

Friday, 4th December 2020

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2 (10.00 am)
3 **MS RICHARDS:** Sir, at the moment my screen is not showing
4 Professor Ludlam.
5 **SIR BRIAN LANGSTAFF:** No.
6 **THE WITNESS:** I am here.
7 **MS RICHARDS:** There you are. Thank you, we can now see
8 you.
9 **SIR BRIAN LANGSTAFF:** So you could hear us but you
10 couldn't see us?
11 **THE WITNESS:** Yes.
12 **SIR BRIAN LANGSTAFF:** Well, you can see us now?
13 **THE WITNESS:** I can see you and hear you. It sounds
14 a little distorted, but I think I can manage.
15 **SIR BRIAN LANGSTAFF:** Right. I think we -- I got a quick
16 flash of your legal representative on -- it must be
17 his camera. I assume it's your legal representative.
18 **THE WITNESS:** Yes.
19 **SIR BRIAN LANGSTAFF:** But, again, just so that those who
20 may have joined us today for the first time -- you are
21 in a room in Edinburgh on your own, I understand, and
22 your solicitor and your counsel are close by in
23 another room; is that right?
24 **THE WITNESS:** That's correct. That's correct, yes.
25 **SIR BRIAN LANGSTAFF:** We are the same, as I've described

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1 would be more appropriate or possible for me to set
2 out the situation, as I see the document, in writing,
3 possibly as a submission.
4 **MS RICHARDS:** Before I seek the Chair's view on that,
5 professor, can I ascertain precisely what it is you're
6 talking about? Do I understand from the evidence you
7 gave yesterday that you're talking about your views on
8 the Cardiff AIDS case?
9 **A.** The Cardiff AIDS case, the statement of -- it was sent
10 out by the Haemophilia Society on 4th May 1983, and
11 the associated CDR report from CDSC, I think dated
12 6th May. It's slightly complicated, or rather there's
13 a chronology, the detail of which is quite important,
14 and I just wonder whether it might be more appropriate
15 for me, if this is permissible, to send in a written
16 statement about it.
17 **Q.** Professor, it may depend upon whether what you're
18 giving is evidence or submission because you're here
19 as a witness of fact before the Inquiry, and so the
20 Inquiry is interested in what you can tell it from
21 your own firsthand knowledge, rather than making
22 submissions on materials relevant to others.
23 Again, so that perhaps the Chair can form
24 a view, correct me if I'm wrong, is the essential
25 thesis that you seek to advance that the Cardiff case

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1 to you earlier, but let me tell others too what the
2 position is in Fleetbank House. I'm sitting at my
3 desk looking at across at four members of the legal
4 team, and at Soumik whose job it is to make sure you
5 get the right document at the right time, and there
6 are three other members of the Inquiry staff currently
7 in the room.
8 They're all wearing masks except for
9 Ms Richards and you understand why that is.
10 **PROFESSOR LUDLAM (continued)**
11 **Questions by MS RICHARDS (continued)**
12 **THE WITNESS:** Ms Richards, I'm sorry, before we begin, I'm
13 sorry, could I seek the Inquiry's view? I yesterday
14 mentioned a document that came to my attention when we
15 were looking at some minutes, and I started to talk
16 about that document. It's an important document of
17 4th May, a statement that Professor Bloom made, over
18 which I think there has been much concern and I think
19 some misunderstanding.
20 As I was indicating, I have done some research
21 and some of what I found was quite by chance, but
22 I think it's important for the Inquiry to learn about it.
23 What I'd be grateful for your -- or the Inquiry's
24 guidance is whether we would pursue this today, as you
25 had suggested we might do yesterday, or whether it

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1 should not have been identified as an AIDS case?
2 **A.** I would be suggesting that Professor Bloom wondered
3 whether the Cardiff case should be classified as AIDS.
4 He was uncertain. I think it was a difficult
5 diagnosis to make in a patient who may be the first
6 one in the UK to have this diagnosis. It was made on
7 a single clinical observation, if I can put it that
8 way. But he wrote to -- gave details to Dr Galbraith
9 at CDSC and it was Dr Galbraith who made the decision
10 and then published it.
11 **Q.** Have you seen what you say is a letter from
12 Professor Bloom to Dr Galbraith?
13 **A.** No, I haven't. I have surmised. I don't have -- it
14 would be very useful, I agree, to have that.
15 **Q.** Do you know anything about the actual clinical
16 condition of the Cardiff patient?
17 **A.** Not beyond what is in the CDR report.
18 **Q.** Do you have sight of or have you ever had sight of the
19 Cardiff patient's medical records?
20 **A.** No.
21 **Q.** Have you seen Professor Bloom's completed surveillance
22 form for the Cardiff patient which he submitted to
23 Dr Craske?
24 **A.** No.
25 **MS RICHARDS:** Sir, I can tell you that the Inquiry has all

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1 those materials and it may be of some assistance that,
 2 rather than inviting Professor Ludlam to do what
 3 I think might be comment rather than evidence, that
 4 your team produce a note in the New Year with
 5 disclosure of relevant materials setting out the
 6 chronology -- setting out exactly what happened to the
 7 poor, unfortunate Cardiff case: we know who it is, we
 8 know what has happened to him, we have his records, we
 9 have Professor Bloom's own accounts.

Questions by SIR BRIAN LANGSTAFF

11 **SIR BRIAN LANGSTAFF:** I think I would be further assisted
 12 by knowing, first of all, what, professor, your view
 13 is as to the single clinical observation.

14 **A.** The diagnosis of candida esophagitis.

15 **SIR BRIAN LANGSTAFF:** So that, as far as you know, is the
 16 only symptom on which the diagnosis is based?

17 **A.** As far as I recall from the statement in the CDR
 18 report, yes.

19 **SIR BRIAN LANGSTAFF:** But you haven't seen the patient
 20 record?

21 **A.** No.

22 **SIR BRIAN LANGSTAFF:** So this is an assumption on your
 23 part?

24 **A.** An assumption of --

25 **SIR BRIAN LANGSTAFF:** That that is what the diagnosis was

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1 patient did cross the threshold into being officially
 2 categorised as having AIDS or not, and seeking
 3 Dr Galbraith's view.

4 **SIR BRIAN LANGSTAFF:** So he would be seeking the advice,
 5 if this were so, of a public health expert, as opposed
 6 to someone who might be considered to be an expert in
 7 AIDS, if there were such. There had been cases of
 8 AIDS before in the UK. I think the first case was in
 9 1982, was it not, in the UK? Actual AIDS, not
 10 a haemophiliac.

11 **A.** Yes, I'm thinking in terms of being the first
 12 individual with haemophilia, who was unwell and was on
 13 the verge, if I can put it that way, of potentially
 14 being diagnosed with AIDS.

15 **SIR BRIAN LANGSTAFF:** Yes, I think it would probably be
 16 more accurate on the information that I have at the
 17 moment to say the first reported, widely reported
 18 case, because there was a case in Bristol, and that
 19 case plainly existed because that patient died late
 20 that year.

21 Do we know, Ms Richards, what became of the
 22 Cardiff case?

23 **MS RICHARDS:** He died of AIDS, sir --

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

25 **MS RICHARDS:** -- at a young age.

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1 based on?

2 **A.** Yes.

3 **SIR BRIAN LANGSTAFF:** The second matter that I need to
 4 know at this stage is at what time did you form the
 5 view that the diagnosis was a diagnosis based, if
 6 I can say, on shaky ground by a political health
 7 expert who was not -- whose patient the individual
 8 concerned was not?

9 **A.** I reached that conclusion from the text of the letter
 10 that Dr Galbraith wrote to The Lancet in, I think it
 11 was November 1983, in response to, I think, a previous
 12 letter in which the Doctors Daly and Scott had
 13 reported the Bristol case in The Lancet, a patient who
 14 died, I think, in August. They sent details of the
 15 case to The Lancet, which was published, and then
 16 Dr Galbraith wrote in response to that letter, saying
 17 that he had read the letter, and he goes on to say in
 18 that letter, just at the end of the first paragraph
 19 that it was he who made the -- at least this is how
 20 I read it -- he made the diagnosis of AIDS in the
 21 Cardiff case. I think I would suggest that
 22 Professor Bloom wrote to Dr Galbraith giving detail
 23 and seeking -- giving full clinical details, more
 24 clinical details than I have access to, and that
 25 Professor Bloom will have wondered whether this

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1 **SIR BRIAN LANGSTAFF:** Well, thank you, doctor.

2 I don't think it necessary, as a matter of
 3 evidence of fact, to explore what is the question
 4 which had been raised. I think it is a matter of
 5 submission. I think we have your submission. If you
 6 want to add to it, by all means, do so afterwards, and
 7 that's at the invitation of the Inquiry, if you wish
 8 to add to what's been said, and your suggested course
 9 of action of showing what we, the Inquiry, know of
 10 this case, what the truth of it or otherwise is, can
 11 be shown later, and then we shall see whether your
 12 assumption as to what may have -- speculation as to
 13 what may have happened is justified by the facts.

14 **A.** That's very fair and I appreciate the invitation.

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

Questions by MS RICHARDS (continued)

17 **MS RICHARDS:** Professor Ludlam, I'm going to ask you next
 18 about events in 1985 and 1986. You've explained in
 19 your statement that heat-treated Factor VIII was made
 20 available by the PFC from a date in December 1984.
 21 That was, I think, NY; is that right?

22 **A.** I think that's what it was called, yes.

23 **Q.** Heated at 68 degrees for two hours initially, and it
 24 was believed to inactivate HIV but not non-A, non-B
 25 hepatitis?

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- 1 **A.** We had no evidence that it would inactivate non-A,
2 non-B hepatitis.
- 3 **Q.** It was, I understand, around April 1987 when PFC ma de
4 generally available a Factor VIII concentrate that was
5 believed to be effective against non-A, non-B
6 hepatitis?
- 7 **A.** Well, they made -- they started to make available.
8 You would need to enquire of people at PFC or in
9 England. I believe they started to make a small
10 amount that was available but there was no indication
11 at that stage as to whether or not it would be
12 reduced -- have a reduced capacity to transmit
13 non-A, non-B.
- 14 **Q.** The PFC product supplied from December 1984, the
15 heat-treated product that was generally available t
16 you from PFC, might still transmit non-A, non-B
17 hepatitis. Would you agree, therefore, there was
18 a continuing need for particular care to be taken, as
19 regards patients who were untreated or minimally
20 treated and so wouldn't hitherto have been exposed to
21 non-A, non-B hepatitis?
- 22 **A.** Yes, there was a continuing -- the situation had no
23 changed in relation to the risk of non-A, non-B
24 hepatitis.
- 25 **Q.** Would you agree that there was a need for a system to

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- 1 well transmit non-A, non-B hepatitis. Indeed, others
2 have referred to it being 100% certainty that a first
3 exposure would transmit non-A, non-B hepatitis. Now,
4 I'm not asking you to address whether it's 100% or
5 very likely or what the precise figure might be, but
6 non-A, non-B hepatitis must have remained an issue of
7 some importance. Now that you could be perhaps
8 reasonably satisfied that the product was safe in
9 relation to HTLV-III, you still had to bear in mind
10 didn't you, that it was not safe in terms of
11 transmission of non-A, non-B hepatitis?
- 12 **A.** I would agree. But I was influenced by the letter
13 that Professor Bloom wrote to the -- I think it was
14 the British Medical Journal in May 1985, so shortly
15 into this time period, in which he questioned the use
16 of cryoprecipitate because of the risk of possible
17 HTLV-III infection.
- 18 In his letter, he mentioned, as an example,
19 a 1 in 20 risk of patients of getting cardiac surgery.
20 That figure of 1 in 20 in fact was a typographical
21 mistake in publishing. There was an erratum to the
22 letter saying it was 1 in 200.
- 23 His view was that by mid-1985 it was probably
24 imprudent to use cryoprecipitate and that heat-treated
25 concentrates were more appropriate. So it was

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- 1 be put in place at the Royal Infirmary and, indeed, in
2 other hospitals to ensure that such patients, who
3 would be perhaps conventionally or most commonly mild
4 haemophiliacs, previously untreated or minimally
5 treated, that they didn't receive NY, if I've got the
6 terminology right, the PFC product, unless absolutely
7 necessary?
- 8 **A.** That was the ... well, a patient with mild haemophi lia
9 or a child with haemophilia who had a significant
10 bleed or a serious bleed might still require treatment
11 with clotting factor concentrate. Perhaps I could say
12 that at this time, over the succeeding year or two,
13 our chief concern was the possibility that blood
14 products might transmit HIV. That was the really
15 important thing. We were very keen indeed to try t
16 avoid HIV transmission because of the consequences of
17 it and that, in our minds, became more important,
18 I think, than the issue of non-A, non-B hepatitis.
- 19 So our first aim was to try to avoid HIV
20 transmission.
- 21 **Q.** Professor, I understand that and that's why, I am, as
22 it were, picking up this picture in the beginning o
23 1985, when you now have a heat-treated product that
24 you believe will have eradicated HIV, and is therefore
25 safe for patients to use, but you know that it may

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- 1 a change in view from December '84, and I think thi
2 reflects the evolving situation, which many of us
3 found difficult to manage.
- 4 **Q.** Just to go back to my original question, the questi on
5 was: would you agree there was a need for there to be
6 a system to ensure that the mildly treated, previou sly
7 untreated patient, didn't receive NY unless absolutely
8 necessary? So I didn't put it to you that they sho uld
9 never receive it under any circumstances whatsoever
10 but unless absolutely necessary; would you agree wi th
11 that?
- 12 **A.** If there was a new patient, I would assess them and ,
13 considering their situation, if they had haemophili a,
14 how they should be treated.
- 15 **Q.** Would you agree that that system would need to buil
16 into it an assurance that such patients, if they di
17 present -- and mild patients may, for example, be more
18 likely to present unexpectedly than a severe patien
19 coming for a regular appointment -- that if they di
20 present, they were told in advance of their treatme nt
21 what the options were and what the risks and benefi ts
22 of the various options were, which would include an
23 assessment about cryoprecipitate, and would include
24 an assessment explaining to them that non-A, non-B
25 hepatitis is something that would be probably

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transmitted, if not certainly transmitted, from the concentrate. So that the patient could take an informed decision, for example, as to whether they wanted treatment at all?

A. I entirely agree that the -- we would have explained, or I would have explained, probably in even greater detail around this time, about the risks because they were changing and there were uncertainties. So I would have explained in great detail, and I'd have discussed the various options with the patient, assuming the patient was in a fit state to do so, or discuss with their partner or relative or whoever came with them to hospital. I agree, it would be very important to think round, think through the issues with the patient.

Q. Bearing in mind that not every patient who presents at the hospital is necessarily going to be seen by you what systems were there in place at the Royal Infirmary to achieve these objectives?

A. There was a consultant on call at all time, and such patients would be referred to the consultant. And even when I wasn't actually on call, officially on call, I was not infrequently rung up because it was my particular area of expertise. But my colleague, Dr Parker, was well aware of the issues that we were

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available on the records that enables judgments to be made perhaps more readily, but I'm really thinking here about the position of patients who were infrequently treated or were previously untreated.

If there were no written processes or guidance or policies, was there an unwritten but nonetheless explicit understanding or instruction as to how such cases should be dealt with?

A. Yes, they should be referred to the consultant. And, of course, there would be patients who would present without us having seen the patients before, as new patients with possible diagnoses of bleeding disorders. So those would certainly be considered by a consultant.

Q. Now, you know and the Inquiry knows that there was a case of a mild haemophiliac in 1986 who presented at the Royal Infirmary, was treated with the PFC heat-treated concentrate and was infected with non-A, non-B hepatitis. I'm not going to ask you about the, as it were, the detailed clinical decision making in that individual's case. Not least because you have responded, I think, to their statement recently, and your response is not a response that is yet available more broadly.

But I do want to look at a couple of documents

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considering at that time, so he would have been -- if I hadn't been available, he would have been consulted and I think would have responded in a similar way to how I've just described.

Q. Were there any written policies or protocols or guidance to ensure that treatment wasn't given to such a patient without that process having been undertaken, or without the consultant having been contacted?

A. I don't recall written guidance or protocol because it wasn't common policy, if I can put it that way, at that time. And for most patients who came up with bleeds, it was very clear what their treatment should be from their case notes, and the blood bank had a list of patients with what their usual treatment was against their name.

So there was reasonably -- well, there was easy access to find out what patients were usually treated with. And that became particularly easy when I managed to get the consulting room, the Haemophilia Centre room in ward 23, divided into two with a small consulting room so that I could keep the patient records in so that they were there when the patient came up, which they weren't previously.

Q. Professor, I understand that where you got a patient who is regularly treated, there may be information

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in which you set out certain views or thoughts. They're in relation to the particular patient, I think. I want to see whether we can explore more generally what your thinking was and what the -- may not have been a way of avoiding such situations.

So if we go, please, Soumik, to PRSE0003845, please. This isn't a letter from you or that was copied to you at the time, but it is a letter that you know you've seen, and it is a letter from Dr Boulton to Dr Perry, June of 1986, 27 June.

"Dear Bob. May I pass on to you a couple of verbal comments about blood products from Christopher Ludlam. The "virgin" patient with Christmas Disease who received heat-treated Defix towards the end of last year [so that would have been towards the end of 1985], and on whom Christopher reported at Scotbloo d, continues to show no elevation of ALT levels or other evidence of non-A, non-B hepatitis."

We can see from that -- and, again, I don't want to go into any particularly detailed analysis of that patient's case, but we can see there was a patient treated with heat-treated Factor IX concentrate at the tail end of 1985.

Then you say:

"A young haemophiliac who previously had

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1 minimal therapy with Factor VIII received an infusion
 2 of the current heat-treated product a month ago. H
 3 now shows signs of liver enzyme rises indicating
 4 non-A, non-B hepatitis. Christopher is a bit ruthless
 5 with his own staff about this because he feels that
 6 this patient should have received VIIIY or an
 7 equivalent product. However, the patient is
 8 apparently quite well clinically."
 9 Why was it, professor, that you felt ruthless?
 10 **A.** Because I had not been informed about the patient and
 11 that he had developed hepatitis, and I was upset about
 12 that. And I'm not sure what the -- well, I know what
 13 the options were, and I was disappointed, to put it
 14 mildly, that I had not been informed when he came in.
 15 And I could have come and seen him myself and assessed
 16 the situation and been involved with helping to make
 17 the decision about what treatment would be
 18 appropriate.
 19 **Q.** And please correct me if I'm wrong, I think I'm right
 20 in understanding that you had been sufficiently
 21 concerned to institute some form of internal inquiry
 22 as to how this had come about?
 23 **A.** That's correct. I was disappointed and cross that
 24 hadn't been consulted, as I would normally have been.
 25 And because the two members of staff who were on-call

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1 been of paramount consideration or you and for all
 2 those involved in providing treatment to patients with
 3 bleeding disorders?
 4 **A.** Yes.
 5 **Q.** So you would have been eager to keep abreast of
 6 developments about safety of products and new
 7 products?
 8 **A.** I would try, yes.
 9 **Q.** What were the mechanisms that were available to you to
 10 get information about products? In relation to PFC
 11 presumably very easy. You have regular meetings,
 12 Dr McClelland is down the corridor. In terms of
 13 products being developed in BPL, what kind of forum
 14 would there be for you to receive updates about their
 15 progress?
 16 **A.** From BPL -- let me say that there was a lot of doubt
 17 about whether the BPL product would be safe from the
 18 point of view of non-A, non-B hepatitis, from heating
 19 at 80 degrees for 72 hours, because of the failure of
 20 some commercial products to be rendered free of the
 21 virus by dry heating and even wet heating, and that
 22 was information published in 1985.
 23 Sorry, I'm having difficulty speaking to you
 24 with this letter up. Can I --
 25 **Q.** Yes, we can take that down now, Soumik. Thank you.

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1 that night were not immediately available the
 2 following day, I wrote to them and asked for an
 3 explanation as to what had happened the previous
 4 night.
 5 **Q.** Now, this letter goes on, as well as expressing your
 6 ruthlessness, it says the reason or a reason, as
 7 expressed by you to Dr Boulton, is a sense that this
 8 was a patient who should have received VIIIY, and
 9 I want to ask you a bit about that. VIIIY is the
 10 product that had been developed by BPL at Elstree?
 11 **A.** Yes.
 12 **Q.** We may look in a moment at the detail a little, but
 13 VIIIY was heat-treated differently, higher and longer
 14 than the PFC product, and there was some evidence that
 15 you at least knew about, by the middle of 1986, that
 16 it was showing itself to be effective against non-A
 17 non-B hepatitis; is that correct?
 18 **A.** Yes, I could expand upon that but, yes, what you said,
 19 I think, is correct.
 20 **Q.** I just want to ask you a little more about how you
 21 would have potentially been able to keep informed
 22 about the BPL's progress with VIIIY. Is it fair to
 23 say that, certainly by early 1986, possibly probably
 24 even in the course of 1985, because of the disastrous
 25 events of 1984, safety of blood products would have

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1 **A.** It's easier if I can see you. Thank you.
 2 **Q.** Yes.
 3 **A.** There was a lot of scepticism about the potential
 4 safety of the 80-degrees, 72-hour material, and that
 5 scepticism even extended as far as 1988, two years
 6 later, and I can point you to references to that. So
 7 the assessment of the VIIIY, the heat-treated, was
 8 undertaken, I think, by -- Dr Jim Smith oversaw the
 9 study, and it started in the autumn of 1985, and
 10 I think it included patients either who had never been
 11 treated with blood products before, or very minimally
 12 treated, and patients were very slowly recruited to
 13 it.

14 There weren't a lot of patients who fulfilled
 15 the criteria for entry into the study. They had to be
 16 followed up at fortnightly intervals for blood samples
 17 for three or four months and then monthly thereafter
 18 for another couple of months.

19 This was a study in England of the English
 20 product and it was a clinical trial, and I assumed,
 21 therefore, that ethical approval would be needed.

