

Thursday, 4 November 2021

(10.00 am)

(Proceedings delayed)

(10.14 am)

CHRISTOPHER BISHOP (called)

SIR BRIAN LANGSTAFF: Good morning, Mr Bishop, can you hear me?

WITNESS: Yes, good morning, Sir Brian, I can hear you loud and clear.

SIR BRIAN LANGSTAFF: And you can see me?

WITNESS: I can, indeed.

SIR BRIAN LANGSTAFF: Good. Now, you are -- where are you?

WITNESS: I'm in Eastbourne.

SIR BRIAN LANGSTAFF: In your house or in a hotel or?

WITNESS: In a hotel.

SIR BRIAN LANGSTAFF: And who is with you?

WITNESS: An engineer at the moment.

SIR BRIAN LANGSTAFF: Okay.

In a moment or two I'm going to ask that Mary administers the oath, and then Ms Richards will have some questions for you, but let me first explain that you're talking to the group of about 50 people here in Aldwych House in central London. But you're also talking to an unknown number, it may well be 100,

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extraordinarily embarrassing! It happens to the best of us.

I'm sorry, Mr Bishop, my phone went off.

A. No problem.

Q. So 1979 to 1981, your responsibility included responsibility for the sales field force; is that right?

A. Yes, yes.

Q. 1981 to 1987, you were manager of the biologicals division at Armour, and that gave you oversight of a number of countries including the UK, but also Ireland, France, Scandinavia, Belgium, Luxembourg and the Netherlands; is that correct?

A. Correct.

Q. And then 1987 to 1993, you were the managing director at Armour UK; is that right?

A. Correct, yes.

Q. And you left in 1993, but you remained a consultant on an *ad hoc* basis for about three years?

A. Yes, yes.

Q. Can you recall what if any training you received from Armour, either when you first joined the company, or as you progressed through these various roles?

A. It was very much training on the job.

Q. So no formal training?

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200 people, who will be watching most of the time throughout the day on the media channel that we are live streamed, and if it's -- so they are your wider audience, and there are representatives of the press here, or watching, as well.

So let Mary ask you to take the oath.

(Oath administered)

Questions from MS RICHARDS

MS RICHARDS: Mr Bishop, can you see and hear me?

A. I can.

Q. I'm just going to ask you first of all about your career. As I understand it, you started work for Armour in 1969?

A. Yes.

Q. Then between 1973 and 1979, you were the products and marketing manager at Armour, and the significance of that period is that plasma products, Factorate concentrate, was launched in the UK in 1976; is that right?

A. Yes.

Q. And then 1979 to 1981, you were the sales and marketing manager at Armour, and that gave you responsibility for the sales field force?

A. Yes.

Q. I'm so sorry! That is my phone, which is really quite

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A. Well, initially, I would have received, obviously, more intense training on the products that I was responsible for marketing and selling.

Q. You provided evidence, your statement tells us, in criminal proceedings in Canada. Those were, I think, the criminal proceedings against a number of organisations and bodies, including Armour and Dr Rodell; is that right?

A. Correct, yes.

Q. And you also gave a deposition, an oral deposition, in the UK but relating to proceedings against Armour in Pennsylvania; is that right?

A. That's correct, although I do not actually recall that particular deposition. The Canadian one I do recall very well.

Q. Well, we may look at, later in the course of the day, the incomplete copy of the 1990 deposition that we've got. We'll see how time pans out.

I'm going to ask for your witness statement to go up on screen, Mr Bishop. It's WITN5529001. I'm going to ask you to look at paragraph 7 on page 5.

So you'll see there a question asked you to:

"... identify senior colleagues ... involved in [the] decision-making as regards the assessment of risks of infection, viral inactivation measures, [and]

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1 the response to the risks of HIV/AIDS ..."
 2 Or, indeed, the other matters you were asked
 3 about. You say in your answer:
 4 "It was not my role to participate in the
 5 decision making as regards the issues identified in
 6 the question, and to the best of my recollection I did
 7 not do so."
 8 You've been provided with a number of further
 9 documents since you made this statement. Does that
 10 remain your evidence, that it wasn't your role to
 11 participate in decision-making relating to these
 12 issues?
 13 **A.** Yes.
 14 **Q.** Well, we may come back to that then at the end of the
 15 day, Mr Bishop, when we've looked at some of the
 16 underlying material.
 17 **A.** Okay.
 18 **Q.** Whose role then was it within Armour UK to participate
 19 in decision-making as regards assessment of risks of
 20 infection and how to respond to those risks?
 21 **A.** That would really have been under the jurisdiction of
 22 Armour US, and the regulatory medical people in the UK
 23 would have been consulted and appraised of discussions
 24 on those, but it would not have been actually taking
 25 decisions, it would have been from the United States.

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1 **Q.** If we just look at some of the names you've then set
 2 out, and perhaps I can ask you to help us with
 3 understanding a little more about their role.
 4 Mr Fitch, whose name we see on a number of
 5 the documents, corporate managing director, what was
 6 his essential role at Armour UK?
 7 **A.** He was the corporate -- as I say, the corporate
 8 managing director, who oversaw the pharmaceutical
 9 operation of the -- of the operation, and also the
 10 plasma side.
 11 **Q.** So was he the most senior person in Armour UK?
 12 **A.** Yes.
 13 **Q.** And then Mr Michelmore, senior executive, what was his
 14 role?
 15 **A.** Similar. He was deputy to Ken Fitch. And I'm not
 16 sure, it's a long time ago, but I think he may well
 17 have taken over from Ken Fitch.
 18 **Q.** Okay. If we go over the page, please, Soumik, top of
 19 the next page.
 20 You've then identified Peter Lloyd, Robin James
 21 quality control, what was their role?
 22 **A.** They were quality control for the whole operation,
 23 both the plasma products and the pharmaceutical
 24 products, which were manufactured in Eastbourne.
 25 **Q.** You've then identified four individuals for Regulatory

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1 Affairs, and we can certainly see their names on
 2 various documents: Mr Brooks, Mr Butchart, Mr Collins,
 3 Mr Tarbit.
 4 As I understand both your statement and the
 5 evidence that you've given a few minutes ago, it's
 6 that department, is it, that would have been primarily
 7 liaising with Armour US to get information about
 8 safety of products and how to respond?
 9 **A.** Yes, them and those listed under (g).
 10 **Q.** Medical affairs?
 11 **A.** Medical affairs, yes.
 12 **Q.** So that's -- I think the names we see probably most of
 13 the documents which we're going to be looking at will
 14 be Dr Christie and Dr Harris. Does that accord with
 15 your recollection?
 16 **A.** It's Mr Christie, he wasn't a doctor.
 17 **Q.** So Mr Christie. Then were the others all doctors?
 18 **A.** Yes. Robert Christie's specialty was pharmaceutical.
 19 **Q.** We can take that down, thank you, Soumik.
 20 Prior to the advent of AIDS, so in the period in
 21 the 70s through to the early 80s, through to, say,
 22 1982, to what extent was there interaction between
 23 Armour UK and Armour US?
 24 **A.** There would be discussions back and forth, information
 25 fed from the UK operation and field operation relating

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1 to these matters, with clinicians, would be reported
 2 back to our own medical department in Eastbourne and
 3 then onward to the States, or indeed directly from the
 4 marketing department to the marketing people in the
 5 States, who would then pass that on to their own
 6 medical and regulatory people.
 7 **Q.** I think the name we see quite often on the
 8 documentation is Anita Bessler. Was she your
 9 equivalent in the States?
 10 **A.** She was a more senior position to me in the States.
 11 I think she was the vice-president, something like
 12 that.
 13 **Q.** But she was in the marketing --
 14 **A.** Yes.
 15 **Q.** -- department --
 16 (Unclear - simultaneous speakers)
 17 **A.** Marketing and sales, yes.
 18 **Q.** When AIDS became an issue, and we'll be looking at
 19 this in more detail in the course of the day, but
 20 let's say 1983 onwards for the purposes of the
 21 question, did the relationship with or dependence upon
 22 Armour US change? Was there a greater degree of
 23 interaction at that point?
 24 **A.** No, sorry, could you repeat that?
 25 **Q.** Yes.

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1 Once AIDS became a live issue, was there a greater
 2 degree of interaction between Armour UK and Armour US?
 3 **A.** Yes.
 4 **Q.** What was the relationship within the UK between
 5 Armour UK and those whom you were working with within
 6 Armour UK, and the other pharmaceutical companies
 7 selling factor concentrates in the UK?
 8 **A.** Well, we would meet, obviously, at national and
 9 international clinical meetings, symposia,
 10 Haemophilia Society meetings, et cetera.
 11 **Q.** To what extent was there any form of information
 12 sharing between Armour and its rivals or competitors
 13 within the UK market?
 14 **A.** Well, as far as I'm concerned, the only people
 15 I interacted with were the -- my equivalent marketing
 16 and salespeople in those companies, and naturally we
 17 would -- at symposia, et cetera, we would be listening
 18 to the same clinical presentations and would be
 19 drawing on the same information.
 20 **Q.** But was there any system of sharing knowledge about
 21 new and emerging risks, for example, between the
 22 different companies?
 23 **A.** Certainly not between the marketing people, and
 24 I don't know of any interrelation with the medical and
 25 regulatory people. But it may have been the States;

1 **A.** Yes, and we performed strictly to it under the strict
 2 guidance and -- well, the strict guidance and
 3 examination of our own Medical and Regulatory
 4 Department.
 5 **Q.** So there was a degree of internal regulation, was
 6 there, from your medical department? Was there any
 7 external regulation of whether you were complying with
 8 this?
 9 **A.** Our internal -- our medical department ensured that
 10 we, in our promotion -- the action of our plasma
 11 specialists in the field, that they conformed to the
 12 code of practice, and our specialists were so well
 13 trained that these principles were embodied in their
 14 activities.
 15 **Q.** So your sales team, I think sometimes referred to as
 16 the "field force" in the documents, they would have
 17 been specifically trained about this code of practice,
 18 would they?
 19 **A.** Yes.
 20 **Q.** And if we just look, for example, down the bottom half
 21 of this page, please, Soumik, paragraph (f), we can
 22 see:
 23 "The Code emphasises the importance in the
 24 public interest of providing the medical and allied
 25 professions with accurate, fair and objective

1 certainly not in the UK.
 2 **Q.** I'm going to ask you to look at a document now which
 3 contains a code of practice for the pharmaceutical
 4 industry. Soumik, it's ABPI0000015, please.
 5 You'll see, Mr Bishop, this is the ABPI's Data
 6 Sheet Compendium, and this one happens to be for 1978.
 7 **A.** Yes.
 8 **Q.** If we go to page 5, you'll see there "Code of Practice
 9 for the Pharmaceutical Industry, Fourth edition
 10 (January 1974)". We can see in the paragraphs below
 11 that it refers to:
 12 "... members of the Association of the British
 13 Pharmaceutical Industry have agreed to voluntarily
 14 observe the principles set out in a Code of Practice
 15 for the Pharmaceutical Industry; a Code which
 16 regulates the standards of conduct to be followed in
 17 the marketing of medicines intended for use under
 18 medical supervision."
 19 Then it tells us that this was first published
 20 in 1958 and has been regularly revised.
 21 So this is the 1974 version, the version in
 22 force at the time Armour began selling factor
 23 concentrates in the UK.
 24 Were you familiar with this code of practice at
 25 the time, Mr Bishop?

1 information on medical products so that rational
 2 prescribing decisions can be made."
 3 That was the guiding principle was it to which
 4 you were expected to operate?
 5 **A.** Yes, yes.
 6 **Q.** If we just go over --
 7 **A.** Which we did.
 8 **Q.** If we go over the page, please, top of this page,
 9 paragraph 3, just look at paragraph 3.2:
 10 "Information about medical products should
 11 accurately reflect current knowledge or responsible
 12 opinion."
 13 And then 3.3:
 14 "Information about medical products must be
 15 accurate, balanced and must not mislead either
 16 directly or by implication.
 17 "3.4. Information must be capable of
 18 substantiation, such substantiation being provided
 19 without delay at the request of members of the medical
 20 profession."
 21 Again, were those parts of the principles to
 22 which you were expected to adhere?
 23 **A.** Yes.
 24 **Q.** Then if we go to the bottom of the next page, please,
 25 Soumik.

1 Paragraph 11, very bottom of the page, has
 2 a heading "Medical representatives", and it says:
 3 "Representatives must be thoroughly trained and
 4 possess sufficient medical and technical knowledge to
 5 present information on the company's products in an
 6 efficient manner."

7 What was your understanding of what a medical
 8 representative was? Did that encompass you and your
 9 workforce?

10 **A.** Well, that was -- we didn't call them
 11 "representatives", we called them "plasma
 12 specialists". And they were very, very highly trained
 13 in the subject of haemophilia, AIDS, as it developed,
 14 and hepatitis C. They were fully empathetic of the
 15 field in which they worked. They had sufficient
 16 knowledge to be able to discuss issues with the
 17 Haemophilia Society -- sorry, the Haemophilia
 18 Directors, and they were particularly respected for
 19 that.

20 In addition to that, they had very effective
 21 support from both -- from the medical department,
 22 especially, in the form of regular technical
 23 bulletins, which were produced from the clinical
 24 papers published at the time. They were very highly
 25 respected specialist people.

1 **Q.** Well, we'll come back to some of these themes,
 2 Mr Bishop, as we go through the documents. This is
 3 really by way of introduction.

4 If we go over the page, please, Soumik. Bottom
 5 of the page, paragraph 13:

6 "Gifts and inducements.

7 "Subject to clause 13.2, no gifts or financial
 8 inducements shall be offered or given to the members
 9 of the medical profession for purposes of sales
 10 promotion.

11 "Gifts in the form of articles designed as
 12 promotional aids, whether related to a particular
 13 product or of general utility, may be distributed to
 14 members of the medical and allied professions provided
 15 the gift is inexpensive and relevant to the practice
 16 of medicine or pharmacy."

17 What kind of, if any, articles or gifts did
 18 Armour provide to clinicians, for example, to whom it
 19 was promoting its products?

20 **A.** Pens, pads, if there was a particular conference we
 21 might have provided folders for their clinical papers
 22 and notes, et cetera. Other than that -- oh, there
 23 might have been -- no, I can't -- oh, perhaps we might
 24 be have given away -- yes, we did -- a calculator,
 25 a little pocket calculator at one time, and a little

1 paper weight at one time. That was the extent of our
 2 gifts.

3 **Q.** Then if we look at paragraph 16, please, bottom half
 4 of the page, Soumik:

5 "Relations with the general public and lay
 6 communication media.

7 "Requests from individual members of the public
 8 for information or advice on medical matters must
 9 always be refused and the enquirer recommended to
 10 consult his or her own doctor.

11 "Information about a scientific discovery or
 12 a medical product should normally be supplied only
 13 where it is desirable or necessary to do so in the
 14 public interest or where the object is to keep the
 15 public informed of scientific and medical progress."

16 Then there is a reference to disclosure to the
 17 public of shareholders or persons with some special
 18 and or valid interest:

19 "Information must be presented in a balanced way
 20 to avoid the risk of raising unfounded hopes in the
 21 public mind the results of treatment. Statements must
 22 not be made or designed for the purpose of encouraging
 23 members of the public to ask their doctor to prescribe
 24 a product."

25 Is it to understand from that that's expectation

1 was that your dealings would be primarily with
 2 doctors, NHS bodies, health authorities and the like?

3 **A.** In the main, yes, but there would have been
 4 interaction with the UK Haemophilia Society, where we
 5 would support and help towards their annual
 6 conference, as indeed other companies did also. And
 7 that would be -- obviously at these conferences or the
 8 Haemophilia Society, their annual meeting, patients
 9 would be there, because they make up members of the
 10 society, executive, et cetera. And there would have
 11 been discussions, but purely -- I remember one,
 12 I think there is one document which refers to me
 13 referring a request for information from one of these
 14 patients who came to me at a particular meeting, which
 15 I didn't comment on, and informed him that I would
 16 pass this to the medical department, which I did, for
 17 further action. We didn't get into a discussion with
 18 an individual patient.

19 **Q.** We may come back that but, I think, just so that there
 20 is no confusion, you're referring to an interaction in
 21 around March 1986, is that right, when you say that
 22 someone I think reported to you at a society meeting
 23 that they had seroconverted from heat-treated
 24 Factorate; is that right?

25 **A.** Yes, I saw one paper but, in general, we would have

1 kept the Haemophilia Society apprised of scientific
2 developments.

3 **Q.** I'll ask you a little more about the Society -- carry
4 on, sorry?

5 **A.** No.

6 **Q.** I'll come back and ask you about the Society in due
7 course.

8 More generally, is it right to understand that,
9 although this code of practice restricted direct
10 communications with individual members of the public
11 for information or advice on matters relating to their
12 personal medical situation, Armour nonetheless
13 communicated to the public, or to patients, not least
14 through what was on a package label or a data sheet or
15 a product insert? So the information that was
16 supplied with your products was there to be read in
17 theory, at least, by patients?

18 **A.** No. That would have been through their haemophilia
19 centre.

20 **Q.** So when Armour was producing its -- the content of its
21 product labels or its package inserts, it was
22 producing them in the expectation that they would be
23 read and considered by doctors rather than patients;
24 is that right?

25 **A.** Yes, exactly.

17

1 **Q.** So we can take that down, thank you, Soumik.
2 Did you or anyone in the sales force receive
3 money by way of commission or bonus?

4 **A.** Well, we would have been on targets from the
5 company --

6 **Q.** Did those --

7 **A.** -- and would have received -- yes, we would have
8 received bonuses.

9 **Q.** So the amount which sales representatives received in
10 terms of their own personal income from Armour would,
11 to some extent at least, be reflective of the volume
12 of sales that they were able to make?

13 **A.** Yes, as it would be with any sales or marketing
14 organisation.

15 **Q.** I want to ask you a little about, first of all,
16 hepatitis. As at 1976, when factor concentrates were
17 first launched by Armour in the UK, what, to the best
18 of your recollection, was your knowledge and
19 understanding of hepatitis B and of non-A, non-B
20 hepatitis?

21 **A.** Well, at the time of the launch there was --
22 everybody, the general public, knew the risks of
23 hepatitis B from blood and body fluids, et cetera. At
24 that time non-A, non-B wasn't on the -- in the domain.

25 **Q.** Can you recall how and when, very roughly, you learnt

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1 about non-A, non-B hepatitis?

2 **A.** No, I can't remember, I can't remember the time, but
3 when it did appear, the general consensus of the
4 scientific fraternity was that non-A, non-B was
5 a mild, flu-like reaction --

6 **Q.** Was that --

7 **A.** -- and as (unclear) developed, it obviously turned out
8 to be something more than that.

9 **Q.** When you say that the consensus of the scientific
10 community, was that what you understood the position
11 to be from your own reading, or was that what you were
12 being told by your medical department?

13 **A.** Well, that's what we were told by the clinicians and
14 I think it was in the literature as well.

15 **Q.** If we just go back to your witness statement,
16 please -- Soumik, could we have that back on screen,
17 WITN5529001. If we go to page 7, please; top of the
18 page.

19 So you are asked a question at the top of the
20 page about your knowledge and understanding in
21 relation to risks, in particular, of hepatitis.
22 Picking it up in the second part of your answer, you
23 say this:

24 "As the Medical and Regulatory Affairs personnel
25 at Armour UK gained knowledge about AIDS and non A

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1 non B Hepatitis (Hepatitis C), they kept me informed.
2 This information would have come from published
3 clinical papers, medical symposia and regular and
4 punctual Medical Bulletins."

5 You give an example, which we'll look at in
6 a while:

7 "I am also aware that the risk of transmission
8 of hepatitis was included on the labelling."

9 So when you describe being kept informed by your
10 Medical and Regulatory Affairs colleagues, would you,
11 yourself, expect to be seeing the clinical papers,
12 attending some of the symposia and receiving the
13 medical bulletins?

14 **A.** Yes.

15 **Q.** Okay. We'll come back to the question of labelling
16 shortly. As a general question then, you'd expect
17 your Medical and Regulatory colleagues to be keeping
18 up to date with the developing scientific and medical
19 knowledge and, in turn, to keep you up to date?

20 **A.** Yes, and it was done meticulously. I recall that
21 all -- that there was a system within the Medical
22 Regulatory Affairs Department, there was a system for
23 them to automatically be advised of any subjects or
24 clinical papers or lay press reports relating to the
25 subject, which they would then scrutinise and then put

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1 out in a medical bulletin, which I would then pass on
 2 to the sales force to keep them informed, as well, of
 3 the current thinking. It was a meticulous exercise.
 4 **Q.** So, by way of just general example, if, say, in
 5 a prominent medical publication such as The Lancet or
 6 something equivalent, a leading haemophilia clinician
 7 published about liver disease, you'd expect that to
 8 come to the attention of your medical department and
 9 be passed on to you?
 10 **A.** It would, yes.
 11 **Q.** Then if we can look at a document from 1981, please,
 12 ARMO0000229.
 13 This is a publication called "Plasma
 14 Perspectives", July 1981. Do you recall this
 15 publication?
 16 **A.** Yes, I do.
 17 **Q.** What, in broad terms, was its purpose, as far as you
 18 can recall?
 19 **A.** Well, to keep everybody informed of the current state
 20 of art.
 21 **Q.** Then if we just go to page 3, and we look at what's
 22 said about non-A, non-B hepatitis. So the top
 23 right-hand side, please, Soumik, there is a heading,
 24 "Non-A Non-B Hepatitis". It says:
 25 "This is now the most common form of hepatitis

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1 that follows the transfusion of blood and certain
 2 plasma derivatives. Specific laboratory tests for the
 3 identification of this most recently recognised type
 4 of hepatitis are not yet available so that diagnosis
 5 can only be made by exclusion of hepatitis A and B.
 6 However, much information is available on its
 7 epidemiology and clinical features. Studies of the
 8 histopathological sequelae of acute non-A, non-B
 9 infections indicate that chronic liver damage, which
 10 may be severe, may occur in as many as 40-50% of the
 11 patients whose infection is associated with blood
 12 transfusion or with treatment by haemodialysis."
 13 So would it be fair to say, Mr Bishop, that
 14 certainly by 1981, which is when this publication was
 15 issued, you and your colleagues would have been aware
 16 that non-A, non-B hepatitis could lead to severe and
 17 chronic liver damage?
 18 **A.** Yes.
 19 **Q.** We can take that down, thank you.
 20 Can I then just ask you again to cast your mind
 21 back to 1975, 1976, when Armour would be about to
 22 launch onto the UK market its Factor VIII concentrate.
 23 We know that there was a World in Action documentary
 24 broadcast in December 1975, called Blood Money, which
 25 talked about the practices of plasma collection in the

22

1 States, and it talked about implications in terms of
 2 transmission of hepatitis to recipients of concentrate
 3 treatment.
 4 Do you recall whether you saw that documentary
 5 at the time, Mr Bishop?
 6 **A.** No, I don't recall.
 7 **Q.** Do you recall any discussion about it within the
 8 company in the UK?
 9 **A.** Not in specific terms, except -- except on reading the
 10 document, you know, we believed that our products were
 11 not the subject of -- or our plasma collection was not
 12 the subject of that programme.
 13 **Q.** You were aware, however, presumably, that Armour's
 14 plasma did come from paid donors in the US?
 15 **A.** Yes, but wholly owned by Armour, and controlled by
 16 Armour.
 17 **Q.** Are you referring there to the Plasma Alliance
 18 plasmapheresis centres in the States?
 19 **A.** Well, that, and prior to that, the centres that Armour
 20 owned. I forget the name of them, but subsequently it
 21 became Plasma Alliance.
 22 **Q.** So was it -- again, I apologise, I'm asking you about
 23 events obviously a long time ago, Mr Bishop, but as
 24 far as you can recall was the feeling within Armour
 25 that the message of the World in Action documentary

23

1 didn't really apply to Armour's product?
 2 **A.** Yes, definitely, it did not.
 3 **Q.** More broadly, what did you understand Armour's
 4 responsibilities to be as regards explaining to the
 5 clinicians or NHS bodies, to whom you were promoting
 6 your product, the risks of hepatitis, or rather
 7 potential adverse consequences or reactions?
 8 **A.** That was not -- that was not my remit.
 9 **Q.** So when you or your sales force were out in the field
 10 talking to haemophilia clinicians or talking to those
 11 in Regional Health Authorities, was it not part of the
 12 sales representatives' responsibilities to talk to
 13 doctors about the risks from using the product?
 14 **A.** It would have come up, obviously, during discussions,
 15 but the reassurance in the minds of everybody in the
 16 Armour company, and which was portrayed to the
 17 clinicians, that our -- the risks associated with the
 18 collection of material for our products was beyond
 19 reproach.
 20 **Q.** So is this right, and please correct me if I've
 21 misunderstood, Mr Bishop -- and we're talking here
 22 really about the second half of the 70s, the beginning
 23 of the 1980s -- your expectation is that your staff
 24 wouldn't have been proactively raising issues about
 25 hepatitis with clinicians, but they would respond if

24

1 clinicians raised it and would give reassurance about
2 the safety of the Armour product?

3 **A.** Yes. Yes.

4 **Q.** If --

5 **A.** That would be reinforced by our medical department, if
6 necessary.

7 **Q.** If we go back to your statement again, WITN5529001,
8 and we go to page 9. So it's question 16, or
9 paragraph 16, you were asked:

10 "What if any steps were taken to ensure that:
11 "a. NHS bodies and/or clinicians purchasing
12 and/or using Armour products were made aware of the
13 risks of hepatitis?"

