome of your application
22 to the [Medical Research Council] and the Haemophilia
23 Society ..."

24 Then a cordial thanks in the last paragraph and
25 looking forward to seeing Dr Rizza again soon. So

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1 that's an example of an interaction with Oxford in
2 1981, I think we saw a little more of that when we
3 looked at the Oxford Haemophilia Centre last year.

4 If we then, by way of an example of interactions
5 with the Royal Free Hospital, look at ARMO0000236,
6 this is a letter dated 15 March 1983 to Mr Bishop at
7 Armour. It's from Dr Kernoff, as we know, director of
8 the Haemophilia Reference Centre at the Royal Free.
9 I ask you to note the date and then the heading. So
10 the date is 15 March 1983. The heading is "Proposal
11 for research support into AIDS at the Royal Free
12 Hospital":

13 "Further to our previous discussions, I now
14 enclose a brief formal proposal requesting support for
15 our AIDS-related project in haemophiliacs.

16 "As you will see, the request is mainly for
17 a 1 year period of salary support for a Senior
18 technician (MLSO) in Professor Janossy's department
19 here, starting 1st April 1983. The gross sum needed,
20 which would of course be spread over the year, is
21 a little over £12,000.

22 "I should of course be very pleased to supply you
23 with any further information you need. Any help
24 Armour is able to give us would be greatly
25 appreciated."

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1 "We regard the acquisition of further information
2 about the immunological defects in haemophiliacs and
3 their relationships with clinical disease and blood
4 product exposure, to be a matter of the highest
5 priority."

6 Then we can see, under the heading "Facilities and
7 expertise available at the Royal Free Hospital", set
8 out why Dr Kernoff said that The Royal Free was
9 particularly well placed to research this. If we go
10 to the next page, "Work proposed":

11 "Preliminary studies using the limited laboratory
12 manpower available have shown that immunological
13 abnormalities in haemophiliacs are not confined to
14 those patients who have received commercial
15 concentrates and have close association with chronic
16 liver disease. The objective of the proposed work,
17 which will extend over a one year period, is to reach
18 more definitive conclusions about the relative
19 morbidity associated with exposure to different blood
20 products, and the relationships between immunological
21 abnormalities in the blood and those in tissue biopsy
22 samples. Comparisons will be made with other groups
23 of patients at increased risk of AIDS."

24 Then there is set out the various analyses that
25 was proposed.

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1 We can see the research proposal over the page.
2 The title of the project is "Effects of blood products
3 on the immune system of patients with haemophilia".
4 The principal investigators are Dr Kernoff and
5 Professor Janossy, who was head of the Immunology
6 Department at the Royal Free.

7 "Background", refers to recent reports of
8 abnormalities suggestive of impaired immunological
9 function in haemophiliacs. You'll see reference in
10 that first paragraph on the screen to patients having
11 clinical evidence of altered immunity and a small
12 number in the USA having developed AIDS.

13 If we go to the -- well, no, I'll read the next
14 paragraph:

15 "The causes of these abnormalities are unknown,
16 but may include transmission of a previously
17 unrecognised virus or other agent. The predictive
18 value of simple tests of immunological function is
19 also unknown. However, the possibility that infusion
20 of essential therapeutic products may be complicated
21 by very serious hazards is causing extreme concern
22 amongst patients and those responsible for their care.
23 It has been suggested that profound changes may have
24 to be made in management practices, particularly as
25 regards the use of imported commercial concentrates.

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1 The reason for requesting support from Armour is
2 set out towards the bottom of the page. We can see
3 what's being asked for is a year's bridging support,
4 and it's said:

5 "Our immediate problem is the lack of skilled
6 technical manpower ..."

7 Hence, the request is for funding for a trained
8 technician. We see again, the overall figure given on
9 the next page: £12,396.