22 You asked how I knew about progress, and the
 23 answer is I was not on any, if you like, circulation
 24 list from BPL because we weren't, you know, users,
 25 regular users of the product. There was a meeting at

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1 Scottish Home and Health in March 1986, at which
 2 Dr Perry presented a paper, I think he had written
 3 a little while previous to the meeting, in which he
 4 said there was some encouraging results from that -
 5 from the study that was ongoing.
 6 At that meeting were most of the senior -- and
 7 probably nearly all the haemophilia directors for
 8 Scotland. Unfortunately, I was not at the meeting.
 9 So I wouldn't have received that document, nor hear
 10 the discussion. But there's nothing in the minutes to
 11 suggest that the other haemophilia directors,
 12 including Dr Forbes, who at that time was chairman of
 13 UKHCDO, so he was well informed about what was going
 14 on throughout the Kingdom. It doesn't appear that
 15 anyone suggested that Scotland should be joining the
 16 VIIIY study.
 17 The other background information is that PFC
 18 had anticipated having an 80-degree, 72-hour product
 19 available for patients, in the spring of 1986. So in
 20 Scotland we were anticipating that this product would
 21 be available and, therefore, it would be reasonable to
 22 assume that it might have the same, or similar safety
 23 profile to VIIIY. One couldn't assume it was
 24 identical because there were different manufacturing
 25 processes, they were different concentrates. I could

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1 suggestion and, as you know, the delivery was made to
 2 PFC.
 3 Whether it was actually prudent of me to have
 4 requested it, I think is rather questionable. Here is
 5 a product under clinical trial. The first few
 6 patients appear to have been, if I can put it this
 7 way, successfully treated, and I was jumping to the
 8 conclusion that maybe this was a good medicine.
 9 When you're doing a clinical trial it's very
 10 important to assess the number of patients that you
 11 need to have in the clinical trial to reach the
 12 endpoint that you anticipate reaching. You may need
 13 five patients, you might need 50,000. There are
 14 techniques for doing it that and, in the case of this
 15 study, and I could take you to the publication if you
 16 wish, my recollection is the estimate was of 30
 17 patients needing to be treated to get a reasonable
 18 degree of certainty that it was safe.
 19 So I was requesting a medicine that had shown
 20 to be efficacious or safe in a few patients. If it
 21 had been a cancer, an anti-cancer medicine, that had
 22 shown to be effective treatment in the first few
 23 patients and, on the basis of that, I had used the --
 24 that a justification for treating a patient outwith
 25 the clinical trial, with the medicine, I would be open

23

1 go into the details if you wanted, but ...

2 So the ambience at that time was PFC is just
 3 about to let us have an equivalent of the VIIIY, an
 4 therefore that's what we would use.

5 Now, I wasn't at that meeting so I didn't get
 6 this update. After the start of the -- or the
 7 incident you referred to of the patient being treated,
 8 I think I had a conversation, probably a corridor
 9 conversation, with Brian McClelland, and he said, oh,
 10 had I heard about the preliminary encouraging results
 11 of the VIIIY study? I said I hadn't. So he said,
 12 well, he'd been at a meeting recently at which there
 13 had been spoken about. So it was at that point that I
 14 wondered whether it would be prudent to perhaps have
 15 some VIIIY in Scotland, because I also learnt that
 16 there were difficulties at PFC in bringing forward the
 17 Scottish product that was going to be equivalent to what
 18 treated.

19 I knew that VIIIY was in very short supply, and
 20 was treated like gold dust in England, and I thought
 21 they were unlikely to let us have any -- but, as you
 22 know, I discussed it with other people in the blood
 23 transfusion and Bob Perry, through his contacts at
 24 BPL, persuaded them to let us have some.

25 Now, whether that actually -- that was at my

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1 to criticism that that was inappropriate therapy,
 2 that I shouldn't have made that -- come to that
 3 conclusion based on the results of such a few
 4 patients.

5 Therefore, perhaps I shouldn't have requested
 6 it, but having acquired it, it was given on the
 7 condition that it was only to be used in previously
 8 untransfused patients as part of a clinical trial and
 9 that ethical approval would, therefore, be needed for
 10 its use.

11 So it wouldn't have been -- even when it
 12 arrived, it wouldn't have been immediately available
 13 on the basis on which it had been supplied to me. So
 14 what I am highlighting is that maybe it was
 15 inappropriate of me to have, if I can put it this way,
 16 jumped the gun and requested the VIIIY.

17 Q. Can I take you back, professor. I know this is
 18 a matter that was gone into in some detail in the
 19 Penrose Inquiry, and so rather than go to a lot of
 20 underlying documents, it may be that I can summarise
 21 some of the key chronological events and then just go
 22 to one or two documents.

23 You were asked at the Penrose Inquiry about an
 24 initial report of encouraging signs made in July of
 25 1985, and there was evidence, I think, of an

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1 information sheet that was sent to Haemophilia
2 Directors in England and Wales, not Scotland, and
3 I understand your evidence to be that you weren't
4 aware of that development?

5 **A.** That's correct.

6 **Q.** If we then come forward to December of 1985, there was
7 a meeting at which you were not present but
8 Dr McClelland was. I'm happy to take you to the
9 Penrose evidence if it would help, but I'm just going
10 to read out what was explored with you in Penrose, and
11 we can look at the content if you need to. At that
12 meeting, Dr Rizza reported upon further trials carried
13 out with heat-treated Factor VIII which he'd now be en
14 using for approximately nine months. He'd confirm
15 that none of his patients, including children, had
16 become clinically ill, and therefore the immediate
17 signs were encouraging.

18 You were asked at the Penrose Inquiry whether
19 Dr McClelland had reported that back to you, and
20 I understand your evidence to have been that he did
21 not; is that correct?

22 **A.** Can I just confirm this was December --

23 **Q.** 1985, yes.

24 **A.** Yes. That's correct. I -- what is in the Penrose
25 report.

25

1 "Directors will be aware that the blood
2 products laboratory are currently issuing
3 a Factor VIII product which has been heated at
4 80 degrees for 72 hours, and preliminary clinical data
5 indicates that this material is non-infective with
6 respect to HTLV-III, non-A, non-B hepatitis, and
7 hepatitis B."

8 And then it refers to the position in relation
9 to PFC:

10 "Unlikely that the current PFC product could be
11 successfully treated under these conditions."

12 And reference to a development programme
13 underway at PFC.

14 So Dr Perry is reporting and his terminology
15 suggests he anticipates that those to whom he is
16 addressing this report will already know, that the
17 preliminary clinical data indicates the material's
18 non-infected with respect to HTLV-III. I understand
19 --

20 **SIR BRIAN LANGSTAFF:** And NANB --

21 **MS RICHARDS:** Sorry, and NANB, which is the whole point of
22 the question --

23 **SIR BRIAN LANGSTAFF:** -- and hepatitis B. It's NANB that
24 you're concerned with in particular.

25 **MS RICHARDS:** It is, yes. I understand you did not attend

27

1 **Q.** Do you consider that Dr McClelland should have been
2 sharing that information with not just you but othe
3 Scottish Haemophilia Centre Directors so that you
4 could potentially consider whether you wanted to make,
5 as it were, an advance request for small amounts to be
6 held in stock?

7 **A.** No, I don't think so. This was very preliminary
8 evidence. And medicine is full of well-intentioned
9 people taking decisions on rather minimal evidence and
10 it not being prudent.

11 **Q.** Let's move forward to early 1986 and the report fro
12 Dr Perry which you referred to. This is the one
13 document which I think we probably should look at the
14 actual document. It's PRSE0003457.

15 We can see it's entitled "PFC report for SHS
16 haemophilia/SNBTS directors meeting, March 1986".
17 And then if we go to the fourth page, please,
18 Soumik. My apologies; it's the sixth page. I just
19 want to look at the date of the report.

20 We can see's authored by Dr Perry, 10 January,
21 1986. Then if we go back to the fourth page, pleas
22 Soumik. Under the heading 3 "Heat treatment of
23 coagulation factor concentrates", can we go down
24 towards the bottom of the page. If we look at the
25 penultimate paragraph, Professor Ludlam, it says:

26

1 and sent your apologies for the meeting in March fo
2 which this report was prepared. We can go to the
3 meeting minutes if we need to, but you weren't ther e.
4 You had yourself, I think, provided a report
5 for that meeting on a separate issue. Presumably
6 these reports are produced in advance -- we see thi
7 is dated 10 January 1986 -- and sent in advance to
8 those who are going to be -- who are invited to the
9 meeting, precisely so that they can read it.

10 Is it not likely that you would have received
11 this report?

12 **A.** I don't think I did because I've only relatively
13 recently seen this report. I think the copies will
14 have been brought to the meeting.

15 **Q.** And is this the case, then: that nobody, after the
16 meeting until the -- what you've described as the
17 "corridor conversation" with Dr McClelland in June or
18 thereabouts, nobody brought to your attention this
19 information?

20 **A.** No, I knew the study was under way, and I knew that it
21 seemed to be going satisfactorily, but I didn't kno
22 any of the details.

23 **Q.** Do you think you should have known? Either you should
24 have taken proactive steps to enquire, or a system
25 should have existed to ensure that you, as one of the

28

1 leading haemophilia clinicians in Scotland, were kept
 2 up to date with this information?
 3 **A.** (Pause) Well, it's always useful to have as much
 4 information as possible but, I'm sorry, it goes bac
 5 to the question at what point would one conclude th at
 6 VIIIY was, in inverted commas, "safe", from the poi nt
 7 of view of non-A, non-B hepatitis transmission? I go
 8 back to my parallel analogy with an anti-cancer dru g.
 9 You don't usually, except under very exceptional
 10 circumstances, start to use the drug just because the
 11 preliminary first few patients treated do well.
 12 That is not acceptable practice.

13 I'm not sure that it quite applies in this
 14 instance, but there is also the situation that, if
 15 you're doing a clinical trial and you are aware of the
 16 results as they come in, but there is the possibili ty
 17 of that influencing the outcome of your study, and
 18 therefore the threshold for clinical significance has
 19 to be raised, and therefore you may have to treat
 20 actually more patients. But, as I say, for VIIIY t
 21 be considered reasonably safe from transmitting
 22 HTLV-III -- sorry, non-A, non-B hepatitis, the
 23 statistics were -- needed about 30 patients and, by
 24 this stage, a handful -- I'm not sure how many the
 25 handful would be, it might be four, five, six,

29

1 **A.** Probably, yes.
 2 **Q.** You didn't have any further information, did you,
 3 other than the corridor conversation with
 4 Dr McClelland, and yet you were at that point willi ng
 5 to ask for some and, indeed, subsequently use it?
 6 **A.** I'm sorry, can you keep the -- oh, there it is. I was
 7 saying I'd be prepared to treat patients with an SNBTS
 8 product that had been treated in a similar way to
 9 VIIIY.
 10 **Q.** Two things. You're absolutely saying that in the
 11 second sentence of the second paragraph, professor.
 12 But you're also saying, or reported as saying -- an
 13 I hadn't understood your evidence to say this
 14 incorrect -- that you that positively asked for som
 15 VIIIY or enquiries to be made at least to see if so me
 16 VIIIY, the BPL product, could be made available.
 17 That's exactly what happened, isn't it? I'm
 18 not going to go -- there's a long chain of letters to
 19 and fro and Mr Pettet at BPL provides some, within
 20 a fairly short space of time after having been aske
 21 by Dr Perry or whoever precisely it was.
 22 What had changed, other than your corridor
 23 conversation with Dr McClelland to make you willing to
 24 use VIIIY?
 25 **A.** Could this letter now be taken down so I could --

31

1 seven -- had been treated.
 2 **Q.** Can we look at PRSE0002000, please. This is a lett er
 3 from Dr Boulton to Dr Cash dated 27th June 1986, an
 4 I just want to look at the first two paragraphs wit
 5 you, "Re: Trials of Factor VIII Products:
 6 "I have again spoken to Christopher Ludlam who
 7 continues to assert his willingness to participate in
 8 studies of new Factor VIII materials for patients,
 9 both virgin and multi-transfused."
 10 Then this:
 11 "Apparently a few weeks ago he was asking
 12 Brian McClelland if VIIIY could be made available i
 13 the event of a 'virgin' haemophiliac being operating.
 14 He tells me that he would be happy to treat such
 15 patients with a product prepared by the SNBTS that has
 16 been subjected to an 'equivalent' heat-treatment
 17 regime."
 18 We don't know the precise date of your
 19 conversation but I don't think you dispute, your
 20 earlier evidence referred to it, that you asked
 21 Brian McClelland if he could get hold of some VIIIY
 22 for you.
 23 **A.** Yes.
 24 **Q.** That conversation must have taken place at least
 25 a little while before the letter of 27th June 1986?

30

1 **Q.** Yes, of course?
 2 **A.** Thank you, and the other one, as well. Thank you.
 3 Thanks very much.
 4 I don't think anything had changed. I was
 5 trying to do the best I could in a difficult
 6 situation, and I am not sure that it was actually
 7 appropriate for me to seek VIIIY on the basis of it
 8 preliminary results. It would be appropriate for m
 9 to offer to put patients into the VIIIY PUP study,
 10 which is what was being envisaged, for which I woul
 11 require ethical approval. I assume, I can't recall at
 12 this stage, that I will have applied to our Ethics
 13 Committee for approval to use the VIIIY. This was --
 14 by this stage it was August, I think, '86. I don't
 15 know when I'd have got ethical approval for its use
 16 **Q.** I think I'm right in thinking not only did you receive
 17 some supplies, I think less than you had asked to b
 18 obtained, but some supplies from Mr Pettet at BPL o
 19 VIIIY, but at some point you obtained an amount of
 20 VIIIY from Newcastle Haemophilia Centre?
 21 **A.** Yes. That was because I had a patient later on in the
 22 year who was reacting badly to the Scottish PFC
 23 product, and so I was left with a difficulty: shoul
 24 I treat him, offer him treatment with commercial
 25 product, or would it be possible to treat him with

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1 VIIIY?
 2 I had some VIIIY available, and I treated him
 3 with it. That was a rather modest supply, as you
 4 know; there were, I think, just 50 bottles. And when
 5 that ran out, I managed to acquire some more from
 6 Newcastle, from a request to the director in
 7 Newcastle, presumably for continuing to treat this
 8 patient.
 9 **Q.** Was the trigger for your request to -- that somebody
 10 contact BPL and see if they can get some supplies of
 11 VIIIY, was the trigger what had happened in May 198
 12 and the infection with non-A, non-B of the mild
 13 haemophiliac who had been treated with NY?
 14 **A.** I think so, yes.
 15 **Q.** And is it fair to say that, although, of course, as
 16 you point out, VIIIY was still being studied, if on
 17 was comparing NY against VIIIY, you're comparing
 18 a product thought to be almost certain to transmit
 19 non-A, non-B hepatitis against a product where,
 20 leaving aside the question of when you became aware of
 21 this, professor, the information that was available
 22 suggested it was less likely to transmit non-A, non-B
 23 hepatitis?
 24 **A.** Well, there were other products potentially available.
 25 There were heat-treated commercial products, one of

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1 blood products at all because of a risk that had
 2 arisen.
 3 So it's a continually evolving situation of
 4 incomplete data and inconclusive data, to some
 5 extent -- certainly inadequate data -- that one has to
 6 make decisions.
 7 **Q.** Professor, I understand that data was incomplete in
 8 relation to VIIIY and potentially in relation to the
 9 commercial heat-treated product that you're referring
 10 to, but in one sense, the data was not incomplete in
 11 relation to NY. You knew, didn't you, that it was
 12 not -- the heat treatment did not prevent the
 13 transmission of non-A, non-B hepatitis? So you had,
 14 on the one hand, certainty against the possible --
 15 near certainty against the possibilities of one or
 16 more product that would reduce the risk or might
 17 reduce the risk of transmission of non-A, non-B
 18 hepatitis.
 19 Did you actually consider at the time getting
 20 some small supplies, either of a commercial product or
 21 of VIIIY at any point earlier than the dates we've
 22 been looking at, in case of the mild haemophiliac
 23 presenting? Or did you remain wedded, loyally wedded,
 24 to the Scottish product for perhaps even historic
 25 reasons?

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1 which had been reported in The Lancet by Peter Kernoff
 2 the previous year as having actually quite a good
 3 track record for not transmitting non-A, non-B
 4 hepatitis. And I think it illustrates, if I could
 5 say, just the hazards of studying a few patients and
 6 drawing conclusions.

7 My recollection is that Dr Kernoff and
 8 colleagues reported on a virally inactivated
 9 concentrate in about July 1985 in a letter to The
 10 Lancet, in which about 20 or 30 patients were treated
 11 with either eight or nine batches of concentrate,
 12 virally inactivated by a new technique. And the
 13 recipients of eight of the batches did not develop any
 14 hepatitis, but four recipients of one batch did
 15 develop hepatitis. This just goes to show that,
 16 although the preliminary results may look optimistic,
 17 one can't draw conclusions from small numbers of
 18 patients.

19 So one option might be -- might have been for
 20 me to have tried to acquire some of that concentrate
 21 in -- for treating patients. As is now well
 22 established, I was keen to avoid commercial
 23 concentrates, but the most important issue was patient
 24 safety, and I move forward to ten years. We were
 25 suggesting that patients shouldn't be treated with UK

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1 **A.** The situation around this time was very difficult, and
 2 there were a lot of uncertainties. I -- yes, I was
 3 committed to Scottish products but not at patient
 4 safety, if I can put it that way. But it's a question
 5 of at what point one should act, and you have had my
 6 view.

7 When Dr Brian Colvin was asked the question at
 8 the Penrose Inquiry as to whether he, if he'd been in
 9 my position, would have asked for a supply of VIIIY
 10 he responded that he would not have done so.

11 There were, at this meeting in March -- SNBTS,
 12 SHHD meetings I was not at -- there were, I think,
 13 probably all the haemophilia directors, including the
 14 chairman of UKHCDO who presumably became aware of the
 15 report Dr Perry produced, and none of those
 16 individuals with that information clearly thought it
 17 was appropriate to acquire any different products.

18 So my requesting some in June might be seen as
 19 not having the support of my colleagues in Scotland.

20 **Q.** As a matter of fact -- I understand the reasoning that
 21 you've provided to us -- but did you, as a matter of
 22 fact, think about looking to source non-PFC product
 23 at any time prior to June 1986?

24 **A.** Um ... there's a slight distortion on this line. Was
 25 your question: had I ever sought PFC products

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1 previously?

2 **Q.** No. I'll repeat it more clearly: did you, as a matter

3 of fact, at any point prior to June 1986, apply your

4 mind to and consider the possibility of obtaining some

5 supplies of non-PFC concentrates?

6 **A.** Yes. We were discussing a couple of days ago my use

7 of commercial concentrates and porcine concentrates

8 So I was aware of, obviously, some of the commercial

9 products that were available, and I had purchased some

10 for very special indications, occasionally, over the

11 previous five years.

12 **Q.** What about in the period 1985 and the first half of

13 1986, did you ever consciously think about getting

14 heat-treated concentrates from a source other than

15 PFC?

16 **A.** Um ... I was aware of -- the commercial concentrate

17 had been heat treated. There was very considerable

18 uncertainty about the safety of commercial

19 concentrates, with respect to HTLV-III, because of --

20 it was considered, if I can put it this way, quite

21 a high level of -- probable quite high level of

22 contamination of the product, and we know that the

23 more virus you have in a product before it goes to its

24 viral inactivation step, the less likely you are to be

25 able to remove all of it. You get perhaps 100 fold or

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1 my understanding, professor, because there's something

2 which is perplexing me a little about this last

3 exchange between counsel and yourself.

4 The clinical trial that you've described in

5 principle we may be familiar with, in particular in

6 recent times because of Covid and the clinical trials

7 for a vaccine. And the process there is that nothing

8 is distributed generally until the trial is

9 successfully shown that the product works and is

10 sufficiently safe.

11 So most clinical trials, I think, are like

12 that, aren't they? That you have a product which is

13 not put on the market, as it were, or distributed

14 generally unless and until clinical trials have

15 demonstrated efficacy and safety.

16 **A.** That's my understanding, yes.

17 **SIR BRIAN LANGSTAFF:** The process with VIIIY was, as I

18 understand it, this: that it was all BPL product that

19 was made -- F8, Factor VIII -- from September 1985 was

20 VIIIY. It was in general distribution. No other

21 product was distributed, as I understand it, after the

22 start of October 1985. So all the product

23 manufactured in Elstree was heat treated and it was

24 VIIIY.

25 So the clinical trials were rather different

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1 1,000 fold reduction, but that will only take it below

2 an infectious dose limit if the viral inactivation

3 process is adequate to the level of viral

4 contamination.

5 As is well known, there were reports of HIV

6 transmission by commercial products in 1985 and 1986,

7 and we were -- I was very keen to avoid that

8 particular situation, more so than the hepatitis

9 situation.

10 **Q.** Before we leave this topic, you described how you felt

11 upset and disappointed about what had happened in

12 May 1986 in relation to the individual patient. Did

13 you tell that patient infected with non-A, non-B

14 hepatitis in May 1986 at the time that you were upset

15 and disappointed at the way he had been treated?

16 **A.** I saw him the following morning, and I had a talk with

17 him, and explained about the hepatitis risk, and, as

18 the case notes record. I can't remember what else

19 I said to him about what had happened the previous

20 night, I'm sorry.

21 **MS RICHARDS:** I'm going to move on to another topic, sir.

22 I don't think it'll take very long.

23 **Questions by SIR BRIAN LANGSTAFF**

24 **SIR BRIAN LANGSTAFF:** Well, I think there is just

25 something I want to raise. I wonder if you can help

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1 because they weren't prior to the introduction of

2 a product; they were after it had come in to use,

3 really to see if it was going to be effective against

4 non-A, non-B hepatitis. Am I right?

5 **A.** I think that that is correct, yes.

6 **SIR BRIAN LANGSTAFF:** So there was a product freely being

7 distributed, literally freely in most parts of England

8 and Wales, which had the prospect of eliminating

9 non-A, non-B.