14 You say that:

15 "... the risk of hepatitis infection was
16 universally known before Armour UK began marketing
17 factor concentrate and the label always warned of such
18 risk."

19 And we'll look at a couple of sample labels in
20 the course of the morning.

21 You say this:

22 "Appropriate and timely Medical
23 Bulletins/position statements [and you give an
24 example] would be produced and circulated by the UK
25 Medical and Regulatory Affairs Departments to both

25

1 or Centres. Do you accept that?

2 **A.** Yes, this particular document wouldn't have been --
3 sorry, yes, no, this particular document wouldn't have
4 been distributed.

5 **Q.** But your recollection, or expectation, is that
6 relevant developments would have been distributed in
7 some form of bulletin or statement?

8 **A.** Only as it would have affected the Armour products.

9 **Q.** So what kind of information would you have expected
10 your Medical or Regulatory Affairs Department to be
11 providing directly to, say, haemophilia centres?

12 **A.** Information as it related to the impact or relevance
13 to our own products.

14 **Q.** So if there was, for example, general information
15 about risks of hepatitis from factor concentrates more
16 broadly, or risk of AIDS from factor concentrates or
17 from blood transfusion more broadly, would you have
18 expected your Medical and Regulatory Departments to be
19 sharing that kind of information with the haemophilia
20 centres?

21 **A.** No, not general information because the haemophilia
22 centres directors would have that information anyway.

23 **Q.** So it would be, would it, a study or a piece of
24 information or a piece of research directly about
25 Armour's own products that you'd expect to be shared

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1 Haemophilia Centres and NHS bodies alike."

2 So, looking at that second part of the
3 paragraph, Mr Bishop, was it your understanding that
4 Armour, through its Medical and Regulatory Affairs
5 Department, would be providing updates about medical
6 and scientific knowledge directly to haemophilia
7 centres and NHS bodies?

8 **A.** Yes.

9 **Q.** If we look at the example you've given in that
10 paragraph, which is ARMO0000614_002, you'll see that
11 this is directed to the plasma team. Who exactly were
12 the plasma team, Mr Bishop?

13 **A.** They were the plasma specialists in the field -- well,
14 and myself, of course.

15 **Q.** So you and your team, whose job it was, essentially,
16 to market and sell the plasma products?

17 **A.** Yes, yes.

18 **Q.** It's from Mr Christie, and this particular bulletin
19 happens to be from October of 1986. Now, we've then
20 got the heading:

21 "This medical bulletin is not for distribution
22 to the medical profession and is for your attention
23 only."

24 So that would suggest this wasn't the kind of
25 material that went directly to haemophilia clinicians

26

1 with haemophilia centres?

2 **A.** Yes, yes.

3 **Q.** Then could we look, please, at ARMO0000458.

4 You'll see, Mr Bishop, this is dated
5 20 January 1986, and it's from you to Lucas,
6 Lofty Lucas. Who was that?

7 **A.** He was a successor to Anita Bessler, I think, from the
8 States.

9 **Q.** So someone within the marketing department in the
10 States?

11 **A.** Yes, correct.

12 **Q.** We can see the subject is "Non A Non B hepatitis -
13 clean virgin patients with Armour Factorate IP/HT".
14 Am I right in understanding intermediate potency and
15 heat treatment, or heat-treated?

16 **A.** Well, the heat treated intermediate purity product,
17 yes.

18 **Q.** Then it says:

19 "Dear Lofty,
20 "For your information, I enclose a copy of
21 a letter from Bob Christie to Dr Green at St Mary's
22 Hospital, Portsmouth, and copies of correspondence
23 with Dr Kernoff, from which you will see that we have
24 had a further three reports of hitherto clean virgin
25 patients treated with our heat treated product, all of

28

1 whom who have succumbed to NANB Hepatitis.
 2 "Although the evidence is not totally
 3 conclusive, it is pretty strong against the Armour
 4 product and the last paragraph of Peter Kernoff's
 5 letter is indicative of the problems which we are now
 6 facing.
 7 "If Peter's two patients had been clean and
 8 remained clean he would have, I am sure, reverted to
 9 the Armour product, as it is he will continue with the
 10 Alpha to our total exclusion.
 11 "The plea once again, therefore, is a revision
 12 of our heat treating process and/or evidence of just
 13 one clean virgin patient treated with Armour's heat
 14 treated product surviving NANB contamination."
 15 Now and I'm going to come on, probably this
 16 afternoon, Mr Bishop, to the question of
 17 seroconversion to HTLV-III in Armour's heat-treated
 18 product. But just looking at this document, it's
 19 apparent that information has come to your attention
 20 about seroconversion to non-A, non-B hepatitis
 21 specifically from an Armour product?
 22 **A.** Yes.
 23 **Q.** Would that information have been shared more widely by
 24 Armour with haemophilia clinicians in the UK?
 25 **A.** Not at that stage, no.

1 **Q.** Why not?
 2 **A.** Well, because it would have to be appropriately
 3 researched and confirmed by the medical technical
 4 department.
 5 **Q.** So with this piece of information, what was your
 6 expectation of what would be done with this
 7 information?
 8 **A.** That it would be passed to the research people and
 9 development people in the States, to -- if the
 10 evidence was correct, to up our own heat-treated
 11 process.
 12 **Q.** In the meantime, however, haemophilia clinicians would
 13 have been potentially treating what you describe as
 14 "clean virgin patients" with a product that you now
 15 knew was transmitting non-A, non-B hepatitis. Isn't
 16 that something that clinicians should have been told?
 17 **A.** Well, we didn't know. It says there that the evidence
 18 is not totally conclusive. So we didn't know for sure
 19 that that was a problem.
 20 **Q.** So "pretty strong" evidence, and I'm looking at the
 21 phrase you use in this memo, wouldn't be enough to
 22 trigger you telling clinicians about the problem?
 23 **A.** Well, it wouldn't -- that wouldn't have been my
 24 decision.
 25 **Q.** Well, whose decision would it have been?

1 **A.** The US and then through the US medical department,
 2 through our own -- and through our own medical
 3 department.
 4 **Q.** If you or a member of your sales force at the time,
 5 having seen this information, had been asked by
 6 a haemophilia clinician about the safety of the Armour
 7 heat-treated product in relation to non-A, non-B
 8 hepatitis, how, hypothetically, do you think you would
 9 have answered?
 10 **A.** That they would refer the matter back -- that concern
 11 back to the medical department.
 12 **Q.** So you wouldn't have answered a clinician who
 13 expressly asked about it by saying, "We do know of
 14 cases where the evidence is pretty strong, but still
 15 remains to be confirmed, that clean virgin patients
 16 are succumbing to non-A, non-B hepatitis"?
 17 **A.** Well, that could have come up in general conversation,
 18 you know, because our people had a very, very close
 19 relationship with the directors. So there would have
 20 been discussions backwards and forwards but, at the
 21 end of the day, the concern that was being expressed
 22 would have been referred back to our medical
 23 department to make further contact, if appropriate,
 24 with that centre director.
 25 **Q.** We can take that down, thank you.

1 I'm just going to ask you a little now about the
 2 licensing process and product warnings on labels and
 3 data sheets, and the like. Firstly, within the United
 4 Kingdom, so within Armour UK, whose responsibility was
 5 it to submit the licence application and approve the
 6 content of any product warnings?
 7 **A.** medical and Regulatory Departments.
 8 **Q.** What involvement or role did you have in that process?
 9 **A.** Absolutely none.
 10 **Q.** I think we, perhaps later on the years see, I think,
 11 a request by you -- I'll check and correct it if I'm
 12 wrong -- Mr Bishop, to want to see what's being put on
 13 a label. I think by this time we're in the mid-'80s
 14 or so on. Did there ever come a point in time, as far
 15 as you can recall, when you wanted to have content of
 16 labels run by you?
 17 **A.** No, never.
 18 **Q.** Well, let's look, shall we, at a handful of
 19 documents --
 20 **A.** I would say it would totally inappropriate for that
 21 sort of subject to be discussed with marketing people.
 22 **Q.** If we go to DHSC0003742_077, please, Soumik.
 23 So this is an internal Department of Health
 24 document, Mr Bishop, not something you would ever have
 25 seen at the time. But it talks about Armour's

1 application for a licence for Factorate, so it's
2 January 1976. It says this:
3 "At the meeting with Dr Owen [that's David Owen,
4 Minister of Health] in connection with the [TV]
5 programme about Factor VIII, he indicated he would
6 wish to see any further applications for product
7 licences to authorise the importation of Factor VIII.
8 Accordingly we have prepared a submission about the
9 application from Armour Pharmaceutical [Company].

10 "I understand that Supply Division have received
11 a 'very favourable' tender from the company for the
12 supply of Factor VIII to haemophilia centres but, of
13 course, action on this depends upon the granting of
14 a product licence."

15 Now, just pausing there, you've told us you
16 weren't involved in the licence application process.
17 Would you have been involved in the submission of
18 a tender to the Department of Health Supply Division?

19 **A.** Yes. Yes.

20 **Q.** I'll come on to some of the marketing techniques and
21 approaches but, when this talks about a "very
22 favourable tender", is that likely, do you think, to
23 be talking about the price at which that the product
24 was being offered?

25 **A.** Probably, yes.

33

1 stipulate hepatitis B or non-A, non-B, it just said
2 risk of hepatitis. So there would have been no need
3 to have changed it.

4 **Q.** Would you have expected Armour to include information
5 about the risk of AIDS in its product labelling and
6 package inserts in 1983, 1984 or 1985?

7 **A.** If, at that time, the Armour product was implicated,
8 yes, but it wasn't.

9 **Q.** When you say it wasn't implicated, what exactly do you
10 mean by that, Mr Bishop?

11 **A.** That if it had been proven at that stage that the
12 Armour product caused seroconversion then, yes, it
13 would have appeared on the labelling, but there was no
14 conclusions at that stage that the Armour product did
15 cause seroconversion, as far as I can recall.

16 **Q.** Okay. So for something to be included on a label or
17 in a package insert, the threshold, as far as you can
18 recall, would have been that there needed to be, what,
19 a scientific study proving that the Armour product had
20 caused that condition?

21 **A.** Yes, but as a layperson the whole -- what goes on
22 a label and data sheet, et cetera, is purely between
23 the regulatory people and the Department of Health,
24 the DHSS.

25 **Q.** You're absolutely right, Mr Bishop, that what goes on

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1 **Q.** Then the paragraph continues -- sorry, the memo
2 continues:

3 "While the submission was being typed I received
4 a telephone call from a representative of the company
5 inquiring as to the outcome of their application."

6 Then there is a discussion about sounding out
7 the company's representative.

8 Would that have been, do you think, you or is it
9 more likely it would have been someone from the
10 Regulatory or Medical Department?

11 **A.** Definitely the Regulatory Department. Marketing would
12 have had absolutely nothing to do with product licence
13 applications.

14 **Q.** We can take that down, thank you, Soumik.

15 As we've seen from your statement, you said in
16 your statement that you we are aware the risk of
17 transmission of hepatitis was included on the
18 labelling of the concentrate.

19 (Audio interference)

20 **A.** Yes.

21 **Q.** As more was learnt about non-A, non-B hepatitis, and
22 its connection with liver disease, would you have
23 expected Armour to reflect that developing knowledge
24 in its labelling of products?

25 **A.** No, because it related to hepatitis. It didn't

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1 the labels is something that is considered by the
2 Department of Health, but there is a choice, is there
3 not, from the pharmaceutical company as to what it
4 includes in its labels. Would you accept that?

5 **A.** As far as I can understand, the company was dictated
6 to by as to what went on the label by the Department
7 of Health. That's as I understood it.

8 **Q.** Well, I won't ask you to go through the detail of the
9 content of the warnings year after year, not least
10 because they don't change. But am going to ask you to
11 look at one example and then just invite your comment
12 on it, if I may. Soumik, could we have ARMO0000145,
13 please.

14 So this is -- this happens to be May 1984, and
15 you'll see it's a letter from Armour's Regulatory
16 Affairs or Assistant Regulatory Affairs Manager to the
17 Department of Health's Medicines Division, and it's
18 an application for a product licence for High Potency
19 Factorate, because the licence that's been in
20 existence is about to expire; okay?

21 **A.** Yes.

22 **Q.** If we go to paragraph 11 -- sorry, page 11, Soumik, my
23 apologies, and we look at heading towards the bottom
24 of the text "Warnings and Adverse Effects". I'm
25 taking this as an example, Mr Bishop, I'm going to

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1 invite you to take it from me that the wording doesn't
 2 change very much in the period between 1976 and 1984.
 3 It says this:
 4 "Factor VIII is prepared from human plasma each
 5 donation of which has been found negative for
 6 hepatitis B surface antigen by the radioimmunoassay
 7 method. In addition, each batch after reconstitution
 8 as recommended, has been tested and found negative by
 9 the RIA method. However, since no completely reliable
 10 laboratory test is yet available to detect all
 11 potentially infectious plasma donations, the risk of
 12 transmitting viral hepatitis to patients is still
 13 present, and personnel administering and handling this
 14 material should also exercise appropriate caution.
 15 "Products of this type are known to cause mild
 16 chills, nausea or stinging at the infusion site. The
 17 possibility of allergic reactions occurring with the
 18 use of AHF concentrates cannot be discounted."
 19 Now, would you accept that there -- obviously,
 20 there is no reference to AIDS, no reference to non-A,
 21 non-B hepatitis specifically?
 22 **A.** No.
 23 **Q.** Acknowledging that weren't directly involved
 24 Mr Bishop, as you have explained to us, in the
 25 licensing application process and in deciding what

1 went on the labels, but looking at this now --
 2 **A.** I wasn't.
 3 **Q.** -- does it cause you any concern, the way in which the
 4 warnings and adverse effects are here described?
 5 **A.** No, no. Because I, you know, just being pure
 6 marketing and sales, I'd known no scientific -- well,
 7 I do have scientific knowledge, but I would bow to the
 8 superior knowledge of the medical and scientific
 9 people, whether it's the Department of Health or our
 10 own personnel.
 11 **Q.** With everything you learned subsequently, so looking
 12 back now, Mr Bishop, and knowing, obviously, perhaps
 13 rather more than you knew at the time, do you think
 14 Armour's own labels should have spelt out the risk of
 15 non-A, non-B hepatitis specifically, or made some
 16 reference to the possible risk of AIDS?
 17 **A.** No, not if that was the recommendation of the
 18 Department of Health and our own medical people.
 19 **SIR BRIAN LANGSTAFF:** May I just ask, before we move from
 20 this, can we just focus upon the very last paragraph
 21 on that page? The wording there is:
 22 "Products of this type are known to cause mild
 23 chills ..."
 24 That might appear, to the reader, to be
 25 something which is not specific to Armour but is

1 specific to the class of pharmaceutical, of which this
 2 is one. Is that the way it appears to you?
 3 **A.** Yes, sir, and I think that was the general scientific
 4 opinion of non-A, non-B hepatitis, that it was a mild,
 5 flu-like reaction, and what --
 6 **SIR BRIAN LANGSTAFF:** So can you help, then, with your
 7 earlier answer that it was really -- I think it to the
 8 effect that it was only if an Armour product itself
 9 was implicated in a particular reaction, that you
 10 would expect there to be a warning, rather than
 11 a product of the type of which Armour was one example?
 12 **A.** I don't know what the timeframe of that -- between
 13 this and that document was.
 14 **SIR BRIAN LANGSTAFF:** I see. Thank you.
 15 **MS RICHARDS:** We can take that down, thank you, Soumik.
 16 I just want to ask you a little more about your
 17 dealings with the Haemophilia Society next, Mr Bishop.
 18 Roughly how often in the second half of the
 19 '70s, first half of the 1980s would you have had
 20 interactions with the Society?
 21 **A.** Well, me, personally, I would have -- I can't recount
 22 the number of times, but perhaps once a month or once
 23 every couple of months, I would have met up with the
 24 general secretary, David Watters at that time, of The
 25 Haemophilia Society.

1 **Q.** What would, broadly speaking, have been the purpose of
 2 those meetings?
 3 **A.** Well, to discuss the current issues, and perhaps
 4 discuss the format of their -- or the arrangements for
 5 their Haemophilia Society meetings, and ways which we
 6 could support them in that.
 7 **Q.** Is it fair to conclude, given that your role was in
 8 sales and marketing, that at least one purpose of
 9 interaction with the Haemophilia Society would be
 10 to -- through the Haemophilia Society to try and
 11 promote sales of Factorate?
 12 **A.** Certainly not, no. Armour were considered a very
 13 valuable member of the team of treating and looking --
 14 well, treating the haemophilia patients, and our
 15 association with The Haemophilia Society was part of
 16 that ethos.
 17 **Q.** Do you recall whether you ever alerted the Society, in
 18 1985 or 1986, to the possibility that Armour's
 19 heat-treatment procedures might be ineffective?
 20 **A.** No, I don't recall any discussion like that at all.
 21 **Q.** Could we have a look at PRSE0003929, please, Soumik,
 22 next. So this is a document that shows financial
 23 contributions being made by pharmaceutical companies,
 24 including, but certainly not limited to, Armour, to
 25 The Haemophilia Society. It doesn't break it down by

1 individual company, although we can see some years,
 2 for example -- no, I think there are no years in which
 3 you're the only contributor.

4 So we can see relatively substantial sums overall
 5 being paid by pharmaceutical companies to The
 6 Haemophilia Society. Who within Armour would decide
 7 how much Armour was going to pay to The Haemophilia
 8 Society in a given year?

9 **A.** That would be during the budgeting process for the
 10 following year and would have been agreed, well,
 11 proposed, perhaps by me in the formulation of the
 12 budgets for the following year.

13 **Q.** Would the funding be for a particular purpose, would
 14 it be for sponsorship of The Society's meetings or
 15 sponsorship of The Society's publication, or was it
 16 a general contribution to The Society's coffers?

17 **A.** No, any of those, any or all of those categories.

18 **Q.** Was it Armour's expectation in making those
 19 contributions that somehow its products would be
 20 regarded as approved by The Haemophilia Society?

21 **A.** Well, I don't know what you mean by "approved" by
 22 them.

23 **Q.** Let me put it a different way, Mr Bishop: what was
 24 Armour's purpose in providing not insubstantial sums
 25 of money to The Haemophilia Society?

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1 **A.** Well, bearing in mind they are a charity and very,
 2 very strong supporters of their members and their
 3 groups, important for them to be kept up to date on
 4 all scientific developments in the interests of their
 5 members, and attendance at international and national
 6 meetings, you know, would be expensive for them as
 7 a charity, and we, along with other companies, felt it
 8 appropriate to support that charity.

9 **Q.** I'm going to ask you next about interactions with
 10 haemophilia centres -- sorry, Mr Bishop?

11 **A.** I was just going to say, looking at that document
 12 again, perhaps I shouldn't say it but I will,
 13 conspicuous by its absence is the BPL, the national
 14 supplier. Sorry, I'll move on.

15 **Q.** I'm going to ask you next about interactions with
 16 haemophilia centres and clinicians and how Armour went
 17 about generally promoting its product in the UK. If
 18 we can start by looking at PRSE0003437. You'll see
 19 this is a table which has, for 1980 and 1981, the
 20 quantities of commercial Factor VIII concentrates used
 21 in the UK by manufacturer. We can see from the second
 22 line that Armour's product, its Factorate product, is
 23 the product most widely in usage in 1980 and 1981, so
 24 it might be fair to say that Armour was dominating the
 25 market by that time. How had that been achieved,

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1 Mr Bishop?

2 **A.** Because of the whole concept and the ethos of the
 3 Armour operation, to be -- we were accepted and we
 4 were the gold standard, in many ways. We were
 5 accepted as an essential member of the team, looking
 6 after the interests of the UK haemophilia patients,
 7 supporting those responsible for their treatment, the
 8 Haemophilia Centre Directors, the nursing personnel,
 9 physiotherapist personnel and, of course, The
 10 Haemophilia Society.

11 And with the experts -- the whole -- it's all down
 12 to the whole ethos of the Armour operation, not only
 13 in the States, but the UK, that, you know, we had
 14 a very real responsibility, and this was accepted and
 15 appreciated by the patients, the Haemophilia Centre
 16 Directors alike. And, therefore, you know, we very
 17 deservedly became -- earned our place as the market
 18 leader, coupled with fact that, of course, we had
 19 a very good product.

20 **Q.** If we go to UHDB0000012, please. This is an example
 21 of a letter written by you to a haemophilia clinician.
 22 This is from November 1977, and it's to Dr Winfield.
 23 First of all, we can see -- just if we go back to the
 24 top of the page, we can see prominently displayed that
 25 sticker "Factorate 1540 donors". What was that meant

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1 to convey to the recipient of the letter?

2 **A.** That was the indication of the average number of
 3 donations making up a batch of Armour material, which
 4 we were particularly proud of, because that compared
 5 with, you know, 20, 25,000 donations applicable to
 6 other products.

7 **Q.** Does that reflect -- I'm sorry, Mr Bishop, carry on.

8 **A.** No, carry on.

9 **Q.** Does that reflect, then, an understanding of the
 10 larger the pool size, the greater the risk of viral
 11 transmission?

12 **A.** Yes.

13 **Q.** Now, if we look further down this letter, it refers
 14 to, in the first paragraph, the contract agreed with
 15 the Department of Health. Prices are then set out.
 16 Under the table it says:

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

22 Over the page, the first paragraph says:

23 "We are very conscious of the fact that all
 24 Centres are working to very tight budgets. We are
 25 also fully aware of the implications of the new

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1 contract prices in respect of maintaining or
 2 increasing current levels of treatment and home
 3 therapy programmes within the limits of these budgets.
 4 "An analysis of the new terms will reveal the
 5 true economic advantage of placing some, if not all,
 6 of your commercial concentrate business with Armour.
 7 "By purchasing FACTORATE against a given [pound]
 8 sterling budget, your Centre will be able to obtain
 9 between 50% and 97.5% more Factor VIII concentrate
 10 than other commercial products approved for sale on
 11 the DHSS contract. By purchasing Factorate there will
 12 be no need to reduce your programme involving the use
 13 of commercial concentrate in order to keep expenditure
 14 within the confines of your budget for 1978. Coupled
 15 with this considerable price differential are the
 16 added benefits of our presentation."
 17 "I'll come back to that point about the
 18 presentation in a moment.
 19 Then you talk in the next paragraph about
 20 Factorate being:
 21 "... firmly established as a leading commercial
 22 concentrate in many UK Centres. The proven quality of
 23 the product, the flexibility of the presentation and
 24 the economic advantages outlined above ..."
 25 This letter places a lot of weight upon what's

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1 said to be the financial advantage to Centres in
 2 purchasing Factorate as compared to another commercial
 3 concentrate, doesn't it?
 4 **A.** Yes, yes.
 5 **Q.** Can you --
 6 **A.** Obviously so.
 7 **Q.** Can you help us in understanding the suggestion that
 8 a Centre would be able to obtain between 50 and
 9 97.5 per cent more Factor VIII concentrate than other
 10 commercial products?
 11 **A.** Well, I can't at this moment work out the
 12 differentials between the other products and -- off
 13 the top of my head, but that would have been
 14 calculated out.
 15 **Q.** So essentially you're offering Armour's product, the
 16 Factorate product, more cheaply than other commercial
 17 concentrates?
 18 **A.** Effectively, yes.
 19 **Q.** Did that play a significant part in Armour's dominance
 20 of the market in the UK?
 21 **A.** Initially it would have been, because in the
 22 pre-marketing exercise and research it very quickly
 23 became obvious, by talking with international
 24 clinicians, that the UK haemophiliac patient was being
 25 grossly under treated in terms of the number of units

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1 with which they were being infused. For example,
 2 places like the Bonn clinic, Dr Brackmann, and
 3 Inga Marie Nilsson in Karolinska in Sweden were
 4 showing that applying or infusing far higher doses of
 5 Factor VIII would seriously improve the quality of the
 6 life and the joints of haemophiliac patients. And the
 7 current rate the UK was prescribing was far, far below
 8 any of these other centres.
 9 So, you know, what we were in fact doing was to
 10 hopefully enable clinicians to up the dosages to the
 11 recommended doses in other centres to improve the
 12 quality of treatment and the life of the UK
 13 haemophiliac patient and their families.
 14 **Q.** Just in relation to pool sizes, I think -- we looked
 15 at the sticker, 1,540 donors, and your statement,
 16 I think, sets out a broad recollection of around 1,500
 17 donors?
 18 **A.** Mm --
 19 **Q.** Can I ask you to look at from further document on
 20 this, which is at ARMO --
 21 **A.** Sorry, can I correct you there? It's not -- that
 22 should have read "donations". That applies to
 23 1,540 donations into a pool of plasma. That wasn't
 24 the number of actual donors, that was donations.
 25 **Q.** Okay, thank you.

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1 If we go to ARMO0000507. Now, this is the note
 2 of a meeting that took place with the Department of
 3 Health in March of 1986, and this is in the context of
 4 the seroconversions to HTLV-III following treatment
 5 with Factorate that was heat-treated. We'll come back
 6 to that. We can see it was -- this is a document that
 7 was copied to you.
 8 If we go over the page, under the heading
 9 "Manufacturing Process" there is reference to the
 10 presentation of data by Dr Rodell, and then it says
 11 this:
 12 "We were asked the size of our donor pool which
 13 was defined as between 5000 and 20,000 donors."
 14 And then it goes on to talk about what the virus
 15 challenge might then be. Can you assist us --
 16 **A.** That's the number of donors in the system.
 17 **Q.** Right.
 18 **A.** It's not the -- it's not -- it's the number of donors;
 19 that's not the number of donations making up a batch
 20 of material.
 21 **Q.** So the reference there to size of the donor pool, and
 22 I understand this is not your document, Mr Bishop, but
 23 you would read that as being the number of donors
 24 available to Armour in the United States generally,
 25 would you?