10 If we go to ARMO0000238, we can see a response
11 from Armour Pharmaceuticals from Mr Bishop to
12 Dr Kernoff, 7 April 1983. He says he encloses a copy
13 of the draft protocol compiled by Dr Helen Townsend,
14 based on the recent proposal. It's been discovered by
15 the Revlon plasma Executive Committee.

16 Then there is an invitation to Dr Kernoff and
17 Professor Janossy to come to Eastbourne and discuss
18 the matter with Armour's medical director and other
19 members of the Medical and Marketing Departments.
20 He's asked to prepare a presentation, and so on. If
21 we go towards the bottom of the page, there's then
22 a suggestion of a spot of lunch, and there's an
23 indication of the number of people that will be
24 present.

25 If we go over the page, we'll see it says, fourth

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1 line:
2 "I confirm that we will do everything possible to
3 provide a definitive answer to the proposal as quickly
4 as possible."

5 I don't think I've got to hand any further
6 correspondence, but this study was undertaken at the
7 Royal Free. It's subsequently written up, I can't
8 remember in which journal, but it's exhibited to the
9 witness statement of Professor Christine Lee and I'm
10 pretty sure we've looked at it in earlier hearings.
11 And it thanks, amongst others, Armour, for their
12 support. So the inference is I think that Armour
13 provided the financial contribution. If we find
14 anything to suggest that that's incorrect, we'll
15 obviously bring that to your attention.

16 Sir, I've only a handful of further documents in
17 relation to Armour. Probably about ten minutes'
18 worth. So the question whether to do it now and then
19 finish, or take a break and then start Bayer, or how
20 you want to --

21 **SIR BRIAN LANGSTAFF:** Which would you prefer to do?

22 **MS RICHARDS:** Well, I think it might be sensible -- if
23 those present don't mind -- if I just finish the
24 documents in relation to Armour. There's just a few
25 more documents on this theme of communications with

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1 ARMO0000246. The summary of the protocol to be -- and
2 the investigator's name is identified as Dr Preston.
3 The summary of the protocol is:

4 "To compare various biochemical, immunological and
5 cytological parameters associated with [AIDS] and
6 Impaired Immunity states in Haemophiliacs, Age Matched
7 Controls, and patients with Histologically proven
8 chronic liver disease (Non-Haemophiliacs)."

9 Then if we go down we can see the funding that's
10 sought is funding in the sum of £22,000.

11 Then if we turn to ARMO0000268, we can see
12 a letter from Dr Preston to Mr Bishop, 22 June 1983:

13 "Research Project into [AIDS] in Haemophilia
14 "You will be pleased to hear that we are now in
15 a position to embark upon the project and we have also
16 found a suitable MLSO to undertake the laboratory
17 investigations for the project. I am, therefore,
18 writing to ask if you would formally accept my
19 proposals for financing of the project ...

20 "If you are in agreement, I would be grateful if
21 a cheque could be made payable to the Haemostasis
22 Research Fund."

23 Then we can see in the last paragraph reference
24 made to the project being:

25 "... already under way, in that one or two of

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1 and funding for research by Haemophilia Centres.

2 **SIR BRIAN LANGSTAFF:** Well, we'll finish by 3.30 on that,
3 I take it?

4 **MS RICHARDS:** Yes.

5 **SIR BRIAN LANGSTAFF:** Yes, let's go ahead.

6 **MS RICHARDS:** So those were the communications between
7 Mr Bishop from Armour and Dr Kernoff in March and
8 April 1983 specifically in relation to AIDS-related
9 research.

10 We see around the same time communications between
11 Armour and Dr Preston at Sheffield, also for research
12 into AIDS, and we can see that from ARMO0000239. This
13 is again from Mr Bishop:

14 "Dear Eric,

15 "Further ..."

16 Sorry, the heading is important:

17 "Proposal for research support into AIDS at the
18 Royal Hallamshire Hospital."

19 There's an invitation then to Dr Preston and
20 Dr Triger to come to Eastbourne to discuss the
21 proposal, and an invitation that he do a presentation.
22 Again, similar to the letter Dr Kernoff, then can have
23 a spot of lunch before the return journey.