10 As I understand it, any person responsible in

11 Scotland for purchasing, or obtaining, I should say

12 suppliers of factor concentrate could have purchased

13 commercial factor concentrate. We know that, and not

14 least because you told us yesterday about the York

15 Hill experience, where Dr Willoughby had done nothing

16 much else than bought in commercial concentrate, and

17 he was using that there. And you yourself, as you

18 told us, and you've been quite open about it, you did

19 buy some commercial concentrate. Not much, but you

20 had some.

21 So if the commercial concentrate was licensed

22 for distribution, and if the Factor VIIIY was

23 permitted to be distributed, would there have been any

24 problem, apart from that of obtaining supply, because

25 it was in short supply, but any other problem in

40

1 getting it and using it? It didn't have to be
 2 supplied to you on the basis of your performing
 3 a clinical trial, did it?
 4 **A.** Yes. That was the basis on which they agreed to make
 5 it available.
 6 **SIR BRIAN LANGSTAFF:** Well, what I want to understand is
 7 why -- it may be, really, that what I'm trespassing on
 8 here is Scottish territory, as opposed to English and
 9 Welsh territory, because one of the matters which this
 10 Inquiry will have to look at is the relationship
 11 between PFC in Scotland and the Scottish products and
 12 PFL in Elstree in England -- in Oxford, and BPL at
 13 Elstree, and the different producers producing product
 14 for the UK.
 15 Is it the case that there was, as it were,
 16 a demarcation which followed the border that if it was
 17 NHS product it had to be VIIIY in England and the
 18 Scottish product in Scotland?
 19 **A.** It was pretty much like that. I think what I would
 20 perhaps add, if I may, to what's been said, that as
 21 I indicated, we were anticipating that an equivalent
 22 of VIIIY would be available in the spring of 1986 and
 23 then Blood Transfusion was unable to deliver that
 24 product to us, and it might perhaps have been
 25 appropriate for the Blood Transfusion Service, or PFC,

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1 that if the -- there was competition between killing
 2 the virus and denaturing the Factor VIII protein that
 3 you want to treat the patient with. So if you give
 4 too much heat, if I can put it that way, you may
 5 denature the protein, patients develop potentially
 6 antibodies to it, and then you can't treat them with
 7 anything.
 8 **SIR BRIAN LANGSTAFF:** Yes, I follow that. But given that
 9 VIIIY was the only NHS product being supplied after
 10 October 1985, there were then some months of
 11 experience where clinicians in England and Wales would
 12 have been giving their patients probably a mixture,
 13 for the adult, of commercial product and NHS product
 14 because there wasn't enough, as I understand it, BP
 15 product to cover everyone; nowhere near it. But there
 16 would have been, if they'd been following the
 17 protocols, quite a number of patients -- new patients,
 18 young patients -- who would have received, in
 19 preference, the NHS concentrate, which would have had
 20 the advantage, would it not, of having been
 21 manufactured from a donor base in which the chance of
 22 hepatitis infection was going to be rather less, as it
 23 must have seemed, than the chance of the -- those who
 24 were being paid for donating their blood in the
 25 States?

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1 to have requested an equivalent product from England
 2 or asked us haemophilia doctors what would we like to
 3 do, because they have failed to deliver what we had
 4 anticipated would be available?
 5 **SIR BRIAN LANGSTAFF:** Because the alternative, I suppose,
 6 would be that, as far as the UK, looking at it as a UK
 7 position, Scotland would be shortchanged in being
 8 supplied, as a matter of course, with a product
 9 through the NHS, which was known to give rise to risk
 10 of non-A, non-B even though it eliminated HIV --
 11 HTLV-III, whereas the English product gave rise to
 12 a real prospect that it might not. Was that a fair
 13 comment, do you think, or not?
 14 **A.** I think not in that it was a fair prospect of.
 15 I think, if I may say, I think that's being too
 16 optimistic about how I and other people were viewing
 17 the VIIIY, and as I've said, there was a lot of
 18 international scepticism about the efficacy of dry
 19 heat treatment. And when I say dry heat treatment,
 20 that's in the final vial. Now, there are the reasons
 21 for -- advantages doing the final vial, but the viral
 22 kill is highly dependent on the water content of the
 23 final freeze-dried material, is my recollection. And
 24 I recall it needed to be about 1% with a small
 25 tolerance on either side because you'll appreciate

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1 Am I right or not?
 2 **A.** Yes. Certainly, the risks of virus transmission by
 3 products derived from the United States, both HIV and
 4 (unclear) non-A, non-B hepatitis. And we have
 5 evidence from some work we did later on that there was
 6 a great deal of non-A, non-B hepatitis in commercial
 7 concentrates, and that the NHS starting material, the
 8 donor plasma pools, yes, had less virus, lower levels
 9 of virus. Yes, I accept that. I accept it on a
 10 statistical basis.
 11 What I would draw to your attention --
 12 **SIR BRIAN LANGSTAFF:** Well, you accept it in more than
 13 that because that was your main reason for preferring
 14 NHS concentrate, wasn't it, right from the start?
 15 **A.** It was twofold. It was, one, that the virus load
 16 might be less. The other is that it was not exposing
 17 patients to a different virus. So it might be a local
 18 virus in Scotland that, anyway, patients may have had
 19 some immunity to. They may have caught it, you know,
 20 socially, if I can put it that way.
 21 **SIR BRIAN LANGSTAFF:** I follow.
 22 **A.** The other point I think I would like to make is that
 23 when a patient is treated to assess the safety of the
 24 Factor VIII concentrate from the point of view of
 25 non-A, non-B hepatitis, they have to be followed up

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1 for six months with the weekly -- or fortnightly, I'm
2 sorry, blood samples. And you can't say that that
3 product is, in inverted commas, not transmitting
4 non-A, non-B hepatitis until they've been followed for
5 six months.

6 So we start in October '85, and so relatively
7 few patients actually have got to their four or six
8 months -- well, six months, actually, of protocol.
9 And the time from injection to developing hepatitis is
10 probably related, often related, to the dose of
11 hepatitis virus. We know this -- I'm sorry, this is
12 subsequent -- we know from hep C testing.

13 **SIR BRIAN LANGSTAFF:** It's really the knowledge that you
14 might have had at the time. And at the time, were you
15 aware of any report, however anecdotal, that there had
16 been an infection of non-A, non-B, consequent upon
17 somebody receiving nothing but VILLY?

18 **A.** No, but, you know, I wasn't on the network to hear any
19 of that. That would have been information that would
20 have been reported to BPL. It also raises the
21 question of how you define non-A, non-B hepatitis. In
22 the ISTD recommendations, it was an elevated ALT on
23 two consecutive occasions a fortnight apart, because
24 the ALT, the alanine aminotransferase, that's a marker
25 of liver disease, can be raised for all sorts of other

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1 their liver or you need to see what other drugs the
2 might have been on, and so on.

3 So there's a broad range of, if I can put it,
4 medical situations that would need to be thought
5 about.

6 **SIR BRIAN LANGSTAFF:** Yes. Well, that's been some help.
7 Can you tell me anything more about your impression of
8 how the border, as it were, worked as between Scottish
9 products made by the NHS and English products, if
10 I can call them that, made by the NHS?

11 **A.** Well, each country collected plasma from its
12 population, processed it locally, and distributed it,
13 as you've heard, in England, and in a slightly
14 different way from Scotland. There was occasional
15 need -- I'm sorry, my memory is failing, but I think
16 BPL made one or two concentrates that PFC didn't, and
17 I'm thinking of Factor XI concentrate. I'm sorry,
18 forget exactly when that became available. But the
19 number of patients with Factor XI deficiency is far
20 fewer in number, and therefore less treatment is --
21 there's less volume needed, if I can put it that way,
22 for therapy.

23 It's not economic for, for example, PFC to make
24 Factor XI concentrate for one or two patients in
25 Scotland, but I think there are a much larger

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1 reasons: acute infection, little alcohol excess, all
2 sorts of things can -- exercise can raise the ALT.

3 So there were lots of reasons why the ALT can
4 be raised, and that's why there has to be a definition
5 of hepatitis, which, in the absence of hep C testing,
6 was the best that could be devised in the mid-1980s

7 **SIR BRIAN LANGSTAFF:** Yes. I think also the diagnosis of
8 exclusion: excluding B, excluding A. Both of which
9 you could test for, except you couldn't obviously you
10 couldn't test for non-A, non-B, that was the whole
11 problem.

12 But would there not have been, do you think,
13 the likelihood of any clinician whose experience was
14 in using just VILLY, that somebody under their care
15 had shown symptoms, whether ALT readings two weeks
16 apart, which were consistently elevated or, for that
17 matter, one of those few cases where non-A, non-B
18 actually produced acute symptoms, that they might have
19 reported that?

20 **A.** Well, I think they would have reported that, but it
21 would have required a significant investigation to
22 assess the patient for all the other possible causes
23 of the rise in ALT, and that might be several weeks'
24 or potentially months' work to see whether they might
25 have other conditions. They might have cancer in

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1 population, total number in England with Factor XI
2 deficiency and, therefore, if we had wanted to treat
3 one of my patients with Factor XI deficiency with
4 concentrate, we would have acquired some or we'd have
5 asked BPL for some, and I think they would have let us
6 have some.

7 **SIR BRIAN LANGSTAFF:** Well, thank you very much. I think
8 I've trespassed a little bit upon your coffee break
9 professor, this morning.

10 **MS RICHARDS:** Sir, just before we finish, because there
11 will be a new topic after the break.

12 **SIR BRIAN LANGSTAFF:** Certainly.

13 **MS RICHARDS:** There isn't really a question for
14 Professor Ludlam, it's more just an observation for
15 the benefit of others. I think Professor Ludlam
16 suggested that the conditions upon which BPL made
17 available the supply of VILLY would have required
18 participation in a clinical trial. The correspondence
19 wasn't correspondence to which Professor Ludlam was
20 directly party, which is don't think it's a question
21 for him. The correspondence is summarised in
22 paragraph 22.64 of the Penrose report, essentially
23 it's a letter from Mr Pettit to BPL to Dr Perry on
24 24th July. There's a suggestion that "Perhaps
25 Scotland would like to participate in our trial of

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Factor VIIIY!", and then he goes on to say, "In cas
there are some patients who didn't strictly meet th
criteria now or in the future", he's put aside a sm all
amount for transmission, and he sends a further
letter, or there's a further communication to the
effect that if it is used in a previously untransfu sed
patient, there's an invitation to take some samples
and feed that back in to the BPL's own work.

So the position is summarised in the Penrose
Report but we have the underlying correspondence, and
I don't want to leave that entirely uncorrected.

SIR BRIAN LANGSTAFF: Thank you very much for that. Well,
no further taking away from coffee time, and we wil
take a break and until 5 to 12.

THE WITNESS: Thank you.

(11.32 am)

(A short break)

(11.57 am)

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Professor Ludlam, I want to turn to the
topic of testing for hepatitis C and ask you to loo
at two paragraphs of your witness statement.
Soumik, it's WITN3428001, and it's page 102.
If we could look at paragraphs 283 and 284, you say
this:

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happens, that the intermittent sound problems have
been resolved. Please let us know if they haven't
because then some further technical work will have to
be done.

Thank you very much.

A. Thank you.

MS RICHARDS: So the first generation tests.

A. Either 1989 or early 1990 is my recollection.
That's --

Q. When -- I'm sorry.

A. -- when it became possible.

Q. When your statement says, "Patients were given resu lts
of investigations when we were confident they were
accurate and informative", does that mean that
patients were not given the results of the
first-generation tests but were only given their
results after you carried out the second-generation
tests?

A. I think that's correct, yes.

Q. Do you know when the second-generation tests were
undertaken, approximately?

A. I think from about 1991 onwards. Exactly when in
1991, I'm not quite sure. Certainly by 1992, I thi nk
we would have had what we called second generation
test results available.

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"Following the identification of the hep C
virus in 1989, we considered our virologic studies
with Professor Simmonds who established the initial
laboratory techniques for assessing the virus and its
specific antibody. As a result of our initial
investigations, it became clear that there were
shortcomings in the first-generation antibody and that
second-generation assay results were more reliable.

"Patients were given results of investigations
when we were confident they were accurate and
informative. They were informed that what had
previously been referred to as 'hepatitis or non-A,
non-B hepatitis' was now identified as hep C. It w as
not a new diagnosis, but rather a renaming of the
condition."

Can I ask you, first of all, when did you
undertake the testing with the first generation test?

A. I think -- can we take down the text, please, so I can
see you?

I think it was probably --

SIR BRIAN LANGSTAFF: Can I just ask you to pause there
for a moment, professor, because we've got it back.
We just lost you on our big screen here and I was
concerned there might have been problems elsewhere in
the country, but I doubt there are. I gather, as i

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Q. In relation to the first-generation tests, were tho se
tests undertaken on stored samples?

A. I think they probably were. In fact, we had a -- m
recollection, although I haven't actually seen any
documentary evidence when I went through my archive
before the lockdown, I have a recollection that we
wrote to patients in -- when the first-generation
tests became available, to ask them about their
history of jaundice and hepatitis, so that we had a
accurate picture. We explained this, that we'd got
a new test and we were looking into its utility and it
would help if we had the -- so patients were alerte
to the fact that there was a potentially new test
coming along.

Q. Were patients told, as a matter of fact, that -- or
offered, as a matter of fact, testing and invited t
consent to it at the first-generation test stage?

A. I know we certainly were -- I don't think we were -
I don't -- I don't think we were inviting people up to
give a blood sample for first-generation test. I may
be wrong. It is likely we would have said new test
had become available, we have samples available in
the -- in the regular storage, but we want -- and w
would like to test it for you, would use these for
assessing the new test, but we would like to be as

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1 clear as possible as to what you, the patient, know
 2 of your hepatitis background.
 3 It was a way of trying to quickly gather up
 4 such information, because some of the patients
 5 obviously had been treated elsewhere and, you know,
 6 their transfusion histories, for example, were -- w
 7 had, obviously, for patients in Edinburgh, but they
 8 may have been treated -- so that's where I was in
 9 1989, early 1990.
 10 **Q.** So you'd think there was a letter sent to patients but
 11 we don't have a copy of it? You haven't provided
 12 a copy?
 13 **A.** I don't. I think it was a letter and questionnaire
 14 along the lines I've described.
 15 **Q.** Would it have been placed in the patient's medical
 16 records?
 17 **A.** I don't think so, no.
 18 **Q.** Where would this material, these documents, go?
 19 **A.** Um ... it was, um ... I don't know where they would
 20 have gone. Um ... I -- this was 30 years ago. It was
 21 not -- it was, if you like, a small research projec
 22 and the paperwork for that is now no longer in
 23 existence. I don't recall -- all the responses would
 24 have been put together in a file, presumably, for this
 25 investigation.

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1 second-generation test almost certainly at their ne xt
 2 clinic visit. We wouldn't have called patients up
 3 specifically to hear the result. They had come to the
 4 clinic, we would say: "As you may know, a new test has
 5 become available for non-A, non-B hepatitis; it's now
 6 a specific test, and so instead of calling it non-A
 7 non-B hepatitis, we can call it hepatitis C". So i
 8 is a condition that has changed its name, but not -
 9 the condition is still the same, but it's now got
 10 a rather more specific name to it.
 11 **Q.** Would you at that stage, whether it's 1992 or 1993, or
 12 whenever they're presenting next at the hospital,
 13 would you have told them anything other than that? Is
 14 there any more information you'd have given them about
 15 the condition or just: "It's what you always had an
 16 it's got a new name"?
 17 **A.** No, we had very close collaboration with
 18 Professor Peter Hayes, who was a hepatologist, and
 19 a very helpful hepatologist, and all the patients were
 20 seen by him, either with myself or with
 21 Dr Rosie Dennis, who worked in the department with me,
 22 at a clinic. Professor Hayes would come regularly,
 23 perhaps every month or so, we'd have a clinic
 24 together, and if patients turned up between times o
 25 my clinic that he wasn't there, he was very helpful if

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1 **Q.** Were all your patients written to, as far as you ca
 2 recall, and tested using the first-generation test on
 3 stored samples, or only some of them?
 4 **A.** I think almost certainly only some of them.
 5 **Q.** Do you know how you decided which patients you migh
 6 perform the first generation test on, and which you
 7 would not?
 8 **A.** I would suspect it would be the people with severe
 9 haemophilia.
 10 **Q.** In terms of the second-generation tests, the more
 11 reliable ones, as you've described them in your
 12 statement, were those tests also undertaken using
 13 stored samples?
 14 **A.** I think they were, yes.
 15 **Q.** Evidence that the Inquiry has received might sugges
 16 that that was done without patients' knowledge and
 17 consent and that they found out only afterwards whe
 18 they were told the result. Is that your understand ing
 19 or do you think it was undertaken in a different wa y?
 20 **A.** No, I think that's correct.
 21 **Q.** What were the arrangements that were made, then, on ce
 22 you had what you regarded as a reliable
 23 second-generation result? What were the arrangemen ts
 24 for telling patients their diagnosis?
 25 **A.** We would have explained the result of the

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1 he was available and I phoned him, he would come down
 2 and see a patient.
 3 So he was very readily available and it was he
 4 who discussed, if you like, the more hepatological
 5 aspects of hepatitis C and what it meant for the
 6 patients.
 7 **Q.** Were post mortems routinely done on bleeding disorder
 8 patients in Scotland, to your knowledge, in the period
 9 from 1980 onwards?
 10 **A.** I'm sorry, I have difficulty responding to that
 11 because the number of patients, fortunately, who died
 12 initially were not very many, but then, of course,
 13 many more died from HIV. And so I can't remember
 14 about autopsies for patients in general, particularly
 15 in the 1980s.
 16 There was general view, particularly working in
 17 a teaching hospital, that it was -- additional
 18 information could often be obtained from an autopsy
 19 and that, depending very much on the circumstances,
 20 one would consider whether an autopsy might be help ful
 21 and, if it seemed appropriate, to ask the relatives
 22 But in relation to how many were undertaken,
 23 and particularly when patients sadly were dying of
 24 HIV, I think there was -- there were probably
 25 a reluctance to undertake autopsies. But I'm sorry

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(14) Pages 53 - 56

1 I can't offer you more than those thoughts.
 2 **Q.** Do you know what tissue or other samples were retained
 3 from deceased bleeding disorder patients?
 4 **A.** From the autopsies?
 5 **Q.** Yes.
 6 **A.** I don't, but I think it would be usual for what are
 7 called the paraffin blocks -- perhaps I could explain.
 8 At autopsies, small pieces of different organs would
 9 be taken for histology to look at down the microscope.
 10 And they would be processed in little -- which
 11 involved little -- making little paraffin blocks of
 12 the tissue which were then very thinly sliced, stained
 13 and looked at under the microscope by the pathologist.
 14 The blocks, paraffin blocks of tissue I think,
 15 as far as I understand it, are kept long term for
 16 a whole variety of reasons, but I think those may have
 17 been retained.
 18 **Q.** Do you know where those would be stored, and indeed
 19 who might be the best authority or person to make
 20 enquiries about this further with?
 21 **A.** They would be stored by the histopathology department.
 22 They would have systems for keeping these.
 23 **Q.** Would the decision as to what to retain be the
 24 decision of the histopathologist, the pathologist, or
 25 the clinician who had been involved during the

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1 **Q.** Apart from that one, are you aware of any others?
 2 **A.** I can't recall any at the moment.
 3 **Q.** Again, do you think it's possible that there may have
 4 been others, and that you might be able to make
 5 further enquiries to find out the answer to that? Or
 6 is it a question better directed at others?
 7 **A.** Let me just be clear. Is your question about whether
 8 there were any other retrospective studies carried out
 9 on stored tissue samples from autopsies?
 10 **Q.** Yes.
 11 **A.** Patients who had died with haemophilia or another
 12 bleeding disorder?
 13 **Q.** Yes.
 14 **A.** I don't know of any others. I'm not -- I think the --
 15 it would probably be appropriate to ask the
 16 pathologists because I think it likely they will have
 17 an index of their reports, and those that have had
 18 haemophilia, and what investigations have been done
 19 I obviously can't speak about patients before 1980.
 20 That's the best I can do. But I don't think --
 21 I think asking histopathologist-s would be the --
 22 **Q.** Did you undertake any research or investigations using
 23 blood samples from deceased patients who'd been
 24 treated at the Edinburgh Centre?
 25 **A.** I take it from that that you mean samples taken while

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1 patient's lifetime, such as yourself?
 2 **A.** Probably the pathologist.
 3 **Q.** Do you --
 4 **A.** I'm sorry. They would have a -- it would be routine
 5 practice, I think, to retain these little paraffin
 6 blocks of particular organs. You'd need to ask
 7 a pathologist exactly what the criteria are, you know.
 8 If they were -- I think they would be kept, whether
 9 they were abnormal or normal, if I can put it that
 10 way. They're not discarded if they're normal. But
 11 it's not an area -- and it's an area that
 12 potentially -- the regulations have changed,
 13 obviously, with the Human Tissue Act, both the one for
 14 England and the separate one for Scotland.
 15 **Q.** Do you know of any research or investigations
 16 undertaken on histological or other tissue or blood
 17 samples from deceased bleeding disorder patients who
 18 were treated at the Edinburgh Centre?
 19 **A.** Well, I was sent and reminded yesterday afternoon,
 20 after our session, about the retrospective studies
 21 that were undertaken in relation to variant CJD.
 22 **Q.** Apart from that one -- sorry to interrupt,
 23 Professor Ludlam. I'll come on to that in just
 24 a moment.
 25 **A.** Yeah, okay.