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- 1 **A.** Yes, that 5000-20,000 -- yeah, depending on any one of
2 the plasmapheresis centres.
- 3 **Q.** Okay.
- 4 **A.** Plasma Alliance centres.
- 5 **Q.** In terms of the number of donations in a pool, did
6 that change significantly, as far as you can recall,
7 from 1976 onwards through to the mid-80s?
- 8 **A.** No, no. It was always known to be that number.
- 9 **Q.** Then if I might just ask you to look at one further
10 document before we break, it's BPLL0002161.
- 11 This is another letter from you, this is now
12 July 1978, to consultant haematologists, so again it's
13 a sales letter, I don't mean that in a pejorative
14 sense. If we look at the third paragraph, you say
15 this:
- 16 "The proven quality of the product, the
17 flexibility of the presentation, and the economical
18 price structure outlined below present a good case for
19 the inclusion of FACTORATE in your routine or
20 emergency treatment programmes ..."
- 21 I'm not going to ask you again about the price,
22 but what did you mean by the flexibility of the
23 presentation?
- 24 **A.** Well, that was the range of potencies between 250 and
25 500, and up to 1,000 units per vial, which the

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- 1 clinician could select from, according to the
2 condition which he was treating now, whether it was on
3 a prophylactic basis or, you know, a spontaneous
4 bleed, so he had a flexibility of a choice of, without
5 under-treating or over-treating, plus the fact that we
6 supplied a sophisticated home treatment kit free of
7 charge, which contained the water for injection,
8 needles, et cetera, et cetera. So that is what was
9 meant by the presentation.
- 10 **Q.** Were there specific home treatment kits tailored
11 towards children?
- 12 **A.** No, they would be the same kits, because the water for
13 reconstitution would be the same, you know, whether it
14 was going into a child or an adult.
- 15 **Q.** We've heard some evidence, for example, and I'm afraid
16 I can't off the top of my head recall whether it
17 related to Armour's product or another product, but
18 we've heard some evidence of the home-treatment kit
19 coming with Mr Men plasters or Mr Men stickers. Was
20 that something which Armour did?
- 21 **A.** Yes, yes.
- 22 **MS RICHARDS:** Sir, I note the time. Would this be a good
23 moment for a break?
- 24 **SIR BRIAN LANGSTAFF:** Yes, it is. So we'll take a break
25 now until 12 o'clock. This is the first of the breaks

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- 1 there will be during this afternoon -- during today;
2 there will be more this afternoon. At any break you
3 must not discuss the evidence which you have been
4 giving or the evidence which you think you may yet be
5 asked to give with anyone, whoever that person may be.
6 You can talk about anything else, but not about that.
7 So I will see you at 12.
- 8 **A.** Okay, thank you very much, Sir Brian.
- 9 **(11.32 am)**
- 10 **(A short break)**
- 11 **(12.00 pm)**
- 12 **SIR BRIAN LANGSTAFF:** Yes.
- 13 **MS RICHARDS:** Mr Bishop, in the second half of the '70s,
14 first half of the 1980s, approximately how big was the
15 Armour UK sales team?
- 16 **A.** About five.
- 17 **Q.** And we --
- 18 **A.** There were two in the UK, one in Sweden, one in
19 Benelux -- oh, four, another one in Ireland, sorry.
- 20 **Q.** We looked before the break at some of the formal
21 materials, the product labels and so on, that Armour
22 produced. From a sales and marketing perspective,
23 other than the correspondence to clinicians that we
24 looked at before the break, what kind of sales and
25 marketing materials did Armour use as far as you can

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- 1 recall?
- 2 **A.** The only materials they had were the technical
3 bulletins, up-to-date information on their own and
4 other products, and on the whole subject of
5 haemophilia nationally and internationally. That's
6 the only things they had. They didn't carry samples
7 or anything like that.
- 8 **Q.** Who were most of your and your team's dealings with in
9 the UK? Was it predominantly with Haemophilia Centre
10 Directors?
- 11 **A.** Yes.
- 12 **Q.** Did you also promote and sell Armour products to
13 individual hard copies that weren't haemophilia
14 centres?
- 15 **A.** No. As far as I can recall, no.
- 16 **Q.** What about regional health -- sorry, Mr Bishop, carry
17 on.
- 18 **A.** No, there was -- I mean, the UK are so well covered by
19 haemophilia centres that whether they were reference
20 centre directors or minor centres, you know, most
21 towns, I think, had a haemophilia centre.
- 22 **Q.** Do you recall whether you had dealings directly with
23 Regional Health Authorities at all?
- 24 **A.** No. No, I don't recall.
- 25 **Q.** And then, very roughly, how often would you expect

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1 either or one of your team to be visiting a particular
2 haemophilia centre?
3 **A.** Well, it depended on their areas. At least once
4 a month. It could be more frequent, depending on the
5 circumstances.
6 **Q.** And did you undertake your own visits to haemophilia
7 centres?
8 **A.** Yes.
9 **Q.** Can you then just describe to us how typically a visit
10 to a haemophilia centre might proceed?
11 **A.** Well, there would be an appointment made, obviously,
12 with the centre, the staff or whoever, and they would
13 meet with the haemophilia centre director to discuss
14 whatever were the issues at the time, would also make
15 contact with the nursing personnel, because, you know,
16 they were the people, invariably, who actually would
17 administer the infusions to out-patients, and perhaps
18 also physiotherapists involved in that team, depending
19 how big the centre was, you know, that they were
20 visiting. It would just be, you know, a general
21 discussion, or a specific discussion, whatever was
22 appropriate at the time.
23 **Q.** Again, this is a very general question, Mr Bishop, but
24 what kind of issues were the clinicians typically most
25 interested in? Was it cost or reliability of supply

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1 **A.** Could I just point out that all of the discussions
2 that took place between our specialists and the
3 centres were reported back on a weekly basis to
4 head office, so that we were fully appraised of what
5 was -- what the discussions were taking place, what
6 concerns were being portrayed, et cetera. So it
7 wasn't just, you know, a constricted discussion
8 between the director and the rep or the specialist.
9 That information was all shared with the people back
10 at head office, and then, depending on the subject, it
11 would have been also shared with the medical
12 department as well.
13 Sorry, I just wanted to make that point clear.
14 **Q.** Thank you.
15 Now the purpose of showing you the document
16 we're going to look at now is just so that I can ask
17 you a little about the efforts made by Armour to
18 achieve sales of its product in Scotland, a country
19 which had its own fractionation facility in Edinburgh.
20 If we go to PRSE00028 -- oh, sorry, we've got
21 it. Page 16, Soumik, of the document. My apologies.
22 Now, these are some figures for the use of
23 products at the haemophilia centre in Edinburgh.
24 I'm not going to ask you to look at the detail
25 of it, Mr Bishop, but it shows, in 1980 and 1981 in

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1 or -- what particular themes would come up time and
2 again?
3 **A.** Well, clinical teams, so questions about the
4 presentation, the delivery or potencies available.
5 The whole -- it could cover the whole subject of
6 haemophilia ongoing nationally and internationally.
7 Because, you know, the haemophilia population, not
8 only in the UK but worldwide, is a very, very small
9 group of people, so they're very sort of intimately
10 involved with each other internationally and
11 nationally.
12 **Q.** And what about safety, risks of viral transmission?
13 To what extent would they -- a discussion of those
14 issues feature in the regular meetings with
15 haemophilia centre directors?
16 **A.** Well, again, it would depend on what was the state of
17 art and thinkings at the time. You know, it's -- you
18 know, it could have followed on from the technical
19 bulletin they'd received from our -- from the medical
20 department, discussion on clarification on issues. It
21 followed -- it could follow the whole -- cover the
22 whole gamut of haemophilia care.
23 **Q.** Can I ask you to look at PRSE0002887.
24 **A.** Could -- sorry.
25 **Q.** Carry on, Mr Bishop, before we look at the document.

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1 particular, substantial amounts of Armour's product
2 being used in Edinburgh, and then it tails off again
3 and the main product being used is Scotland's own
4 domestically produced product.
5 Did you have any direct dealings yourself with
6 the haemophilia centres in Scotland that you can
7 recall?
8 **A.** Oh, yes, yes, we did. They were part of the UK.
9 Hopefully they still are.
10 **Q.** Can you remember anything about what led to Factorate
11 being used in Edinburgh in particular in 1980 and '81?
12 **A.** No, no, they were, you know, just another -- just
13 another centre.
14 **Q.** If we go to page 25 of this document, we have
15 a similar table for the Glasgow Royal Hospital for
16 Sick Children at Yorkhill, and again I'm not going to
17 go through the detail of figures, we've looked at it
18 on other occasions with other witnesses, Mr Bishop.
19 But Factorate was used to a very substantial degree at
20 this Children's Hospital in 1979, 1980, 1981 and 1982.
21 Do you recall any particular discussions or visits to
22 Yorkhill Hospital which led to Armour being a favoured
23 product there?
24 **A.** No, I don't recall any specific meetings, no.
25 **Q.** We can take that down, thank you.

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1 Was there any specific or different approach
2 taken by Armour to promoting its product for children,
3 as opposed to adults?
4 **A.** No, none whatsoever, apart from the provision of
5 smaller potency vials.
6 **Q.** I want to ask you about a handful of interactions with
7 specific haemophilia clinicians.
8 **SIR BRIAN LANGSTAFF:** May I just ask, did adults get the
9 Mr Men stickers too?
10 **A.** They would have been included as a general thing.
11 **SIR BRIAN LANGSTAFF:** So they would?
12 **A.** They might have liked the Mr Men badges as well.
13 **SIR BRIAN LANGSTAFF:** Thank you.
14 **MS RICHARDS:** Could we, please, have RFLT0000014.
15 This is a letter from Dr Kernoff at the Royal
16 Free Hospital to you:
17 "Dear Chris
18 "Re: Armour 'hepatitis low risk' factor VIII."
19 It's not entirely clear what year it is. It's
20 19 September 1980-something.
21 It refers to a discussion with you and then you
22 are asked by Dr Kernoff about Armour's hepatitis
23 low-risk product. Then Dr Kernoff sets out a range of
24 pieces of information he wants:
25 "1. A full specification ...

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1 "2. Donor pool source and size information.
2 "3. An outline of the production process.
3 "4. Results of animal experiments designed to
4 investigate safety and efficacy.
5 "5. Any information you have about in-vivo
6 studies in patients."
7 Can you recall the kind of interactions that you
8 had with Dr Kernoff on this issue and whether you
9 would have provided the information that he was
10 seeking?
11 **A.** Can you scroll back down to the title of the letter,
12 or the heading of the letter? "Hepatitis low risk";
13 I don't -- I don't know what he meant by that,
14 actually, whether it was the heat-treat -- whether he
15 was referring to heat-treated product or not, I don't
16 know.
17 **Q.** Okay.
18 **A.** But he would have been supplied with appropriate
19 information and I would have passed that on to our
20 medical department, probably, to respond to.
21 **Q.** Okay. So if a clinician positively asked for
22 information of that kind, you'd endeavour to supply it
23 through your Medical Regulatory Affairs Department?
24 **A.** Of course, yes; of course.
25 **Q.** If --

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1 **A.** As I said, it was literally part of the occupation.
2 **Q.** If we then go to an interaction with a different
3 clinician, this is HHFT0001201_003.
4 This is a letter dated December 23, 1980, to
5 Dr Peter Jones. If we go to the second page, we'll
6 see it from Dr Lott, head of medical services, and
7 then if we go back to the first page, we can see it
8 refers to a protocol, it says:
9 "I apologize for the delay but I was waiting for
10 the additional information from your technical staff,
11 although I understand from Chris Bishop that you're
12 waiting for me to write."
13 And then details are set out of what appears to
14 be some form of study that's going to be initiated
15 involving Newcastle and Alton, so that's Treloar's?
16 **A.** Yes, Lord Mayor Treloar.
17 **Q.** Do you recall anything about this particular study?
18 **A.** No, I don't, no.
19 **Q.** Would you have had or do you think your colleagues
20 would have had any particular concerns about a study
21 involving children?
22 **A.** No, no. If that was the, you know, decision of the
23 medical and technical people and the clinicians
24 involved, then, you know, who was I to question it?
25 **Q.** If we then look at OXUH0001624_003.

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1 This next letter is from Dr Rizza, at Oxford. So
2 we can see, August 1981, Dr Rizza is writing to you.
3 He refers to a letter he's received from you. Then he
4 says:
5 "As you know I discussed with Sue Job the
6 possibility of Armour supplying financial support to
7 enable us to continue employing a Health Visitor in
8 our Hepatitis Studies. We are looking for an
9 immediate source of money to enable us to bridge the
10 gap between now and the time when the MRC will make
11 its decision."
12 Then if we just look at your response before
13 I ask you about this.
14 Soumik, it's OXUH0001624_004. This is a letter
15 from you. If we pick it up in the third paragraph:
16 "... grateful for your comments regarding future
17 sponsorships and with regard to the health visitor
18 which you discussed with Sue, I suggest we wait until
19 the outcome of your application to the MRC and the
20 Haemophilia Society is known ... Since this would
21 create a precedent I would prefer to leave it until
22 this time before making any application to the Grants
23 and Donations Committee ..."
24 **SIR BRIAN LANGSTAFF:** Can we just go back to the previous
25 letter, at 003, and look at the date?

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1 **MS RICHARDS:** Oh, I'm sorry, I got them the wrong way
2 around in terms of time, yes, sir.

3 So Mr Bishop's letter to Dr Rizza is the first
4 letter, and then Dr Rizza's letter to Mr Bishop is
5 sent later.

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

7 **MS RICHARDS:** Thank you.

8 If we look at your letter in response, thank
9 you, what was the "Grants and Donations Committee"
10 that you're referring to here?

11 **A.** That was just a local UK -- we didn't have an actual
12 committee, I think it was just a name given to -- you
13 know, that we employed at the time to cover this
14 unusual request.

15 **Q.** And how common was it for Armour to be asked by
16 haemophilia centres for financial support?

17 **A.** Very, very, very infrequently.

18 **Q.** And can you --

19 **A.** And apart -- the exception to that would be possible
20 sponsorship or help towards attendance at the
21 World Federation of Hemophilia meetings, which every
22 company supported. But requests of this were very,
23 very -- were extremely rare.

24 **Q.** Do you know what the ultimate outcome of this request
25 was?

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1 **A.** No, I'm afraid I don't, no.

2 **Q.** If we then move on from 1981 to 1985, ARMO0000370.
3 This letter is not from you, it's from Mr Christie to
4 Dr Frank Hill in Birmingham Children's Hospital,
5 27 March 1985.

6 First paragraph says this:

7 "You will note from the enclosed copy letter
8 that I paid our first 1985 donation to your research
9 fund to the Finance Department of the Central
10 Birmingham Health Authority."

11 Then Mr Christie expresses interest in the
12 "progress of [the] project, its extension into
13 HTLV-III screening of children", and then there is
14 a reference to a "Hepatitis B problem" in the third
15 paragraph.

16 It would appear from this that there were
17 regular donations or one inference might be there are
18 regular donations made by Armour to a research fund at
19 the Children's Hospital. What do you know about that?

20 **A.** I can't recall the details but that would appear to
21 be, you know, a part-payment of a one-off research
22 programme, which had been, you know, previously agreed
23 with our medical technical people.

24 **Q.** Now, we --

25 **A.** It had nothing to do with marketing.

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1 **Q.** We know from other material that the Children's
2 Hospital, or the Haemophilia Centre at the Children's
3 Hospital in Birmingham, under the directorship of
4 Dr Frank Hill, used the Armour product to a very
5 substantial degree. Can you recall anything about the
6 relationship between Armour and Dr Hill?

7 **A.** Well, it was very professional, very close, friendly
8 relationship.

9 **Q.** Was there ever any sense that he'd buy your product or
10 the Children's Hospital would buy your product and you
11 would look favourably upon requests for support for
12 research?

13 **A.** No, certainly not, no. No. All centre's directors
14 were treated, you know, equally.

15 **Q.** Were there any particular centre directors that you
16 had more dealings with than others in the second half
17 of the '70s and the first half of the '80s?

18 **A.** Not really because, as I said, they were, you know,
19 there were larger centres and smaller centres and, you
20 know, there were leading opinion formers in the larger
21 centres, so, therefore, it would have been more
22 contact and correspondence backwards and forwards with
23 those larger centres. Because the smaller centres
24 would invariably refer to the local reference centre
25 before they came to us.

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1 **Q.** I'm going to ask you next, Mr Bishop, about your
2 knowledge of AIDS and its connection with blood and
3 blood products. Can we start just by looking at your
4 statement again, WITN5529001. If we pick it up at the
5 bottom of page 10, paragraph 21.

6 This is in response to a question about what
7 enquiries for investigations Armour carried out in
8 respect of risks of transmission of HTLV-III prior to
9 '85. You say:

10 "All enquiries and/or investigations were
11 carried out under the auspices of the Medical and
12 Regulatory bodies. As a Sales/Marketing employee, I
13 was informed as appropriate, and any involvement I had
14 would have been limited to acting as a point of
15 liaison between clinicians and the Medical and
16 Regulatory Affairs Departments."

17 What do you mean by "acting as a point of
18 liaison between clinicians" and those departments?

19 **A.** Well, on our normal visits and relationships, sorry,
20 normal visits with directors, there may have been some
21 feedback of a medical technical nature, which we would
22 then pass on to the Medical and Regulatory Affairs
23 Department. Very often the clinicians would write --
24 or discuss it with the specialist or write directly to
25 me because of our very good relationship, friendly

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1 relationship we had. So we would have been the first
 2 points of contact.
 3 **Q.** Now, if we take that down, thank you.
 4 The issue of AIDS must have come up in
 5 discussions with haemophilia centre directors in 1983
 6 and 1984. What, if anything, can you recall about
 7 discussions with centre directors about AIDS at that
 8 time?
 9 **A.** Well, the discussions, so, you know, between our
 10 specialists and myself would be based purely on the
 11 state of art knowledge at the time. I can't remember,
 12 you know, specific discussions or details of specific
 13 discussions, but it would have all been related to the
 14 state of art knowledge.
 15 **Q.** Would there have been, as it were, a line to take by
 16 your sales team -- if they were asked about AIDS in
 17 1983 or 1984 by a haemophilia centre director, would
 18 there have been some guidance to your team as to how
 19 they should answer such queries?
 20 **A.** No, only as a result of any position statement or
 21 document that I sent out or the medical department
 22 sent out.
 23 **Q.** Let's look at some of the documents relating to AIDS
 24 in 1983. So if we start with ARMO0000234. This is
 25 a memo from you, Mr Bishop, dated 11 January 1983, to

1 Hans Kjellman. Who was that?
 2 **A.** He was in Germany, at Armour Eschwege in Germany.
 3 **Q.** Then the subject of AIDS, and if we look at the text
 4 of your memo:
 5 "I enclose for your information, articles
 6 relating to the above, and I would confirm to you that
 7 this is now of particular concern to clinicians in the
 8 UK, particularly if it is felt that regular infusions
 9 of Factor VIII Concentrate are the prime cause of this
 10 associated immune deficiency syndrome.
 11 "Have you got any comments to make, and is it of
 12 equal concern elsewhere."
 13 So it's pretty clear from this, Mr Bishop, that
 14 clinicians in the UK had been raising concerns, either
 15 with you or with members of your team about AIDS. Is
 16 that fair?
 17 **A.** Yes, yes. It seems --
 18 **Q.** Do you have any recollection now of which clinicians,
 19 at this point in time, beginning of '83, were raising
 20 these concerns?
 21 **A.** No, no. Not -- I know there is some reference in many
 22 documents that have been sent through, but I don't
 23 recall any particular, none at this time.
 24 **Q.** Again, in broad terms, what was your purpose in
 25 sharing this information that's come to your

1 attention, if you go over the page, we don't need to
 2 look at the detail of it, but you're enclosing
 3 material from the New England Journal of Medicine. If
 4 we go back then to the first page in the memo. Why
 5 were you raising this directly with a colleague in
 6 Germany, rather than simply passing it on to your
 7 medical affairs department in Eastbourne?
 8 **A.** I don't know. That was -- I was just trying to get
 9 feedback from a marketing point of view from the
 10 German perspective, so that I could feed that back,
 11 you know, to our own medical people. Our own medical
 12 department could well have done that themselves but,
 13 you know, obviously I took it upon myself to do that.
 14 **Q.** Still in January '83, if we go to ARMO0000250_002,
 15 please.
 16 Now, this is a publication from the States,
 17 there is a letter -- sorry, there is a date under the
 18 stamp, which is 17 January 1983, it's reporting on the
 19 advice of the National Hemophilia Foundation's Medical
 20 and Scientific Advisory Council in the States. But if
 21 we look at the handwriting at the very top of the
 22 page, there are some names scribbled on there, one of
 23 which is yours, C Bishop?
 24 **A.** Yes, so that's Clare De Schott and Fritz Frichter who
 25 are both -- (*unclear*) whatever, but they were both

1 from Germany, Armour Eschwege, Germany.
 2 **Q.** So would it be right to understand that someone within
 3 Armour has identified that this is a document that
 4 should be brought to your attention and the attention
 5 of the others listed there, and there may indeed be
 6 other names that we can't read?
 7 **A.** Yes, because it was sent to HLS, Dr Shaw, the medical
 8 director in Eastbourne, and also passed on to Robert
 9 Christie, (*unclear*) -- yes. So he would have passed
 10 it on.
 11 **Q.** So if we go to the third page, we can see the
 12 recommendations themselves that had been produced in
 13 the States on 14 January '83, "Recommendations to
 14 Prevent AIDS in Patients with Hemophilia". Then
 15 paragraph 1 is "Recommendations for physicians
 16 treating patients with hemophilia", and that's
 17 encouraging, in particular, the use of cryoprecipitate
 18 or DDAVP. Then, if we go further down the page,
 19 paragraph 2 is "Recommendations to factor VIII
 20 concentrate manufacturers":
 21 "Serious efforts should be made to exclude
 22 donors that might transmit AIDS. These should include
 23 ..."
 24 Then there is a number of steps: questioning
 25 directly individuals belonging to high-risk groups,

1 surrogate laboratory tests, ceasing using plasma
 2 obtained from donor centres that draw from population
 3 groups in which there is a significant AIDS incidence.
 4 Then paragraph B is "expedite the development of
 5 processing methods that will inactivate viruses". Do
 6 you have any recollection of whether within Armour
 7 there was discussion of these specific
 8 recommendations?
 9 **A.** Well, there obviously would have been but, as far as
 10 I can tell, looking down those, Armour would have
 11 complied with all of that.
 12 **Q.** But you don't recall your own involvement in any
 13 particular discussions arising from this?
 14 **A.** Oh no, no.
 15 **Q.** If we just then look back --
 16 **A.** It was quite clear that Armour -- well, it's not from
 17 the document, but I know that Armour complied with all
 18 those MASAC recommendations.
 19 **Q.** If we just go back towards the top half of the page,
 20 the recommendations for physicians, which were -- and
 21 I summarise -- but steering physicians towards using
 22 treatment other than concentrates, as much as
 23 possible, that would have had commercial implications
 24 for companies such as Armour, would it not, if
 25 physicians switched to non-concentrate treatment? Do

1 you recall that being discussed?
 2 **A.** Not specifically, no, and the amount -- the impact of
 3 that particular recommendation would have been fairly
 4 minimal, because the major treatment was, of course,
 5 the more severe patients, and those with inhibitors,
 6 for example.
 7 **Q.** Can you recall whether this particular set of
 8 recommendations from the States ever came up in
 9 discussions between you and your team, on the one
 10 hand, and haemophilia centre directors in the UK, on
 11 the other hand?
 12 **A.** No, no.
 13 **Q.** So you don't recall or you don't think they were
 14 discussed?
 15 **A.** I don't think they were discussed.
 16 **Q.** Can we then, still sticking with '83, and I'm trying
 17 to go through some documents chronologically,
 18 Mr Bishop, in the interests of simplicity. If we go
 19 to ARMO0000236, please.
 20 This is letter of 15 March 1983 from Dr Kernoff
 21 at the Royal Free to you, the heading is "Proposal for
 22 research support into AIDS at the Royal Free
 23 Hospital":
 24 "Further to our previous discussions, I now
 25 enclose a brief formal proposal requesting support for

1 our AIDS-related project in haemophiliacs."
 2 Then he sets out what is being sought, which is
 3 effectively the salary for a year of a senior
 4 technician. If we go over the page, we have the brief
 5 research proposal there set out, and the background is
 6 in paragraph 3. If we just look at the second
 7 paragraph under that heading:
 8 "The causes of these abnormalities [and that's
 9 a reference to immunological function abnormalities]
 10 are unknown, but may include transmission of
 11 a previously recognised virus or other agent."
 12 Then it goes on to say:
 13 "... the possibility of the infusion of
 14 essential therapeutic products may be complicated by
 15 very serious hazards is causing extreme concern
 16 amongst patients and those responsible for their care.
 17 It has been suggested that profound changes may have
 18 to be made in management practices, particularly as
 19 regards the use of imported commercial concentrates.
 20 "We regard the acquisition of further
 21 information about the immunological defects in
 22 haemophiliacs, and their relationship with clinical
 23 disease and blood product exposure, to be a matter of
 24 the highest priority."
 25 So that's a brief summary of the background to