24 In terms of the details of the proposal for which
25 funding was being sought, we can see that at

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1 interest Dr Triger's own liver disease patients are
2 currently being investigated."

3 We then go to ARMO0000272. We can see from this,
4 although it's a letter about asking else, that funding
5 was provided. So 19 July 1983, Mr Bishop wrote to
6 Dr Preston. He's clearly met up with him at the
7 conference that we know took place in Stockholm in the
8 middle of 1983, and then he refers to the funding.
9 And if we go to the bottom of the page, very bottom,
10 it says:

11 "CC ..."

12 And Mr Bishop said:

13 "I will leave it to you to sort out the payments,
14 which I understand is against a budgeted £7,000 for
15 83, £10,000 for 84, and £5,000 for 85."

16 I think it's reasonable to infer from that that
17 the funding was being made available, and there are
18 subsequent communications which enclose copies of
19 cheques to Dr Preston for the purposes of the
20 research.

21 The last set of documents within this category
22 relate to communications with Dr Hill at Birmingham,
23 ARMO0000370. This is a letter of 27 March 1985 to
24 Dr Hill from Mr Christie at Armour.

25 "You will note from the enclosed copy letter that

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1 I have paid our first 1985 donation to your research
2 fund to the Finance Department of the Central
3 Birmingham Health Authority.

4 "We continue to be very interested in the progress
5 of this project, and of course, its extension into
6 HTLV-III screening of children who have been treated
7 with non-treated and latterly Heat Treated Factorate."

8 You'll recall, of course, sir, that Birmingham
9 Children's Hospital was a hospital where the Armour
10 Factorate product was in very substantial use indeed.

11 Then there's reference to an anticipated -- or:

12 "I hope to ... visit ... to discuss the current
13 status of your research and the recent Hepatitis B
14 problem."

15 And there's reference to a need to notify the DHSS
16 of the findings.

17 There's one other communication with Dr Preston at
18 Sheffield I meant to refer to. It's ARMO0000369.
19 It's again from Dr Christie, director of clinical
20 sciences at Armour to Dr Preston.

21 It's March of 1985, so it's two years further on
22 from the material we looked at before. We can see
23 reference to a cheque for £2,500 to "cover our first
24 quarter 1985 support for research in your unit".

25 It's may well be that's an ongoing payment in

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1 middle of 1983 interactions between Armour and the
2 Department, when consideration was being given within
3 the Department to the way to respond to the fear of
4 the dumping of pre-March plasma from the US, and then,
5 secondly, the important interactions with the
6 Department that took place in the course of 1986, and
7 particularly with Dr Rotblatt of the Department in
8 relation to the issue of seroconversion from HTLV-III.
9 But I'm not going to attempt to deal with any of those
10 issues in any more detail now. We will deal with that
11 when we come back in November.

12 So that finishes the picture in terms of Armour
13 for the purposes of this week.

14 **SIR BRIAN LANGSTAFF:** In which case we'll start up looking
15 at Bayer at five to four.

16 **MS RICHARDS:** Certainly, sir.

17 **SIR BRIAN LANGSTAFF:** Five to four.

18 (3.26 pm)

(A short break)

20 (3.55 pm)

21 **MS RICHARDS:** Sir, before I start with Bayer there's just
22 one further matter in relation to Armour I wanted to
23 mention briefly.

24 Going back to the trial of heat-treated Factorate
25 in 1983, 1984, so that issue of the protocol that we

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1 relation to the same research.

2 But the point I wanted to draw attention to is the
3 rest of the letter:

4 "With respect to this research work and the
5 publication of your experience with the heat treated
6 Factorate in two patients, I hope to come and see you
7 when next in Sheffield. Incidentally, do you have any
8 information on the pre and post-dosing status of these
9 two patients in respect of HTLV-III antibody.