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1 the patient was alive --
 2 **Q.** Yes.
 3 **A.** -- stored, and unfortunately the patient died, and we
 4 did investigations after they had died on the sample
 5 taken before, not samples taken at autopsy.
 6 **Q.** You've correctly understood the question, professor
 7 **A.** Right. I think it likely we will have assessed
 8 samples later. I am ... I'm trying to view 30 year
 9 of work in a teaching hospital, and I can't say
 10 I didn't, but I'm trying to think when we might have
 11 done. Obviously, I'm thinking in terms of these
 12 various viral infections that we've been discussing,
 13 because most of the investigations we did were on
 14 people who were alive and for their benefit. I can't
 15 say it never happened but I'm struggling to see when
 16 it might have happened. I'm sorry to be -- I'm not
 17 trying to be evasive; I'm trying to be accurate, and
 18 I'm finding it difficult.
 19 **Q.** Okay. Do you know if there were ever any fatal
 20 accident inquiries contemplated or undertaken in
 21 relation to any of the deaths of patients treated at
 22 the Edinburgh Centre?
 23 **A.** No, I don't think there were, no.
 24 **Q.** Then if we look at the report that I think you've got
 25 a copy of, we'll put it on the screen, as well,

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1 HCDO0000133_024. So it's "Retrospective
2 Neuropathological Review of Prion Disease in UK
3 Haemophiliac Patients". We can see there's a number
4 of authors, Professor Lee is first, Dr Giangrande and
5 then your name, we can also see the name of
6 Professor Ironside. Then we see a list of bodies
7 involved, of which we can see the CJD Surveillance
8 Unit in Edinburgh and then the Royal Infirmary in
9 Edinburgh.
10 If we go to page 3, please. In the first
11 paragraph, we can see, picking it up in the second
12 line:
13 "... we have examined the brains of 33
14 HIV positive haemophiliac patients who had died from
15 HIV/AIDS or liver disease. The patients were treated
16 with clotting factor manufactured from British and
17 Commercial, (predominantly from the US), plasma pools
18 averaging 20,000 donors. However, it has been the
19 practice at all three Haemophilia Centres: Royal Free,
20 Oxford and Edinburgh to use British donor source
21 plasma clotting concentrate whenever possible."
22 Then it goes on to discuss that in further
23 detail. Professor, my questions are just going to be
24 about the process, not about the findings themselves.
25 How did patients of Edinburgh, deceased patients of

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1 uncertainty about whether vCJD could be transmitted by
2 clotting factor concentrates.
3 **Q.** What was your involvement in the study?
4 **A.** I think this was led by Christine Lee, and I forget
5 exactly what my involvement was. I knew the
6 colleagues, James Ironside and Jeanne Bell, well. I'm
7 sure I had some discussions with them, but they would
8 be the individuals who obviously carried out the study
9 in their unit and in their university department.
10 **Q.** It would seem from the passage that we just looked at
11 that the study would have involved examination of
12 samples of brain tissue from some Edinburgh patients.
13 Do you know where those samples had been held?
14 **A.** They would have been held by the pathology departments
15 in Edinburgh.
16 **Q.** Do you know how many of the 33 patients referred to in
17 the study were Edinburgh patients?
18 **A.** No, I don't.
19 **Q.** Do you know whether any attempt was made to inform or
20 seek the views of or seek the agreement of the
21 families of the deceased patients, either for the
22 retention of the tissue samples or for the involvement
23 in the study?
24 **A.** I imagine the retention of the -- what I take to be
25 what we were talking about earlier, the paraffin

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1 Edinburgh, come to be involved, or how did you come to
2 be involved in this study?
3 **A.** This arose because of the appearance of variant CJD in
4 1996, and, as I think the Inquiry is aware, I arranged
5 a meeting in 1997 at which we considered the
6 possibility that the prion, vCJD prion, if I can put
7 it that way, might be transmitted by blood products,
8 and -- but at that stage, there had been no episode
9 of apparent vCJD transmission by blood. As you'll be
10 aware subsequently, there were, I think, three
11 episodes in which patients developed variant CJD from
12 blood transfusions but, at this stage, there hadn't
13 been any, but the possibility had been raised -- was
14 taken sufficiently -- our recommendations were taken
15 sufficiently seriously that major changes occurred in
16 the way blood products were provided within the UK.
17 The situation was that we weren't aware of any
18 patients with haemophilia having developed
19 variant CJD, but we wondered whether there was any
20 possibility that patients could have been so, if I can
21 put it this way, infected. One way of potentially
22 looking for evidence is what this study was about
23 because, at that stage and even now, there is no blood
24 test that will detect the abnormal prion reliably. So
25 that was the background at a time when there was much

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1 blocks, that would be part of the routine way in which
2 samples were stored. Not just, obviously, these
3 patients but all patients who underwent autopsy.
4 You also ask whether relatives were asked for
5 their consent. I think almost certainly they weren't.
6 **Q.** I want to come on more broadly to --
7 **A.** Sorry, could I -- if you wish to leave that topic,
8 I think it highly likely that this study will have
9 been reviewed by the Lothian Ethics Committee, and it
10 may well have been undertaken -- the patients may have
11 been anonymised. These sort of details are important,
12 and I think James Ironside and Jeanne Bell were
13 eminent, very good histopathologist, academic
14 histopathologists, and I think they would only have
15 moved forward perhaps on that basis.
16 **MS RICHARDS:** Sir, just before we move on to the next
17 topic, I know a question has been raised by a core
18 participant as to the circumstances in which
19 Professor Ludlam was sent overnight the documents.
20 I can confirm it was sent to him by the Inquiry --
21 **SIR BRIAN LANGSTAFF:** Yes.
22 **MS RICHARDS:** -- for the very reason of wanting to ask
23 a question about it.
24 Professor, I'm going to move on more generally
25 to questions of research. And before we look at

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1 a couple of examples of specific studies or areas o
 2 research at the Centre, I just have some general
 3 questions I wanted to ask you.
 4 Do you accept that it's always been
 5 a fundamental principle of medical research that it's
 6 based on the participants, the subjects, having given
 7 their informed consent to participation?
 8 **A.** I think that's reasonable, yes.
 9 **Q.** In the studies with which you were involved, the
 10 research studies with which you were involved, did you
 11 ensure that patients were told that they could
 12 withdraw from it at any stage?
 13 **A.** Most of the investigations that we were doing,
 14 although they were labelled as research, were in fact
 15 for the ongoing evaluation of the patient. We woul
 16 often refer to new investigations as research, and
 17 they were, as I say, mostly or for the ongoing bene fit
 18 of the patients. And patients were actually quite
 19 interested to learn a bit more about the research, and
 20 we were happy to tell them.
 21 We were working in a teaching hospital
 22 environment, and research was something they were
 23 familiar with. They were often kind enough to see
 24 students and for me to teach students around the be
 25 or in the -- kind enough to come along to seminar

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1 be clear that they didn't have to agree to that.
 2 **Q.** But were they expressly told that, if they did agre e,
 3 they could change their mind and withdraw?
 4 **A.** I don't think they -- we were explicit with that, but
 5 no one, I recall, had reservations -- showed
 6 reservations about the sort of -- what they were being
 7 asked to do, and I was happy to talk to them about it,
 8 and a lot of it was actually, although it's called
 9 research -- in my statement I've gone into differen
 10 sorts of research, I don't know whether you want to go
 11 there just now, but what we described as research were
 12 often new investigations that were for the patient'
 13 benefit, or potentially.
 14 **Q.** In relation to the process you describe about takin
 15 some extra blood and saying, "Can I take some extra
 16 blood for Dr Ludlam's research", two questions, if
 17 I may. First of all, who amongst the Centre's staf
 18 would ordinarily be the person having that
 19 conversation?
 20 **A.** That would be whoever was taking the blood sample.
 21 **Q.** How often would that be you?
 22 **A.** Particularly in the early 1980s, it would be me mos
 23 of the -- well, the review clinics, it would be me
 24 most of the time, because we didn't have a haemophi lia
 25 sister, we didn't have a phlebotomist, so it would be

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1 rooms and tell other doctors about haemophilia and
 2 what it is like as a condition.
 3 So there was a very open relationship with the
 4 patients. I would say that they were giving their
 5 agreement to the sort of work that we were doing
 6 because it only involved usually an extra teaspoonful
 7 of blood when they were having blood taken anyway, and
 8 they were asked if they'd be happy for some to be p ut
 9 aside for Dr Ludlam's research projects.
 10 In relation to your specific question, were
 11 they specifically told they could refuse? I don't
 12 actually recall anyone expressing a wish not to
 13 participate. They might ask more questions. And
 14 I think there's research and research, if I can put it
 15 that way, or investigation and investigation. Ther
 16 is investigations, ongoing investigations, that could
 17 be done on blood samples when patients that come up to
 18 the hospital for their routine appointments or for
 19 what other reason they may be seen for.
 20 There's then quite different research in which
 21 they may be asked to participate in new therapy, or
 22 some procedure, and that would be very carefully
 23 explained to them. There might well be, particularly
 24 for new therapy, an information sheet and a formal
 25 consent form, a very formal arrangement, and it would

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1 me who would be -- and the other people would be th
 2 registrars working with me.
 3 **Q.** Did you spell out to the patient what the -- what t he
 4 actual research was going to be?
 5 **A.** I would probably have said what we were doing at th at
 6 particular moment, what our interest was, what the new
 7 area of interest was. Consent is an ongoing proces s,
 8 in a sense. It's keeping people informed about wha
 9 is happening, and as time went by and the situation
 10 changed, for example when HIV came along, then the
 11 discussion would have been what we are doing in
 12 relation to HIV to monitor their situation.
 13 So it was a continuous process, and part of
 14 the -- what I think was a close relationship betwee
 15 this relatively small group of patients and a small
 16 group of staff who were working together trying to
 17 help the patients.
 18 **Q.** It sounds, and please correct me if I'm wrong,
 19 professor, it sounds as though the kind of
 20 conversation you're describing, the kind of
 21 information being given to patients when you're taking
 22 the extra vial of blood, is pretty general in nature;
 23 is that fair?
 24 **A.** I think that is fair. We did consider at one stage
 25 actually having an information sheet explaining about

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what the blood was being tested for, and for research investigations. I came across the form when I was going through my archives earlier this year and I can't actually remember whether we introduced it or not. I remember a discussion about the form because, as I say, the form is in the archive. I remember we had a discussion and I can't remember whether the result of the discussion was, "Well, let's use it", or whether -- and this was the discussion within the team -- or whether the outcome was "Well, the patients are pretty well informed anyway so we don't need this".

I'm sorry I can't be more helpful than that. What I can say is that when the patients came up, particularly for a treatment with acute bleeds and general practitioner issues, they were all entered into the diary, the clinic diary, and what the outcome was of their visit, how they were treated, and a record was kept of what blood samples had been taken and for what purposes.

So there was a pretty careful record of what went on in the Haemophilia Centre in relation to samples, and I tell you about this consent form and, I am sorry, I can't remember whether we actually instituted it and they signed it and they were put

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"... such detailed analysis would only be possible where there is a longitudinal sera store - possibly only Edinburgh and The Royal Free."

I want to ask you a little more about this sera store, described here as a "longitudinal sera store"; how far back did the Edinburgh sera store go?

A. Well, in the virology department, it went back into the 1970s. In haematology, I, for reasons that I explained a day or two ago, we started a parallel store about 1982, is my recollection. When I referred to the deep freeze failure in the virology department, that was one of -- they had a whole bank of deep freezes and I don't know over what time period the haematology samples -- haemophilia samples were that were destroyed. There may well have been ones that went back to the 1970s that were still intact, that weren't in the freezer that broke down.

Q. Was there something different or unique about the position at the Edinburgh Centre and the Royal Free than other hospitals, other Haemophilia Centres, in terms of the sera store?

A. I'm just trying to think of what happened at other Haemophilia Centres and, of course, I don't have detailed insight. It was one of the advantages of the audit process that we started in Scotland and then

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away in a folder or whether we decided that, actually, the patients were well informed that we were trying to promote and develop good haemophilia care through our endeavours.

Q. Your witness statement says that the principal responsibilities of the Centre included undertaking research and participating in trials. Was that actually set out as a requirement, as a job description, as it were, for you or for the Centre?

A. Yes, that's part of HSC 76(c) health circular was also applied in Scotland that sets out the responsibilities of Haemophilia Centres.

Q. Do you think it possible that your extensive research commitments limited your ability to provide clinical care to your patients?

A. Absolutely not. I think our research activities promoted better clinical care.

Q. Can we look at BART0000552_001. We can see here it's a letter -- it's not a letter that you'd have seen, it's July 1996 it's Professor Lee to Professor Preston, if we just go further down, paragraph (ii):

"In individuals who had been infected with HCV PCR positivity [et cetera, et cetera] ..."

Then it says this:

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extended to England in the early 1990s, that actually one had the opportunity to go round and see how other Haemophilia Centres operate. It was very educational, actually. But, in relation to this particular question, I can think possibly Birmingham -- or Birmingham must have had a similar store, because they were able to detect seroconversions to commercial concentrate in 1986.

So it was not unique. I have to say, I think it was good practice, if not almost -- well, good practice. I wouldn't say it's essential, but it was good practice to do so.

Q. You can take the document down, Soumik.

What were patients told about the store, the storage of their samples and the uses to which they might be put?

A. They were told that they were for research on new tests.

Q. Did you take the view that that was sufficient, in terms of consent, for the stored samples to be used for whatever research purposes or testing you chose?

A. I -- it certainly wouldn't be nowadays, and I like to think that our patients were pretty much in touch with what our research interests were, because we shared this information with the patients. It's part of

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1 coming up and seeing -- something to talk about whe
2 they were at the clinic and when they were getting
3 their treatment.
4 But I didn't, at that stage, explain in detail
5 to individual patients exactly what tests would be
6 done on these samples.
7 **Q.** Did you ever, when using the samples subsequently,
8 whether it's for testing for hepatitis C or for any
9 other form of research or study, did you ever go back
10 to the patient and say, "We now want to use the sam ple
11 you gave for us, and which has been sitting in our
12 deep freeze for eight years, for the following
13 purposes"?
14 **A.** My reason for pausing is because I was thinking of the
15 various things we had done and what was research an
16 what was for the benefit of the patients, and I wou ld
17 like to say two things, I think. One is perhaps to
18 reiterate that the patients were in touch with what
19 our general research endeavours were, in other word
20 infections and immunity. I recall an instance in the
21 haemophilia treatment room where the nurse had take
22 some blood from a patient that I'd come to see, and
23 the little bottles were lined up on the counter, an
24 the patient said, "Ooh, gosh, they've got four or five
25 tubes there, where are they all going? What are they

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1 at samples in the deep freeze." I might easily hav
2 said that to the patient, and we'd have looked back
3 and been able to help the patient. And the same,
4 obviously, happened, not with the same consent, if you
5 like, with HTLV-III. Although some of the people who
6 came to see me, we may have had positive results an
7 then negative results, and part of the discussion
8 would have been, you know, "Should we look back, or
9 should I see if another Haemophilia Centre where yo
10 have been treated previously has samples?" Because
11 patients, you know, move house and so on.
12 So there were instances when patients were
13 ultimately(?) asked.
14 **Q.** I'll ask you about the AIDS study, which I understa nd
15 you began on in 1983. Now, you gave quite extensiv
16 evidence to the Penrose Inquiry in relation to this,
17 and I don't want to go -- simply repeat that exerci se.
18 What you told the Penrose Inquiry, in summary,
19 was that you began work with Dr Michael Steel, who was
20 a cell biologist and immunologist at the Western
21 General Hospital in early 1983, on a study of CD4 and
22 CD8 lymphocytes in people with haemophilia; is that
23 correct?
24 **A.** That's correct, yes.
25 **Q.** And that involved taking blood from haemophilia

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1 all for?" The nurse went down them each in turn,
2 explaining what they were going to be used for, and
3 I think one of them, in this instance, was in relat ion
4 to HIV virus, and was explaining about that.
5 There were other investigations that the
6 patients may not have been aware of but that we
7 thought important to do for the patient's benefit and
8 I take, as an example, parvovirus. We've not talke
9 about parvovirus yet, and I'm happy to do so. But one
10 of the criteria for using recombinant concentrates,
11 one of the priorities were people who were parvo
12 negative, and therefore we needed to screen the
13 patients to see who had been infected with parvo
14 previously, because most of us are infected, as you're
15 probably aware, as small children.
16 **Q.** Can you actually recall any instance in which attempt s
17 were made to inform and seek consent from a patient
18 when a sample that had been stored for a period of
19 time was being used?
20 **A.** Used for?
21 **Q.** For whatever purposes you might want to use it for.
22 **A.** Oh, yes, absolutely. I could easily have said to the
23 patient, let's say someone who turns out with
24 hepatitis C, "We could try and ascertain when you
25 became infected, and we could do that by looking back

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1 patients at the Haemophilia Centre.
2 **A.** That involved taking an extra either half
3 a teaspoonful or a teaspoonful of blood when they were
4 having blood taken anyway.
5 **Q.** And, again, without wanting to go through the lengt hy
6 pages of the Penrose transcripts in relation to this,
7 my understanding of what you told them is that ther
8 would be some form of analysis performed within the
9 Royal Infirmary, and then the samples would be
10 couriered to Dr Steel at the Western General Hospit al
11 for his work. Is that a -- it's a brief summary, b ut
12 is that correct?
13 **A.** Yeah. I think that's reasonable, yes.
14 **Q.** The forms or documents -- I don't have an example
15 here, but I'm sure you know the ones I'm talking
16 about; you looked at them at the Penrose Inquiry
17 again -- describe this as an "AIDS study". Those are
18 the words written on various forms.
19 Why do you say it was so described?
20 **A.** Well, it was a study because of the -- when I say i t's
21 a study, investigations were being carried out as
22 a result of the AIDS that had appeared in -- and been
23 reported in people with haemophilia in the United
24 States. It was not a -- it was an immunological
25 study, but it was labelled "AIDS study" in rather

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1 large letters so that when the samples reached the
2 laboratory in the Royal Infirmary, it was clear tha
3 the extra small sample needed to be couriered rapidly
4 to the Western.

5 **Q.** And results or findings from the analyses that were
6 undertaken were, again, as I understand from your
7 evidence to the Penrose Inquiry, not included in th
8 patient's notes?

9 **A.** They're included in the computer records, the
10 patient's computer records, yes.

11 **Q.** Okay. What --

12 **A.** Not in their paper records because there were no
13 hospital forms. You could only put into the patien t's
14 notes approved forms, forms approved by the Medical
15 Records Committee. And we had a computer -- we wer
16 about the lead department in the hospital for
17 computerisation. We set up a small database -- it
18 innovative at the time -- with patients' results on so
19 that when we were in the Haemophilia Centre or the
20 ward or my office or the registrar's office, we cou ld
21 get hold of results easily. It was very carefully
22 password protected, so it was very confidential. But
23 it was seen as very innovative in the hospital, so
24 much so that they asked me to form and chair
25 a computer committee, so that was one more thing I had

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1 apart from an AIDS virus, but I was surprised that
2 they showed up these abnormalities.

3 **Q.** Your and Dr Steel's analysis of results and
4 conclusions that you drew from them were published,
5 I think, in The Lancet in 1983 and further in The
6 Lancet in 1984. I wasn't proposing to go to the
7 detail of your findings, but that's right, isn't it?

8 **A.** That's correct, yes.

9 **Q.** Do you still maintain, as you told the Penrose
10 Inquiry, that this was not research but was part of
11 the general monitoring of patients?

12 **A.** Yes, I do. It was monitoring the patients because
13 abnormalities had been shown in other patients with
14 haemophilia that might be of significance, and I felt
15 that it was my obligation to conduct similar
16 investigations on our patients.

17 **Q.** It's right, I think, that in relation to the work
18 you've been describing, you didn't obtain -- seek o
19 obtain ethical approval?

20 **A.** Not for this particular -- these particular
21 investigations because I consider them to be part o
22 what we should be doing to monitor the health of ou
23 patients.

24 **Q.** You did seek ethical approval, I think you've said,
25 for work undertaken in 1984 as part of the same

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1 to do as a result of this rather successful
2 enterprise. But the result of these tests done by
3 Dr Steel's department were entered on this system.

4 **Q.** And patients were not advised of the results of wha
5 the analysis showed, were they?

6 **A.** I think that's correct.

7 **Q.** And they didn't lead to any advice being given, for
8 example, to patients about the management of their
9 conditions in light of the results?

10 **A.** Well, let me say I undertook and started these
11 investigations because of the abnormalities that ha
12 been described in the New England Journal of Medicine
13 in January 1983. And one of the possible conclusions
14 from those studies was that there was -- the
15 abnormalities reflected the presence of an AIDS virus,
16 or putative AIDS virus, in this -- widely dissemina ted
17 in the haemophilia population. And I thought that we
18 should look at similar investigations in our
19 department because I felt, as you know, that our
20 patients hadn't been exposed to the virus, and I fu lly
21 expected the results to be normal. And it was --
22 I nearly didn't do the study or set up the
23 investigations. And when they started coming back
24 abnormal, I was very surprised and perplexed and quite
25 a bit of puzzlement. There were other explanations

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1 research which involved skin tests?

2 **A.** Certainly, I -- the skin testing was part of the
3 ongoing assessment of immunity, but it was less cle ar
4 what the results might be or how they might be
5 interpreted. But it involved a procedure, applying
6 a small device to the forearm of patients, and we
7 didn't invite everybody to do this because they had to
8 come back two days later and have the skin test
9 results read. So we only invited people who would
10 find it easy and convenient to come back two days
11 later. But I sought ethical approval for this beca use
12 it was, if you like, an invasive -- although small --
13 procedure.

14 **Q.** Why was the skin testing research, but the blood
15 testing analysis and investigation not research, when
16 the purpose of the two was identical?

17 **A.** **(Pause).** I think it was because the results of the --
18 and one only does this in prospect, you must know the
19 results are going to be. The skin testing was
20 a rather more speculative investigation. The fact
21 that it produced some very interesting and importan
22 results is perhaps a separate issue.