1 Dr Kernoff's request. If we just go back to the first
 2 page in the letter, it would appear you'd had
 3 discussions with Dr Kernoff about this project. Can
 4 you recall anything about that?
 5 **A.** Not specifically, no.
 6 **Q.** Why would this request for support for research be
 7 coming to you, rather than your medical department?
 8 **A.** From there, it's obvious we had further -- we had
 9 previous discussions, about doing such research.
 10 **Q.** Within Armour, whose decision would it have been to
 11 agree to funding of this research?
 12 **A.** Sorry, what?
 13 **Q.** Within Armour --
 14 **A.** Sorry, can you repeat that?
 15 **Q.** Yes, of course. Within Armour, whose decision would
 16 it have been to agree the funding for this research?
 17 **A.** That would be a decision between the UK medical
 18 department and the approval of the US medical people,
 19 the research people.
 20 **Q.** If we just look at one follow-up letter from you on
 21 this issue, ARMO0000238.
 22 This is you to Dr Kernoff, 7 April. It would
 23 appear from the first paragraph that there has been
 24 potentially some revision to the protocol by
 25 Dr Townsend, and it refers to a discussion "by the

1 Revlon Plasma Executive Committee on the 30th March".
 2 Was the Revlon plasma executive committee US or
 3 UK-based?
 4 **A.** UK -- sorry, US. It was the -- called PEC, the plasma
 5 executive committee.
 6 **Q.** Then there is an invitation to Dr Kernoff and
 7 Professor Janossy to come to Eastbourne and
 8 essentially do a presentation on the proposal?
 9 **A.** Yes.
 10 **Q.** Would you have been involved in listening to or
 11 assessing that presentation?
 12 **A.** I would have sat -- probably sat in the corner in the
 13 back row or something, but I would have no -- no input
 14 into it at all.
 15 **Q.** Would it be fair to say that you would at least have
 16 understood from your discussions with Dr Kernoff and
 17 what he'd set out to you in his letter that the
 18 possible connection between factor concentrates and
 19 AIDS was a matter of some significant concern to
 20 clinicians by this stage?
 21 **A.** Yes, yes.
 22 **Q.** If we then look, around the same time, at your
 23 interactions with Dr Preston in Sheffield,
 24 ARMO0000239.
 25 This is a letter from you to Dr Preston,

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1 21 April 1983:
 2 "Dear Eric,
 3 "re: Proposal for research support into AIDS at
 4 the Royal Hallamshire Hospital."
 5 Then there is a similar invitation to
 6 Dr Preston, together with his colleague, Dr Triger, to
 7 undertake a presentation.
 8 **A.** Yes.
 9 **Q.** Again, is it right to understand you would have sat in
 10 probably and listened to the presentation, so you'd
 11 know what was being discussed and why, but you
 12 wouldn't have been deciding on whether to fund the
 13 work?
 14 **A.** Correct.
 15 **Q.** Then if we just go to one further document about this
 16 particular study, ARMO0000251.
 17 So this not a letter from you, it's to Dr Preston,
 18 but it's been sent on behalf of Dr Townsend, and it's
 19 a draft protocol.
 20 If we go over the page, we can see the heading
 21 "Draft protocol for investigation of immunological
 22 status of haemophilic patients with associated liver
 23 disease".
 24 I'm not going to ask you to look at the detail of
 25 it now, Mr Bishop, but if we go to the final page,

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1 you'll see there a heading, "Ethical approval":
 2 "Ethical approval will be obtained from the
 3 Ethical Committee of the Royal Hallamshire Hospital,
 4 Sheffield."
 5 Then a heading, "Written informed consent:
 6 "Written informed consent will be obtained from
 7 adult patients or from the parents or guardians of any
 8 children who agree to participate in this
 9 investigation."
 10 **A.** Yes.
 11 **Q.** Do you know whether Armour would have taken steps to
 12 satisfy itself that both ethical approval and
 13 written -- true written informed consent was being
 14 sought and obtained, or would it have just trusted to
 15 the doctors involved to do that?
 16 **A.** It would be up to the doctors to do that.
 17 **Q.** So, looking then at the materials that we've just
 18 considered from January through to April, Mr Bishop,
 19 would it be fair to say that by April 1983 you, as
 20 manager of Armour's biologicals division, would
 21 plainly have been aware of the threat of AIDS, and of
 22 advice in the States at least to clinicians to use
 23 concentrates less, and you would have been aware that
 24 clinicians in the UK were starting to undertake
 25 research studies into AIDS?

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1 **A.** I would have understood that, yes.
 2 **Q.** Well, did any of those matters lead to any change of
 3 approach by Armour to the selling and marketing of its
 4 product, or was it very much business as usual still?
 5 **A.** Yes, business as usual, unless there were significant
 6 directives to amend that from the medical department,
 7 or the US.
 8 **Q.** Let's look then, next, at a telex that you sent at the
 9 end of April '83.
 10 It's ARMO0000242, please, Soumik.
 11 So we can see it's from you, your name appears
 12 at the bottom of the page. The date is 27 April 1983.
 13 It's for the attention of Anita Bessler in the States,
 14 whose role we've already discussed, and then it's
 15 copied to a number of people.
 16 Can you just help us with understanding who
 17 Mr I Regier in Paris was?
 18 **A.** He was at -- he would have been at the Paris branch.
 19 I forget what they were -- yes, they had a branch in
 20 Paris, which he would have been heading up.
 21 **Q.** Can you recall, was he marketing as well, or was he in
 22 a medical or regulatory capacity there?
 23 **A.** No, he was a vice-president.
 24 **Q.** Okay.
 25 **A.** But essentially sales and marketing I think he was --

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1 yes.
 2 **Q.** Then we can see the subject of the telex,
 3 "AIDS -- Armour policy":
 4 "Further to our telecon 26th April I would
 5 confirm that the circulars sent by Travenol and Cutter
 6 to the UK haemophilia centre directors are on their
 7 way to you, and that sent by Alpha will be following
 8 shortly, 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 "I understand that Ingo Regier will be
 16 discussing this with you in detail. I should like to
 17 receive your recommended circular, painting as
 18 positive a picture as possible and emphasising
 19 our small batch/donor pool sizes."
 20 **A.** Mm.
 21 **Q.** What was it that you were after here, Mr Bishop, and
 22 why were you concerned?
 23 **A.** Well, without sight of those circulars by Travenol and
 24 Cutter and Alpha, you know, I -- you know, I don't
 25 know, except that there was something in there, either

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1 criticising the Armour procedure ... that's all I can
 2 assume from this document.
 3 **Q.** The reference in the second paragraph to a more
 4 simplified statement would suggest that you were
 5 envisaging not just something to go to UK haemophilia
 6 centre directors, but something which they could
 7 themselves pass on directly to patients. Is that the
 8 right way to understand that?
 9 **A.** Yes.
 10 **Q.** And --
 11 **A.** Yes, yes.
 12 **Q.** Then the third paragraph --
 13 **A.** We wouldn't advise -- we wouldn't go directly to the
 14 patients themselves.
 15 **Q.** No, you were producing something that the clinicians
 16 could give to the patients, is that right, or that's
 17 what you were suggesting?
 18 **A.** The information which we'd pass on, yes.
 19 **Q.** Then what did you have in mind when you talked about
 20 "painting as positive a picture as possible"?
 21 **A.** Well, emphasising the benefits of our own procedures
 22 and product and, if appropriate, nullifying any
 23 criticism that appeared in the Travenol, Cutter and
 24 Alpha directives.
 25 **Q.** Was the aim of getting some kind of statement or

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1 statements along these lines, to try and ensure that
 2 clinicians would still treat patients with Armour
 3 product and patients would continue to accept
 4 treatment with Armour product?
 5 **A.** Yes, of course. That was my responsibility as
 6 a marketing person.
 7 **Q.** If we then turn --
 8 **A.** Sorry. Obviously depending, of course, on the safety,
 9 safety being paramount. Not just thinking of the
 10 sales aspect of it.
 11 **Q.** Well, we'll come to look in a moment at what I think
 12 is probably the statement that was produced following
 13 your suggestion, or one of the statements produced.
 14 But before we do that, the next document
 15 chronologically, May 3, 1983, is ARMO0000244.
 16 This is a joint memo from you and Mr Christie to
 17 Mr Fitch, subject "Factorate and AIDS". Then you say
 18 in the first paragraph:
 19 "The potential problem of AIDS ... and products
 20 of human blood origin has been identified since the
 21 early part of this year.
 22 "Increasing numbers of clinical papers, reviews
 23 and the letters in the world medical press has
 24 highlighted this condition which has a high mortality,
 25 a puzzling set of symptoms and is of unknown

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1 aetiology.
 2 "The disease was originally thought to be
 3 restricted to homosexuals, but it is now known that
 4 while those affected are usually (75% of cases so far)
 5 homosexuals, the remaining 25% are recipients of blood
 6 products for donations, drug abusers, infants of
 7 infected AIDS victims, or Haitians."
 8 Then there is reference to cases being reported
 9 in various parts of the world.
 10 There is then a description about publicity and
 11 the press over the weekend. I'm not going to go
 12 through the detail of that, Mr Bishop, but you refer
 13 to a publication in The Observer and The Mail on
 14 Sunday -- or you and Mr Christie jointly refer to
 15 that.
 16 If we go over the page. The second
 17 paragraph says this:
 18 "Since the 11th January we have been in constant
 19 touch with Messrs Regier and Kjellman and direct to
 20 the US to attempt to obtain a specific policy
 21 statement suitable for transmission to Haemophilia
 22 Centre Directors."
 23 Then there is a reference to the European task
 24 force having agreed on action to be taken.
 25 Can you assist us any more with what the

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1 European task force was, and Armour's involvement with
 2 it?
 3 **A.** I don't recall a specific body, a European task force.
 4 Again, I think it was probably a collection of medical
 5 and marketing people between the UK and Germany.
 6 **Q.** If we go to the bottom of the page it says:
 7 "In spite of repeated follow up, we have not yet
 8 received the data and reassurance that we need to
 9 prepare a policy document, press release or updated
 10 authoritative advice to our sales force.
 11 "In view of the recent adverse publicity against
 12 US imports of blood products, it is vital that we
 13 promptly issue our policy document, particularly as
 14 all but one of our competitors has already done and so
 15 we are under increasing pressure from our customers to
 16 do so as market leader in the UK."
 17 Would it be fair to understand, Mr Bishop, that
 18 what you wanted was something that could be provided
 19 to haemophilia centre directors to provide a degree of
 20 reassurance that Armour's product was safe, or as safe
 21 as its competitor products?
 22 **A.** Yes. Yes. That was exactly what it meant, yes.
 23 **Q.** Then if we go to BART0000863. This is a document
 24 dated 19 May 1983. It's to all haemophilia centre
 25 directors. If we go to page 5 we can see it's from

1 **A.** The addition of the word "proven" would have been
 2 appropriate, looking at it:
 3 "Despite the fact that there is little [proven]
 4 evidence ..."
 5 Or "substantiated evidence".
 6 **Q.** Was Armour trying to downplay the causal connection
 7 between concentrates and the risks of AIDS?
 8 **A.** I -- just trying to reflect the current -- the current
 9 scientific thinking.
 10 **SIR BRIAN LANGSTAFF:** Can you just help for a moment with
 11 the words you've just used there. You spoke about
 12 "little proven evidence" or "little substantiated
 13 evidence". It might be thought that evidence is
 14 evidence. What is "proven evidence" as opposed to
 15 "evidence"?
 16 **A.** Oh ... well, it's just terminology, isn't it?
 17 **SIR BRIAN LANGSTAFF:** Well, no, that's why I'm asking you,
 18 because it's your terminology and I want to understand
 19 what you're trying to say.
 20 **A.** Well, substantiated proof, I suppose.
 21 **SIR BRIAN LANGSTAFF:** I see. So you're looking for more
 22 than evidence, you're looking for evidence which
 23 amounts to substantiated proof?
 24 **A.** Yes.
 25 **SIR BRIAN LANGSTAFF:** I see. Thank you.

1 Mr Fitch, chairman and managing director. And if we
 2 go back to the first page we see the topic is AIDS.
 3 Before we look at the contents of some of this, is
 4 it right to understand that this is the policy
 5 statement that you and Mr Christie had been pressing
 6 for?
 7 **A.** Yes, it would appear so.
 8 **Q.** And we can see it's directed to all haemophilia centre
 9 directors, and then it says in the first paragraph:
 10 "... Armour ... is acutely aware of the current
 11 concern of the Medical world regarding Acquired Immune
 12 Deficiency Syndrome (AIDS) and its possible
 13 implication to Haemophilia care and treatment."
 14 And then this:
 15 "Despite the fact that there is little evidence
 16 to associate plasma component therapy with the
 17 transmission of AIDS, Armour, through its affiliate
 18 organisation, Plasma Alliance, has had programmes in
 19 operation for several months ... designed to help
 20 prevent the utilisation of plasma obtained from
 21 members of high risk groups associated with AIDS in
 22 the production of clotting factor concentrates."
 23 The use of "little evidence", is that a correct
 24 reflection of the position as at May 1983, do you
 25 think?

1 **MS RICHARDS:** If we go on to page 3 of this document, we
 2 can then see a discussion of various matters relating
 3 to measures that could be taken, and the second
 4 paragraph of this letter refers to what is sometimes
 5 called surrogate testing.
 6 So if pick it up in the fourth line:
 7 "Testing of AIDS patients for antibody to
 8 Hepatitis B core antigen ... shows that over 85% of
 9 them are positive for this marker. However,
 10 extrapolation of these findings to a general screening
 11 programme in order to identify potential AIDS victims
 12 or carriers may not be practical."
 13 Do you know whose decision it was to take this
 14 particular approach to the use of hepatitis B core
 15 antigen testing?
 16 **A.** That would be a US -- US decision.
 17 **Q.** So are you able to assist us in understanding why it
 18 was said that it may not be practical to extrapolate
 19 those findings to a general screening programme?
 20 **A.** No, I don't, no.
 21 **Q.** If we then go towards the bottom of the page we've got
 22 a heading, "Plasma collection and utilisation by
 23 Armour Pharmaceutical Company USA", and then there is
 24 a reference to Plasma Alliance's centres.
 25 If we go over the page, the second paragraph talks

1 about the display of informational posters at the
2 centres from December 1982 onwards, and there is
3 a very broad description about what the posters
4 advised.

5 Then the next paragraph deals with what is said to
6 be "a more aggressive programme", initiated in
7 February 1983: direct questioning of donors, written
8 and oral information and questions.

9 Do you recall whether you ever saw the actual
10 posters or questionnaires themselves, or were you
11 simply reliant upon being told that this programme was
12 in operation in the States?

13 **A.** I didn't see the actual posters themselves, no, but
14 I would rely on the integrity and honesty of the
15 information that was being fed back to me.

16 **Q.** Okay.

17 **A.** I had no reason to doubt what they're saying.

18 **Q.** Do you recall receiving any feedback from
19 the haemophilia centre directors that you or your team
20 were visiting, about this statement?

21 **A.** No. I don't recall.

22 **Q.** Then if we could turn to ARMO0000252. This is
23 a letter from you, 24 May 1983, to a Dr Colledge it
24 looks from the address as though it's a letter to
25 a general practitioner. If we go to the second page

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1 we can see that this is a letter from you, C Bishop,
2 Manager, Plasma Division.

3 If we go back to the first page, I just want to
4 ask you about the terms in which you were writing to
5 this doctor:

6 "We acknowledge receipt of letter of the 10th May,
7 asking whether we are able to supply non-American
8 material.

9 "Presumably your letter has been prompted by the
10 enormous publicity given to the subject of AIDS and
11 the possibility that you have a haemophilia patient
12 under your care at the present time.

13 "Much of the publicity, as you know, has been
14 emotive and to a great extent, inaccurate. Conversely
15 there have been numbers of well informed authoritative
16 publications, which have done much to place things in
17 their true [perspective] and to allay many of the
18 fears and the concern felt by the UK patients
19 receiving regular blood component therapy, and in
20 particular, the UK haemophiliac."

21 Then you refer in the next paragraph to
22 Haemophilia Society publications, a letter from
23 Professor Bloom, and an overview of the AIDS
24 situations by Dr Kernoff, which then you say:

25 "... [we hope will] help to further reassure the

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1 UK haemophiliac and those charged with his care."

2 You then go on to talk about Armour's collection
3 processes for plasma in the States. Then, bottom of
4 the page, we can see the phrase "little evidence"
5 again:

6 "Despite the fact there is little evidence to
7 associate plasma component therapy with the
8 transmission of AIDS, Armour, through its affiliated
9 organisation, Plasma Alliance, has had programmes in
10 operation for several months ..."

11 Top of the next page:

12 "We are firmly committed to providing safe and
13 effective products to the medical profession, and will
14 continue to devote our energies and resources to the
15 problems associated with AIDS and haemophilia
16 treatment and will continue our efforts to resolve
17 them."

18 But if we just go back to the first page, it
19 might be said, Mr Bishop, you're speaking here in
20 fairly strong terms, you talk about "erroneous
21 publicity", "emotive", to a great extent "inaccurate",
22 why did you regard the publicity in those particular
23 lights?

24 **A.** Because I was reflecting the state of art knowledge at
25 the time.

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1 **Q.** When you say, in that third paragraph, there have been
2 "well informed authoritative publications, which have
3 done much to place things in their true
4 [perspective]", what did you mean by "true
5 perspective"?

6 **A.** Well, the pros, the articles for and against, you
7 know, the problems.

8 **Q.** If it --

9 **A.** To reflect the balanced -- a balanced opinion of the
10 leading opinion formers, not only in the UK but
11 internationally.

12 **Q.** If it were to be said that what you were trying to do
13 here was to persuade the doctor that there was no real
14 reason to be concerned about the use of Armour
15 concentrates, would that be a fair observation about
16 this letter?

17 **A.** This doctor obviously had a haemophiliac patient who
18 expressed concerns to him, and the idea of this letter
19 was to, just to try and reassure him and his patient,
20 and if he passed it on to his patient, just to
21 reassure them, and to update them with the current
22 thinking.

23 **Q.** Would you accept that you don't say here, Mr Bishop,
24 well, there is a risk or there is a likely connection
25 but we don't yet know the true extent of the risk, or

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1 words to that effect, do you? It's all very much on
 2 the positive side of trying to dispel concerns, is it
 3 not?
 4 **A.** Yes, yes, which -- with the -- again, the state of art
 5 knowledge at the time, it would be quite wrong to
 6 cause consternation with individual patients, until,
 7 you know, more was known and the science and knowledge
 8 evolved.
 9 **Q.** I'll ask you about one further letter from you, this
 10 is to Professor Bloom, ARMO0000265. Letter from you,
 11 21 June '83, "re: Factorate -- Batch No T40405". Then
 12 the first paragraph says:
 13 "I am very grateful for your letter of the
 14 9th June on the subject of above, and for advising us
 15 of further details relating to the patient involved.
 16 Unfortunately, we have still not heard
 17 officially from Dr Craske and, therefore, the
 18 information you have supplied has assumed even more
 19 importance and enabled us to provide further feedback
 20 to our colleagues in the USA."
 21 Then you talk about the record-keeping
 22 facilities that would enable you to trace the location
 23 of vials and the traceability of batches in the
 24 States.
 25 Just looking at that first paragraph,

1 unfortunately, Mr Bishop, we don't have -- or haven't
 2 been able to find -- the letter of 9 June to which you
 3 were responding, but it would -- the timing would
 4 suggest that this may have been a letter about the
 5 patient that we know to have been under Professor
 6 Bloom's care, who was said to be the first haemophilia
 7 patient in the UK to be displaying signs of AIDS, and
 8 the fact that that patient had received, amongst other
 9 treatments, a particular batch of Factor VIII. Does
 10 that trigger any recollection of this discussion,
 11 Mr Bishop?
 12 **A.** No, not really, unless I see Dr Bloom's letter of
 13 9 June, I can't really comment any further on that.
 14 **Q.** In that case, perhaps you can help us more generally.
 15 If, as would appear to be the case, a particular batch
 16 had been implicated as possibly involved in the
 17 transmission of AIDS to this unfortunate patient, what
 18 steps would you expect Armour to be taking in response
 19 to that information?
 20 **A.** Well, the information would be fed back to the
 21 medical -- in the US and then I would be directed by
 22 whatever the experts decreed.
 23 **Q.** Would you expect --
 24 **A.** No doubt, if it turned out, for example, the material
 25 was one of the donors contributing to that batch of

1 material had gone down with AIDS, then, yes, one would
 2 expect the product to -- any product from that to be
 3 withdrawn.
 4 **Q.** Would you expect contact to be made by Armour with
 5 other centres to whom that particular batch had been
 6 supplied, vials from that batch had been supplied?
 7 **A.** Well, if it was appropriate to do so. I mean, if it
 8 was just an isolated case, and then there was some
 9 evidence to, you know, implicate that -- the material
 10 produced from that batch, or that -- then, you know,
 11 action would have been taken appropriately.
 12 **Q.** Do you know now what, as a matter of fact, Armour did
 13 do in relation to that batch?
 14 **A.** No.
 15 **Q.** Last question before lunch, Mr Bishop, and this really
 16 takes us through to the middle of 1983, July 1983. We
 17 know from a letter you wrote to Dr Preston -- I don't
 18 think we need to look at the letter itself -- that you
 19 attended the World Federation of Haemophilia
 20 conference in Stockholm in mid-1983, and you write to
 21 Dr Preston saying it was nice to meet you there, or
 22 words to that effect.
 23 **A.** Yes.
 24 **Q.** What recollection do you have of attendance that
 25 meeting in Stockholm and any discussions about AIDS,

1 or any presentations by Dr Bruce Evatt, for example?
 2 **A.** No specific recall, no.
 3 **Q.** If there were --
 4 **A.** This was --
 5 **Q.** Sorry.
 6 **A.** No, just, this was an annual meeting which we attended
 7 and, you know.
 8 **Q.** Would you have attended alone from Armour or would
 9 other colleagues from Armour UK be likely to have
 10 attended with you?
 11 **A.** No, again, this is what we took pride on, that we
 12 involved all our specialists in attending that
 13 conference, so that they could sit alongside their
 14 customers and the experts and hear the same evidence
 15 and the same clinical presentations, so that their
 16 credibility, when next they're back in the UK talking
 17 to one of their customers, their credibility wouldn't
 18 be questioned.
 19 **Q.** So, whilst I appreciate you can't remember the
 20 specifics, if there were discussion and presentations
 21 on the topic of AIDS at the Stockholm conference, as
 22 we understand there to have been, you would have
 23 expected either you or your colleagues would have been
 24 in the audience listening to that?
 25 **A.** Definitely there would be. And the outcomes of those

1 presentations would be in the abstracts of the
2 conference, if I had them.
3 **MS RICHARDS:** Sir, is that a convenient moment to break
4 for lunch?

5 **SIR BRIAN LANGSTAFF:** Yes, it is.
6 So we'll take a break then until 2 o'clock.
7 2 o'clock.

8 **MS RICHARDS:** Thank you, sir.

9 **A.** Okay.

10 **(1.03 pm)**

11 **(The luncheon adjournment)**

12 **(2.00 pm)**

13 **SIR BRIAN LANGSTAFF:** Yes.

14 **MS RICHARDS:** Mr Bishop.

15 **A.** Good afternoon.

16 **Q.** Good afternoon. You will know from documents that
17 you've seen that between May and July of 1983 there
18 were exchanges between the Department of Health and
19 Armour, with the Department requesting information
20 about what additional measures were being taken by all
21 pharmaceutical companies, including Armour, and
22 discussion of the consequences of recommendations from
23 the Food and Drug Administration in the States.

24 Now, I'm not going to ask you about the detail of
25 those, there is a range of telexes and communications

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1 So in relation to Armour, you'll see
2 1.14 million international units there set out.
3 "Proportion collected in accordance with
4 companies' special precautions", and, as I understand
5 it, those were the additional measures that Armour
6 had, and indeed others, said that they'd adopted prior
7 to March 1983, 0.8 million international units, and
8 then a clearance date.

9 Is it right to understand, Mr Bishop, that as at
10 August 1983 there was still a significant amount of
11 pre-March '83 material held in the UK which had not
12 been collected in accordance with Armour's own special
13 precautions?

14 **A.** I don't know.

15 **Q.** Well, let's pick matters up then in a telex that you
16 sent that same month, ARMO000287.

17 So this is a telex from you to Anita Bessler,
18 18 August 1983, re AIDS screening data. It says this:

19 "Further to the telexes on the above subject,
20 culminating in mine of 29.7, Will Tarbit of our
21 Regulatory Affairs Department has recently visited the
22 DHSS and he has ascertained that they will allow us to
23 dispose of Factorate manufactured from plasma
24 collected prior to March 23rd in the UK.

25 "It would appear that the DHSS called a meeting,

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1 which were copied into, but you were not, I think, the
2 author of those.

3 So that's a rather long-winded explanation so that
4 those listening understand I'm not going to ask you
5 specifically about the dealings with the Department in
6 the summer of 1983.

7 What I want to do is pick up with you the
8 position in terms of stocks of Armour product held in
9 the UK in August of 1983, and then look at
10 a communication that you sent to the States in that
11 same month.

12 So if we start with DHSC0002231_052.

13 You'll see this is an internal Department of
14 Health memo from Mr Egerton to Dr Walford, and it
15 refers:

16 "... in the attached note setting the latest
17 stock position of blood products manufactured from
18 plasma collected prior to March 1983."

19 If we go to the second page, please. You'll see
20 there, Mr Bishop, a table. It's stock of blood
21 products August '83, manufactured from plasma
22 collected prior to March 1983, and then we have the
23 five companies set out. And then the next column is
24 the "Stock of pre-[March] '83 material for sale in
25 the UK".