10 A negative picture before and after treatment in both
11 cases would be valuable information for us if it could
12 be demonstrated."

13 So a request there for specific information from
14 Dr Preston about the HTLV-III status of two patients.

15 That's a flavour of some of the interactions with
16 the Haemophilia Centre Directors and some of the
17 funding that was made available by Armour to
18 Haemophilia Centre Directors.

19 The other body, of course, with whom Armour's
20 relationship in the UK is particularly important is
21 the Department of Health and Social Security. We've
22 looked at a number of the interactions in relation to
23 the licensing application process. We'll look again
24 in November at interactions in two specific points in
25 time, anything more we find out about the 1983 --

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1 saw with Dr Rizza identified as lead investigator,
2 which we know was then stopped because of participants
3 in the study developing non-A, non-B hepatitis.

4 It might have been thought from what I'd said that
5 the patients who developed non-A, non-B hepatitis were
6 Oxford patients under Dr Rizza's care. In fact, such
7 information as there is available suggests as
8 follows -- and I'm not going to put the document up
9 onscreen but I'll give the reference: it's
10 CGRA0000570, and it's the top of page 3. It's
11 a document we looked at earlier for a different
12 purpose.

13 That says:

14 "A multi-centre UK trial of Factorate heat treated
15 was conducted in 1984. Two virgin patients were
16 admitted in Sheffield and one in Glasgow. All three
17 developed non-A, non-B hepatitis. Two had severe
18 symptoms and the third exhibited markedly elevated ALT
19 from five and a half weeks to four months following
20 dosage but remained clinically well. The trial was
21 stopped."

22 Then the document, which is an Armour document,
23 says:

24 "Isolated reports have reached us since this date
25 indicating that virgin or minimally treated patients

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1 who have received Factorate heat treated have
2 developed raised ALTs or jaundice and have been
3 diagnosed as having non-A, non-B hepatitis."

4 So the specific patients whose -- the description
5 of whose reaction seems to have led to the trial being
6 stopped were either two Sheffield patients or
7 a Sheffield and a Glasgow patient, and then broader
8 reports since the trial was stopped of further
9 patients developing non-A, non-B hepatitis.

10 I just wanted to clarify that before we turn to
11 Bayer.

12 Sir, I'm going to start with the corporate
13 structure, and it's not easy to describe. There will
14 be four principal names that come up in the documents:
15 Bayer, Cutter, Miles and Speywood.

16 Speywood had, as we'll see in due course, an
17 arrangement whereby it distributed the product
18 produced by Cutter and Koate for a period of time.
19 That will become clearer both tomorrow and in the
20 course to of the Speywood presentation on Friday.

21 Bayer, Cutter and Miles are all related entities.
22 There will also be reference from time to time in the
23 documents to a company called Tuta, which manufactured
24 blood bags. To try to unravel them, I'll give the
25 following by way of an introductory explanation.

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1 example, if we go to MHRA0009276, we will see here the
2 grant of a licence in July 1976 by the Committee on
3 Safety of Medicines to an application made by Bayer
4 UK Limited, and we can see the name there written in
5 handwriting.

6 Just to complicate the picture, the Koate product
7 to which the licence related was distributed, as
8 I say, for the first few years by Speywood.

9 And if we go to CBLA0000006_011 -- that's
10 CBLA0000006_011. Okay, I can explain the document and
11 we can correct its absence tomorrow when we look at
12 the licensing documents in more details.

13 The document is referenced and I've given -- which
14 for some reason we don't have to display -- is
15 a product licence granted only a month after the one
16 onscreen, which is now granted to Speywood
17 Laboratories to distribute the same product, Koate,
18 manufactured by Cutter Laboratories Inc in California.

19 If we try this document, Soumik, BAYP0000020_051.
20 No? No. For some reason I don't think we've got the
21 right documents available.