23 There is a dividing line, I think, between --
24 I could have done the ... I could have done, I thin k,
25 the skin testing perhaps without ethical approval but

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1 I had a very low threshold for applying for ethical
 2 approval and I thought, well, this is something
 3 that is new. It's a little bit uncomfortable and
 4 invasive, it's not hazardous, but that I should obtain
 5 ethical approval for it.
 6 I could have applied for ethical approval for
 7 doing the lymphocyte subset, but I -- that seemed t
 8 me so much part of my responsibility to try to provide
 9 the best care, to be curious about my patient's immune
 10 system, it seemed very pertinent in the early 1980s,
 11 and if I could do that simply and that my results
 12 might be helpful for the patients, then that was
 13 the right thing to do.
 14 **Q.** You know, professor, that patients have told this
 15 Inquiry that they were not aware of their
 16 participation in something called the AIDS Study. The
 17 Inquiry obviously has written evidence from Dr Carr
 18 about his involvement. Were you yourself directly
 19 involved in discussions with patients about the
 20 samples for the AIDS study and what they were required
 21 for, or was that left to Dr Carr?
 22 **A.** Dr Carr certainly saw most of the patients because it
 23 was his responsibility to see people who -- you know,
 24 when they first came up with acute bleeds. I'm sure
 25 I will have seen some of the patients, possibly not

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1 covered.
 2 If you go over the page, if we look at (j),
 3 please. It says:
 4 "Part of continuing to use blood products was
 5 to establish from early 1983 onwards an active
 6 programme to monitor the immune status of those with
 7 haemophilia."
 8 One reading at least of that, professor, is
 9 that one of the reasons for continuing to use blood
 10 products after you became aware of the risk of AIDS
 11 was to see if your patients developed the signs of
 12 AIDS. Is that what you meant?
 13 **A.** No. What I meant by this sentence in (j) is that I
 14 had become clear in 1982 that the immune status of
 15 some patients could decline very markedly and give
 16 rise to a clinical condition of AIDS in the United
 17 States. There was much uncertainty about the cause
 18 and that uncertainty persisted until, I would
 19 suggest -- and I have evidence -- at least until
 20 February 1984.
 21 It was therefore, I think, very important to
 22 monitor the immune status of patients, because one of
 23 the possibilities is that the immune decline was in
 24 some way related to the treatment they were receiving,
 25 separate from a putative AIDS virus. It's clear from

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1 only when they came up acutely with bleeds or other
 2 reasons, but at my review clinic, and I would have
 3 explained what we were doing.
 4 **Q.** When you say you would have explained what you were
 5 doing, what can you remember actually explaining as
 6 a matter of fact about this work to patients?
 7 **A.** I was asked about this at the Penrose Inquiry in some
 8 detail. I'm afraid my memory has faded rather, and
 9 I would ask you to view the Penrose Inquiry as the
 10 best I could do in -- 10 years ago.
 11 **Q.** Can I ask you -- I note the time, sir, but on the same
 12 topic, just a question arising out of one paragraph in
 13 your witness statement that I think is related to
 14 this.
 15 WITN3428001, please, Soumik, page 81.
 16 You'll see the question that you were asked at
 17 the top of the page:
 18 "Did you continue to use blood products to
 19 treat patients, after becoming aware of the possible
 20 risks of infection of HIV? Why?"
 21 Then in paragraph 211 you say:
 22 "I continued to use blood products after it
 23 became apparent that AIDS in 1982 might be caused by
 24 a transmissible virus for the following reasons ...
 25 You've set out a number, many of which we've

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1 the studies we did, that and others, that the clotting
 2 factor concentrates did, in fact, cause immune
 3 suppression, sufficient, I would suggest, to
 4 pre-dispose the children in Birmingham to
 5 tuberculosis, to a patient I reported -- or Dr Watson,
 6 now Professor Watson, when he was working with me,
 7 reported a patient who had features of AIDS and
 8 candida esophagitis in 1992, but was HIV negative but
 9 was clearly immunosuppressed by the concentrate.
 10 I don't know if we're going to come on to
 11 discuss it but when patients were exposed,
 12 unfortunately, to this implicated batch that was
 13 infected in Edinburgh in the spring of 1984, it was
 14 those with the most abnormal T cell ratios that were
 15 at greater risk of infection. So these, I think, are
 16 clinical evidence that use of clotting factor
 17 concentrates led to immune suppression.
 18 Having reviewed some of the literature
 19 recently, I think it's probably because of the
 20 immunoglobulin of the clotting factor -- the
 21 Factor VIII concentrates that was responsible, and it
 22 may be that is why patients with haemophilia B, who
 23 are treated with a different product, who had normal T
 24 cell numbers, they didn't get -- tended not to get
 25 infected. They were at far lower risk of HIV

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1 infection, and that has only occurred to me in the
2 last couple of months, that maybe many more people got
3 HIV with haemophilia A because they were pre-disposed
4 as a result of the immunoglobulin in -- call it
5 a contaminant, it wasn't meant to be there, whereas
6 there was very little immunoglobulin in Factor IX
7 concentrates.

8 That's a bit speculative, but it occurred to me
9 that that could be a possible explanation as to why
10 people with haemophilia B, not so many became
11 infected. There were other possible explanations, if
12 you want me to go into them, I'm happy to do so, but
13 I suspect you don't.

14 **Q.** Is one of the reasons why you were resolved to
15 continue using factor concentrates your desire or
16 ambition to have this active programme of monitorin
17 immune status, which you could only undertake if
18 patients were receiving factor concentrates?

19 **A.** We assess the immunity of people on cryoprecipitate,
20 as well, and probably no treatment, as well. Sorry
21 is that your question? Was it only people who got
22 concentrates who got immune tests?

23 **Q.** It wasn't quite my question, I am trying to underst and
24 you were saying -- it may be a partial answer, but I'm
25 trying to understand what you say in paragraph 211(j),

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1 event, separately, give rise to a deterioration in the
2 immune system which, in general, would not be a goo
3 thing. Have I understood that correctly?

4 **A.** Absolutely correctly, yes.

5 **SIR BRIAN LANGSTAFF:** So there were now three reasons why
6 factor concentrates were potentially undesirable if
7 there were any proper alternative?

8 **A.** Yes.

9 **SIR BRIAN LANGSTAFF:** The -- so far as monitoring was
10 concerned, what would you -- what was the purpose, had
11 the monitoring shown a decline in the immune system
12 What treatment -- how would treatment differ in
13 consequence?

14 **A.** Well, what we did was to repeat the immune tests we
15 were doing, the subset tests, and one of the things we
16 observed was that they didn't decline; they stayed
17 steady. Which was, if you like, reassuring. What
18 wasn't reassuring, and I've not described the resul ts
19 of the skin tests, but in a word, the skin tests sh ow
20 the more factor concentrate you received, the lower
21 score you got on your skin test. So there was
22 a direct dose relationship between the skin test
23 results and -- and that was more concerning.

24 We followed that up over the years, and in
25 people who are HIV negative, that stayed constant; it

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1 which appears to suggest that a reason for continui ng
2 to use factor concentrates was your wish to be able to
3 monitor immune status. In other words, professor, did
4 your, whether you call it research or investigative
5 ambitions, drive the treatment policy?

6 **A.** No, no, no, no, no. Treatment decisions were drive
7 by what seemed to be best for the patient, but if w hat
8 seemed to be best for the patient was the use of
9 clotting factor concentrates or other therapy, then
10 that should be monitored, as we were doing for all the
11 other monitoring investigations. I'm sorry, no. I
12 was not the other way round.

13 **MS RICHARDS:** Sir, I note the time. I've not yet finished
14 my questions. I don't have a huge number of furthe
15 questions myself but I do have some and I have some
16 that have been suggested by core participants.

17 **SIR BRIAN LANGSTAFF:** Let me turn to that in a moment but
18 I'm just fascinated by this recent exchange because ,
19 if I've understood it correctly -- please tell me i
20 I am wrong -- what you are describing is 1983, earl
21 1983, you realised that factor concentrates not onl
22 gave rise to a potential risk of non-A, non-B
23 infection and a real risk of HIV infection, but the re
24 was a third problem, which was neither hepatitis or
25 HIV, but that was the problem that it might, in any

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1 didn't decline further. Unfortunately, the people who
2 developed HIV infection, their skin tests declined
3 further.

4 **SIR BRIAN LANGSTAFF:** Now, the -- as you said in your
5 exchange with counsel, the purpose of monitoring ha
6 to be determined at the outset. You know what you're
7 monitoring for, and you have an idea why you're
8 monitoring.

9 **A. (Witness nodded).**

10 **SIR BRIAN LANGSTAFF:** You would not necessarily have known
11 when you started monitoring that the immune functio n,
12 as displayed by the T cell count, CD4 count, would be
13 the same from reading to reading, at least in those
14 who were HIV negative.

15 So what were you anticipating would or might
16 happen if the readings in such a person varied to the
17 disadvantage of the individual; showed that there w as
18 a decline in their immune system? What was going t
19 happen?

20 **A.** The first thing is, it was a little bit reassuring
21 that the lymphocyte abnormalities were not related to
22 the dose of treatment. So the degree of abnormalit
23 was not related to the amount of therapy. That was
24 reassuring.

25 **SIR BRIAN LANGSTAFF:** It didn't exclude, I suppose,

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1 a threshold effect. But beyond that, certainly, th at
 2 would be the --
 3 **A.** There may well have been a threshold. I mean, I'm
 4 happy to go to the 1984 paper if that would help.
 5 I --
 6 **SIR BRIAN LANGSTAFF:** No, I don't want to trouble you with
 7 that. I've taken you out of your answer, I'm sorry
 8 with my interruption. I beg your pardon.
 9 **A.** The reason I was suggesting going to it was a figur
 10 in the paper that shows two peaks, a graph with two
 11 peaks, of helper/suppressor ratios. One peak is
 12 equivalent to normal, and there's a completely
 13 separate peak for some of the -- in some of the
 14 patients. Patients were about half and half. Half
 15 had abnormal levels, as a peak, if I can put it tha
 16 way, and half the patients had a peak that
 17 corresponded to normal people.
 18 So it looked rather as if there was a switch.
 19 Now, I'm not an immunologist, but it looked as if s ome
 20 patients were particularly susceptible to having
 21 abnormal ratios, and it wasn't related to the dose of
 22 concentrate that they received. So we showed later on
 23 that the tissue type, the HLA type, of individuals was
 24 related particularly to the rate at which they
 25 declined clinically, sadly, after they got HIV

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1 got some idea of core participant questions because
 2 I've had a number overnight, but obviously the
 3 opportunity needs to be given to core participants to
 4 suggest some more.
 5 I would think I've got about an hour, including
 6 the questions I've had so far from core participant
 7 that I'm proposing to ask. There may be some more
 8 that arise out of this morning's evidence, I don't
 9 know. But it would -- it's roughly of that magnitu de,
 10 but you know how poor counsel are at time estimates .
 11 **SIR BRIAN LANGSTAFF:** Generally speaking, professor, if
 12 I'm given an estimate by counsel, I double it.
 13 **MS RICHARDS:** I don't think so.
 14 **SIR BRIAN LANGSTAFF:** It's a useful rule of thumb. The
 15 offer, really, is to give you a choice whether we g
 16 on this afternoon. We'll finish at some time this
 17 afternoon, probably earlier rather than later, I th ink
 18 is the sense of what has just been said to me, or
 19 whether you would prefer to come back on another da y,
 20 the other day, most probably, would be the
 21 14th December, Monday week.
 22 **THE WITNESS:** Thank you for the invitation. I think it
 23 would be most helpful to the Inquiry if I continued
 24 this afternoon. I'm happy to have a break for lunc h,
 25 and continue this afternoon.

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1 infection.
 2 I'm sorry, I can't quite remember how the HLA
 3 data might have related to the lymphocyte subset da ta
 4 in 1982. I can't remember whether we looked at tha t.
 5 I think we did look at it, but it would be an
 6 indication, possibly, of a genetic predispositio n
 7 switch.
 8 **SIR BRIAN LANGSTAFF:** Thank you very much. Now, what
 9 counsel has just told me is that she has some more
 10 questions for you, and I think what she's indicatin
 11 is that they aren't questions which might be finish ed
 12 within the next 20 minutes or so, in which case we
 13 might ask you to go on.
 14 So I think you're entitled to a choice because
 15 you had anticipated finishing at about lunchtime
 16 today, but let me give you a choice, whether we fin ish
 17 by continuing this afternoon. You will finish this
 18 afternoon?
 19 **MS RICHARDS:** Oh, yes.
 20 **SIR BRIAN LANGSTAFF:** And do you have any sense of timing?
 21 It may be difficult because you don't know what
 22 questions core participants might have to ask, or, for
 23 that matter, what Mr Reid might want to ask if he
 24 wants to ask any questions to clarify the evidence.
 25 **MS RICHARDS:** I certainly have no idea as to that. I've

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1 **SIR BRIAN LANGSTAFF:** I thought that's what you might say
 2 but I want to, particularly in the light of recent
 3 conversation about other things, to give you the
 4 chance of consenting, knowing what the position is.
 5 **THE WITNESS:** Thank you for explaining what the offers
 6 are, and I accept to come back after the lunch.
 7 **SIR BRIAN LANGSTAFF:** Well, thank you very much,
 8 professor. Much appreciated. We'll take a break n ow,
 9 then, until quarter past two. Quarter past two lon
 10 enough? Quarter past two.
 11 **THE WITNESS:** Yes, fine.
 12 **MS RICHARDS:** Thank you.
 13 (1.21 pm)
 14 (The Short Adjournment)
 15 (2.15 pm)
 16 **MS RICHARDS:** Professor Ludlam --
 17 **A.** Just before you start, could I say a couple of thin gs?
 18 Firstly, Sir Brian asked me about how we might chan ge
 19 therapy if -- having discovered that concentrates
 20 caused immune depression, separate from the viral
 21 infections. I didn't answer that question, sorry, the
 22 discussion moved on. The answer is that there was
 23 a move to produce purer concentrates, the Factor VII I
 24 concentrates produced in the early 1980s were very
 25 impure; they contained a lot of fibrinogen

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1 immunoglobulins, fibronectin, all sort of other
2 proteins. The amount of Factor VIII was minuscule, if
3 I can put it that way, and in the later 1980s or
4 mid-to late 1980s, the move was to produce much purer,
5 much more refined concentrates that had many fewer of
6 these impurities in. There were a number of
7 advantages in such concentrates, they were easier to
8 mix up.

9 There was a view, not supported by very much
10 evidence, but a view that possibly impure concentrates
11 would cause immune decline in those infected with HIV
12 more rapidly. If the concentrates were impure, the
13 would cause the CD4 counts to go down more rapidly and
14 therefore patients develop AIDS more quickly, and
15 there was a move, for that reason, to produce purer
16 concentrates.

17 The evidence was pretty flimsy, but people were
18 very keen to give every opportunity for patients to
19 get the best possible treatment, and that's why the re
20 was a move towards high purity, particularly in the
21 late '80s/early '90s. I realise I hadn't responded to
22 your question but that's the drift of where we were
23 moving.

24 **SIR BRIAN LANGSTAFF:** Thank you very much for that, I too
25 realised over the break that you hadn't answered that

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1 **Q.** What use did you make of heat-treated products in 1983
2 or 1984?

3 **A.** We assessed -- it might have been two different
4 concentrates that PFC were developing in -- at that
5 time. I think there were, if I can put it this way
6 trial Phase I infusions of a couple of products.

7 **Q.** How many of your patients in 1983 or 1984, prior to
8 December 1984, as far as you're able to recall, did
9 you treat with some form of heat-treated product?

10 **A.** None of them were treated with a heat-treated product.
11 These were test infusions to assess how the patient
12 responded to them.

13 **Q.** In December 1984 at the meeting that you've told us
14 about, I think you've indicated that patients were
15 told that they were now going to be receiving
16 a heat-treated product that was understood to be safe
17 in terms of transmission of HTLV-III. How was it
18 known, in December 1984, that the new NY product was
19 safe vis à vis HTLV-III?

20 **A.** I didn't say that it would be safe; I said it was
21 being treated and we hoped it would be safer. There
22 was no guarantee that it would not transmit the
23 HTLV-III.

24 **Q.** Had there been clinical trials of NY at that point?

25 **A.** There had been no clinical -- no, no. It had only

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1 particular part of the question. So thank you very
2 much.

3 **A.** Pleasure. Ms Richards, if I might just say I had
4 reflected on why I hadn't -- why I had asked for
5 ethical approval for the skin tests but not for the
6 lymphocyte tests and, as you saw this morning, I had
7 to think about it, and I've been thinking about over
8 lunch a little further, and I think it was because the
9 skin tests had not been previously carried out in
10 people with haemophilia. So it was a rather more
11 speculative investigation, and I think for that reason
12 I would probably have applied for ethical approval, as
13 well as it being an invasive investigation.

14 **MS RICHARDS:** Thank you.

15 **A.** I hope that helps.

16 **Q.** Most of the questions I'm going to be asking you
17 professor, are questions that I've been invited to ask
18 by various core participants. I mention that just
19 because we may leap around from topic to topic and
20 come back to some topics as a result of that. At the
21 time when the patients at the Edinburgh Centre
22 received the implicated batch in the spring of 1984
23 did you have available to you a heat-treated product
24 for clinical trial?

25 **A.** No.

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1 been heat treated the previous month, after the
2 publication of the Cutter and J Lilly's work from
3 San Francisco on mouse retroviruses.

4 **Q.** So is this right: it was hoped that it would not be
5 infective but there had been little, if any, by way of
6 testing or trialing that would establish that?

7 **A.** That's correct, yes.

8 **Q.** In terms of the AIDS Study that we were talking about
9 before lunch, were all of the Edinburgh cohort who
10 were subsequently infected part of the AIDS study?

11 **A.** I know that a goodly number had their lymphocyte
12 subsets measured prior to being exposed to the
13 presumed infected batch, because they all had severe
14 haemophilia and therefore were, you know, frequent or
15 relatively frequent attenders at the centre.

16 **Q.** So is it right that none of those patients who were
17 part of the AIDS study were given heat-treated
18 products prior to December 1984?

19 **A.** No, it is ... no, I'm thinking of one particular
20 individual who had -- was kind enough to allow us to
21 treat him with the test dose of one of the
22 heat-treated concentrates. It's very likely we had T
23 cell subsets on him. Sorry, was that your question?

24 **Q.** Yes, I think so.

25 **A.** The other thing is that there were four patients

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1 treated in November 1984 with the SNBTS NY that had
 2 been treated at 68 degrees for two hours to check that
 3 there weren't going to be any adverse -- immediate
 4 adverse effects from the treatment.

5 **Q.** We looked on Tuesday, I think it was, at a letter
 6 you'd written to Dr Craske in 1980 which described the
 7 patients at the Edinburgh Centre as being an almost
 8 unique group. You'll recall that's also the letter
 9 with the phrase in about being "useful material".
 10 I think subsequently it's been reported, described,
 11 that this was a unique group of haemophiliacs.
 12 I think you've used phrases in correspondence and
 13 publications about them having been very carefully
 14 followed up, close monitoring, and they've been
 15 described as one of the most extensively studied
 16 groups of HIV infected individuals in the world.

17 Patients who were infected in 1984 who may have
 18 learnt subsequently that they were participants in
 19 something called an AIDS study in 1983, have, as I'
 20 sure you're aware, raised concerns or expressed the
 21 belief that they were somehow deliberately infected
 22 for the purpose of research. Do you understand how
 23 and why they may have come to that view, and do you
 24 have any observations to make about it?

25 **A.** Thank you for asking me. Because I do have an

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1 to a further external authority like, for example, the
 2 General Medical Council. The problem with complaining
 3 to the General Medical Council in those days was that
 4 it was then impossible for me to meet with the patient
 5 to explain -- to offer an explanation.

6 And so the -- I submitted to the General
 7 Medical Council a report as to what had happened,
 8 about lymphocyte subset testing and so on, and then
 9 the -- how the infected batch had been identified.

10 The whole history was laid out to the General
 11 Medical Council. I assumed that that had been passed
 12 to the patient in response to the complaint because
 13 I responded to the written complaints that the patient
 14 had made to the GMC. So I replied to those
 15 complaints. I did my best to address them.

16 And I was horrified to learn recently, as a
 17 result of the Inquiry asking the GMC how it had
 18 handled a complaint, I was horrified to learn that my
 19 response to the patient's complaints had never been
 20 forwarded to him. I was appalled at that. So the
 21 patient then was left not having learnt how I viewed,
 22 how I responded to his complaint. I think that's
 23 absolutely appalling. And the patient didn't want to
 24 approach me. He thought I wouldn't provide the
 25 information. So I hope it's all right for me to say

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1 observation to make about it. I understand how the
 2 shortcut of writing "AIDS study" on a form then might
 3 have been misinterpreted when seen by the patient
 4 subsequently.

5 What I would say is I think it's very
 6 regrettable that the patient didn't either raise with
 7 me the question, or complain to the hospital about
 8 what their suspicions were because I would have been
 9 able to explain to them what I perceived to be the
 10 true situation that we were talking about before
 11 lunch. And I hope that would have satisfied the
 12 patient's concern. If they weren't happy with my
 13 explanation, if they had complained to the hospital
 14 the hospital would have taken it very seriously --
 15 clearly, it's a very serious allegation -- and
 16 a meeting would have been arranged, as happens with
 17 all complaints by patients, in which there would have
 18 been an independent chairperson. The patient perhaps
 19 might have wanted to come with a supporter, a spouse,
 20 or partner, or any other friend, and the questions
 21 would have been put to me, and I could have answered
 22 and explained what had happened.

23 If the patient, then having heard the
 24 explanation from me twice, still felt I was not giving
 25 them true information, then agreed it could be taken

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1 here that I have made available to the patient my
 2 response to the GMC, along with its appendices, that
 3 I had assumed had been sent to him 15 years ago.

4 I should say that the GMC arrangements now,
 5 I think, are different. They now -- there is now
 6 better liaison and initial assessment of the patients'
 7 complaints and making sure that they are appropriately
 8 addressed.

9 But I am appalled by what has transpired over
 10 the last almost 20 years in relation to this patient's
 11 very legitimate anxiety about what the AIDS Study was.
 12 I appreciate the details were laid out in the Penrose
 13 Inquiry, but then the patient shouldn't have to read
 14 Penrose reports in order to get a response to his
 15 anxieties.