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1 presumably of haemophilia centre directors, although
2 we have been unable to ascertain who attended this
3 meeting apart from Professor A Bloom. At this
4 meeting, it was decided by a small majority to allow
5 suppliers of AHF concentrates to dispose of stocks
6 manufactured from plasma collected prior to the FDA
7 memorandum of the 23.3.

8 "It was also indicated that the DHSS will be
9 closely monitoring the disposal of 'such product'. It
10 is therefore clearly vitally important that we
11 endeavour to dispose of 'such product' as soon as
12 possible. During this time, it is essentially that we
13 have full details, as requested by you, of the dates
14 plasma was collected for each of the batches so that
15 we are in a position to supply either the DHSS or
16 customers with any information requested."

17 In the second paragraph, Mr Bishop, it refers to
18 your understanding that there had been a meeting
19 attended by Professor Bloom, at which the decision to
20 allow pre-March plasma to be sold in the UK was taken.
21 Do you recall who you got that information from?

22 **A.** No. I'm afraid not, no.

23 **Q.** And do you recall any more about that, other than what
24 we see set out in this document?

25 **A.** No, no, I'm afraid not.

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1 Q. In any event, is it right to understand from this
2 document, your understanding was: you could continue
3 to sell in the UK your stock made from plasma
4 collected before 23 March, and you were keen to do
5 that as soon as possible; is that right?

6 A. That's what it says, yes.

7 Q. Can you help us in understanding why, in the last
8 paragraph that you see on the screen there, you
9 thought it clearly vitally important to try and
10 dispose of the product as soon as possible? Did you
11 fear the Department might change its mind?

12 A. I don't know. That would appear to be the
13 implication. Yes, I do know that centres were
14 concerned, or the Department of Health was concerned
15 about the amount of material, you know, held in the UK
16 by all the different companies. Other than that,
17 I can't comment any further on this.

18 Q. There is no reference here to any safety implications
19 of disposing of, or selling in the UK the pre-March 23
20 product. Do you recall Armour having any concerns
21 internally at the time about this?

22 A. No, I don't recall any -- I don't recall anything of
23 that nature.

24 Q. If we just take a quick look now at ARMO0000285. This
25 is a letter to you from The Institute of Cancer

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1 Research in Denmark, August 10, 1983, and it refers to
2 papers being sent to scientists invited to attend
3 a particular conference that was going to be taking
4 place I think in Denmark, a congress.

5 If we go to page 5, please. You'll see, under the
6 heading "Scope and purpose", the second paragraph says
7 this:

8 "Epidemiologic evidence clearly indicates that
9 AIDS is infectious and probably transmitted by sexual
10 contact and by blood contact. No agent has so far
11 been identified."

12 By this time, August 1983, was it generally
13 accepted within Armour that AIDS was probably
14 transmissible by blood and blood products?

15 A. No -- well, I don't recall the timeframe.

16 Q. If we go to ARMO0000291, this is an internal
17 memorandum, 1 September 1983, about the Denmark
18 conference, "AIDS in Europe status quo". We can see
19 it's copied to you.

20 Then the second paragraph says:

21 "A number of key UK clinicians will be attending
22 the meeting which is by invitation only. We have
23 received an invitation to attend in return for
24 a contribution to the Congress funds.
25 "We feel that our attendance at this is vital

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1 and Chris Bishop will be representing the
2 UK Plasma Division."

3 Then there is a request to allow Dr Townsend to
4 attended as well.

5 Why was it seen as vital that you in particular
6 should be representing Armour at this particular
7 Congress?

8 A. I don't know. The fact that Dr Townsend should attend
9 as well means it's mainly, you know, a scientific, or
10 technical issue. I don't know why, you know, I'm the
11 first one on that list to attend it -- I can't
12 remember -- other than the fact that, you know, it was
13 one of my customers.

14 Q. If we move -- do you have any recollection now of
15 attendance at the Denmark Congress and what was
16 discussed?

17 A. No, no.

18 Q. ARMO0000302. This is a telex from Ingo Regier to you
19 dated 4 November 1983. I'll just read it out because
20 it's not very easy to read:

21 "Cutter recalled 16 AHF lots ... distributed to
22 33 countries, including Japan. Several other lots are
23 on hold. One of Cutter's plasma donors recently died
24 because of AIDS. The man donated about 5 liters of
25 plasma over the time, but apparently failed to

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1 indicate any information about his disease during that
2 time. We will probably have to expect very detailed
3 questions regarding donor screening/selection of
4 donors during the BGA hearing at Berlin. I am also
5 concerned about suggestions that paid donors are less
6 likely to be truthful when asked questions which would
7 disqualify them as donors.

8 "Under the circumstances I suggest that we have
9 a meeting ..."

10 Then the date and location is set out:

11 "The Cutter incident is under investigations now
12 and Dr Rodell will have detailed information available
13 for our meeting. We regret the unfortunate
14 circumstances of the Cutter incident. However, the
15 possibility of something like that happening to any
16 plasma manufacturer cannot be excluded. It should be
17 to our advantage to remind our customers in an
18 appropriate form, that Armour processes plasma from
19 our wholly owned and fully controlled plasmapheresis
20 centers."

21 Then there is a reference to Plasma Alliance's
22 reputation. Then Mr Regier continues:

23 "Although it is obvious that it is actually not
24 known how to avoid transmission of AIDS, it should
25 also be emphasized that we have recently introduced

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1 Factorate HT to improve the safety of our product."
 2 Just pausing there, the reference to the BGA
 3 hearing in Berlin, that's the German regulator. Did
 4 you have any involvement in the preparations for or
 5 attendance for that hearing?
 6 **A.** No.
 7 **Q.** And can you recall anything about it, why it's being
 8 raised in a telex to you?
 9 **A.** No, no.
 10 **Q.** If we just go to look at the top paragraph again,
 11 Mr Regier is recorded as expressing concern "about
 12 suggestions that paid donors are less likely to be
 13 truthful when asked questions which would disqualify
 14 them as donors".
 15 What to the best of your knowledge was the
 16 thinking within Armour on that topic? Was it
 17 generally accepted and understood that paid donors had
 18 less incentive, if I can put it that way, to be
 19 truthful when asked questions which would disqualify
 20 them as donors?
 21 **A.** No, I think the sources from which Cutter collected
 22 their plasma was completely different from Armour,
 23 and -- suggestions that paid donors were less
 24 truthful, from our donor pools, I think, you know,
 25 were less likely because of the stringent controls

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1 **Q.** I'm going to move now to the issue of heat-treated
 2 Factor VIII. I'm going to pick it up, if I may, at
 3 the beginning of 1985, ARMO0000341.
 4 This a letter dated 3 January 1985, from
 5 Dr Kernoff at the Royal Free to you, and we can see
 6 from the second paragraph -- sorry, it refers first of
 7 all to a meeting he had with you on 13 December. The
 8 second paragraph then says:
 9 "As a matter of policy, we have decided to
 10 discontinue using non-heat-treated factor VIII
 11 concentrates, whether of commercial or NHS origin.
 12 While there will clearly be an interim period of
 13 change-over in which we shall be using both
 14 heat-treated and non-heat-treated product, I would
 15 hope to keep this period as short as possible."
 16 Then the next paragraph contains a request that
 17 you'll be able to arrange collection of their current
 18 stock of non-heat-treated Factorate, and provide
 19 a credit against the price of the heated product.
 20 **A.** Yes.
 21 **Q.** Then there is reference in the next paragraph to
 22 a list of named patients. Then Dr Kernoff says this:
 23 "Our requirements for factor VIII concentrate
 24 during the financial year 1985/86 will probably be
 25 similar to the current year. Patient safety, cost

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1 that we implicated (*sic*) at our wholly owned
 2 centres --
 3 **Q.** Was it --
 4 **A.** -- rather than --
 5 **Q.** No, carry on, please.
 6 **A.** No, that's all right, carry on.
 7 **Q.** Was it nonetheless the case, as a matter of fact, that
 8 Armour's donors, albeit donating to the Plasma
 9 Alliance's centres, they were paid donors, were they
 10 not?
 11 **A.** Yes, they were, yes. But all away from the
 12 notoriously bad areas, at-risk areas. And --
 13 **Q.** Other -- sorry.
 14 **A.** And the type of donor that compiled our pool would --
 15 was, it was felt, to be unlikely to be dishonest.
 16 **Q.** Other than the letter that we saw Mr Fitch sending to
 17 all haemophilia centre directors earlier in 1983, are
 18 you aware of any other policy statement or bulletin or
 19 information about AIDS which Armour provided to
 20 haemophilia centres in 1983 or 1984?
 21 **A.** No, I can't recall without actually seeing them.
 22 **Q.** Well, I don't think we've uncovered any, Mr Bishop,
 23 I just wanted to give you the opportunity to explain
 24 whether you were aware of any others.
 25 **A.** No.

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1 containment, and reliability of supply will continue
 2 to be the issues which dominate our purchasing policy
 3 and I look forward to receiving your proposals as soon
 4 as possible. So far as patient safety is concerned,
 5 it is of critical importance for me to know the
 6 evidence regarding inactivation of HTLV 3 by the
 7 Armour heating protocol."
 8 Then there is a discussion about
 9 transmissibility of non-A, non-B hepatitis.
 10 Mr Bishop, I haven't deciphered the handwriting,
 11 but is that your handwriting, do you know, or ...
 12 **A.** Yes, it is.
 13 **Q.** Can you then just assist us with what's written by the
 14 side of that last sentence I read out, where
 15 Dr Kernoff says "it is of critical importance for me
 16 to know the evidence regarding inactivation of HTLV 3
 17 by the Armour heating protocol", and then it says --
 18 **A.** Just "Awaiting DC (see [product licence]
 19 application)".
 20 **Q.** What does "Awaiting DC" mean?
 21 **A.** I don't -- I think that's the initials of Dean
 22 Cockburn, but I can't --
 23 **Q.** Okay.
 24 **A.** No, I can't -- obviously awaiting something. No,
 25 I don't know what the DC could -- it's obviously

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1 somebody's initials, but I can't recall.

2 **SIR BRIAN LANGSTAFF:** Does it help at all that you mention

3 DC further up the same slide?

4 **MS RICHARDS:** Yes, by the sentence saying:

5 "I hope you will soon have a full licence for

6 the product."

7 **A.** Oh ... can you just highlight that a bit more,

8 "Awaiting DC"?

9 **Q.** "Discuss preliminary data", does that say?

10 **SIR BRIAN LANGSTAFF:** It's the entry in the middle, the

11 third entry down.

12 **A.** "Awaiting" -- I think that refers to Dave Kocane.

13 **MS RICHARDS:** Who was that?

14 **A.** It might have been a regulatory discussion, you know,

15 discuss P&L with the Department of Health, awaiting

16 that person's discussion with the Department of

17 Health, I would assume that means.

18 **Q.** Okay.

19 **A.** I can't recall.

20 **Q.** And --

21 **A.** And then the last paragraph, "Awaiting DC (see P/L

22 application", I would assume that was the licence

23 application for the heat-treated product.

24 **Q.** Now, we'll look in a moment at a memo you then wrote

25 to Dr Rodell in which you made reference to this

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1 letter. Before we do that, can you just assist us

2 more generally: Dr Kernoff's request for Armour to

3 collect the non-heat-treated Factorate was presumably

4 reflected by similar requests from other haemophilia

5 centres. Would that be right?

6 **A.** Yes. Yes.

7 **Q.** What did Armour do, did it agree to those requests and

8 take back the unheated product?

9 **A.** Oh yes, yes, because the note against that is "Within

10 the next 10 to 14 days liaise with PAL", Pauline

11 Luckhurst(?) **, who was the distribution manager.

12 **Q.** What --

13 **A.** So we're agreeing, yes, collect that within the next

14 10 to 14 days.

15 **Q.** What, as far as you can recall, was done with the

16 returned non-heat-treated stocks of Factorate?

17 **A.** I don't recall.

18 **Q.** Do you know whether it was sold at other markets?

19 **A.** I'm just speculating whether that would have -- if it

20 was from screened donors, whether that would form part

21 of the recycling or so-called recycling process of

22 heat treating products in Germany.

23 **Q.** But you can't recall with any clarity?

24 **A.** No.

25 **Q.** Let's then just look, please, at a memo you then sent

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1 to Dr Rodell, ARMO000346. 16 January 1985, from you

2 to Mike Rodell, and you say this:

3 "Further to my memo of the 19th December in

4 which I expressed concern regarding the advantageous

5 position that Alpha were now enjoying, I now attach

6 for your information the letter received from one of

7 our biggest and most important Centres, the Royal Free

8 Hospital, and I would particularly draw your attention

9 to the points made in the last two paragraphs

10 regarding evidence of inactivation of HTLV III and the

11 renewed concern regarding [non-A, non-B] transmissible

12 agents."

13 Then you refer to a discussion amongst

14 haemophilia centre directors at a meeting at

15 St Thomas', in which they discussed the Alpha product

16 and you say:

17 "... there was a general agreement that together

18 with the Behring product ... the Alpha product is the

19 best product available at the moment."

20 You say:

21 "Do we know of the worldwide results on the

22 Alpha heat treated product, which would nullify or

23 substantiate the results currently being achieved in

24 the UK?

25 "We urgently need your authoritative comments

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1 and help in order to enhance our own product and/or

2 nullify the apparent advantages now being enjoyed by

3 Alpha and Behring.

4 "I do appreciate the question of low-yields with

5 these products, but this is of secondary interest now

6 to our Clinicians and we are in extreme danger of

7 losing our market position."

8 So if we go back up to the first paragraph, why

9 were you particularly drawing Dr Rodell's attention to

10 the point about evidence of inactivation of HTLV-III?

11 **A.** Is that referring to -- just refresh me what those two

12 paragraphs were?

13 **Q.** Yes, of course, it's the letter we just looked at from

14 Dr Kernoff, ARMO000341. If we look at bottom of the

15 page, he said:

16 "... it is of critical importance for me to know

17 the evidence regarding inactivation of HTLV 3 by the

18 Armour heating protocol."

19 So he wanted to know the evidence substantiating

20 Armour's particular heat-treatment process, and then

21 the next paragraph talks about non-A, non-B hepatitis.

22 So that appears to be what you're drawing Dr Rodell's

23 attention to. Are you able to assist us in

24 understanding why you were particularly flagging up

25 those matters?

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1 A. Well, because it was of concern to Peter Kernoff.
 2 Q. Do you know whether Dr Kernoff was supplied by Armour
 3 with evidence regarding the Armour heating protocol
 4 and its success or otherwise in inactivating HTLV-III?
 5 A. I can't remember, but if it was in the public domain,
 6 or even amongst the haemophilia centres directors, he
 7 would be aware of it.
 8 Q. Then if we go back to ARMO0000346, your memo to
 9 Dr Rodell --
 10 A. Yes.
 11 Q. -- it seems pretty clear that you were worried that
 12 Alpha's product was being favoured by clinicians over
 13 Armour's product; is that right?
 14 A. Yes. Yes.
 15 Q. You wanted to be able to enhance Armour's product.
 16 What kind of assistance were you anticipating
 17 Dr Rodell might be able to provide in that regard?
 18 A. Can I just refer back to that -- your comments on the
 19 penultimate paragraph, and note there that I say
 20 yields is of secondary interest so, in other words,
 21 our major concern was the safety of the product, not
 22 necessarily our market position.
 23 Q. Well, as I read that memo, Mr Bishop, correct me if
 24 I'm wrong, you're saying low yields was of secondary
 25 interest to clinicians.

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1 A. No. Well, low yields in general -- I mean, low yields
 2 of a product would affect the profitability of the
 3 product, but what I'm saying is that if we institute
 4 a more stringent inactivation process, that could well
 5 affect the yields, and therefore the profits of the
 6 product. But that's -- what I'm saying is that that
 7 issue is of secondary interest both to us and to our
 8 clinicians.
 9 Q. Okay. Well, let's move on to the middle of 1985,
 10 shall we? ARMO0000379.
 11 This is a letter from you to Dr Bell,
 12 Southampton Haemophilia Centre, there are a number of
 13 letters in identical form to other haemophilia
 14 directors. We can see it says:
 15 "Confirmation of telephone advice 10th May 1985
 16 "Heat Treated Factorate
 17 "Batch No Y69402."
 18 You say this:
 19 "As a result of the on-going [US] surveillance
 20 programme, we have been advised that one donor, whose
 21 plasma was incorporated into pools from which our
 22 Antihaemophilic Factor, FACTORATE, was produced has
 23 developed [AIDS].
 24 "When this donor was given plasma, we exerted
 25 our strict routine screening, the donor showed no

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1 indications of ill-health, stated he was not a member
 2 of any risk group associated with AIDS, and was on
 3 active military duty."
 4 Just pausing there, Mr Bishop, the reference to
 5 active military duty, would we be right to understand
 6 that Armour didn't regard military involvement as
 7 indicating any higher risk on the part of donors?
 8 A. No, no, on the contrary. I think it was implying
 9 that, you know, he was a clean, good living, active
 10 military operative.
 11 Q. Then you say this:
 12 "Only one batch in the [UK]" --
 13 A. So it would not be one of the at-risk donors.
 14 Q. Then you say:
 15 "Only one batch in the [UK] is implicated.
 16 Fortunately this is a heat treated batch No Y69402.
 17 This small heat treated batch was distributed in
 18 December 1984 and January 1985 to a few centres only,
 19 of which yours is one, and we anticipate the product
 20 has already been used. If you should still hold any
 21 of this batch, kindly notify us so that we can arrange
 22 for its return."
 23 Other than contacting the Department -- sorry,
 24 the centres concerned in the way which we see here, by
 25 phone and by letter, are you aware of what other steps

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1 were taken by Armour in response to this knowledge
 2 about batch Y69402?
 3 A. I don't know, but I'm sure that the medical department
 4 would have been in touch with the Department of
 5 Health --
 6 Q. Yes.
 7 A. -- relating to it.
 8 Q. I won't go to the document, but there is a document
 9 which suggests a report to the Department and, for the
 10 benefit of you, sir, and the transcript it's
 11 ARMO0000172. It lists eight haemophilia centres to
 12 which this particular batch had been supplied between
 13 December 1984 and January 1985.
 14 We'll pick up events in relation to that batch
 15 in a few minutes, Mr Bishop, but, in the meantime, can
 16 we look at ARMO0000416.
 17 Now, this is called a "house message", it's
 18 dated 12 July '85, it's from you, it's about
 19 heat-treated Factorate. If you look at who it's
 20 addressed to, is this your field plasma team, those
 21 who were going out visiting centres, selling the
 22 product?
 23 A. Yes. Yes.
 24 Q. Now, the subject of this memo or message is not risk
 25 of AIDS but transmission of non-A, non-B hepatitis, so

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1 you refer to a copy of a paper by Colombo and others
2 published in The Lancet, relating to Travenol, and
3 then in the third paragraph, you say:

4 "There is a paper due to be published shortly by
5 the Sheffield Group (E Preston) on the results of our
6 study last year in which you will recall all three
7 'clean virgin' patients treated with our intermediate
8 heat treated product acquired Non-A, Non-B Hepatitis.
9 I am advised that this will be appearing in the next
10 3-4 weeks and the conclusion to the paper will be
11 along the following lines:

12 "Whilst all three of our patients have remained
13 HTLV III antibody negative, it seems clear that at
14 least from commercial sources the dry heated product
15 remains disappointing."

16 You then say this:

17 "This together with the Colombo paper is quite
18 clearly an indictment of the dry heat treated
19 processes in totally eliminating Non-A, Non-B,
20 although in Chimpanzee studies both products showed
21 effectivity against the Hutchinson strain of the
22 non-A, non-B virus."

23 You then refer to an Alpha trial, which seemed
24 to be going well but now three patients have "gone
25 down with Non-A, Non-B Hepatitis".

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1 unequivocally states that any proven superior product
2 is really only indicated in clean virgin untreated
3 patients and there is little point in altering the
4 treatment of those who have already been exposed to
5 concentrates."

6 Then you refer again to the Alpha position:

7 "Although Alpha's unpublished evidence may look
8 better ... it is not the answer -- it is still very
9 much the luck of the draw which batch you get.

10 "There may be a case for 'clean virgin' patients
11 for Alpha but certainly not a case for universal
12 change ..."

13 Then you say this:

14 "Use the above argument and the Hay paper to
15 maximum effect when discussing the merits of the Alpha
16 [versus] the Armour product."

17 Then you say you'll update your team after the
18 San Diego meeting.

19 How common was it for you to study the medical
20 literature and then draw out points from the medical
21 literature and tell your team what they should make of
22 it and how they did you discuss it with clinicians?

23 **A.** That would have been done in collaboration and with
24 the approval of the Medical and Regulatory
25 Departments. I wouldn't have produced that document

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1 Then if we go over the page, you pose the
2 question, at the top of the page:

3 "What should be our strategy, therefore?"

4 You refer to a study by Professor Charles Hay
5 and others from Sheffield, also published in The
6 Lancet in June, "Progressive Liver Disease in
7 Haemophilia: An Understated Problem?" You say have
8 you arrowed certain important paragraphs, and we have
9 your copy on the next page, we don't need to look at
10 it but we can see where you've marked them with an
11 arrow, "and would ask you to note the following".

12 Then you've set out there five points:

13 "Leading workers conclude that liver disease in
14 haemophilia is benign and non-progressive but the
15 Sheffield Group question this.

16 "Factor VIII therapy/consumption is unrelated to
17 the severity and progression of liver disease.

18 "Studies in patients who are not receiving
19 regular supplies of blood products shows the scheme
20 prevalence and frequency of progression as
21 haemophiliacs being repeatedly challenged.

22 "The Sheffield Group speculate that repeated
23 exposures to viruses may, repeat may, modify the
24 usually benign course of the disease.

25 "The last sentence quite clearly and

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1 off my own bat, that would have been after discussion
2 with people more qualified to make those points.

3 **Q.** Okay. Well, if we just looking at the next page,
4 we've got the two Lancet articles, so we have your
5 initials, CB, on the corner, then we have the Colombo
6 article. Then if we turn on, I think, five pages,
7 Soumik. Sorry, could go back two pages, my fault.

8 We've there got Professor Hay or Dr Hay, as he
9 then was, his article. Then we can see that the
10 arrows you referred to, there is a handwritten arrow
11 there, if we go over, say, two pages, we can see
12 a number of other of the arrows that you refer to. It
13 does look as though you've gone through this document
14 and you're drawing particular bits to the attention of
15 your team. Is that the right way of understanding
16 this, Mr Bishop?

17 **A.** Yes, I don't know whether they are my points, my
18 arrows.

19 **Q.** Well, your house message said "I have arrowed certain
20 important paragraphs".

21 **A.** Oh, I'm sorry. Okay, I'm sorry, I apologise. Okay.

22 **Q.** That's all right.

23 You're trying to tell your team, are you not,
24 that the strategy should be to talk up the Armour
25 product and try and address any concerns about non-A,

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1 non-B hepatitis and repudiate any expression of
2 preference for the Alpha product. That's what you
3 were --

4 **A.** Yes, based on those -- based on the clinical
5 references that I've shown.

6 **Q.** Let's then pick up the picture in relation to AIDS,
7 and that particular batch that we were looking at,
8 with ARMO0000418.

9 Now, this is 17 July 1985. This is a letter
10 from Mr Christie, if we look at the bottom of the
11 page, but it's copied to you, as well as to Dr Harris
12 and Mr Collins. It's addressed to Dr Whitmore at the
13 Lewisham Hospital. It refers to a letter that
14 Dr Whitmore sent:

15 "Your report on the two patients who received
16 Heat Treated Factorate Y69402 is much appreciated, and
17 the results for Patient 1 are of particular interest.

18 This patient is the first to show sero-conversion from
19 HTLV-III negative to positive following administration
20 of the batch of Factorate heat-treated in question."

21 Then there is a suggestion of a meeting, and
22 Mr Christie says he'll make an appointment to visit
23 Dr Whitmore in the next month or so.

24 This --

25 **A.** The third paragraph -- sorry.

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1 **Q.** "As you know, the time from challenge with HTLV-III
2 virus to sero-conversion is variable and may be over
3 a month, hence it would be useful to assess any
4 Factor VIII or blood product treatment for
5 a reasonable period prior to 17/1/85."

6 Now, this a report of a patient apparently
7 seroconverting from HTLV-III negative to positive
8 following administration of what Armour knew to be
9 an implicated batch; yes?

10 **A.** Batch produced -- yes, okay, yes.

11 **Q.** It's the batch we saw you writing to Dr Bell and
12 others about in May. This must have been a matter of
13 some considerable concern to Armour. What can you
14 recall about it?

15 **A.** Well, you know, it is of concern, hence we, you know,
16 we were requesting further information on it, and, you
17 know, looking at what the treatment was, you know,
18 during that prior period, in case there are other risk
19 factors involved, or other treatment involved.

20 **Q.** Did your approach -- Armour's approach in the UK -- to
21 marketing and selling the heat-treated Factorate
22 change at all in light of this report of a patient who
23 may have been infected with HTLV-III from the Armour
24 heat-treated batch?

25 **A.** No, I can't recall any specific reaction to this.

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1 **Q.** Was information that a patient had seroconverted and
2 that it might have been due to this batch shared by
3 Armour with any other haemophilia centre clinicians?

4 **A.** I don't know. We certainly, until the whole thing was
5 absolutely clear, based on the further information
6 requested, until everything was clear none of this
7 would be divulged to the salespeople.

8 **Q.** But this particular piece of information was something
9 you were aware of, because you were copied into this
10 letter?

11 **A.** Yes, yes.

12 **Q.** So is your understanding that it wouldn't have been
13 shared with your team?