22 Soumik, let me just try one other because I can --
23 do you have that one? No -- I can do most of this
24 without looking at the documents for the rest of the
25 day.

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1 If we start with an understanding of an
2 organisation called Bayer AG, that is a German
3 multinational pharmaceutical and life sciences company
4 originally founded in Germany in 1863. It has a wide
5 range of areas of business.

6 Bayer AG is the ultimate owner of Bayer plc, which
7 is a UK-based company, and Bayer AG was, as we
8 understand it, also at all material times the parent
9 company of Cutter Laboratories Inc, and, from 1978,
10 the parent company of Miles Laboratories Inc.
11 Cutter Laboratories and Miles Laboratories were
12 US-based companies involved in the manufacture of
13 blood products supplied to the UK market.

14 So that is Bayer AG.

15 Turning then to the UK-based Bayer company,
16 a company was registered in the UK in July 1968 called
17 Bayer (UK) Limited, and it was so known from 1968
18 to 1974.

19 In 1974 it was renamed Bayer UK Limited, without
20 the UK in brackets, and then in March 1992 it changed
21 its name to Bayer plc. As indicated, the ultimate
22 owner of Bayer plc is Bayer AG.

23 We'll see, therefore, materials from time to time
24 which refer to Bayer UK, with or without the brackets,
25 depending upon the date of the document. By way of

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1 WITN2988001. No? No, there isn't a different
2 reference to that.

3 I'm sorry, sir, we don't appear to have the
4 available documents for display.

5 Let me just spend a few minutes outlining the
6 corporate structures, because I can do that, I think,
7 without showing you particular documents, and then we
8 can ensure that we've got the right materials
9 tomorrow, and if I need to go back to any of the
10 actual documents for the purposes of demonstrating
11 what I'm talking about, we can do so then, but it'll
12 make the best use of time now.

13 So the close relationship between these various
14 entities is illustrated by the fact that in 1976,
15 Cutter Laboratories International write to Bayer UK
16 Limited thanking them for pursuing an application for
17 a licence on behalf of Cutter Laboratories, which is
18 a licence granted to Speywood. So really the
19 important thing about all of these companies at this
20 point in time is, whatever name appears, they are an
21 associated group of companies with the -- Speywood is
22 separate in terms of the company relationship, but
23 there are -- Miles, Bayer and Cutter are all
24 associated groups of companies which are dealing with
25 the manufacture and distribution of Koate. That's the

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1 principal product with which we're concerned.
 2 There will be some other products which I come
 3 on to.
 4 The contract with Speywood to distribute Koate was
 5 terminated in around 1980 and we'll hear more about
 6 this potentially on Friday. But for a period of time,
 7 Speywood continued to distribute Koate, but they
 8 distributed it under a different name, Humanate. So
 9 they imported it from the US and sold it as Humanate.
 10 We also see the name of Bayer UK appearing on
 11 various documents later in the 1980s. Bayer UK
 12 become, for example, the distributor for heat-treated
 13 Koate in 1988, although the product licence is in the
 14 name of Miles Laboratories Limited. Then from 1990
 15 onwards Cutter products are imported by Bayer UK in
 16 place of Miles Limited.
 17 So we have this relationship with Bayer UK, with
 18 its various different name changes, and then, in the
 19 UK, Miles Laboratories Limited and Cutter Laboratories
 20 Limited, they are effectively sister companies.
 21 Cutter Laboratories Limited as a UK company was
 22 established in I think 1979. The US manifestation of
 23 Cutter was Cutter Laboratories Inc, which was acquired
 24 by Bayer AG in 1974. Cutter Laboratories Inc in turn
 25 had been originally founded in the States in 1897. So