16 Does that help?

17 **Q.** Yes. I may come back to some broader questions about
 18 the impact of events on doctor-patient relationships,
 19 but I'm going to move now to a separate topic.

20 If we could have, please, ARCH0003312_020,
 21 please. We can see this is a note of a meeting held
 22 on 10 February 2000 to discuss the information
 23 required to assist in the examination of the
 24 circumstances surrounding the safety of SNBTS blood
 25 products from hepatitis C. And we can see, in terms

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1 of the list of attendees, there are various, as it
 2 were, government representatives, including Dr Keel
 3 who I think is there in the capacity of being Deput
 4 Chief Medical Officer; is that right?
 5 **A.** That's correct, yes.
 6 **Q.** And then there are a number of clinicians present,
 7 Haemophilia Centre Directors present, including
 8 yourself. And if we look at the first paragraph, s
 9 if we just go slightly further down the page, please,
 10 Soumik. Paragraph 1 says:
 11 "Miss Teale opened the meeting with the
 12 introductions and apologies and explained the
 13 background to the request for information from the
 14 Haemophilia Directors. She outlined the minister's
 15 meeting with the Haemophilia Society and the
 16 minister's undertaking to examine the circumstances
 17 surrounding the safety of SNBTS products from
 18 hepatitis, C with particular reference to the
 19 Society's claim that Scottish patients were exposed to
 20 HCV longer than patients in England were."
 21 That was the purpose of the meeting, professor.
 22 There's then some exchange of information about
 23 potential numbers infected which I'm not going to ask
 24 you to look at.
 25 If we could go to page 4. If we look at

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1 could be tested for hepatitis C and presumably receive
 2 treatment. Is that right?
 3 **A.** I think that's correct, yes.
 4 **Q.** Now, what this appears to say is you're being told by
 5 those who are there representing the NHS and
 6 Government in Scotland that that's something for the
 7 Central Legal Office to decide, and there appears to
 8 be a concern that information might be used in future
 9 court actions. Do you understand what that concern
 10 was?
 11 **A.** Um ... **(Pause)**. I don't know whether it was triggered
 12 by the episode of non-A, non-B hepatitis experience
 13 by a patient in Edinburgh in 1986, or whether this was
 14 a more general -- I'm sorry. I can't ... I don't
 15 quite understand why the CLO would have reservations
 16 about doing this because it would be in -- potentially
 17 in the patient's interests.
 18 **Q.** Yes. You're suggesting, if I can put it colloquially,
 19 the right thing to do for patients, and you're being
 20 told that the haemophilia directors should follow
 21 Central Legal Office's advice on whether there should
 22 be any further tracking down of patients.
 23 Do you know what happened after this?
 24 **A.** I don't recall getting any advice from the CLO in
 25 relation to this matter, and in fact there was a very

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1 paragraph 9, it records this:
 2 "Professor Lowe pointed out that most patients
 3 would have been infected while their predecessors were
 4 in post and asked whether it was necessary to contact
 5 them to make them aware of the situation. Mrs Towers
 6 explained that this was a factual information
 7 gathering exercise, but it should be borne in mind
 8 that the information might be used in future court
 9 actions. Professor Ludlam also sought advice on
 10 whether Haemophilia Directors should be looking back
 11 to try to identify what had happened to patients whose
 12 whereabouts and status were unknown. Mrs Towers
 13 confirmed that the Central Legal Office was
 14 representing the Trusts and SNBTS, and that the
 15 Haemophilia Directors should therefore follow Central
 16 Legal Office advice on whether any further
 17 investigation or the tracking down of patients was
 18 necessary."
 19 As I understand this paragraph, or the summary
 20 of the discussion that's in this paragraph,
 21 Professor Lowe, and then in particular you, were
 22 raising the question of whether there was action that
 23 you should be taking to undertake some form of
 24 look-back and try to find out if there were patients
 25 who may have been treated in the past so that they

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1 full survey carried out in Scotland published in,
 2 I think, 2013 by Dr Khan from -- he and
 3 Professor Watson led this from Aberdeen in which they
 4 looked at patients who had, if I can put it this way,
 5 at some stage lived in Scotland who had haemophilia
 6 and what had become of them, and what treatment they
 7 had received, and whether they had responded to the
 8 interferon and ribavirin therapy, which was the best
 9 that was available at the time.
 10 The situation, obviously, is now very
 11 different. But there was this very comprehensive and
 12 very carefully conducted study from Aberdeen on behalf
 13 of Haemophilia Directors in Scotland to try to address
 14 some of this.
 15 **Q.** That's, with respect, professor, 13 years later
 16 because this meeting is in 2000. Do I understand from
 17 your evidence that whether or not you received further
 18 advice from the Central Legal Office, that you
 19 yourself did not take any action at that stage to try
 20 and identify what had happened to patients whose
 21 whereabouts and status was unknown?
 22 **A.** Oh, well, status -- any patient who would -- who was
 23 attending the Centre would be -- when they were
 24 reviewed annually, part of that review would be to see
 25 whether they had been tested for hepatitis C.

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I think we would have looked back -- I'm sure we looked back through our files at people who had moved on. And depending a bit on who they were, or at least what kind of haemophilia they had, and where they had gone, we might have contacted, if we had a follow-up address for them, and then we might have been in touch with them.

It was certainly something we thought about, but we didn't keep complete records of absolutely everyone who came through our door easily obtainable.

Q. Yes. It does look as though what you're proposing here is something more proactive and potentially extensive by way of a look-back exercise. Is it right to understand that that wasn't done until a number of years later with the exercise you've described from Aberdeen?

A. I think each Haemophilia Centre adopted a similar policy to what I've described. I think what the Kh an paper also reviewed was how patients had responded to different therapies that were being used during the previous decade or so. It was to bring together, if you like, the Scottish experience and to stimulate further inquiry in case there were other patients who, if I can put it this way, hadn't been traced -- or could be traced and hadn't been.

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questions about it. It's about a proposal for there to be data gathering about the HTLV-III status of sexual partners and household contacts.

So this is a letter from Dr Forbes, or Professor Forbes, in his capacity as Chair of the Haemophilia Directors AIDS Committee. This letter is not dated, but I think it's about August 1985, I think probably, from other information.

You'll see it's addressed to Centre Directors:

"The response to our request for anti-HTLV-III results on individual haemophiliacs has been very gratifying ..."

There's going to be a report. The next paragraph says:

"We have ... decided to ask Centre Directors to let us have data on the anti-HTLV-III status of regular sexual partners of patients who are both anti-HTLV-III positive and negative. We should also like any results on other household members (other than sexual contacts) again of both anti-HTLV-III positive and negative patients."

Then there's a request for brief details, if any of those family members have clinical manifestations likely to be due to HTLV-III, and then it says:

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SIR BRIAN LANGSTAFF: Can I ask this, Ms Richards, what was the capacity in which Mrs Towers was present.

MS RICHARDS: If you go back to the first page, Scottish Executive Solicitors Office.

SIR BRIAN LANGSTAFF: Yes, so she was legal, in effect?

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So if we go back to where we just were, please.

MS RICHARDS: On to page 4 again, thank you.

SIR BRIAN LANGSTAFF: This a lawyer hinting strongly, it might be thought -- but we'll have to see what is said -- that there shouldn't -- or that there should be great care in gathering facts because, in some way, future court actions might be affected.

MS RICHARDS: That appears to be what it says.

SIR BRIAN LANGSTAFF: Yes. I see.

MS RICHARDS: Yes, and so you're right, we may need to make enquiries elsewhere in relation to that.

SIR BRIAN LANGSTAFF: Yes, well, better I say nothing more about that at the moment.

MS RICHARDS: Professor Ludlam, I'm going to ask you now to look at another document on a completely different topic, HCDO0000271_101. HCDO0000271_101.

Professor, I'm going to ask you to look at four documents that are on the same topic and then ask you

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"... you may not have tested all sexual contacts or household members but any results that are available would be most useful. The results ... will be important as an estimate of the transmissibility of HTLV-III."

So that's the request that went out from Dr Forbes, Professor Forbes. If we then go to HCDO0000271_088, please. This is a reply from Dr Peter Jones, or a letter from Dr Peter Jones, to Dr Forbes 22nd October 1985. He refers to:

"At the last Reference Centre Directors meeting ... we agreed that a formal protocol be drawn up so that we knew exactly what we were looking for in this proposed study."

I should have said the letter is headed, "Sexual and Household Survey":

"At the meeting yesterday a form very similar to the one I had raised objections to in London was again presented by Chris Ludlam without a protocol. I did not want to say too much at the meeting but I am now writing to you formally to say that in its present form it is my opinion that the questionnaire that you intend to circulate to all Haemophilia Centre Directors is unethical. It could be construed as a breach of human rights. This a very sensitive an

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delicate area and the suggestion that any information concerning the sexual lives of our patients and their families be collected centrally will, I think, meet with a reaction which will do untold harm.

"I am as aware as anyone of the need for as much factual information as we can gather about HTLV-III disease but do not think that the people who are putting up this project have thought it through adequately. Until we have had a chance to discuss a proper protocol I must ask you not to circulate any forms requiring either the names or numbers of sexual partners of haemophiliacs to the Directors."

So that's Dr Jones, October 1985.

Third document, Professor Ludlam, it's dated a week or so later. It's HCDO0000271_096. We can see it's 30th October 1985, and it's a letter from Dr Forbes to directors on the same topic, a survey of the HTLV-III status of the contacts of haemophiliacs:

"There is much public anxiety about the transmission of HTLV-III between individuals. To investigate this further we are asking Centre Directors if they would like to participate in a study to assess the anti-HTLV-III status of household and sexual contacts of haemophiliac patients. It is suggested that these contacts of haemophiliacs should

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Directors as a whole. He says:

"As I shall be in America when the AIDS group meet next week, I'm writing to express my concern about how this survey is being conducted."

Then he sets out various specific concerns about forms and so on. I'm not going to go through it paragraph by paragraph. If we go towards the bottom of the page, we will pick it up in the last paragraph:

"In his covering letter to the Directors, Dr Forbes suggests that the ethical consent might be appropriate, but without a clear statement of the intent of this survey, local ethical committees face a difficult task. What the survey appears to be asking for is lists of the sexual and household contacts of haemophiliacs of whatever severity to be written down on the same form (thereby identifying families in smaller centres, even without the use of names) and sent to Dr Rizza. From earlier discussion, it would appear that these 'Confidential' details will then be studied by at least a further four people."

And from the initials there, I think one of them is probably you, CL.

Then if we go to the next page:

"... and be processed either by hand or computer on at least two sites (Oxford and

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be studied, whether the haemophiliacs are anti-HTLV-III positive or negative.

"A study such as this may raise anxieties in the patients and their families. It is therefore important for Directors to discuss the nature of the study and the possible implications of the results with families before seeking their permission to participate. You may feel it would be desirable to obtain formal written consent from the individuals taking part in the study. If so, we suggest you use your own Consent Form for this purpose. It also might be appropriate to seek approval from your local ethical committee before embarking on the study.

"Clearly it will not be possible to test all sexual or household contacts of all patients. Furthermore, you may have reservations about asking haemophiliacs to divulge details of sexual contacts. Even if you are unable to test all potential contacts we would welcome the return of any available data.

"The form should be returned to Dr Rizza in an envelope marked 'Confidential'."

Very last document, Professor Ludlam, before I ask you about this issue. HCDO0000271_87.

This Dr Peter Jones again, 27 November 1985, and we'll see he's writing here to Reference Centre

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Manchester). No guidance is given, nor details asked about the type of anti-HTLV-III test in use, nor about the value of confirming a single positive result."

Then Dr Jones says this:

"This is shoddy stuff, and we should be ashamed to see it go out from an organisation that purports to care for people with haemophilia."

Then he quotes from a Lancet leader on AIDS. And then says:

"If it continues without proper ethical and epidemiological guidance and without 'a free exchange of information with those at risk', this survey will fulfil Mayer's definition and make the more important sexual survey of risk factors proposed by Dr Johnson extremely difficult if not impossible to conduct."

Professor Ludlam, I wanted to show you all four of those, just so you see how the exchange of correspondence went.

First of all, looking at it broadly from a UKHCDO perspective, why did UKHCDO consider it was part of its role as an organisation concerned with the care of people with haemophilia to gather information about the HTLV-III status of the partners and household contacts of haemophilia patients, whether they are HTLV-III positive or not?

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1 **A.** Well, I think we were concerned, very concerned, about
2 possibility of sexual transmission, and it was
3 valuable to know how extensive this had been, or this
4 was.

5 **Q.** Why would you need for that purpose to have the
6 HTLV-III status of household contacts, not those in
7 a sexual relationship, and the HTLV-III status of
8 partners and household contacts of haemophilia
9 patients who were themselves negative?

10 **A.** Um, let me deal with the second question first about
11 patients anti-HTLV-III negative.

12 As this was at a time shortly after the
13 introduction of the test, and we thought that proba bly
14 people who were negative were not infected with the
15 virus, we couldn't be absolutely certain. And that's
16 why we gave out the advice, as you know, that all
17 patients should use, for example, contraceptive
18 sheaths and assume that there could be sexual
19 transmission.

20 Your first question was about -- was it
21 household contacts?

22 **Q.** Yes. If your concern is about sexual transmission,
23 why would you need data about household contacts?

24 **A.** Well, that's clearly not sexual transmission; that is
25 a concern about household transmission within

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1 Directors being a sensible group of physicians, if
2 I can put it that way, seeing the problems of this,
3 and just not responding. And so the survey was
4 never -- I don't know whether Dr Rizza got any form
5 back. Certainly none came my way. I think the thi ng
6 never got off the ground, and I think probably righ tly
7 so.

8 **Q.** If it didn't get off of the ground on a UKHCDO leve l,
9 did you yourself seek to gather similar data in
10 relation to the partners and household contacts of
11 your patients?

12 **A.** Well, I think I indicated a day or two ago that we
13 were very keen that sexual contacts were offered
14 a test.

15 Household contacts -- we had one or two
16 requests for household contacts, but the evidence was
17 that it was not spread to non-sexual household
18 contacts, so we didn't routinely encourage members of
19 the family living in the same house to come forward

20 Because, as I say, we had one or two queries
21 from people who were particularly concerned, and
22 I remember one -- I think there was a possible medi cal
23 reason -- and they were tested, so -- but it wasn't
24 a blanket policy. It wasn't a policy at all.

25 **Q.** Other than in the circumstances in which you've

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1 a household.

2 **Q.** Did this survey go ahead?

3 **A.** No. I think you've seen the history of it. It was
4 raised, I think, initially by me because of the -- our
5 concern, and I wanted to -- for the organisation to
6 think about the risks of sexual transmission. And
7 I think it was Dr Rizza who drew up the forms. I o nly
8 recently, I think -- well, reminded of the forms. It
9 was discussed at, I think, an AGM. It might have b een
10 the AGM -- it must have been -- perhaps it was the AGM
11 in '85, and agreed.

12 I fully understood the reservations and agreed
13 with much of what Dr Jones was saying in his
14 correspondence and what is recorded in the minutes of
15 the meeting, the one that he attended. And I think
16 the forms were sent out, but I don't recall any of
17 them being returned.

18 The Haemophilia Centre Directors, as you see,
19 were independent-minded people, and most of them were
20 quite sensible people and saw that this was --
21 particularly the way the forms had been set out -- was
22 going to be extremely difficult. I mean, I hadn't
23 envisaged the results being sent in in quite the wa
24 that Dr Rizza had set out the forms.

25 But it's a good example of Haemophilia

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1 described in relation to specifically undertaking
2 HTLV-III tests for the sexual contacts, over what
3 period of time was blood taken, sought, from the
4 partners of haemophiliacs at the Centre?

5 **A.** I think, apart from the samples that we'd talked ab out
6 that were taken for the -- initially for genetic
7 tests, the samples that will be taken for
8 anti-HTLV-III testing for sexual contacts would go
9 direct to virology. There wouldn't be any stored i
10 haematology. It would just be a simple anti-HTLV-I II
11 investigation. I presume -- I imagine -- you would
12 need to ask the virologist -- I imagine they were
13 stored there for a period. -- (overspeaking) --

14 **Q.** Do you know whether, by the time you retired in 201
15 from the Royal Infirmary, whether there were still
16 serum samples from spouses or family members of
17 bleeding disorder patients held in the hospital?

18 **A.** There would have been from patients. Spouses -- th
19 samples from the genetic studies back in the
20 mid-2000s, I suspect -- the need for those had long
21 gone, and I suspect they were probably disposed of.

22 Whether there were -- there were samples from
23 patients, as far as I recall, still in existence in
24 deep freezes when I retired, yes.

25 **Q.** And just --

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1 **A.** Was that the result of -- does that answer your
 2 question?
 3 **Q.** Yes. Just before I move on to another topic,
 4 specifically again in relation to spouses or family
 5 members, you told us earlier in the week about the
 6 genetic testing. We looked at a letter which invited
 7 recipients to agree to have stored samples used for
 8 hepatitis testing. You've told us about HTLV-III
 9 testing.
 10 Are there any other purposes, research or
 11 otherwise, as far as you can recall, to which the
 12 samples of spouses and household contacts or family
 13 members were put?
 14 **A.** No, I don't think they'd been used -- they may well
 15 have been thrown out. I'm sorry, I can't -- I'm sure
 16 they weren't used.
 17 **Q.** Another completely different topic, Professor Ludlam.
 18 I want you to cast your mind back to the first half of
 19 the 1980s and the relationship with Northern Ireland
 20 and with the Belfast Haemophilia Centre and Dr Mayne.
 21 What do you know about the arrangements for
 22 SNBTS, Scotland, to supply Northern Ireland with blood
 23 products?
 24 **A.** My recollection is that the Blood Transfusion Service
 25 in Northern Ireland obviously collected the blood,

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1 I think the Factor VIII Working Party it was initially
 2 called; meetings of Haemophilia Centre Directors for
 3 Scotland and Northern Ireland to develop coordinate
 4 arrangements for haemophilia care. How did that come
 5 about and why?
 6 **A.** The Coagulation Factor Working Party was established
 7 at the suggestion of Scottish Home & Health Department
 8 because there was a need to develop a new Factor VIII
 9 concentrate for Scotland, one of higher purity. An
 10 the Scottish office, I think very sensibly, suggested
 11 that there should be discussions between the potential
 12 producers, SNBTS, and the users, the Haemophilia
 13 Directors, and that this needed to be taken forward
 14 reasonably rapidly.
 15 And so I was asked to chair a working party of
 16 key individuals in SNBTS, the Scottish office, and
 17 haemophilia directors. I chaired the meeting. There
 18 was Professor Lowe from Glasgow, there was
 19 Professor Cash from SNBTS, Dr Perry from Protein
 20 Fractionation Centre, Dr Keel from Scottish Home &
 21 Health. There was -- I'm sorry, I've forgotten his
 22 name -- a colleague from SNBTS who provided
 23 secretarial services for the group, and we met quite
 24 frequently, almost monthly, to consider the
 25 development, what kind of clotting factor concentrates

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1 separated the plasma, and sent the plasma to
 2 Edinburgh, a protein fractionation centre, for
 3 processing into blood components, blood products, like
 4 Factor VIII and albumin and Factor IX and possibly
 5 immunoglobulin, and that was returned to Northern
 6 Ireland, I think, on a, if I can put it this way, pro
 7 rata basis. In other words, they got back roughly the
 8 amount from the plasma that they supplied.
 9 **Q.** Was Scottish and Northern Irish plasma pooled?
 10 **A.** I can't answer that question. You'd need to ask
 11 SNBTS.
 12 **Q.** Do you recall any discussions with Dr Mayne from the
 13 first half of the 1980s about blood product safety and
 14 product usage?
 15 **A.** She was, like the rest of us, keen to keep patients on
 16 the same type of concentrate and not to switch between
 17 different sources, if I can put it that way, of
 18 concentrate.
 19 Like I've been keen to try to keep everyone on
 20 PFC Factor VIII. You raised the issue, perhaps
 21 yesterday, about batch dedication and the importance
 22 of trying to limit the donor exposure of patients.
 23 Dr Mayne, I think, was -- had the same philosophy.
 24 **Q.** Your statement tells us that there came a point in
 25 1988 in which there was a formal arrangement --

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1 should replace Z8, which was the one that was
 2 introduced in 1987; heat treated like the VIIIY at
 3 80 degrees for 72 hours.
 4 **Q.** Do you know whether any consideration was ever given
 5 to plasma from Wales being fractionated by SNBTS in
 6 a similar way to the arrangement with Northern
 7 Ireland?
 8 **A.** I've never heard of that suggestion.
 9 **Q.** You've referred, on a number of occasions, to
 10 an archive, Professor Ludlam, your archive. Is that
 11 an archive within Edinburgh University, or is there
 12 some other kind of archive?
 13 **A.** There are two archives, if I can put it that way.
 14 When I retired, I had received, a year or two before,
 15 a leaflet describing the Lothian Health Board archive,
 16 and they were keen to receive administrative material
 17 from individuals about their life and work in the
 18 hospital, and I have files that went back over many
 19 years, some of which I thought covered quite
 20 interesting topics, and I asked the archive if they
 21 would be interested and they seemed very enthusiastic.
 22 I said: "Look, I can't be absolutely certain
 23 that there isn't any patient identifiable information
 24 in any of these, it's mostly about minutes of meetings
 25 and other such administrative documents, but there may

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be reference to patients or there may have been things misfiled in the files". I said "I can't be responsible for that", and they said, "Oh no, not a worry", they very carefully looked through everything before they make it available.

So I let them have what I could describe as administrative files, and they went off to the Lothian Health Board archive.

After the Penrose Inquiry concluded, I -- with assistance, because there's quite a lot of material -- boxed up all the information I had in relation to haemophilia matters, and including information about the cohort, some of the original documentation that Dr McClelland and I looked at to try to assess what had happened. I thought this was important information, for all sorts of reasons, as is very clear to the Inquiry.

All this was boxed up, and stored -- I don't know where it was stored -- by the hospital, the Royal Infirmary.