14 **A.** No, it wouldn't have been. Not at this stage.

15 **Q.** This is July 1985, I think we pick the matter up next
16 in the UK in February 1986. Before we do that, we
17 know from other materials that, in October 1985, there
18 was a meeting in New York to discuss, amongst other
19 things, the work undertaken by Dr Alfred Prince. You
20 were not, I think, a party to those meetings, although
21 Anita Bessler was. Do you recall issues about the
22 Prince data being shared with you in the UK at all, at
23 this point in time, 1985?

24 **A.** I was aware of the Prince study, but I can't recall
25 the actual details without seeing more.

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1 **Q.** Do you know whether within the UK, so within
2 Armour UK, there was any consideration of whether the
3 Prince data should be provided to the Department of
4 Health?

5 **A.** That will have been a discussion between the States
6 and the UK medical people.

7 **Q.** So if there was any such consideration, you weren't
8 party to it; is that right?

9 **A.** Correct.

10 **Q.** So let's pick matters up with Factorate heat-treated
11 in February 1986, the Newcastle AIDS conference, when
12 Dr Peter Jones expressed concerns about the efficacy
13 of Armour's heat-treated product in inactivating
14 HTLV-III and referred to possible American and Dutch
15 cases of seroconversion. Were you at that Newcastle
16 conference?

17 **A.** Yes.

18 **Q.** What do you recall of the reaction to Dr Jones's
19 address?

20 **A.** What I can recall is one of outrage and concern at
21 a statement -- a statement by Peter Jones, based on
22 confidential information from Dr Ten Cate to Peter
23 Jones, and without the full knowledge of the patient
24 involved or his history. Because at that meeting,
25 there were haemophilic patients present in the

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1 audience, in the meeting, and it did cause great
 2 concern and was -- it really was, you know, an
 3 ill-conceived statement at that stage.
 4 **Q.** Was the outrage at Dr Jones having the temerity to
 5 raise these issues, rather than concern at the
 6 potential risk to patients then?
 7 **A.** No, the potential -- sorry, the concern was that this
 8 was putting the frighteners into patients without the
 9 full facts being available.
 10 **Q.** Let's look at some internal discussions that followed
 11 within Armour. If we start with CGRA0000517. This is
 12 a file note of 13 February 1986, I think the name on
 13 the bottom -- sorry, the note is dated 14 February.
 14 The name on the bottom, PAH, would be Dr Harris,
 15 I think; is that right?
 16 **A.** That's -- yes.
 17 **Q.** Top of the page, we can see it's copied to you, to
 18 Mr Christie and to Mr Fitch. Then we can see:
 19 "9.30 am received telephone call from Dr Rotblat
 20 of the DHSS Medicines Division concerning the Dutch
 21 patient who originally contracts AIDS after receiving
 22 heat treated Factorate."
 23 Then there is reference to reports about
 24 Dr Jones' speech and Dr Rotblat wanting information.
 25 If we then just look at a little further down, we have

1 case.
 2 **Q.** But the Netherlands is part of your patch, was it not?
 3 You were responsible for the Benelux countries?
 4 **A.** Yes, yes.
 5 **Q.** Do I understand that you can't now then recall how and
 6 when you first became aware of this particular case?
 7 **A.** No, I don't know the timeframe, I'm sorry.
 8 **Q.** Okay. But would you accept that the only way to read
 9 this is to suggest that, at least prior to the
 10 discussions being described here, Armour had
 11 previously been informed of it, albeit recording that
 12 the haematologist wanted to keep the matter secret?
 13 **A.** Sorry, are you asking whether we knew of this before
 14 Peter Jones's --
 15 **Q.** Yes.
 16 **A.** Outburst.
 17 **Q.** Yes.
 18 **A.** We may well have been but, again, on a confidential
 19 basis, pending the further information that was
 20 requested.
 21 **Q.** Well, let's then just follow things through in the
 22 month of February '86, by looking next at ARMO0000475.
 23 So this is from Dr Harris to Dr Swartz. Who was
 24 Dr Swartz?
 25 **A.** Swartz.

1 the paragraph beginning:
 2 "Discussions with RBC and CB [so that's with
 3 Mr Christie and with you] confirm that this was
 4 a patient about whom we had previously been informed
 5 but the haematologist concerned (Dr Ten Cate) had
 6 wished to keep the matter secret until he had
 7 investigated the total clinical situation."
 8 Then it refers to:
 9 "... it was established that this patient had,
 10 in fact, received Factorate batch number X57610-6, the
 11 batch known to have contained donations from
 12 a confirmed AIDS sufferer ...
 13 "Outstanding actions include", and then there is
 14 just confirmation with Germany, a medical report
 15 obtained from Dr Ten Cate, and then:
 16 "Review overall status with RBC and CB before
 17 discussing again with DHSS."
 18 So is it right to understand from this, then,
 19 that you, within Armour and you, yourself, personally,
 20 were already aware that there was a Dutch case of at
 21 least potential seroconversion, or actual
 22 seroconversion, but potentially from the Factorate
 23 heat-treated product?
 24 **A.** Yes, I can't recall the previous -- I can't recall the
 25 details of the previous reference to the Ten Cate

1 **Q.** Swartz, sorry.
 2 **A.** Germany, I think.
 3 **Q.** 17 February 86 -- copied to you:
 4 "Please find attached a copy of my memo on the
 5 above. You will note that our Department of Health
 6 wish to receive details of our viral inactivation
 7 studies of this product, including those involved with
 8 spiking using HTLV-III virus."
 9 Then if we go over the page, we can see the memo
 10 that's been provided, same date, this is a memo of
 11 Dr Harris to Mr Fitch, 17 February, copied to you.
 12 The first paragraph again refers to the receipt of the
 13 telephone call from Dr Rotblat at the Department of
 14 Health. If we pick it up about six lines into that
 15 first paragraph:
 16 "Dr Rotblat wanted confirmation that all our
 17 Factorate now being supplied is collected from
 18 individually AIDS tested donors; I gave her this
 19 confirmation and after discussing this with both Chris
 20 Bishop and Peter Lloyd it has been agreed that,
 21 although we still hold stocks of product from untested
 22 donors, this will no longer be supplied by us."
 23 Is it right to understand from this that prior
 24 to Dr Harris giving this confirmation on or about
 25 13 February, Armour had been supplying Factorate

1 collected from untested donors?

2 **A.** I don't know.

3 **Q.** We can see then in the third paragraph, it says --

4 sorry, I'll just wait until we've got to it:

5 "PAH [so that's Mr Harris], RBC [Mr Christie]

6 and CB [that's you] on 14th February met and agreed

7 an outline communication to send to our plasma field

8 force. RBC and PAH finalised this on Monday morning

9 for immediate transmission to the field force via

10 Chris Bishop's office."

11 Now I want to look at that document, please,

12 with you that was prepared to be sent to the field

13 force. It's at ARMO0000474.

14 We can see the date, 17 February '86, from

15 Mr Christie to the plasma team, subject "Heat treated

16 Factor VIII and AIDS risk":

17 "As you are aware Dr Peter Jones has made

18 observations at a recent AIDS Conference in Newcastle

19 that cast doubt on the efficacy of heat treatment of

20 Factor VIII products as a means of killing the

21 HTLV-III virus.

22 "You can rest assured that we have already

23 contacted the specialist in Holland and that we are in

24 the process of obtaining all of the details of the

25 Dutch case cited by Dr Jones. Having regard to the

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1 views expressed by Dr Tedder, that the HTLV-III virus

2 may have a much longer incubation period (up

3 to 4 years) than originally believed, any patients

4 previously treated with an unheated blood product

5 within the last four years could theoretically have

6 acquired an infection from this source.

7 "We therefore take the view that the statement

8 by Dr Jones was speculative and premature, and the

9 criticism from Professor Donald Acheson of the DHSS as

10 reported in the Guardian is worthy of note 'It was an

11 error of judgment for him to go public on scanty and

12 slender evidence'. The thousands of haemophiliacs who

13 needed the life-saving treatment could be confident

14 that they were receiving safe supplies."

15 Is it right, Mr Bishop, to understand from this,

16 the message Armour was sending to your sales team was

17 that haemophiliacs could be confident that

18 heat-treated Factorate was safe?

19 **A.** Yes, according to Professor Acheson.

20 **Q.** Well, the quote from Professor Acheson, who was the

21 Chief Medical Officer, seems to be about Dr Jones

22 going public on "scanty and slender evidence".

23 **SIR BRIAN LANGSTAFF:** The quotes stop after the word

24 "evidence".

25 **MS RICHARDS:** So the last sentence in bold print, as

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1 I read it, is Armour, not the Chief Medical Officer.

2 **A.** Well, that was our thoughts at the time, following

3 that -- Professor Acheson's statement.

4 **Q.** You knew -- Armour knew and you knew -- that you'd

5 been selling products from untested donors. You knew

6 of Dr Whitmore's Lewisham case, and of the Dutch

7 patient. On what basis could you then confidently

8 assert that the thousands of haemophiliacs who needed

9 the life-saving treatment could be confident that they

10 were receiving safe supplies?

11 **A.** That was based on the advice given to me by the

12 US and UK medical people.

13 **Q.** Did you say, "Hang on a second, why are we saying this

14 when we know there might be a patient treated in

15 the UK and a patient treated in the Netherlands who

16 seroconverted to HTLV-III, quite possibly after

17 receiving heat-treated Factorate"?

18 **A.** Until further information was available and proven

19 that, you know, there was no -- we were still

20 confident that our product was safe.

21 **Q.** So is it right to understand Armour's approach was

22 that, until it was proven, you could effectively

23 pretend that there were no such cases, at least in

24 terms of public messaging?

25 **A.** No, no, we weren't pretending anything. This was

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1 based on the evidence and the science available. We

2 weren't pretending anything.

3 **SIR BRIAN LANGSTAFF:** Can I just ask you again about your

4 use of words there. You're talking about being

5 "confident that it was safe until we had finished our

6 investigations".

7 **A.** Mm.

8 **SIR BRIAN LANGSTAFF:** But if you're investigating whether

9 it is safe, how can you be confident that it is,

10 without waiting? In other words, have you not got it

11 perhaps the wrong way around, that you can't be

12 confident until you've done the investigations and

13 they show there is no reason to worry?

14 **A.** Well, one way is a negative way of putting it, the

15 other way is a positive way.

16 **SIR BRIAN LANGSTAFF:** Yes. But there is a big difference

17 in what the accurate position might be, perhaps, might

18 there?

19 **A.** Well, I don't think so.

20 **SIR BRIAN LANGSTAFF:** Very well.

21 **MS RICHARDS:** Can we look next, then, and we're still in

22 February of '86, which was a busy month for Armour,

23 CGRA0000520.

24 This is Mr Christie to Dr Harris,

25 18 February 1986. It doesn't appear to have been

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1 copied to you, the "Copies to" is blank.
2 It refers to a further telephone call from
3 Dr Rotblat in the first paragraph. Fourth
4 paragraph talks about attempts to contact Dr Ten Cate.
5 And then there is further discussion recorded between
6 Mr Christie and Dr Rotblat.

7 The bottom of the page refers to:

8 "Dr Rotblat [asking] for our heat treatment
9 process which I gave to her -- 60°C for 30 hours. She
10 then asked for any viral inactivation studies that we
11 had to confirm that this was a lethal process for
12 spiked plasma samples. I promised to send everything
13 available [to her]."

14 Then if we go over the page, last paragraph:

15 "As you know, I am now obliged to report
16 Dr Whitmore's patient who sero-converted following
17 treatment with Factorate HT Y69402 (AIDS donor in
18 pool) to her as Dr Whitmore has confirmed that the
19 patient remains HTLV-III positive."

20 So some eight months or so, seven or
21 eight months after Dr Whitmore has told you -- when
22 I say "you", sorry, Armour -- about this patient, is
23 it right to understand that that case still had not
24 been reported to the Department of Health?

25 **A.** I don't know. This -- all this is really under

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1 the remit of the medical department. Now, whatever
2 I think or speculate about, you know, what appears in
3 these documents is not important, it's what
4 the medical departments and Department of Health are
5 discussing between themselves.

6 **Q.** Do you think, looking at things now, that Armour
7 should have reported Dr Whitmore's patient to the
8 Department of Health an awful lot sooner than February
9 of 1986?

10 **A.** No, that is a decision of the medical department, not
11 me.

12 **Q.** Can we look at ARMO0000489, please.

13 This is a letter 25 February 1986 from

14 Dr Peter Jones to Dr Harris at Armour. If we look at
15 the handwriting at the top, it says:

16 "RBC CC CB"

17 So it looks likely that a copy of this was
18 provided to you; yes?

19 **A.** Yes.

20 **Q.** If we look towards the bottom of the very long
21 paragraph, I just want to read the last few lines,
22 where Dr Jones says this:

23 "From the clinician's point of view I do not
24 think that we can afford to take a less pragmatic
25 approach of waiting for epidemiological studies to

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1 confirm or deny some sero-conversion in previously
2 untreated patients. I do not think that the Armour
3 material should be prescribed to previously untreated
4 sero-negative patients and am particularly averse to
5 its prescription for children."

6 Was there any discussion within Armour following
7 receipt of Dr Jones' letter about what he was there
8 saying?

9 **A.** I don't recall.

10 **Q.** And Armour continued, did it not, to sell Factorate
11 heat-treated for use, amongst other things, in the
12 treatment of children, because it continued to supply
13 haemophilia centres such as Birmingham with its
14 product?

15 **A.** I can't comment on that.

16 **Q.** Now, we know that on 27 February 1986 there was
17 a meeting in Fort Washington, in the States, to
18 discuss the issue about heat-treated product.

19 I'm not going to go to it, Mr Bishop wasn't there,
20 but the reference for you, sir, and for the
21 transcript, is CGRA0000514.

22 What I want show you, Mr Bishop, is a memo
23 copied to you which then discussed that meeting, so
24 ARMO0000496.

25 We can see from the bottom of the page this note

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1 is dated 28 February. Again, it's Dr Harris's
2 initials, copied to you and to Mr Christie.

3 If we go to the top of the page, it would appear
4 that Dr Harris is recording there -- well, first of
5 all, reference to a "Telephone conversation PAG".
6 Should that have been PAH, do you think?

7 Then "CB", and then "Anita Bessler 28.2.86".

8 So it looks as though you, Anita Bessler and
9 someone who might have been Dr Harris, were all having
10 a telephone conversation about this issue on
11 28 February; is that right?

12 **A.** PAG is Pauline Goldsmith, I think.

13 **Q.** Okay. But nonetheless CB is you, is not?

14 **A.** Sorry?

15 **Q.** CB would have been you?

16 **A.** I presume so.

17 **Q.** Yes. And then it says:

18 "Report of meeting held in Fort Washington to
19 discuss Factorate on 27.2.86 ..."

20 Then there is a reference to those who were
21 present at the meeting in Fort Washington. Then we
22 have a paragraph beginning:

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

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1 If we pick it up about six lines down, it says:
 2 "The net result of these discussions was that,
 3 in the opinion of everyone at the meeting, there is no
 4 problem with Factorate drawn from unscreened donors.
 5 However, it was felt that, just as with any ongoing
 6 improvements which have been mad with Factorate,
 7 adding the screening to the donor pool is an
 8 improvement to the product and we should, first of
 9 all, withhold from distribution all non-screened
 10 product, under one stipulation. This is that,
 11 withholding that non-screened product does not result
 12 in patients being unable to obtain a product or the
 13 potency they want when they order, or hospitals or
 14 physicians not being able to have access to the
 15 particular product that they have designated for the
 16 use of specific patients.
 17 "In other words, the meeting felt that there
 18 [was] no reason to believe there was a problem with
 19 non-screened product but, at least in theory, by
 20 screening, we will improve the product even more and
 21 we should do as much as we can to implement these
 22 improvements as quickly as possible."
 23 Then the next paragraph, it says:
 24 "In the meantime, it was considered there was no
 25 reason to cause any problems in terms of the normal

1 day to day delivery of Factorate to our customers, etc
 2 based on all of the information available to date. In
 3 terms of the US and UK and everybody else who has
 4 non-screened product in the inventory, we will
 5 continue to withhold the distribution of that product
 6 as long as, or unless, we only have that type of
 7 product to distribute within the market. In other
 8 words, it's a voluntary withholding, and not
 9 a withdrawal from the market."
 10 Can you recall the discussion that was had about
 11 this within Armour UK that you were privy to, about
 12 the Fort Washington recommendations?
 13 A. No, I can't recall.
 14 Q. Did you have any concern about -- if we just go to
 15 that long second paragraph "The meeting then
 16 reviewed", so I read out the sentence:
 17 "The net result of these discussions was that,
 18 in the opinion of everyone at the meeting, there is no
 19 problem with Factorate drawn from unscreened donors."
 20 Knowing, as you knew, that there was at least
 21 a possible case in the UK and a possible case in the
 22 Netherlands, do you recall having any concern yourself
 23 about Armour US concluding that there was no problem?
 24 A. No, I was -- well, I was going -- I was guided, as
 25 I always have been, by the US personnel, who were more

1 qualified than I am to, you know, to make these
 2 decisions.
 3 Q. Let's then just look at a report you pulled together
 4 early the next month, CGRA0000393. 3 March 1986 from
 5 you, "Status report on Factorate and HTLV-III/LAV
 6 sero-conversion".
 7 You set out, under the heading "Background",
 8 a chronology of events, beginning with Dr Jones at the
 9 Newcastle AIDS conference. I am not going to go
 10 through the details of that, and if we go over the
 11 page, you'll see then you refer 28 February '86 to the
 12 Fort Washington meeting, and then you record,
 13 3 March -- so the date of this report -- that there
 14 was a visit to the DHSS that day awaited. Then you
 15 identify a number of outstanding issues and I just
 16 wanted to ask you about that:
 17 "Disposal of existing unscreened product:
 18 "Mechanics [and]
 19 "Financial issues."
 20 Are you able to assist us in understanding what
 21 was meant by "disposal of existing unscreened
 22 product", were you talking about its destruction or
 23 its sale to other markets?
 24 A. That was the item for discussion, how it should be
 25 handled, what were the financial issues involved,

1 presumably as far as the marketing was concerned.
 2 Q. Then the next subparagraph says, "Revision of D&S",
 3 what was D&S?
 4 A. Demand and supply.
 5 Q. Then subparagraph (v) "Marketing position
 6 statement/strategy [relevant] to", and then you set
 7 out a number of matters, (f) is "Circular to all
 8 Haemophilia Centre Directors".
 9 Is it right to understand that you were keen that
 10 there should be some form of statement from Armour
 11 sent to haemophilia centre directors on this issue?
 12 A. Yes, yes.
 13 Q. We'll come on to look at, I think, a couple of further
 14 documents that address that. But before we do so, can
 15 we then, still in March 1986, look at ARMO0000505_001,
 16 please.
 17 This is a report from you to Dr Harris,
 18 6 March 1986 it would appear you were anticipating the
 19 UK haemophilia centres directors meeting that was
 20 going to be held on 17 March. You said this:
 21 "Following the above, at which it is anticipated
 22 most, if not all, the UK Directors will be present,
 23 a Meeting of the Haemostasis Club will be held, the
 24 topic being 'Blood Products'.
 25 What was the Haemostasis Club?

1 **A.** That presumably was within the UK directors
2 organisation.

3 **Q.** Well, if we read on, it might perhaps become clearer,
4 and prompt your memory. So the next paragraph records
5 a number of doctors who are going to be invited to
6 talk on various issues, including Dr Lane on
7 self-sufficiency. Then it says this:
8 "The Chairman will be Geoff Savidge from St
9 Thomas' who, together with Drs Kernoff and Preston,
10 are the leading advocates for the 'safer wet heat
11 treated' Alpha factor VIII (Profilate).
12 "I suspect that this could be a very cleverly
13 connived Meeting at the instigation of either these
14 three Clinicians or Alpha themselves to convert all
15 Directors to a product/s which can be shown to have
16 a better track record with regard to the elimination
17 of [non-A, non-B] hepatitis. It is also, obviously,
18 an attempt to expose the potential mid/long term
19 problems associated with liver disease in haemophilia,
20 as initially advocated by Hay et al in articles in The
21 Lancet during 1985.
22 "The attached letter in The Lancet ... from
23 Professor Schimpf from Heidelberg, further adds fuel
24 to the current argument and from which we can glean
25 little comfort in the light of our previous

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1 **A.** No, I can't recall -- I can only assume it was -- as
2 I said before, you know, a group of the UK haemophilia
3 centre directors.

4 **Q.** Now, why were you thinking that there was a cleverly
5 connived meeting at the instigation of the named
6 clinicians or Alpha to convert directors to a product
7 with a better track record than your own?

8 **A.** Well, it was a suspicion on my part, that was all.

9 **Q.** In that fourth paragraph, beginning "I suspect that
10 this could be", the last sentence says:
11 "It is also, obviously, an attempt to expose the
12 potential mid/long term problems associated with liver
13 disease in haemophilia ..."
14 Wasn't that a good thing, Mr Bishop? If there
15 were long-term or mid-term problems associated with
16 liver disease, shouldn't that be exposed so clinicians
17 would be informed --

18 **A.** Yes.

19 **Q.** -- and patients --

20 **A.** Yes. I don't criticise that.

21 **Q.** What were you criticising here then, Mr Bishop?

22 **A.** It's a fact. Sorry?

23 **Q.** You appear to have been very exercised by the prospect
24 of this meeting. Why was that?

25 **A.** Well, because of, you know, the evidence for the Alpha

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1 experiences with the Factorate Intermediate product."
2 Then you say this:
3 "However, I know you will appreciate the vital
4 significance and importance of this Meeting to
5 haemophiliacs, clinicians and the factor VIII
6 producers alike and, in your absence, Robert has
7 agreed to accompany me. I also strongly urge, in most
8 forceful terms, that Bill Terry or Mike Hrinda, or
9 somebody from the US attends this Meeting to hear the
10 story 'from the horse's mouth', and particularly as it
11 relates to our market position in the UK. Geoff
12 Savidge has kindly agreed to put questions on our
13 behalf to the panel and this will be an ideal
14 opportunity to obtain an authoritative opinion from
15 the leaders in the field on any subjects which are of
16 particular interest to us and I would suggest that one
17 or two very carefully constructed questions be
18 discussed between us and put to Geoff in advance."
19 Then, just over the page, the second paragraph
20 says:
21 "This is perhaps the most vital Meeting
22 affecting our plasma business which has yet been held
23 ..."
24 Does looking at that document more fully prompt
25 your recollection of what the Haemostasis Club was?

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1 product, and the enthusiasm, you know, being expressed
2 by leading clinicians for that product over the Armour
3 product.

4 **Q.** If we then go to ARMO0000512, this is a letter dated
5 13 March 1986, it's from Dr Harris. This is a blank
6 form, so it looks as though it was -- a form of letter
7 intended to be sent to haemophilia centre directors,
8 because it says in the first paragraph:
9 "Over recent months Haemophilia Centre Directors
10 have requested the HTLV-III ... inactivation data
11 relating to our heat treatment process ... In response
12 to those requests and having regard to recent media
13 comment, we set out below details of the viral
14 inactivation data along with other important
15 information."
16 Then there is information about that in the next
17 paragraph.
18 If we go two paragraphs further down:
19 "There has been no reported case of AIDS, and no
20 reported sero-conversion associated with the
21 administration of Factorate to a virgin patient not at
22 risk of AIDS."
23 Then there is reference to a publication and
24 then in the next paragraph to plasma collection
25 centres.

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1 Now, it might be said, Mr Bishop, that the words
 2 chosen there have been very carefully and deliberately
 3 chosen, by reference to "no reported sero-conversion
 4 associated with the administration of Factorate to
 5 a virgin patient not at risk for AIDS". There had
 6 been reported seroconversions associated with the
 7 administration of Factorate, had there not?
 8 **A.** Yes, yes.
 9 **Q.** We haven't looked at everything, but we have the
 10 Whitmore case and the Dutch case, yes? But does it
 11 concern you, looking at this now, that haemophilia
 12 centre directors were not being given a full, candid
 13 and transparent account of the current state of
 14 knowledge?
 15 **A.** (*Shook head*) No, I think, no ... no, this -- I mean,
 16 it's a long time ago, so I just do not recall the
 17 thinking at that time.
 18 **Q.** Okay, well, let's then look at --
 19 **A.** This letter, you see it's -- it would have been -- it
 20 would have come from the medical department. That is
 21 a statement of the medical people, that's not
 22 a statement from me, is it?
 23 **Q.** It's not, I'm asking your perspective as a senior
 24 marketing official, indeed, I think, manager of the
 25 plasma or biologicals division by this time in Armour,

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1 as to whether it concerns you that this was not
 2 necessarily the most complete and candid account that
 3 could have been given?
 4 **A.** I would have been guided by the medical people. What
 5 my -- I don't know what my personal views were at that
 6 particular moment in time but, as I say, you know,
 7 I would be guided by the medical department.
 8 **Q.** Can we look at --
 9 **A.** These are not marketing issues for which I would
 10 be -- I was responsible for, these are all medical
 11 scientific data questions, which were the
 12 responsibility of the medical departments.
 13 **Q.** But it's material being provided to the very
 14 individuals who you and your team are then approaching
 15 to try and sell your products?
 16 **A.** Yes, based on the information that I'd been given by
 17 the experts. I, in many of these cases, we and the
 18 plasma team were postmen.
 19 **Q.** Let's look, perhaps, at one further document before we
 20 break, 24 April 1986, from you, ARMO0000525. This is
 21 from you to Lofty Lucas, 24 April, and you say this:
 22 "Dear Lofty,
 23 "There is ample and increasing evidence to
 24 support the fact that our current heat treating
 25 process eliminates the HTLV-III virus ..."