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1 Miles and Cutter in the US merge, and Cutter
 2 Laboratories Limited in the UK is acquired by Miles
 3 Laboratories Limited in the UK. There's a document,
 4 we wouldn't need to go to it even if we could, but
 5 I'll give the reference for the transcript,
 6 BAYP0004280, and page 4 of that document, which are
 7 the minutes of a board of directors of Cutter
 8 Laboratories Inc in the States in November '82, talks
 9 about Cutter and Miles having combined to form
 10 a single business with the critical mass necessary to
 11 compete successfully in the healthcare market.
 12 We see then, if we look at what was happening in
 13 the UK, a meeting taking place around the same time,
 14 autumn of 1982, between the Department of Health and
 15 representatives of Cutter Laboratories Inc and Miles
 16 Laboratories Inc, to talk about the practicalities of
 17 transferring the responsibilities for Koate from
 18 Cutter Laboratories to Miles Laboratories.
 19 What we will then see, quite often on the
 20 documents thereafter, is Cutter Laboratories described
 21 as a division of Miles Laboratories Inc in the US, and
 22 a lot of the documents will say "Cutter, Division of
 23 Miles", as a result.
 24 We then, I think, get to a point in time, I think
 25 it's 1983, but we can check when we look at the

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1 that was one company involved in the manufacture of
 2 blood products in the States. And a lot of the
 3 licence documents that we'll look at tomorrow identify
 4 the manufacturer as Cutter Laboratories.
 5 After Bayer acquired Cutter Laboratories in the
 6 States, it also acquired a company called Tuta (UK)
 7 Limited which supplied blood bags in the UK, and the
 8 name of TUTA was changed to Cutter Laboratories
 9 Limited. So that's the UK Cutter company. And that
 10 explains why there will be some documents that refer
 11 to Tuta.
 12 Again, we'll see as we go through, when we get
 13 to 1980 we see product licence applications in
 14 relation to Koate being made by Cutter Laboratories
 15 Limited, and it's Cutter Laboratories Limited which is
 16 granted the licence, the product licence in relation
 17 to Koate, in the early 1980s.
 18 We then have Miles Laboratories. The American
 19 company Miles Laboratories Inc was purchased in 1978
 20 by Bayer, and Bayer therefore became the ultimate
 21 parent company of Miles Laboratories Inc, and then the
 22 UK branch, which was Miles Laboratories Limited, which
 23 was established in 1946.
 24 Then in the early 1980s, there's a degree of
 25 rationalisation and merger between the companies.

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1 licence applications tomorrow, when the product
 2 licence begins to be held by Miles Laboratories
 3 Limited, rather than Cutter Laboratories Limited, but
 4 it's still the same product we're talking about,
 5 Koate, and certainly there's a product licence granted
 6 to Miles Laboratories August 1983.
 7 Then, again, I'll pick it up as we look at the
 8 licensing applications tomorrow, the close
 9 relationship between these various entities is
 10 apparent when we look, for example, at a product
 11 licence application for the heat-treated version of
 12 the Factor VIII concentrate, Koate-HT. Miles
 13 Laboratories Limited in the UK is responsible for
 14 packaging and labelling, it's the product licence
 15 holder. The product is described as manufactured by
 16 the Cutter division of Miles Laboratories Inc in the
 17 US.
 18 Then there comes a point in time, I think it's in
 19 the late 1980s, where the trading name effectively, or
 20 the way in which the organisation is described, is
 21 then Cutter Biological, described in one of the
 22 product licences as a trading style of Bayer
 23 UK Limited.
 24 None of it, I think, particularly matters for the
 25 purposes of the issues with which you are concerned

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1 but I hope that helps explain why we will look at
2 documents at different times and they will all be
3 about Koate, or sometimes they will be about Konyne,
4 the Factor IX product, and they might say Bayer, they
5 might say Cutter, they might say Miles, they might say
6 two or three of those names at any one particular
7 point in time. But we're talking essentially about
8 companies which had relationships with one another and
9 ultimately were owned by Bayer AG.