I retired and I don't know where they stored it, what they did with it, but it was securely stored.

It was then conveyed, or I saw it first in the University of Edinburgh archive, I think it's probably where part of the Lothian Health Board archive is.

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interactions and meetings with the Scottish Home & Health Department. Do you know whether similar arrangements and meetings took place on a regular basis with other medical specialities, so non-haemophilia? Did you, for example, have similar arrangements to do with leukaemia care?

A. Well, I wasn't, as you know, leading the leukaemia service. I don't recall long term meetings at the Scottish Home & Health for, let's say, leukaemia. There might have been a series of meetings in relation to particular topics, like bone marrow transplantation and resources, where should resources be put for bone marrow transplantation in Scotland?

So they would be, if I can put it this way, in response to a need, sort of project based arrangements.

I'm sorry, I've been out of it for a little while. I'm just trying to think of what other specialties might have had long-term relationships. I mean, I think I would say about, if I may, haemophilia care, historically, it has tended to be organised on a national basis, not just in the UK, but to some extent in other countries, because of its dependency on the Blood Transfusion Service and its ability to produce cryoprecipitate. So there needs

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Well, it is, as far as I know, stored there at the moment.

Q. Just in terms of information that may be direct patient information, there may be some -- or, in fact, there's likely to be some -- in the material that you've referred to which -- including the raw data that you and Dr McClelland worked on, and that's documentation you handed over to the Royal Infirmary, so we would need to look to them to find the answer to that.

The material that is held by the Lothian Health Board might also include some patient information, although you thought it was largely minutes and the like; is that correct?

A. The second part is correct. The first part is the information in relation to haemophilia that I boxed up, if I can put it that way, after the Penrose Inquiry. That is, as I understand it, is now in the university library in a secure -- a very secure environment. I'm not quite sure whether it's formally part of the Lothian Health Board archive or whether it's being held on behalf of the hospital. You would need to ask the Royal Infirmary, I think. I presume they are the technical owners of the documentation.

Q. You've referred, and indeed been asked about,

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to be co-ordination between the producers, the Blood Transfusion Services, and the users, the haemophilic physicians and their patients.

So there's a long history, and the World Federation of Haemophilia run by the patients is extremely successful, going in to less-well-developed countries with a programme for developing haemophilia care, and part of their protocol is getting the blood transfusion services and the Government and the patients and the patients' physicians all together to develop the arrangements.

Q. I asked you earlier in the week, professor, about your knowledge of the safety of the donor pool in Scotland and, in particular, the Edinburgh region.

Did you know anything at the time of the Medicines Inspectorate report relating to the PFC in the early 1980s?

A. I don't think I did and, even now, I'm not sure I remember any of the detail. So I don't think -- I knew subsequently there had been but, I'm sorry, I don't think -- it didn't enter into, as far as I recall, part of my thinking in terms of working with SNBTS and PFC.

Q. You told us about your policy of using domestic concentrates, considering them to be safer than

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1 imported concentrates; do you accept and were you
2 aware at the relevant time in the 1980s that, given
3 that these domestic concentrates were nonetheless
4 pooled products, did you understand that the pool was
5 only as safe as its least safe donor?

6 **A.** You see by my hesitation it's quite a difficult
7 question to answer, and it depends in what way the
8 least safe donor is, in inverted commas, "unsafe". If
9 the unsafety is potentially damaged by the process of
10 fractionation, then that isn't, or may not be,
11 clinically important.

12 The unsafe donor, if I can use that term,
13 whatever is unsafe in that donation might be
14 neutralised by antibodies, assuming it's -- thinkin
15 in terms of viruses -- might be neutralised by
16 antibodies in the -- provided by the rest of the
17 donors, and parvovirus, I think, is an example of
18 that, where a lot of us have antibodies to parvovirus,
19 and that may neutralise the odd parvovirus positive
20 donation. So if you like, there's a built-in
21 self-neutralising arrangement.

22 So that's why I'm slightly delayed in
23 responding, because it's complex.

24 **Q.** Perhaps a similar way of asking the question is this:
25 did your loyalty to local concentrates lead you, do

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1 to me to suggest to you that they were 10 to 15-minute
2 appointments, usually.

3 **A.** It would depend on the patient. They are very
4 variable. It might be a patient who had had few
5 difficulties in the year with feeling well, had hardly
6 had any bleeds, might have had no bleeds, and we
7 reviewed the results, and we would have -- I would
8 have reviewed how things were for him, he might have
9 been only in seeing me for a quarter of an hour,
10 perhaps.

11 There might be other patients who have had
12 difficulties during the previous few months, or who
13 brought concerns to me, questions, and the occasion
14 would go on much longer. I don't remember -- and I
15 there were times when -- I hardly remember any of
16 these -- one couldn't consider everything the patient
17 wanted to talk about or, more likely, as some medical
18 issue arose that required a bit more thought and
19 investigation, then they may well have gone off for
20 some investigations, I would see them on a further
21 occasion and one would have discussed it. But review
22 appointments, my recollection is that they were for
23 half-hour slots on the diary, on the -- on my Tuesday
24 afternoon clinic.

25 **Q.** You've described the -- the somewhat limited physical

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1 you think, to disregard the possibility of risks of
2 viral transmission from the local pool?

3 **A.** If you're thinking of HTLV-III and disregard, no.
4 I appreciated there was a possibility, but I thought
5 the chance was very small.

6 **Q.** If we come on back to the question of information
7 provided to patients and recorded in their notes about
8 risk, you said, I think possibly on Tuesday, that
9 you've been trained not to note things which were said
10 to patients which were obvious. You gave an example
11 of there being nothing wrong with somebody's spleen
12 so you wouldn't record it. Why would it be obvious
13 that you would have discussed the risks of treatment
14 with patients and hence didn't need to record it in
15 the notes?

16 **A.** Because it would be part of the general conversation
17 in discussing the results, for example from their
18 previous visit, the hepatitis B results, the liver
19 function tests, the blood count results, which can be
20 abnormal in infections.

21 It would be -- on that basis, I think, was
22 generally believed and accepted by patients that there
23 were risks of virus transmission by concentrates.

24 **Q.** What was the length of an average regular appointment
25 in the first half of the 1980s? It's been suggested

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1 facilities at the Centre, certainly in the earliest
2 part of the 1980s. Where, typically, you would have
3 the conversations with patients about risks or
4 research or AIDS studies or whatever it might be,
5 where would those conversations physically be taking
6 place?

7 **A.** Those would take place either in the review clinics in
8 the medical outpatient department, the Tuesday
9 afternoon that I've discussed, and they would also
10 take place in the Haemophilia Centre room in ward 23.
11 Those are the most common. Occasionally patients came
12 to the Department of Haematology, and we had a small
13 consulting room there, but that was pretty infrequent
14 because there were a number of stairs up and down to
15 get there, and I think that was difficult, if you had
16 haemophilia.

17 **Q.** What efforts did you make in the discussions you saw
18 you had with patients about risks and research, and so
19 on, to ensure that they understood the explanation
20 that you had given them?

21 **A.** I suppose just by their responses, and by their
22 further questions.

23 **Q.** Does that mean you would, as a matter of generality
24 assume they'd understood you unless, what, they
25 physically looked puzzled, or they asked you

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1 a question?

2 **A.** Perhaps I should say, if I felt I hadn't made myself

3 clear, I'd -- I would ask, you know, "Do you

4 understand this?" Or "Have I confused you?" Or "Can

5 I put it a different way?"

6 I tried to -- not only about viral infections,

7 but any interaction with a patient, part of the

8 process is assessing the patient is understanding what

9 I am saying and trying to check it out if I don't

10 think it's going right. That's part of what

11 a consultation is.

12 **MS RICHARDS:** Sir, I've been over an hour. Counsel's

13 estimate as ever. I don't expect to be another hour,

14 but I'm going to be more than another few minutes.

15 I don't know whether Professor Ludlam would like

16 a break before we complete his evidence, or whether he

17 wishes to continue, or what you'd like to --

18 **SIR BRIAN LANGSTAFF:** Perhaps you could give him some

19 sense of what a "few" might be.

20 **MS RICHARDS:** Possibly 20 minutes, half an hour, I'd say.

21 **SIR BRIAN LANGSTAFF:** Professor, would you like a break,

22 or would you like to continue?

23 **THE WITNESS:** Could I have a short break?

24 **SIR BRIAN LANGSTAFF:** Certainly.

25 **THE WITNESS:** My mental ability is not like it used to be,

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1 high ALT, or there were disturbances of the other

2 liver tests, or the patient had symptoms that might be

3 ascribed to hepatitis, then of course I would mention

4 that in the letter. My hesitation is, I think at one

5 stage we did experiment with -- when the letters were

6 typed, there was a sort of automatic way in which

7 laboratory results were sort of tabulated at the end

8 of the letter.

9 I can't remember what became of that. I don't

10 think it was terribly routine but I think it was

11 an attempt to -- and because, certainly, the full

12 blood count results for other patients with

13 haematological disorders would be routinely put at the

14 bottom of the page.

15 **Q.** At the meeting in December 1984, that lecture theatre

16 meeting that you've told us about, did you spell out

17 to those who were in attendance that the source of the

18 infection for those who were infected was an SNBTS

19 product?

20 **A.** Oh, that was -- yes, that was made clear and

21 Dr McClelland, who was the director of the Blood

22 Transfusion South-East Scotland, was at the meeting

23 and spoke at the meeting, and explained the situation.

24 **Q.** On the issue of the possibility of AIDS in the blood

25 donor population, I think you've told us earlier in

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1 I'm afraid. I get slower as the day goes on. Cup of

2 tea and a biscuit, I think, will improve the quality

3 of my responses.

4 **SIR BRIAN LANGSTAFF:** What, 15 minutes, do you think?

5 Would that do it, or would you like longer? Fifteen?

6 **MS RICHARDS:** Professor Ludlam, is 15 minutes sufficient?

7 **THE WITNESS:** Fifteen minutes is fine for me, thank you.

8 **SIR BRIAN LANGSTAFF:** Twenty to four, in that case.

9 Twenty to four.

10 **(3.25 pm)**

11 **(A short break)**

12 **(3.42 pm)**

13 **SIR BRIAN LANGSTAFF:** Yes?

14 **MS RICHARDS:** Professor Ludlam, when you told patients --

15 sorry, let me go back a step. I think you told the

16 Inquiry in the course of the week that patients were

17 told about their ALT results.

18 **A.** Yes.

19 **Q.** When you did that, did you send details of the actual

20 results, as a matter of routine, to the patient's GP?

21 **A.** My hesitation is because I think the system may have

22 changed. Mostly, one -- I would not send detailed

23 results, and because mostly the ALT would only be

24 minimally elevated. That was one of the features.

25 If the patient appeared to have particularly

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1 the week that you did make some enquiries about

2 infections in Scotland. Can you recall who you made

3 those enquiries of and when?

4 **A.** I certainly had contact with Dr John Emslie, who was

5 in the Scottish equivalent of the CDSC in Colindale,

6 he ran the Scottish service, and I think I was in

7 touch with one of our GUM physicians who I knew quite

8 well. It was a colleague.

9 I think that would be probably 1983, but I'm --

10 I certainly kept my ears to the ground when I met

11 people who I thought might know, and I didn't get a

12 inkling from the Blood Transfusion Service that there

13 had -- if I can put it this way -- experienced

14 individuals coming to give donations and then there

15 being some uncertainty about their suitability.

16 I got no inkling, no suggestion at all from

17 them, that there was any reason for concern.

18 **Q.** Earlier in the course of your evidence this week

19 I asked you about cryoprecipitate, the use of

20 cryoprecipitate, and in particular we looked at

21 a meeting from February 1984, which recorded you

22 saying that cryoprecipitate was preferred in the

23 treatment of children at present because of the new

24 danger of AIDS. You'll recall that, I'm sure.

25 Two children under your care were infected in

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1 1984 with the SNBTS batch. Why were those children
 2 not being treated by that time with cryoprecipitate
 3 **A.** Because they both had severe haemophilia and were o
 4 home treatment, very successfully.
 5 **Q.** Do you recall, and again I don't want to ask you
 6 a question which leads to any patient-identifying
 7 information, but do you recall whether you talked t
 8 their parents and offered cryoprecipitate as
 9 an alternative, even if it meant suspending home
 10 treatment?
 11 **A.** I don't think I did offer it.
 12 **Q.** You said, in the course of your evidence again, whe
 13 I was asking you about the December 1984 meeting, that
 14 you couldn't tell the 16 infected patients sooner than
 15 you did because that would have been logistically
 16 problematic. But your evidence suggests that you did
 17 invite around 200 patients to make appointments wit
 18 you in the weeks that followed. Is it really the case
 19 that you couldn't have seen those 16 patients withi
 20 a fairly short span of time, as soon as you'd got the
 21 results?
 22 **A.** It clearly, logistically would have been possible.
 23 I think the difficulty was at our end, coming to terms
 24 with what had happened and what the implications were,
 25 and if we had started to see a few patients, it would

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1 situation was carried out by Mrs Geraldine Brown, who
 2 is our social worker, and that's something she would,
 3 I think, have explored in discussions with patients
 4 **Q.** Did --
 5 **A.** And also, I should also say, as Dr Alison Richardson,
 6 who came in perhaps a little later into our service
 7 but it was very generally known that I was keen that
 8 all sexual contacts should be offered testing. Not
 9 just the social worker but the nurses formed --
 10 patients not infrequently latched on to a particula
 11 member of staff in the small team and shared their
 12 difficulties with that individual. And that system
 13 seemed to work really well, and everyone knew about
 14 sexual transmission and the importance of
 15 anti-HTLV-III testing of partners.
 16 **Q.** Did you take up the post of consultant and director at
 17 the Haemophilia Centre because of the opportunities it
 18 offered for research with this almost unique group of
 19 haemophiliacs?
 20 **A.** Oh, no. I had been born in Edinburgh, brought up
 21 first part of my life there. I've been back as
 22 a student. I had worked for 3 years -- 4 years, after
 23 graduating. I think it's a great place to live. It's
 24 got a very good medical school, and I was very lucky
 25 indeed to be appointed -- had nothing to do with ho

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1 very quickly have got round, because the patients were
 2 very much in touch with each other, it was quite
 3 a close-knit community. It would have got round very
 4 quickly that I had arranged to see specific
 5 individuals, and make this information available to
 6 them, which would raise anxieties amongst the rest of
 7 them.

8 It was -- I agree it could have been done, but
 9 it was not without consequence and, as I have learn
 10 over the years, you can do things with the best of
 11 intentions and, subsequently, in retrospect, one might
 12 have done them differently; one is continually
 13 learning. We certainly learnt a lot from this
 14 episode, this whole, awful tragedy, that helped us
 15 with the hepatitis C and the variant CJD issues later
 16 on.

17 **Q.** You've talked about the importance of offering
 18 HTLV-III testing to the partners of patients who were
 19 HTLV-III positive, how did you address the position of
 20 the partners of the patients who did not know their
 21 HTLV-III positive status?

22 **A.** I would need to think about that a little further.
 23 I can't give you a straight answer but what I can say
 24 is that much of the counselling of these patients and
 25 the thinking through the implications of their

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1 the patients with haemophilia were being treated.
 2 **Q.** I'm going to ask you to look at a document from 197
 3 which I hope you received from the Inquiry this
 4 morning. If not, it's a very short passage, so I hope
 5 it won't inconvenience you.

6 It's LOTH0000119_006. You will see,
 7 Professor Ludlam, it's the minutes of a meeting in the
 8 Royal Infirmary on 22 July 1970. It's, in fact,
 9 looking at the issue of the outbreak of hepatitis i
 10 the Royal Infirmary that you've discussed earlier i
 11 your evidence.

12 If we could go, please, to page 4, Soumik. Can
 13 we look at the bottom half of the page. I'm really
 14 using this as a convenient reference point, professor.
 15 I don't know if it's a document you ever saw in
 16 Edinburgh.

17 The penultimate -- so you've got heading
 18 "Ethics of clinical research", and the penultimate
 19 paragraph says -- well, actually, no, I'll pick it up
 20 part way through that first main paragraph under the
 21 heading of "Ethics of clinical research":

22 "The executive committee also recommended that
 23 all research projects or investigative procedures not
 24 directly related to patient management or treatment
 25 and involving discomfort or risk should be referred to

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the Ethics Committee for approval, and that new methods of treatment involving potential risk should be referred for agreement. It had been considered that signed documented consent by the patient should not be obtained, but that the position should be explained to the patient in the presence of a second doctor or state-registered nurse. The fact that permission had been obtained should be put into the case notes."

Now, first of all, did you know of these recommendations?

A. I've not seen this document before, no. Not until about quarter of an hour before we started this morning.

Q. I think we sent you another document from 1976 which is to similar effect. The reason we've sent them to you, professor, is obviously because they're local documents.

Was what's set out here, even though you hadn't seen it, nonetheless, your understanding of the procedures that should be applied in relation to research projects?

A. Well, the last sentence of the first paragraph, I think, is particularly telling:

"The executive committee also recommended that

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experimental, so I wrote and got ethical approval for that.

Q. What about the next paragraph? It suggests that if a patient is participating in clinical research, the position should be explained to the patient in the presence of another doctor or nurse, and it should be recorded in the case notes. Which elements of those did you adhere to?

A. I'm not sure that I would adhere to the witness side of it.

As I mentioned earlier, consent for -- patients one is seeing over a long period of time, you get to know really rather well, and it's important that there is a free exchange of information and views and trust between both parties. It's part of the doctor-patient relationship. And part of that relationship is finding out how the patient is getting along, and part of that relationship is my explaining where we are, what we are doing to monitor their therapy, and telling them what we are doing, and seek their approval for doing so.

So it's really very important with any patient that one is in a long-term professional relationship with, in my view, to be very open and honest, straightforward, to build up and maintain trust,

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all research projects or investigative procedures not directly related to patient management or treatment."

And obviously those involving risk should be referred. It rather implies that if the research is related to the patient's management, then perhaps it needn't be referred to the Ethics Committee.

Now, I have no idea what guidance was given to individuals as to which patients -- which projects should be identified as being referred to the Ethics Committee. Clearly, any project that involves intervention or risk should be, but I just highlight that.

Q. Irrespective of what this document says, what was your guiding principle in the 1980s, in terms of an application for referral to the -- an application to the Ethics Committee or referral to the Ethics Committee?

A. I would -- I had a very low threshold for seeking ethical approval. As you know, I sought ethical approval for the skin tests, which are hardly invasive. I even sought ethical approval in, I think, December 1984 to undertake anti-HTLV-III testing in all my patients who were receiving concentrate. It seemed self-evident that it was sensible to do that. But it was something new, and someone might view it as

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because if that isn't successful, then there are difficulties.

In relation to signed consent and written consent, I've mentioned earlier how we felt patient didn't need to sign a document, though we did prepare one, and wondered whether it would be helpful.

I would say that we recorded in the notes of the patients what investigations had been done, as well as the Haemophilia Centre keeping a book with a list. But I have seen some case notes in which the doctor has written out a list of all the individual investigations, including one that says, "Serum to store" with a tick beside it. I'm afraid I was a bit more abbreviated. I used to write "Routine tests" and tick it, to imply that our routine investigations had been done.

So that's the basis on which I felt we had consent from patients. It was part of the relationship with them. They knew me, they knew us and we mostly got along pretty well together. And the patients were interested in what we were trying to do, as we were interested in them as individuals and part of their families.

Q. Again, on a new topic, you -- in relation to the Z8 clinical trials in, I think, 1987 onwards, you were

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1 not prepared to have your patients involved in
2 clinical trials of PFC products at that stage, unless
3 compensation was put in place for adverse events; is
4 that correct?

5 **A.** That is correct, yes.

6 **Q.** And I think you'd advocated for that for a longer
7 period of time, prior to 1987?

8 **A.** I first raised the issue in 1983.

9 **Q.** Why did you regard it as important?

10 **A.** Because I felt that there was a-- an informal
11 understanding that if a patient had suffered as a
12 result of a trial of a PFC product, that the patient
13 would be reasonably compensated financially. It was
14 a sort of an informal understanding, and I thought
15 that wasn't good enough.

16 The ABPI, Association of British Pharmaceutical
17 Industries, had a Code of Practice for assessing
18 patients or volunteers, both patients and healthy
19 volunteers, who took part in the assessment of new
20 drugs. And in that assessment arrangement, it was
21 carried out by, I think, three individuals; three
22 prominent, well informed individuals, I'm sure one of
23 whom was a senior lawyer. And it was a very clear
24 process, an open process, and it seemed, as an
25 outsider, a reasonable process.

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1 whether or not there was a formal clinical trial, for
2 the purpose of adding to knowledge of the pros and
3 cons of the product?

4 **A.** Oh, yes, certainly. Any adverse reaction was
5 automatically sent to the Blood Transfusion, so the
6 had knowledge of significant events, yes.

7 **Q.** We're nearing the end. Not quite there yet.

8 PRSE0002656. This should, I hope, be the
9 minutes of a UKHCDO meeting on 16 June 1989.

10 Yes. So we can see it's an extraordinary
11 general meeting of UK Haemophilia Centre Directors to
12 discuss haemophilia HIV and litigation on 16 June. If
13 we can carry on down, please, Soumik. Go to the next
14 page. Sorry, actually, forgive me, Soumik. Go back
15 to the first page. Go to the bottom of the page.

16 We can see representatives of medical defence
17 organisations, department and health, and legal
18 advisors were there.

19 And then if we go on to the next page, please,
20 Soumik. Yes, so we can see here that previously
21 Dr Rizza had done a presentation about allegations
22 being raised. You are then here recorded, second half
23 of the page, as presenting a document about the
24 history of progress of HIV and haemophilia.

25 And then if we go to the next page, please, we

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1 There wasn't such a process in existence, as
2 far as I could ascertain, for PFC or SNBTS products
3 And I was just a bit unhappy about that, and I raised
4 this; could we not have a system similar to the ABPI?
5 I can't remember all the history of it, but it's
6 a rather torturous history, that there were long
7 delays in getting Government approval. It involved
8 the Treasury, and a whole range of issues got drawn in
9 to it, and so it lost its focus, as far as I was
10 concerned.