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1 Then you refer to a paper. You've been at
 2 pains, Mr Bishop, to emphasise that medical and
 3 scientific matters were not your remit. But here is
 4 you highlighting what you say is the conclusion to
 5 draw from a particular scientific paper. Why is that?
 6 **A.** After discussion with them.
 7 **Q.** What --
 8 **A.** I wouldn't come out with the phrase "ample and
 9 increasing evidence" unless the medical people had
 10 cleared that. They would have cleared documents like
 11 this.
 12 **Q.** You record in the next paragraph that you've been
 13 advised by Professor Bloom that:
 14 "... 'treaters' are likely to play safe and go for
 15 the most severe heat treatment."
 16 Then in the next paragraph you say:
 17 "... there is currently a 'league table' for heat
 18 treatment effectively on HTLV-III as well as NANB and,
 19 as you are aware, unfortunately ours appears in the
 20 'relegation zone'.
 21 "Professor Bloom and other opinion leaders accept
 22 our HTLV-III viral inactivation data but I think we
 23 are now talking about a psychological barrier and
 24 treaters do not wish to be confused with facts!?"
 25 Are you able to cast any further light on the

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1 discussions that you'd been having with Professor
 2 Bloom on this issue?
 3 **A.** No, only the fact that, you know, as I say there, they
 4 accept our -- the effectiveness of our process against
 5 the HTLV-III.
 6 **Q.** As far as you know, had Professor Bloom and others
 7 been sent your HTLV-III viral inactivation data in
 8 full?
 9 **A.** I don't -- I can't say. I would imagine so, but
 10 I can't say.
 11 **Q.** Then if we just pick things up in the penultimate
 12 paragraph, so towards the bottom of the page --
 13 **A.** He would certainly have picked up the papers relating
 14 to our -- the process that had been.
 15 **Q.** Then the penultimate paragraph, you say:
 16 "I attach a copy of my memo of 27 October 1985,
 17 in which I made the point, very strongly, that a new
 18 viral inactivation procedure must be devised or
 19 licensed for both the existing product and MONO C.
 20 This was nearly six months ago now and I would have
 21 thought ample time to provide new data on a new heat
 22 treating procedure."
 23 So you, from a marketing perspective, at least
 24 had been advocating a change to the heat treatment
 25 process, had you?

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1 A. Yes.
 2 Q. Because doubts were being expressed about the efficacy
 3 of Armour's existing heat treatment protocol?
 4 A. Yes, it was a marketing issue. Irrespective of the
 5 effectiveness or otherwise of the Armour process,
 6 people were looking for stronger heat treatment for
 7 longer periods, and that was the concept.
 8 MS RICHARDS: Sir, I note the time, I've still got
 9 probably another 10 to 15 minutes or so on this
 10 particular topic, which is my last main topic.
 11 I wonder whether perhaps we have a short break now to
 12 give Mr Bishop a rest, amongst other things.
 13 SIR BRIAN LANGSTAFF: Yes, we will, but let me just ask
 14 one question first, if I may.
 15 Can we go back, please, Soumik, to ARMO0000512.
 16 This is the letter, I think, drafted by Dr Harris.
 17 You've told us that that's prepared by the medical
 18 side, you had no particular hand in it. But if this
 19 is sent to haemophilia centre directors, the first
 20 line of contact between Armour and them would be one
 21 of the sales force, would it?
 22 A. Yes.
 23 SIR BRIAN LANGSTAFF: So --
 24 A. Except possibly on issues like this, on the technical
 25 side, where clinicians could well contact the medical

1 department directly or through the sales people.
 2 SIR BRIAN LANGSTAFF: Well, if they were doing it through
 3 the sales team, the position, as I imagine it may have
 4 been but tell me if I'm wrong, would be that you or
 5 one of your team would go and have a word with the
 6 haemophilia centre director who was dealing with
 7 Armour product, and they might, perhaps, having read
 8 this, say, "Well, I've read what you say here about
 9 there is no reported case of AIDS and no reported
 10 seroconversion associated with the administration of
 11 Factorate to a virgin patient not at risk of AIDS, but
 12 what's this I've heard about what Peter Jones said in
 13 Newcastle about and I've read reports of it", because
 14 it got a certain amount of prominence in the press,
 15 did it?
 16 A. Well, on that particular issue, fellow haemophilia
 17 centre directors, and I've had this from the horse's
 18 mouth, were horrified at Peter Jones' statement.
 19 SIR BRIAN LANGSTAFF: So they knew about it.
 20 How would you answer them if they said, "Well,
 21 what is the safety of Factorate? Have you had
 22 seroconversions with Factorate at all?"
 23 Would this not give you a problem, marketing,
 24 that this is perhaps -- looks as though it's trying,
 25 it may be seen to be trying to evade the facts rather

1 than be what the ABPI, you told us earlier on,
 2 expected, which was to be accurate, which it may be,
 3 fair and objective? Would it give you a problem,
 4 marketing? How were you going to deal with it?
 5 A. It would depend how the discussion evolved. You know,
 6 I wouldn't have been at each individual discussion
 7 when these points were raised. I really can't, you
 8 know, add anything to that.
 9 SIR BRIAN LANGSTAFF: If the conversation had been with
 10 you, I don't know if any were, would you have said,
 11 "Well, actually I've been pressing since October the
 12 year before for a rather different viral inactivation
 13 process which uses more heat for longer"?
 14 A. Yes, if that was me personally, yes.
 15 SIR BRIAN LANGSTAFF: Thank you.
 16 That's all that I'm going to ask. Let's take
 17 a break now until quarter to 4. Quarter to 4.
 18 (3.24 pm)
 19 (A short break)
 20 (3.47 pm)
 21 SIR BRIAN LANGSTAFF: Yes.
 22 MS RICHARDS: Mr Bishop, I'm going to ask you to look now
 23 at a memo you sent in July of 1986, it's ARMO0000548.
 24 We can see the date from the top of the page,
 25 4 July, it's from you to, I think, the members of your

1 field force, your sales team. In the first
 2 paragraph you say:
 3 "... I enclose for your information a copy of an
 4 article from Cutter Laboratories ... [from] The Lancet
 5 ... virtually a repeat of a letter from the same
 6 Company ... of The Lancet ... [in] May.
 7 "Both these articles, besides attempting to
 8 clarify their own heat-treating procedure, identify
 9 ours as being implicated in the cases quoted.
 10 "The decision has been taken to respond to
 11 The Lancet within 2-3 weeks with a carefully prepared
 12 'defence' statement setting the facts straight. As
 13 soon as this document is prepared, copies will be
 14 forwarded to you together with a Technical Bulletin
 15 from Robert Christie. However, in the meantime, this
 16 subject is sure to be raised again and in order that
 17 you are well prepared, I enclose, besides copies of
 18 the recent Lancet letters, further copies of
 19 Robert Christie's Technical Bulletin and paper
 20 relating to the Dutch case, The Lancet article of
 21 March 15th relating to the Chapel Hill case and also
 22 the Technical Bulletin and paper prepared by
 23 Robert Christie of the 25th March on the McDougal
 24 article."
 25 You then refer to the McDougal paper. You say

1 the letter is very misleading. I'm not going to go
 2 through the detail of that. Then at the bottom of the
 3 page you say:
 4 "The defence document referred to above will be
 5 based on the following information which please feel
 6 free to discuss openly with any of your contacts but
 7 under no circumstances let copies be made."
 8 And if we go over the page, we'll see you say
 9 this -- thus far, am I right in understanding that
 10 what now follows is information you're suggesting your
 11 sales team use when questions -- or if and when
 12 questions are raised with them about Armour's product?
 13 **A.** Yes.
 14 **Q.** Okay. So you say:
 15 "The suggested implication of Armour
 16 heat-treated FACTORATE in HTLV III Ab sero-conversion
 17 is based on two cases, both of which received prior
 18 treatment with non-heat treated products."
 19 Then you refer to the Dutch case. I'm not going
 20 to go through the detail of it. That's case 1.
 21 Case 2 you refer to is a, I think, a US case, the
 22 Chapel Hill case, and you refer there to a line set
 23 article. Then you say:
 24 "The 'defence' against FACTORATE should take
 25 into consideration the following factors ..."

1 **Q.** -- in Pennsylvania.
 2 So it's CGRA0000521, please, Soumik.
 3 We'll see top of the page:
 4 "In the Court of Common Pleas of Philadelphia
 5 County, Pennsylvania."
 6 Then if we go further down the page:
 7 "Oral deposition of Christopher Roy Bishop.
 8 "Held at: Richards Butler, Solicitors ...
 9 London ... June 6th, 1990."
 10 Now what we have, Mr Bishop, is a very
 11 incomplete record, so we only have some pages, not all
 12 or, indeed, most of the deposition. But if we go to
 13 page-- it's probably page 12, electronically, Soumik.
 14 You'll see, and it's not entirely easy to follow
 15 this document, Mr Bishop, as you may recall if you've
 16 re-read it, because there's lots of objections from
 17 the American lawyers involved to the questions. But
 18 you were being asked -- and if we pick it up at
 19 line 15 and 16, you're being asked in the July
 20 document -- which may be a reference to the document
 21 we were just looking at -- why you hadn't mentioned
 22 Dr Whitmore's patient. And the bottom of the page you
 23 give an answer. You say:
 24 "The reason it did not appear in that is,
 25 I repeat my earlier statements, referring to

1 Then you refer to various studies.
 2 Then if we go over the page, you then refer to
 3 various personal communications, so said to be
 4 a personal communication from Dr Anna Pettigrew in
 5 Glasgow, a personal communication from Smit Sbinga in
 6 Groningen, from what's said to be Maggs, University
 7 College, London. That, I think, is probably
 8 Dr Bolton-Maggs. And then Dr Kernoff and Amsterdam.
 9 And then you list a number of centres, and you say:
 10 "No reports from the above, almost exclusively
 11 on Armour, or other UK Centres of sero-negative
 12 conversions since UK introduction of HT product in
 13 November/December 1984."
 14 Now, what's missing from this, Mr Bishop, is any
 15 reference to Dr Whitmore's case in Lewisham. Why was
 16 that?
 17 **A.** I don't know. I don't know.
 18 **Q.** The one case that you know had been reported, you're
 19 not telling your sales team about?
 20 **A.** Whether that was because it was still under review,
 21 I don't know.
 22 **Q.** I think in fairness, Mr Bishop, I should probably show
 23 you what you said about this issue when you gave your
 24 deposition in 1990 in the proceedings --
 25 **A.** Okay.

1 Mr Christie's memo again, or these two memos in there
 2 now, which refer to the confidential nature of that
 3 information. And again, referring to my previous
 4 statement where I said that unless material is cleared
 5 by the clinical and technical affairs department it
 6 would not appear in a sales and marketing document."
 7 Then if we look down the same page to line 18
 8 onwards, question:
 9 "In that context, what about again Dr Whitmore's
 10 patients?
 11 "A. Well, we weren't authorised to make
 12 reference to Dr Whitmore's patient.
 13 "Q. And who withheld authorisation?
 14 "A. Precisely who, I do not know, but it would
 15 have been ... We would not have had permission from
 16 that department to include that report in the sales
 17 and marketing document."
 18 And then over the page, we pick it up at
 19 line 13, you're asked by Mr Shrager:
 20 "To what department do you refer - 'withheld
 21 authorisation'?
 22 "A. Clinical and medical - technical affairs
 23 department of Revlon UK.
 24 "Q. Is it your best recollection now that we
 25 have reviewed this that you took up with them the

1 subject of Dr Whitmore's patients and they told you
 2 not to refer to them?
 3 "A. I can't recall specifically taking up the
 4 case of Dr Whitmore."
 5 Then, bottom of the page, you were asked:
 6 "Is it your best recollection that that
 7 department did withhold authorisation?"
 8 Go to the next page. The question is repeated
 9 lines 3 to 4. Your answer at line 5:
 10 "Yes, because thinking back I do recall
 11 a specific request from Dr Whitmore that this
 12 information should be deemed highly confidential."
 13 And you give a little more information about
 14 that. Line 12:
 15 "Q. So that bench mark for whether or not you
 16 were to report was whether you had permission from the
 17 clinician?"
 18 "A. The bench mark for the medical and
 19 technical affairs department, whether to act upon
 20 that, would have been from the clinician. My bench
 21 mark would have been the permission from the critical
 22 and technical, medical affairs department."
 23 A question Revlon might answer:
 24 "Yes."
 25 Now, I don't know whether -- actually, sorry to

1 just complete it, over the page, so that we don't need
 2 to look back at this document, Mr Bishop. Line 11:
 3 "New question: as of July 1986 as the director
 4 of marketing were you seriously concerned about the
 5 adverse impact on your sales of haemophiliac by
 6 discussion in the literature of alleged
 7 seroconversions in associations with the product?"
 8 "A. I was concerned at the interpretation being
 9 place by competition especially on those reports."
 10 I just wanted to show you that out of fairness,
 11 Mr Bishop, because I'm asking you about events a long
 12 time ago. You appear to be saying in this deposition
 13 that you didn't include reference to Dr Whitmore's
 14 patient because you didn't have permission from your
 15 Regulatory Affairs Department to do so?
 16 **A.** That's the same point, it's the same as the
 17 US deposition, isn't it? I didn't have permission --
 18 I didn't have the clear -- clearance from my medical
 19 department. At the same time as I said in the US
 20 deposition.
 21 **Q.** So if we just go back to ARMO0000548, page 3, do we
 22 understand then, looking at this list of
 23 communications, that you did have express permission
 24 from your Regulatory Affairs Department to record what
 25 Dr Pettigrew, Smit Sbinga, Dr Bolton-Maggs, Dr Kernoff

1 and all of the various centres listed there were
 2 telling you, but you didn't have permission to include
 3 reference to the one patient believed to have
 4 sero-converted in the UK?
 5 **A.** That would appear to be the case.
 6 **Q.** Why was permission from your Regulatory Affairs
 7 Department required for you to tell your own sales
 8 team, your own Armour employees, that there was indeed
 9 a case in the UK of sero-conversion on heat-treated
 10 Factorate?
 11 **A.** Why was that, sorry?
 12 **Q.** Why was permission required from the Regulatory
 13 Affairs Department for you to tell your own staff
 14 about this case?
 15 **SIR BRIAN LANGSTAFF:** I'm not sure that's --
 16 **A.** Because that's where I took my instructions from
 17 regarding talking on regulatory and medical matters.
 18 **SIR BRIAN LANGSTAFF:** I think there may be a prior
 19 question, which is whether he did tell his own staff,
 20 because this document is designed, as I understand it,
 21 for his sales force to tell others, so this is
 22 a question of what they should tell doctors, not what
 23 they should themselves be told.
 24 **MS RICHARDS:** I'll ask that logically prior question, sir,
 25 you're quite right.

1 Did you tell your own staff about the Lewisham
 2 case?
 3 **A.** I don't recall. Probably not.
 4 **Q.** Probably not.
 5 Did you say to whoever it was you were dealing
 6 with in the Regulatory Affairs Department, "I'm very
 7 uncomfortable about the sales line I'm telling my
 8 staff to take because we are concealing the one
 9 positive case we know about"?
 10 **A.** No, no, it wasn't -- no, no, it wasn't my place to
 11 question what they were saying.
 12 **Q.** Were you uncomfortable about the fact that this one
 13 positive case was not being referred to?
 14 **A.** No, I don't recall one way or the other. I'm sure if
 15 I had -- if I had some concerns, there would have been
 16 some official document somewhere in the volumes
 17 expressing that displeasure or unease to -- officially
 18 to the medical department.
 19 **Q.** And so it's right, isn't it, to read this document,
 20 which, as the chair rightly points out, is what you
 21 were telling your staff to tell clinicians -- would
 22 you accept, it's giving clinicians an incomplete
 23 picture? It's missing one crucial piece of
 24 information, isn't it?
 25 **A.** No, not at all.

1 Q. Why is it relevant for clinicians --
 2 A. The details of those cases were not -- as far as
 3 I remember, were not finalised, and the
 4 confidentiality of the clinician should be respected.
 5 So I had no qualms about not including them,
 6 notwithstanding the fact that the medical department
 7 didn't clear it.
 8 Q. Now, we've saw from the first page of this letter that
 9 you were advocating a defence statement, essentially
 10 defending Armour's product, defending its viral
 11 inactivation process?
 12 A. Mm.
 13 Q. If we look next at CGRA0000527, this is from you to
 14 Dr Harris, 16 July 1986. It says:
 15 "In the light of the US refusal to originate
 16 a Defence Document as discussed, I propose the
 17 following to form a basis for a UK originated
 18 document."
 19 Just pausing there, do you know why the US was
 20 refusing to do the defence document that you'd asked
 21 for?
 22 A. No, I don't.
 23 Q. Then we see:
 24 "Objective
 25 "1. To nullify negative impact of the published

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1 You said in next paragraph you'd been told they
 2 were initiated by the actions of Dr Peter Jones. You
 3 then say in the next paragraph:
 4 "It may well be, and it's to be hoped, that the
 5 majority of Doctors will view the articles in the
 6 light of this objective ..."
 7 The objective being to, you say, for Dr Jones to
 8 justify what he'd said in Newcastle.
 9 "... and the contents immediately discredited."
 10 Then you set out a number of comments. So these
 11 are points first of all made by reference to the New
 12 Scientist article. Bottom of the page you say this:
 13 "The two Britons referred to have not been
 14 proven and are still undergoing tests and
 15 investigations, but there is yet no proof that they
 16 developed antibodies as a result of treatment with
 17 Armour's FACTORATE."
 18 Why were you seeking to emphasise that point,
 19 Mr Bishop?
 20 A. Well, I think it's obvious, to protect the good name
 21 of the Armour product.
 22 Q. Over the page you assert that:
 23 "The Dutch patient was not, repeat not, a clean
 24 virgin patient."
 25 Then you say, by reference to a comment on the New

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1 'sero-conversion' stories.
 2 "2. To restore/confirm confidence in our heat
 3 treating process regard HIV inactivation.
 4 "3. To demonstrate our faith in our own
 5 product."
 6 Those objectives are all about Armour keeping
 7 hold of its market share, are they not? They don't
 8 relate to patient safety at all?
 9 A. That, by our people, would be implicit and understood.
 10 Q. Okay. And then, "Suggested format", I don't think we
 11 need to go through the details of that, but you
 12 suggest some points that should be made, and then you
 13 conclude:
 14 "I would emphasise that this document is
 15 essential for the maintenance of FACTORATE business in
 16 our markets."
 17 A. Yes.
 18 Q. If we then turn to a memo you sent a couple of days
 19 later to your sales force, ARMO0000562. So this is
 20 another house message, 18 July, from you to the sales
 21 team:
 22 "Factorate recall - Media response:
 23 "As discussed with you individually, I enclose
 24 copies of the New Scientist and Guardian articles of
 25 the 17th July on the above mentioned subject."

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1 Scientist article, paragraph 2:
 2 "The whole tone of this paragraph is an attempt
 3 to undermine Armour's objectives and integrity. Yes,
 4 we did want to keep the exchange low key in order not
 5 to cause adverse publicity and, this, distress to the
 6 patient. We would emphasise that the recall was
 7 voluntary and agreed with the Department of Health."
 8 In what sense would you say, or did you consider
 9 Armour had demonstrated integrity in the process that
 10 we've been looking at in relation to its heat-treated
 11 Factorate product?
 12 A. Well, by keeping them informed via the -- by the sales
 13 force -- information given to the sales force.
 14 Q. Sorry, I didn't quite --
 15 A. We were keeping -- we were keeping them totally up to
 16 date on our position with regards to the papers and
 17 publicity that was being published.
 18 Q. You can't have been keeping your own sales force
 19 completely up to date if you weren't telling them
 20 about Dr Whitmore's Lewisham patient, can you?
 21 A. We've already covered why we didn't include the
 22 Whitmore patient.
 23 Q. If we look at the third page of this document --
 24 again, I'm not going to go through your detailed
 25 comments on the New Scientist and Guardian articles.

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1 You say this in the third paragraph:
 2 "It is now a feeling, and that of our advisors,
 3 (who include members of the UK Haemophilia Centre
 4 fraternity) ..."
 5 Just pausing there. Who were your advisors who
 6 were "members of the UK Haemophilia Centre
 7 fraternity"?
 8 **A.** That was the committee of the Haemophilia Society --
 9 the UK Haemophilia Society.
 10 **Q.** So you're not, there, referring to any clinicians?
 11 **A.** Well, it could be -- it could be -- yes, it could
 12 include any physicians that had, you know, made
 13 comment. I can't recall any specific ... I certainly
 14 recall discussions with some directors about --
 15 about the way, you know, the publicity was being --
 16 these things were being covered by the -- not only the
 17 lay press, but by the medical press.
 18 **Q.** And then continuing with that paragraph:
 19 "... our feeling, and that of our advisors ...
 20 that these articles be treated with the contempt they
 21 deserve and, therefore, we propose to take no further
 22 action other than discussion by you with individual
 23 doctors who may express some concern which you are in
 24 a position to discuss on a sensible level."
 25 And then this. You say:

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1 "Unfortunately, the mention of Dr Michael
 2 Rodell's statement that we are reviewing our heat
 3 treatment process now prevents us from preparing an
 4 official 'defence document/article' to The Lancet,
 5 which would not be totally misconstrued by those
 6 wishing to cast dispersions on the Armour operation.
 7 We can not on the one hand defend our existing
 8 treatment and then immediately introduce a new one,
 9 although the reasons for introducing the new process
 10 are primarily to attack the NANB problem."
 11 **A.** Yes.
 12 **Q.** It might be said that you're expressing a degree of
 13 frustration, or -- that Armour was reviewing its heat
 14 treatment process. Is that right, or wasn't that
 15 exactly what you'd been arguing for months previously?
 16 **A.** It was, yes. And that was to -- you know, to counter
 17 the perception that hotter for longer was better,
 18 although we showed our -- you know, our treatment was
 19 more than effective in -- against HTLV-III.
 20 **Q.** Do you now understand, Mr Bishop, even if you didn't
 21 at the time, that Armour's viral inactivation process
 22 was not effective in eradicating HTLV-III, or are you
 23 still maintaining the view that it was effective?
 24 **A.** As I understand it, it is -- it was effective.
 25 **Q.** Okay.

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1 **A.** Against HTLV-III, but not non-A, non-B.
 2 **Q.** Let's conclude the saga in relation to heat-treated
 3 Factorate by looking at ARMO0000585.
 4 This is a memo of 29 September 1986, from
 5 Mr Christie. It's copied to you and to Dr Harris. It
 6 refers to a communication from Dr Frank Hill at
 7 Birmingham Children's Hospital:
 8 "Dr Hill rang me this morning to report two
 9 haemophilic children who had sero-converted to HIV
 10 antibody positive following a long course of Armour
 11 Heat Treated Factorate. Both children had received
 12 NON-Heat Treated Factor VIII products but not since
 13 1984.
 14 "Dr Hill agreed that this incident should be
 15 reported to the DHSS and he also believed that
 16 a publication describing his experience should be
 17 prepared."
 18 And then details are given of the cases and
 19 batches of product.
 20 If we go over the page, you'll see, Mr Bishop,
 21 the lists of batch numbers, and then they have either
 22 an asterisk or two asterisks beside them.
 23 If we go further down the page, just below that
 24 list, we can see the meaning of those asterisks. So
 25 a single asterisk is a "Non-donor screened - on recall

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1 list", a double asterisk is "Non-donor screened - not
 2 on recall list", and then the final mark refers to
 3 "Donor screened product".
 4 Can we just go back and look at the list at the
 5 top of the page. I'm just taking this case by way of
 6 example.
 7 It would appear from this that there had been
 8 some treatment of a child with the non-donor screened
 9 product that was not on the recall list.
 10 Can you help us understand why unscreened
 11 product had not been recalled and was still in use for
 12 the treatment of children?
 13 **A.** No, no. Which are the non-screened?
 14 **Q.** So the double asterisk is the non-donor screened, not
 15 on recall list, the single asterisk is non-donor
 16 screened but on the recall list.
 17 Do you understand the difference between what
 18 batches were recalled and what weren't?
 19 **A.** It could well have been that they -- Frank Hill chose
 20 not to return the unscreened product because of
 21 whatever reason, whether it's shortage of stock at the
 22 time, or whether -- I don't know, I can only assume
 23 that's a decision by the hospital, not by Armour.
 24 **Q.** What was your reaction on learning that children at
 25 the Birmingham Children's Hospital had been infected

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1 with HIV following treatment with Armour's Factorate
 2 heat-treated product?
 3 **A.** Well, obviously, devastated.
 4 **Q.** Did you continue to think that there was no problem
 5 with the product and that it should be proactively
 6 defended?
 7 **A.** Where are we, September '86? Well, we're coming up to
 8 the period then of discontinuation of the products,
 9 aren't we?
 10 **Q.** Yes, very shortly afterwards it was withdrawn, and
 11 we'll come on to that shortly in a moment, but what
 12 was your own view in relation to whether the product
 13 should be withdrawn or should continue to be supplied?
 14 **A.** What, coming up to that period?
 15 **Q.** Once you learnt on 29 September that there were these
 16 additional cases now involving children at the
 17 Birmingham Children's Hospital, can you recall what
 18 your thinking was about what should now be done?
 19 **A.** No, I can't, I'm sorry.
 20 **Q.** Now we know that there was a meeting with the DHSS on
 21 3 October, another on 6 October. You were not at
 22 those meetings so I'm not going to ask you about them.
 23 Can I ask you to look at, however, at a very short
 24 note of a meeting you were at, CGRA0000530.
 25 So this is headed "Factorate - General recall -

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1 October 1986, Recall Committee Meeting - Tuesday,
 2 7th October - 0800 hrs."
 3 **A.** This was the day after the meeting with the DHSS, was
 4 it?
 5 **Q.** It looks like that, yes.
 6 **A.** Yes.
 7 **Q.** It says:
 8 "London Meeting."
 9 And then it's got a list of attendees, which
 10 include you, and then it says the "Asterisked
 11 personnel attended DHSS", so that didn't include you,
 12 so --
 13 **A.** That's --
 14 (Unclear - simultaneous speakers)
 15 **Q.** -- you didn't go to the DHSS --
 16 **A.** We had to stay in the hotel.
 17 **Q.** But there appears to be an account of the meeting.
 18 It's said that:
 19 "Jefferies [that's Dr Jefferies, who was from the
 20 DHSS] cut across all Armour arguments about new
 21 developments etc to require withdrawal.
 22 "PAH [that's Dr Harris] summarised our case
 23 including gaps in knowledge of seroconversions
 24 together with donor-testing on current product.
 25 "From DHSS - heat treatment is invalidated -

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1 Armour has seroconversions and no-one else has.
 2 Licence would be revoked if product not withdrawn."
 3 It's right, isn't it, that Armour was
 4 effectually given no choice now; it was told in terms
 5 by the Department that the licence would be withdrawn?
 6 **A.** Yes.
 7 **Q.** Do you recall the discussions that took place that
 8 morning about what to do?
 9 **A.** Not specifically, no.
 10 **Q.** We know, I'm not going to --
 11 **A.** Those action points were obviously agreed.
 12 **Q.** We know that on 7 October there is a letter announcing
 13 the withdrawal of Factorate, there is a press release,
 14 I'm not going to take you to those.
 15 Do you know what was done with the product that
 16 was held in Haemophilia Centres at that point in time?
 17 Was it all returned to Eastbourne; and, if so, what
 18 was then done with it?
 19 **A.** It would obviously be returned but I don't know how it
 20 was disposed of.
 21 **Q.** Do you know if was sold elsewhere, in other countries?
 22 **A.** No, certainly not. No, it certainly would not have
 23 been.
 24 **Q.** Was heat-treated Factorate withdrawn from other
 25 markets at this time, or just in the United Kingdom?