10 Sir, that's all I wanted to say about the
11 corporate structure. In a statement that we have from
12 the head of legal and compliance at Bayer plc,
13 Mr Wilkinson, and again, I'll just read the reference
14 into the transcript, it's WITN2988001, as well as
15 giving a detailed account of these various companies
16 and their relationships, he has set out in the
17 statement his understanding of Bayer plc's archiving
18 system and document retention policy, and he explains
19 why there were certain documents that had been
20 retained, not least because of litigation. He
21 describes how there were documents that had been held
22 by law firms acting for various incarnations of the
23 corporate entities at different points, and explains
24 how all material identified as relevant was then drawn
25 together and identified to the Inquiry in the form of

1 a schedule.

2 So that's why we have documents that we'll often
3 see with the URN "BAYP" for Bayer. They've been
4 provided to us through that route. More often than
5 not, they're more Cutter or Miles documents. So in
6 view of the fact that we don't have any further
7 documents to display and the fact that I'm going to go
8 on to look at the licence application, for which we do
9 need the documents, I am going to suggest that we take
10 a -- have a slightly early finish and sort out the
11 documents overnight so we can start again with Bayer's
12 licensing at ten o'clock tomorrow.

13 **SIR BRIAN LANGSTAFF:** Right. Well, let's do that, thank
14 you very much. So it's ten o'clock tomorrow for more
15 about Bayer, Cutter, Miles and Speywood.

16 **(4.14 pm)**

17 **(The hearing adjourned until 10.00 am the following day)**

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<p>Y</p> <p>yes... [15] 122/24 123/11 125/17 125/20 126/13 126/20 126/24 127/1 131/17 131/21 131/22 132/1 144/20 154/4 154/5</p> <p>yesterday [16] 1/6 1/7 1/20 5/17 6/24 8/20 11/25 12/1 12/5 12/25 13/3 25/17 27/23 29/8 29/12 107/14</p> <p>yet [9] 25/12 36/13 50/13 62/4 65/21 108/11 112/4 115/21 123/18</p> <p>York [3] 63/7 68/8 76/24</p> <p>you [104] 2/13 4/21 5/6 5/8 6/23 6/25 7/24 7/25 8/3 11/13 11/23 16/16 18/10 20/13 20/13 22/3 24/8 24/19 25/19 28/3 29/20 44/9 54/15 59/25 60/19 60/20 66/17 67/25 68/6 68/10 68/18 69/1 69/8 69/24 70/23 71/10 71/13 71/16 71/20 71/22 75/13 79/7 82/15 85/6 85/25 87/4 88/7 88/17 89/25 94/17 95/21 100/25 101/22 102/6 103/17 103/19 107/3 110/10 112/14 112/15 113/8 116/17 120/21 124/4 126/9 126/10 126/18 131/6 132/1 136/24 138/16 140/3 142/21 143/15 143/17 144/4 144/5 144/6 144/25 145/5 146/6 146/12 146/16 146/25 147/18 147/20 147/23 149/9 149/16 149/22 149/23 153/20 153/21 155/14 155/18 155/20 156/13 156/25 158/6 158/7 163/23 164/7 168/25 170/14</p> <p>you'll [22] 9/14 10/23 13/15 24/25 26/1 29/16 38/5 47/15 53/17 56/21 59/24 62/16 79/12 79/15 86/21 103/25 110/13 113/23 117/12 117/24 150/9 157/8</p> <p>you're [2] 28/20 29/2 you've [1] 20/11</p>	<p>young [1] 54/21</p> <p>your [42] 4/19 5/10 8/11 9/21 10/9 10/11 10/15 10/17 24/21 34/22 49/18 67/12 68/11 68/13 68/23 69/8 69/14 69/21 69/25 71/13 74/25 83/24 85/6 88/18 90/8 94/14 94/22 103/17 104/15 107/1 108/21 131/24 132/7 144/7 145/7 147/20 148/21 153/15 157/1 157/13 157/24 158/5</p> <hr/> <p>Z</p> <p>zero [1] 1/14</p> <p>zoom [2] 112/10 113/9</p>				
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