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1 **A.** I believe it was just the United Kingdom.
 2 **Q.** Did you have concerns about -- I'm sorry, carry on?
 3 **A.** No, no.
 4 **Q.** You had responsibility for a bigger geographical area,
 5 Netherlands, Scandinavia, Ireland, et cetera. What
 6 consideration can you recall being given to
 7 withdrawing the product in any of those other
 8 countries?
 9 **A.** Well, the products were withdrawn and that was it.
 10 These markets were supplied from the UK.
 11 **Q.** I'm asking just now a number of rather more general
 12 questions reflecting on the issues that I've been
 13 asking you about.
 14 Did the discovery from Dr Hill that children had
 15 seroconverted on the Armour product -- and there is
 16 reference in the documents I won't take you to a third
 17 case coming to light very shortly afterwards -- did
 18 that lead to any reflection within Armour about how it
 19 had dealt with this whole issue of its viral
 20 inactivation process?
 21 **A.** I can't recall, after 30 or 40 years.
 22 **Q.** Was there ever, that you can recall, any attempt
 23 within Armour to look back to see what had gone wrong,
 24 whether in relation to its heat-treated product or its
 25 un-heat-treated product?

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- 1 **A.** I can't -- I can't -- I can't believe that we even
2 thought that we'd done anything wrong. On the
3 contrary, as a company, we'd done everything possible
4 to provide the best possible treatment and the most
5 up-to-date systems in accordance with the state of art
6 at that time. It's very easy to be Monday morning
7 quarter backs who will have the benefit of hindsight.
- 8 **Q.** You may have effectively answered by next handful of
9 questions by that response, Mr Bishop, but I'm going
10 to ask them anyway.
- 11 Is there anything you think you or Armour should
12 have done differently with regards to your
13 non-heat-treated product?
- 14 **A.** No.
- 15 **Q.** Anything you or Armour should have done differently in
16 relation to the heat-treated product?
- 17 **A.** No.
- 18 **Q.** Having regard to the documents that we've looked at
19 today, do you accept that Armour should have withdrawn
20 the heat-treated product earlier than October 1986?
- 21 **A.** No, I do not accept that.
- 22 **Q.** Do you accept that Armour should have been more open
23 and transparent with the information it was providing
24 to clinicians about possible risks from its
25 heat-treated product?

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- 1 **A.** No, I think we did everything we could with the
2 information that we had available on any patient or
3 the disease, or what have you. We at all times -- you
4 know, we did, I feel -- and I'm very proud of the fact
5 that we did do everything in the right way.
- 6 **Q.** Were any lessons learnt by Armour from what had
7 happened?
- 8 **A.** Not that I -- no, no specific lessons because we, you
9 know -- again, you know, with the benefit of hindsight
10 lots of things could be done differently. But we
11 didn't, you know, we didn't have benefit of hindsight.
- 12 **Q.** It might be said, at least in relation to the
13 1985/1986 period that we've been looking at, that
14 Armour's overriding focus was concern about losing
15 ground to the competition rather than ensuring the
16 safety of patients treated with its product. Do you
17 have any comment on that?
- 18 **A.** That was my -- as a marketing person, for which I was
19 employed, that was a major concern, commensurate and
20 secondary only to the safety factor and the welfare of
21 the haemophiliac patient and his family and the teams
22 looking after him.
- 23 **MS RICHARDS:** Sir, those are questions I had for
24 Mr Bishop, but we now obviously need to give
25 an opportunity to the CPs, through their recognised

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- 1 legal representatives to suggest any further questions
2 that they wish me to explore with Mr Bishop, so
3 although it means sitting later this evening, could we
4 take a break now to give people a proper chance to
5 suggest any further lines of questioning.
- 6 **SIR BRIAN LANGSTAFF:** Yes. Let me just explain to you,
7 Mr Bishop, all of the questions you've been asked,
8 apart from the odd question by me, have been asked by
9 Ms Richards, who is counsel to the Inquiry, and she
10 will ask the questions, unless -- it's unlikely --
11 there is any particular application for anyone else to
12 ask you one.
- 13 **A.** Okay.
- 14 **SIR BRIAN LANGSTAFF:** But at this stage it is usual for
15 her to field questions. There are a lot of Core
16 Participants who have different approaches to the
17 Inquiry who are entitled to ask questions of you, and
18 we must give them an opportunity to formulate those
19 and counsel to work out how she's going to put those
20 points to you. So it will take a little while.
- 21 It always happens with every witness, I don't
22 know if you've seen any of our proceedings before, but
23 this is standard, and it does mean, I'm afraid, that
24 we're going to have to ask you to stay on a bit. We
25 won't come back before 4.45. I hope by then we may be

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- 1 ready, we may not, you'll be told if there is
2 a further delay. But after that, just to give you
3 an idea of timing, I would expect probably, but
4 I can't say, because I don't know how many questions
5 there will be, that you should be finished before 5.30
6 and probably a little bit before that. I hope that
7 helps with your planning.
- 8 **A.** That's fine, Sir Brian, thank you.
- 9 **SIR BRIAN LANGSTAFF:** Well, we'll take a break then until
10 4.45.
- 11 **(4.23 pm)**
- 12 **(A short break)**
- 13 **(4.58 pm)**
- 14 **SIR BRIAN LANGSTAFF:** Yes.
- 15 **MS RICHARDS:** Mr Bishop, I've got a number of questions
16 that I'm going to ask you now. Because they've come
17 from a number of different sources, they'll move
18 around from topic to topic.
- 19 You referred to your team as being "plasma
20 specialists". What training or expertise would your
21 team have had in the risks of viral transmission from
22 pooled products?
- 23 **A.** The training would be relating to the published
24 clinical papers at the time. That would be an ongoing
25 and progressive thing. Plus the state of art

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1 knowledge that existed, you know, at the time. It was
 2 continuing -- continual training process, and
 3 attendance at world -- national symposia, where all
 4 the scientists and everybody was, you know, presenting
 5 papers and posters, that they would access to that,
 6 and it would be an ongoing training process.

7 **Q.** You said this morning in your evidence that in 1976
 8 the general public knew of the risk of hepatitis B
 9 from blood and blood products. What's the source of
 10 your understanding of the general public's knowledge
 11 of hepatitis B?

12 **A.** Well, I just assumed that everybody knew the problems
 13 with hepatitis B, and hepatitis C, because, you
 14 know -- well, as I say, I thought it to be general
 15 knowledge.

16 **Q.** You referred to you having more contact with the
 17 leading opinion formers in the larger centres. Who
 18 would you identify as the leading opinion formers in
 19 the late 70s and early 80s?

20 **A.** Without upsetting anybody, I suppose Dr Rizza and
 21 Peter Kernoff, Professor Bloom, Frank Hill,
 22 Eric Preston, Charlie Hay. There is many of them.

23 **Q.** How was Armour able to offer its product to the market
 24 in the UK at a lower price than its competitors?

25 **A.** Well, that was just a decision made by the US in

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1 relation to, you know, sales and marketing plans, and
 2 I can't say how exactly the price was arrived at,
 3 except to say that the profit made from selling at
 4 that price would have been acceptable and in the
 5 budgeted numbers.

6 **Q.** Did you --

7 **A.** And acceptable.

8 **Q.** Did you, yourself, ever visit a Plasma Alliance centre
 9 in the States?

10 **A.** Yes, Knoxville -- at Knoxville, yeah.

11 **Q.** Can you recall roughly what year that might have been,
 12 or what decade?

13 **A.** No, I can't. No, I can't. Well, as did a number of
 14 UK haemophilia centre directors, including
 15 Peter Jones, et cetera.

16 **Q.** I'd asked you earlier about Armour managing to sell
 17 its product in Scotland, which, broadly speaking, had
 18 been less reliant on commercial products, and we
 19 looked at the figures for the Yorkhill Hospital in
 20 Glasgow and Edinburgh. Do you recall which individual
 21 or individuals in your sales team was responsible for
 22 selling products to the Scottish market in the
 23 late 70s and early 80s? Was it you or was there
 24 another particular individual?

25 **A.** It would have -- I'm trying to think of the plasma

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1 specialist for the north at that time. It would have
 2 been a combination of myself and the northern plasma
 3 specialist at that time.

4 **Q.** Were any particular incentives offered by Armour to
 5 the Yorkhill Hospital in Glasgow to break into the
 6 Scottish market?

7 **A.** Absolutely not, no.

8 **Q.** When testing for HIV became available, were all prior
 9 and current batches tested for positivity?

10 **A.** I don't recall.

11 **Q.** The same question in relation to the availability of
 12 testing for hepatitis C. Do you recall whether
 13 batches were tested for positivity?

14 **A.** No, I don't recall.

15 **Q.** What, if any, investigations were undertaken within or
 16 on behalf of Armour to establish whether there was
 17 ultimately HIV positivity in the batches of
 18 heat-treated Factorate said to have been associated
 19 with HIV infections in the UK?

20 **A.** I don't recall.

21 **Q.** Are you aware of Armour settling legal claims, whether
 22 Armour UK or Armour US, arising out of treatment with
 23 Factorate HT?

24 **A.** No. The UK certainly there was no litigation.

25 **Q.** When I asked you this morning about your interactions

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1 with the Haemophilia Society, you said you met them
 2 fairly frequently, every month or so it might have
 3 been, but you didn't alert them in 1985 and 1986 to
 4 the possibility that Armour's heat-treated product
 5 could be infected. Why not, and how did that fit with
 6 what you described Armour's ethos to have been?

7 **A.** It may well have been unofficially discussed, but The
 8 Haemophilia Society and, indeed, individual patients,
 9 were very, very well informed about their condition
 10 and about the -- you know, about the science. You
 11 know, more so, I think, than any other specialty. So
 12 they, you know, they may well have been -- you know,
 13 found out things for their own -- in their own
 14 observations.

15 **Q.** Would it not have been more in keeping with what you
 16 describe Armour's ethos to have been, to tell, not
 17 unofficially but officially, The Haemophilia Society
 18 of the concerns that the heat-treated product might
 19 have been infected?

20 **A.** No, again, that would have been under the direction of
 21 the medical department. I think possibly that -- the
 22 concern about the divulging too much unproven
 23 information would have been -- had the same impact as
 24 the -- Peter Jones' premature statement at that AIDS
 25 meeting.

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- 1 Q. I asked you whether you told your own sales staff
2 about the Lewisham case, Dr Whitmore's case, and you
3 said "probably not". Even if you were prevented by
4 the Regulatory Affairs Department from telling
5 clinicians about that case, why did you not tell your
6 own staff?
- 7 A. I can't remember specifically if we did or not, but
8 obviously the plasma specialist responsible for that
9 region will, of course, have been acquainted with it
10 by his or her meetings with Dr Whitmore. But because,
11 you know, everything was not proven and above board,
12 one was very careful, they were very careful as to how
13 that information was divulged, and to whom.
- 14 Q. During the second half of the '70s, first half of the
15 '80s, did you or your team show or give to your -- the
16 clients, the customers to whom you were trying to sell
17 your product, any materials that would compare the
18 risks posed by Armour products to the risks posed by
19 Armour's competition?
- 20 A. Only in terms of the technical bulletins that were
21 issued to the plasma team.
- 22 Q. Sorry, that's bulletins provided to the plasma team?
- 23 A. **(Unclear - simultaneous speakers)**
- 24 Q. Was comparative material comparing Armour as against
25 other products, Alpha's or whoever's, part of the

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- 1 marketing materials you provided haemophilia centres
2 with?
- 3 A. Only in the form of the, you know, of the plasma
4 bulletins. I don't recall distributing any specific
5 information, as in -- you know, in tabular form,
6 comparing the different companies.
- 7 Q. As we established this afternoon, Armour withdrew its
8 heat-treated product from the UK market in
9 October 1986, and indeed relinquished its licence in
10 October 1986?
- 11 A. Yes.
- 12 Q. The Krever Report suggests that the Dutch Government
13 in the Netherlands recalled heat-treated Factorate in
14 February 1988. Can you recall that, or what led to
15 that?
- 16 A. No. No.
- 17 Q. The products having been withdrawn from the UK market
18 in October 1986, what, if anything, did you tell
19 people in the other markets for which you were
20 responsible about that withdrawal or about the safety
21 or otherwise of the Armour product?
- 22 A. Well, the specialist responsible for the other markets
23 would be -- would have the same information and,
24 presumably, it would be discussed with the other
25 countries. But I can't recall whether, you know,

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- 1 direct correspondence went to haemophilia centres in
2 the other countries from the Medical Department.
- 3 **(Unclear - simultaneous speakers)**
- 4 Q. Okay. In relation to those other countries for which
5 you were responsible, do you recall any express
6 consideration being given within Armour UK or to
7 whether the product should be withdrawn in those other
8 countries?
- 9 A. No, no special consideration.
- 10 Q. You described Armour as an essential member of the
11 team looking after the interests of people with
12 haemophilia. How was it in patients' interests for
13 a team member to withhold information about the
14 seroconversions on Factorate HT?
- 15 A. Sorry, can you repeat that again?
- 16 Q. Yes. The question picks up on your own description of
17 Armour as an essential member of the team looking
18 after the interests of people with haemophilia. How
19 was it in the interests of people with haemophilia not
20 to give them full information about the suspected
21 sero-conversions?
- 22 A. Well, the information -- are you talking about to
23 patients?
- 24 Q. Yes, or to centres for transmission to patients or
25 through some form of public material, or to

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- 1 The Haemophilia Society.
- 2 A. Well, to patients it would be the initiative of the
3 clinician.
- 4 Q. The clinician can't tell patients what the clinician
5 doesn't know. So how was it part of the team ethos
6 that you describe for Armour not to ensure that
7 clinicians were fully informed about the possible
8 sero-conversions on Factorate HT?
- 9 A. But they were fully informed as far as our own medical
10 people were able to inform them, with the data,
11 et cetera, available.
- 12 Q. Is the following a fair way to sum up Armour UK's
13 attitude to risk in the 1980s in relation to AIDS:
14 that unless and until there was conclusive proof that
15 the Armour product could transmit AIDS, Armour's
16 products were safe and risk-free?
- 17 A. Yes, as far as the evidence relates to that.
- 18 **MS RICHARDS:** Sir, those are the additional questions that
19 I propose to ask from those suggested by
20 Core Participants. Do you have any questions for
21 Mr Bishop?
- 22 **Questioned by SIR BRIAN LANGSTAFF**
- 23 **SIR BRIAN LANGSTAFF:** Yes, I do.
24 As someone who was marketing Armour and
25 establishing it as a market leader, did you keep tabs

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1 on what your rivals were doing?

2 **A.** Yes.

3 **SIR BRIAN LANGSTAFF:** So you would have known quite a lot,

4 as much as you could find out, anyway, about what

5 Alpha and Cutter and Hyland were doing to achieve

6 a market share?

7 **A.** As I said earlier, the haemophilia community,

8 including the company supplying product, you know, it

9 was a very, very closed and small speciality, and

10 people from the industry, you know, at senior level

11 and at my level and the representatives' levels, would

12 be, you know, often -- constantly -- constant

13 conversation with each other. So invariably

14 information was -- well, it was discussed and ...

15 **SIR BRIAN LANGSTAFF:** Well, this leads on for me to ask

16 you about a document which we looked at. It's

17 ARMO0000252.

18 Soumik, can we? Thank you.

19 This is the letter which you wrote to

20 Mr Colledge, possibly a GP, as it would appear from

21 the heading --

22 **A.** Yes.

23 **SIR BRIAN LANGSTAFF:** -- and at the very bottom of the

24 page that we're looking at, the paragraph beginning --

25 it's a paragraph which led to an exchange between you

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1 and me at the time:

2 "Despite the fact that there is ..."

3 Can we just highlight that? Thank you:

4 "Despite the fact there is little evidence to

5 associate plasma component therapy with the

6 transmission of AIDS ..."

7 Now, the date of this, let's go back to the top

8 of the page, 24 May 1983. So "little evidence to

9 associate plasma component therapy with the

10 transmission of AIDS". That was your position on

11 behalf of Armour --

12 **A.** Mm.

13 **SIR BRIAN LANGSTAFF:** -- you would have been aware,

14 I suppose -- can we have a look, please, Soumik,

15 I hope you've got it still on the system.

16 **A.** Sorry, Sir Brian, I think we agreed that that should

17 be "little proof", didn't we?

18 **SIR BRIAN LANGSTAFF:** I beg your pardon?

19 **A.** Didn't we agree, you know, the terminology that there

20 was "little proof".

21 **SIR BRIAN LANGSTAFF:** Little proof, yes. Very well.

22 Well, let me just ask you about the document

23 CBLA0000060_607.

24 I hope you've still got that on the system,

25 Soumik.

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1 It's a document we saw in the last few days. If

2 you can't find it --

3 **MS RICHARDS:** If Soumik doesn't have it currently, it's

4 because it wasn't provided to Mr Bishop in advance of

5 his evidence.

6 **SIR BRIAN LANGSTAFF:** Don't worry about that. The

7 evidence which we've heard was that on 7 January 1983,

8 Alpha published a press release which says that the

9 evidence suggests, although it does not absolutely

10 prove, that the cause of AIDS is a virus or other

11 disease agent which can be transmitted to haemophilic

12 patients with AIDS in the Factor VIII concentrate.

13 So that -- take it from me, that's the wording

14 which there is in the press release in January.

15 **A.** Is that Factorate VIII, V, one, one, one, or --

16 **SIR BRIAN LANGSTAFF:** V, one, one, one. Not your

17 Factorate, but Factor VIII.

18 **A.** Yes.

19 **SIR BRIAN LANGSTAFF:** So it's talking generally about the

20 product made by pharmaceutical companies. Obviously

21 it's Alpha who are saying it, so it has particular

22 relevance to their own product.

23 **A.** Mm.

24 **SIR BRIAN LANGSTAFF:** How do you see that -- how did that

25 influence your thinking and your view of the state of

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1 the art in May when you were saying there was little

2 evidence to associate plasma component therapy?

3 Little evidence to associate, little proof of

4 association? It seemed to be sufficient, perhaps,

5 to -- for Alpha to think there might well be an

6 association.

7 **A.** Well, that was the way they thought or interpreted

8 whatever information was out there, and it differed

9 from the Armour interpretation.

10 **SIR BRIAN LANGSTAFF:** You would have been aware of that,

11 would you, at the time, be keeping tabs on the

12 opposition?

13 **A.** Oh yes, yes.

14 **SIR BRIAN LANGSTAFF:** You described how you were keen that

15 what you said was state-of-the-art, and you were taken

16 to ARMO0000250_002. Thank you.

17 If we scroll down through this, this is from the

18 National Hemophilia Foundation in the United States,

19 can we scroll down to the next page, and to the next

20 page, please:

21 "Recommendations to prevent AIDS in patients

22 with hemophilia."

23 What you said this morning was -- do you have

24 any recollection of whether within Armour there was

25 discussion of these specific recommendations, and you

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1 say, well, obviously, there would have been but, as
2 far as you can tell, looking down those, Armour would
3 have complied with all of that. Do you want to just
4 look down and check. Can we scroll this up a bit,
5 please, up the page? Thank you.

6 It's recommendations to Factor VIII concentrate
7 manufacturers under A2, are you satisfied that Armour
8 would have evaluated and implemented surrogate
9 laboratory tests?

10 **A.** Yes, yes.

11 **SIR BRIAN LANGSTAFF:** We have heard in the course of this
12 week, in counsel's presentation to me, that the
13 pharmaceutical industry was, in the view at least of
14 one of the observers, I think from Cutter, doing its
15 best to put off the introduction of surrogate
16 laboratory tests for as long as it could, and the
17 chair of the committee considering the question was
18 Michael Rodell, who was an Armour employee at the
19 time. Do you have any comment to make on that?

20 **A.** No. No.

21 **SIR BRIAN LANGSTAFF:** So it would still appear to you,
22 despite that, that the evaluation implementation of
23 surrogate laboratory tests was something which,
24 looking at that, Armour would have complied with.

25 **A.** I would have assumed that and felt confident of that,

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1 yes.

2 **SIR BRIAN LANGSTAFF:** Assumed it?

3 **A.** (Nodded)

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

5 **A.** Yes.

6 **SIR BRIAN LANGSTAFF:** Well, thank you very much, that's
7 all that I am going to ask.

8 **A.** Thank you, Sir Brian, thank you.

9 **MS RICHARDS:** Mr Bishop, is there anything you wanted to
10 add to your evidence?

11 **A.** No. If we're -- are we at the end of the questions?

12 **Q.** Yes.

13 **A.** Yes, I would just like to reiterate my comments at the
14 end of my first statement, that the whole thing, you
15 know, the development of AIDS and hep B has been
16 a terrible tragedy. None felt more so than us --
17 well, certainly at Armour -- in the industry, because
18 over the course of time we, ourselves, had many
19 friends in the haemophilia community who were lost,
20 and so we feel, you know, equally -- not equally, but
21 we also feel the pain and concern to those who
22 suffered and those affected. And, again, just
23 reiterate our sincere apologies and sympathies to all
24 those people and their families.

25 **MS RICHARDS:** Thank you.

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1 Sir Brian.

2 **SIR BRIAN LANGSTAFF:** Well, thank you, Mr Bishop, for your
3 patience in what's been a long day for you, I know,
4 and answering as best you can some searching
5 questions. We've benefited by listening to you.

6 I think what we'll take from your evidence is
7 that you're firm that, whatever might be said about it
8 by others, Armour did its very best to ensure the
9 safety of patients who had their products, and did
10 everything it could, as indeed you tell us so did you,
11 within the limits of the powers that were given to
12 you, given that the Regulatory and Medical Departments
13 had so much to do with the more technical aspects of
14 matters. So I think we've understood that's your
15 position, and thank you for coming to display it to
16 us.

17 **A.** Okay, well, thank you, Sir Brian. I hope it's been of
18 some help, anyway.

19 **SIR BRIAN LANGSTAFF:** Ms Richards?

20 **MS RICHARDS:** Sir, that concludes the hearings for this
21 week, we resume on Tuesday with the start of a number
22 of weeks of hearings looking at the blood services.
23 The Inquiry's timetable has been updated on the
24 Inquiry's website this morning to give details of all
25 witnesses between now and Christmas.

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1 We've also then given details of the sitting
2 weeks from January through to Easter and the broad
3 topics that will be considered but not yet the details
4 of witnesses but we will populate that as soon as
5 we're practically able to.

6 **SIR BRIAN LANGSTAFF:** Well, I hope that allows those who
7 are here and those who are listening to be able to do
8 a bit of forward planning. That's the purpose of
9 releasing it and letting people know as soon as we can
10 at least when we're going to be sitting, even if we
11 can't quite yet say who precisely will be giving
12 evidence on which particular date.

13 **MS RICHARDS:** Yes. Next week is entirely comprised of
14 presentations on the structure of the National Blood
15 Transfusion Services, early look-back exercises, and
16 then looking at Professor Cash and Dr Gunson, and then
17 the following week we turn to hear the first of
18 a number of oral witnesses from amongst the Regional
19 Transfusion Directors.

20 **SIR BRIAN LANGSTAFF:** Yes. Well, thank you very much,
21 thank you for your patience, and I look forward to
22 seeing you, those of you who are here, next Tuesday,
23 10 o'clock.

24 (5.27 pm)

25 (Adjourned until 10.00 am on Tuesday, 9 November 2021)

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