11 And it came to a bit of a head in I think it
12 was the beginning of 1987 -- you might be able to
13 correct me if have the documentation -- when I said,
14 well, I'm not going to test anything more from PFC
15 until I get a written assurance that the arrangements
16 are going to be what I and my colleagues consider fair
17 and reasonable. And eventually, that did the trick
18 The Scottish Government eventually agreed. I could go
19 through some of the details. I'm sure you don't want
20 to hear it.

21 **Q.** No, I don't need to ask you the detail. We do have
22 a number of documents relating to it.

23 Is this right, though, as a matter of fact, you
24 have consistently reported information about reactions
25 to PFC products throughout your time in Edinburgh,

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1 can see there's a presentation from Dr Hill. And then
2 at the bottom of the page, we then get the
3 interventions or advice from, I think, the Medical
4 Defence Organisations. If we go on to the next page,
5 please.

6 We can then see in paragraph 4, so bottom half
7 of the page, it's being said by Dr Allsop that
8 Haemophilia Centre Directors should be prepared to
9 take on the role of giving expert advice, and it's
10 said:

11 "If the Directors did not agree to act as
12 experts the plaintiffs' solicitor would have to see
13 expert advice from outside the Directors' group. This
14 would be undesirable and not in the best interests of
15 anyone."

16 Do you know why it was being said it would be
17 undesirable to have the involvement of those who were
18 outside of UKHCDO?

19 **A.** No, except that all the experts, if I can put it this
20 way, were within UKHCDO. So people outside UKHCDO are
21 not in a position to be treating individuals with
22 haemophilia. There was the occasional haematologist,
23 for one reason or another, who looked after a patient
24 with haemophilia at this time, but they would hardly
25 be regarded as an expert. So all the experts were

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1 within UKHCDO.
 2 **Q.** Within the UK, that might be the case --
 3 **A.** Yes.
 4 **Q.** -- but there could of course have been internationa
 5 experts, and was this is an attempt for directors t
 6 protect themselves, and UKHCDO to protect its own?
 7 **A.** I don't think so, no. I think we would have
 8 welcomed -- at least, I can only speak for myself.
 9 I would have welcomed experts from outside the UK t
 10 come and comment upon the way things were rolled ou
 11 in the UK.
 12 **Q.** If we go to page 11, please, now Soumik.
 13 So if we zoom in on the third paragraph,
 14 please. We can see you say this -- sorry, just to put
 15 it in context, at the top of the page, one or two
 16 people that raised the question of continuing to treat
 17 patients who were suing them. Then it said it's
 18 a matter for the patient and consultant to discuss:
 19 "Dr Ludlam said he asked his patients in front
 20 of a witness if they wished still to be treated by him
 21 and made a note of the conversations in the patient's
 22 file. Dr Allsop thought it was a good idea to do a
 23 Dr Ludlam did."
 24 Why did you have your patients in, those
 25 involved in litigation, and ask them in front of

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1 So, as you know, I -- or yes, I think you do
 2 know, because I was sent some of the correspondence --
 3 I wrote to Kenneth Clarke when he was Minister of
 4 Health to ask that the government offer no-fault
 5 payments in support for the patients, and I wrote t
 6 various other MPs in both parties to promote this, and
 7 I and, I can say all, haemophilia treaters were put in
 8 an awful position, having a pile of writs saying we
 9 were incompetent with patients we had loved and looked
 10 after. As you see, it was awful and it made we won der
 11 what on other was going on at the Department of
 12 Health.
 13 Here they were funding the Health Service,
 14 trying to support patients, at the same time drivin
 15 a wedge between a group of very vulnerable patients
 16 and their treaters.
 17 **Q.** Before --
 18 **A.** I think I have probably said enough on the topic.
 19 **Q.** I'm, in fact, going to ask you to look at the lette
 20 you wrote to Mr Clarke in a moment, but before we
 21 leave this document or the issue on this document, as
 22 a matter of fact, a patient with a lifelong bleedin
 23 disorder living in a particular area is not really
 24 going to have much of an alternative, are they, other
 25 than to carry on being treated by the Centre at which

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1 a witness if they wanted to continue to be treated by
 2 you?
 3 **A.** Well, I received, as did other haemophilia directors,
 4 a summons or perhaps you call them writs, suggestin
 5 that I had fallen below the standard of an ordinary
 6 competent haematologist. Therefore it seemed only
 7 appropriate either that another physician looked after
 8 the patient or, at least, I discussed the situation
 9 with the patient.
 10 It was a dreadful position to put us in, and
 11 this was because of government policy, that patient
 12 had to demonstrate negligence. I can't think of an
 13 better way of splitting up the precious relationshi
 14 between a patient and his physician than to act in
 15 this particular way, and it -- I have to say, I did
 16 this for four or five patients, what I've -- what I
 17 said -- stated here. I stopped doing it after that
 18 because it felt so awful to have to do. But when
 19 you're being accused in a legal document of falling
 20 below a standard of an average haematologist, when
 21 you're trying to do your best, you think you're
 22 reasonably well up in the specialty, in a teaching
 23 hospital and, until this writ arrived, the patient
 24 seemed pleased with the way they were being looked
 25 after.

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1 they were infected, potentially under the directors hip
 2 of the consultant at the time.
 3 **A.** You're absolutely right. It's the Hobson's choice.
 4 I was the only person with the expertise in southea st
 5 Scotland at the time and, subsequently, there were
 6 situations in which I tried to recruit another
 7 consultant to help, and I couldn't find anyone who was
 8 prepared to assist me.
 9 It's also at a time, I would say in the decade
 10 after this, that it became very difficult to recrui
 11 into the specialty, because of the difficulties tha
 12 had arisen in relation to all of this.
 13 **Q.** I am going to ask now that we look at the letter yo
 14 wrote to Mr Clarke and use that, as it were, as the
 15 springboard for my final questions for you.
 16 LOTH0000069_022, please, Soumik. We can see
 17 it's November 1989, to Kenneth Clarke, and you've s aid
 18 this:
 19 "I know you are aware of the great tragedy that
 20 has befallen 1,200 haemophiliacs in the UK who have
 21 become infected by HIV."
 22 You refer then to the Macfarlane Trust and the
 23 payment and say:
 24 "Whilst this is clearly of some benefit to them
 25 it is a long way short of what might be considered

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a reasonable settlement as compensation.

"The campaign to obtain no fault compensation for these unfortunate individuals will continue. I is clear it has received a great deal of support ..."

Then you say:

"It would greatly enhance the standing of the Government if it could be seen to be caring for the patients.

"I have been approached by your Department to ask if I would be prepared to act as an Expert Witness in the forthcoming litigation. I am therefore very familiar with much of the background to the HIV problem and know that such litigation will be potentially very damaging.

"I very strongly urge you to have discussions with the Haemophilia Society and The Macfarlane Trust to try and devise a system of reasonable compensation, after all many European countries have already gone along this path."

I wanted to ask you, first of all, arising from this, about what you say about litigation being potentially very damaging. Not going to put on the screen yet other further UKHCDO minutes, but there are number of UKHCDO meetings at this time, at which there is a substantial discussion about litigation and there

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years.

Q. Did the work being undertaken in relation to litigation lead UKHCDO or its clinician members to adopt a closed or overly defensive position, in your view?

A. Oh, I don't think so. We had nothing to be, I think, particularly defensive about, in general. No, I think -- I don't think UKHCDO had a particular position. You mentioned that I joined, or a small group litigation group was formed. I'm sorry, I can't remember if we ever actually met or what happened. Perhaps I could add, as the letter to Mr Clarke has been taken down off the screen, I mention apparently I had been approached by the DoH to act as an expert witness. I did not act as an expert witness for the impending class action. I was asked by the English Health Authorities if I would do so, and I agreed, and you have a copy of my draft report to them from that time.

Q. Did the UKHCDO's collective work and response to litigation, or the advice and involvement of organisations such as -- sorry, such as the Medical Defence Organisations have the effect of discouraging individual clinicians from providing a full and independent account of the events involved?

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was the formation of a litigation group, I think, of which you were included: you, Dr Jones Dr Rizza, and Dr Savidge.

Did the work on litigation which, first of all, the UKHCDO as an organisation decided to undertake, distract or divert that organisation and its member from the core purpose of improving the treatment of haemophilia patients, do you think?

A. I think that's a very pertinent question because all of this has had a very detrimental effect upon the development of haemophilia services in the UK. The time spent by many of us has been huge, and staff have found it very demoralising with all the various investigations and the time spent in writing reports. It has taken us -- I think, the minutes you had up on the screen a moment ago, I was glancing at the other day, and I think I said in that meeting that I spent -- I was given three months off from my routine duties in order to be able to compile medical reports in response to this litigation that was arriving around this time.

That was very depressing work. It took me away from actually providing a service for patients, and was very demoralising. It has had a dreadful effect upon the whole of haemophilia over the last 20 or more

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A. I don't think so. I think people were very prepared to very openly and straightforwardly explain the history, if it was an individual patient, or what policies we had adopted. I don't think recall us -- we were concerned, but I don't think we were being defensive in the way I think you're suggesting we might have been.

Q. In the letter that you wrote to Mr Clarke, you urge the Government to provide some form of financial recompense, even without an admission of liability, and you talked about, I think, the importance of the Government being seen to be caring towards those infected.

Was there also some merit in Government, the NHS, health boards, UKHCDO, individual clinicians, making some form of public statement of regret for this tragedy at the time?

A. I think it was the views of UKHCDO members, the physicians, the Haemophilia Directors, that this was all a terrible tragedy. UKHCDO was not one to -- actually to issue statements. It's not like a Government department with a press office.

I think it was clear, at least, that it was a terrible tragedy. A regrettable terrible tragedy. But I do have a difficulty with some of the statements

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that come from members of the Government, when they said -- they say that the events should never have occurred, implying that HIV and HCV infection should not have occurred. For prime ministers to make those statements shows to me a paucity, to put it politely, of understanding of the history and the difficulties of the last 50 years, and I am disappointed when they speak in such terms.

Q. Modern medical practice emphasises the importance of the need for candour, for insight, and for reflection when things go wrong or when things could have been done better than they were. Do you think those qualities were shown by you and your colleagues at the time?

A. I could always do better. I always try and learn from experiences. I'm sure I could have done things better than I did, and I have certainly learnt from the experiences of those years.

Q. Looking back --

A. And I -- sorry. I'm sorry. I agree that there's now a more open way of being able to discuss when things go wrong. That is sometimes difficult, I have to say, when you suddenly find that you get a writ from a patient's solicitor accusing you of negligence, and you're then expected to go on looking after the

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19 December 84, then the process of informing the patients would have rolled out in a much more reasonable and controlled way, and I think patients would have been better managed as a group. But it was this -- it was difficult enough to manage the many issues raised by HIV without the difficulties of the Yorkshire Post.

Q. Are there any other observations you would want to make about the way in which you or your colleagues or the NHS bodies with which you were associated responded to the events with which this Inquiry is concerned?

A. I suppose I'm surprised by some of the comments that I've received from the Rule 9 requests; patients apparently not understanding their situation, which I found didn't quite accord with my reflections of the individuals.

Now, that may reflect the passage of time for myself and for the patient. But I suppose it's emphasised to me the importance which can't, I suppose, be over-emphasised, of spending time, thinking through with the patient their situation, and I think perhaps checking out more that they have understood what I think I have said to them.

I think one of the things I have learnt over

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patient. Not only that, but the patient seems pleased to come and see me; rather see me than another physician who might actually have been more appropriate to look after the patient.

So it's a very difficult situation, and one that takes some difficulty to accommodate, when you have a writ for negligence, and at the same time the patient is keen to come and see you. It doesn't make life terribly easy. I'm delighted to see the patients, but it is difficult.

I think much has improved as a result of the terrible tragedies of HIV, not just in haemophilia but in the wider community. And what we have learnt in medicine as a result of the consequences -- not the medical consequences; the social consequences and the medical consequences -- of HIV and the way we practice medicine now is completely different from how it was in the early 1980s much for the better, I add.

Q. And looking back now, what do you wish you had done differently?

A. I wish I had perhaps been more proactive in encouraging patients to come up and find out about their HTLV-III results. I -- if there hadn't been the Yorkshire Post and the need to have -- or the way I had responded, by having the meeting in

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the years, and this applies beyond this particular situation, is the importance of not making assumptions. One has to make assumptions all the time to get through life, every day. But to check this in out more carefully as to what a patient understands. And not only a patient, but when I'm talking to my friends and relatives, I'm more careful now to check out that they've understood what I'm saying and that I've understood them.

MS RICHARDS: Sir, unless Mr Hill tells me there have been any further questions suggested, those are my questions, for Professor Ludlam. I don't know whether Mr Reid has any questions.

MR REID: No, I don't. Sir, thank you for the invitation, but it's a thank you but no thank you from me.

MS RICHARDS: Before I ask Professor Ludlam if there's anything further he wants to add.

Questions by SIR BRIAN LANGSTAFF

SIR BRIAN LANGSTAFF: I do just have two questions. At the moment, I'm looking at you, Mr Reid, so I'd rather look at Professor Ludlam. No disrespect intended.

MR REID: I'll turn my camera off.

THE WITNESS: I can't see anything now.

SIR BRIAN LANGSTAFF: We can see you now.

Just two matters. To take you back, really, to

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1 part of today's testimony and part of yesterday's when
2 we were talking about AIDS and the tests. The AIDS
3 Study that we talked about earlier today, when did you
4 get the first results from it, do you think?

5 **A.** Oh, they were back within a week or two. And we
6 started -- I can't remember exactly, but perhaps in
7 February '83, so I'd have had some results by
8 March '83. I have those dates in my mind because, as
9 you may recall, I wrote to The Lancet in response to
10 a letter of Robert Gordon's, and I think my letter was
11 written perhaps in April '83, so we must have had the
12 results by then.

13 **SIR BRIAN LANGSTAFF:** You described the effect on you
14 today in these terms: that you were very surprised and
15 perplexed and quite a bit of puzzlement. So it came
16 as a bit of a shock to you, did it? Because you had
17 expected that there would be no problem with those who
18 had been on Scottish PFC concentrate.

19 **A.** Yes.

20 **SIR BRIAN LANGSTAFF:** You're nodding.

21 **A.** Yes.

22 **SIR BRIAN LANGSTAFF:** The reason I ask that is when you
23 were asked the day before -- actually, 2 December --
24 about the tests which were done by Dr Tedder for you,
25 you put it in almost exactly the same terms, that you

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1 evolution of damage done to a cohort evolved. That
2 was the very early testing when he sent us cohorts of
3 samples, which he already had a clinical suspicion
4 something had occurred."

5 That was the beginning of the evolution of the
6 knowledge of the Edinburgh context. And you said no,
7 you had no clinical suspicion.

8 **A.** That's correct.

9 **SIR BRIAN LANGSTAFF:** Can you clarify for me whether, by
10 the time you got the reports back from Tedder, you did
11 or didn't have a clinical suspicion at that time?

12 **A.** I -- (overspeaking) --

13 **SIR BRIAN LANGSTAFF:** I'm trying to reconcile these two
14 accounts.

15 **A.** I didn't have any clinical suspicion. It was only
16 when I got the results back, probably of the larger
17 number, perhaps the second batch, and that I went
18 through who the patients were, and I saw that one of
19 them was the individual who had had the operation in,
20 I think it was March or April 1984, and had had
21 a horrendous postoperative course. It was only when
22 I saw that his result was positive that I began to
23 wonder whether it was actually due to the HIV, and
24 because we had these stored samples, I could go back
25 and see that he was negative before and he was

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1 were, in effect, shocked at the results because you
2 hadn't expected any adverse results.

3 **A.** Yes. I would say that my degree of shock was far
4 greater with Dr Tedder. In 1983, it was more
5 puzzlement and surprise and wonder about the result
6 because I didn't think in 1983 that the abnormalities
7 that I was finding were due to a putative AIDS virus
8 or AIDS effect. AIDS virus, yeah.

9 **SIR BRIAN LANGSTAFF:** Although you did know by then that
10 such findings were known to exist in those who had
11 later or were diagnosed as suffering from AIDS?

12 **A.** Yes. Individuals with AIDS had much more severe
13 immune abnormalities than I had demonstrated or I had
14 found in my patients, and the memory -- the sort of
15 results that I was finding were the same order of
16 magnitude as were reported by Michael Lederman and the
17 colleague -- the other paper in the New England
18 Journal in January 1983 in the asymptomatic people
19 with haemophilia.

20 **SIR BRIAN LANGSTAFF:** Now, when Dr Tedder spoke to the
21 Lindsay Tribunal, the passage that counsel took you to
22 on 2 December, she quoted to you what he had said,
23 that:

24 "Christopher Ludlam obviously getting more and
25 more pensive and me feeling less and less kind as this

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1 positive afterwards, and it then began to make sense,
2 although I don't think anyone had previously described
3 anything like this in the literature, and that's why
4 I wrote it up for others to learn from our experience,
5 because it was -- it was a frightening episode.

6 **SIR BRIAN LANGSTAFF:** So the study which had been designed
7 to monitor patients' progress, so far as immune
8 systems were concerned, and your surprise and
9 astonishment at the results a while earlier than your
10 discussion or your conversation with Dr Tedder, had
11 given you no suspicion at all that something might be
12 untoward?

13 **A.** There was still puzzlement. As I mentioned this
14 morning, one of the things that was positive, if I can
15 put it that way, was that the immune tests, these
16 lymphocyte tests didn't seem to decline over time,
17 they were static, so that gave me a bit of confidence.
18 As I mentioned, I think this morning, when we did the
19 skin tests, they didn't change over time either, so
20 again, that was good. It doesn't -- it was
21 reassuring, I should say, because one of the -- as
22 I was hinting this morning, one of the other
23 possibilities was that AIDS could occur in people with
24 haemophilia, as a result of, if you like, side effects
25 of the impurities in the concentrate, and I was

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1 fascinated to read minutes of a meeting that were sent
2 to me as part of the documentation prior to this week.

3 Minutes of a meeting in February 1984, at the
4 National Institute of Biological Standards and Control
5 discussing infections transmitted by blood and, in
6 that, Dr Tedder was talking about the cause of AIDS
7 and he said, well, there were sort of two point of
8 views: one is that it's due to a virus and, at the
9 other end of the spectrum, it's not due to a virus,
10 it's due to side effects of the contaminants and the
11 blood products, and he said the truth probably lies
12 somewhere between the two.

13 I was fascinated to read that in February 1984
14 from a virologist, a prominent, not at this stage in
15 the field, but in the field of hepatitis B, he was
16 an international expert, and, as we all know, he came
17 into this field, what he described himself as
18 a recycled hepatitis B virologist.

19 But I was fascinated to read that even
20 a virologist took that breadth of view in
21 February 1984.

22 **SIR BRIAN LANGSTAFF:** So that suggestion might be read as
23 being that those who had an overload of protein
24 causing alterations to their immune system might have
25 been more pre-disposed than others to fall victim to

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1 **SIR BRIAN LANGSTAFF:** Thank you. The second question
2 relates to the letter to Ken Clarke. At the time that
3 that letter was written, 29th November 1989, did you
4 know that suggestions were being made about you and
5 your own practice in Edinburgh?

6 **A.** I had received writs before that. I think the first
7 writ I received was 1988. I received several,
8 I think, in 1988, of patients who were told that they
9 had to demonstrate negligence before they received
10 support.

11 **SIR BRIAN LANGSTAFF:** When was it that you first raised
12 the question of compensation being paid on a no-fault
13 basis, do you recall? Was it this letter to
14 Ken Clarke or not?

15 **A.** I think I wrote to MPs in 1987, when all the
16 difficulties were starting to roll out. I wrote to
17 a number of MPs to say that the Government should
18 consider some way in which it can help these
19 individuals.

20 **SIR BRIAN LANGSTAFF:** By "difficulties", what do you mean?

21 **A.** Oh, they were starting to become ill, they needed more
22 support. There was a lot of need by the --
23 particularly support by the -- for the patients. You
24 know, they became less well, they needed to spend more
25 on simple things like heating. I remember a patient

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1 the HIV virus once it was exposed, once they were
2 exposed to it in the form of developing AIDS?

3 **A.** We demonstrated from our analysis of the cohort, if
4 I can put it that way, the individuals who got this
5 infected batch, that not only were people with the
6 abnormal lymphocyte tests more likely to get infected,
7 but those who used, in general, more Factor VIII in
8 the year, in fact in the previous three years, were
9 more likely to get infected.

10 So they were pre-disposed, and --

11 **SIR BRIAN LANGSTAFF:** By Factor VIII, you mean Factor VIII
12 concentrate?

13 **A.** Yes. Yes. So they were pre-disposed in two ways.
14 One is -- well, they would -- if they got a lot of
15 Factor VIII in general, not from the implicated batch,
16 but over the years, if they were big users, when they
17 were exposed to the virus, they were more likely to
18 get infected.

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

20 **A.** We also demonstrated that if they got more bottles, as
21 you know, of the batch, they were more likely to get
22 infected. So there was an underlying -- in my view
23 an underlying predisposition to infections, not just
24 HIV but perhaps TB and candida as well, as a result of
25 the concentrate therapy.

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1 who got central heating in his house, I think, paid
2 for by the Macfarlane Trust, and how much better he
3 felt, for actually being warmer. He got arthritis.
4 It's not good being cold, if you're warm -- and I was
5 amazed actually he volunteered this at one time I saw
6 him. It was good.

7 **SIR BRIAN LANGSTAFF:** Thank you. That's all that I have
8 to ask.

9 Ms Richards?

10 **MS RICHARDS:** Professor Ludlam, there are no further
11 questions for you. Is there anything further that you
12 would wish to say?

13 **THE WITNESS:** I would thank you for hearing me out this
14 week, and I'm sorry I've been a bit slow on occasions.
15 I would thank the Inquiry for, if I can put it this
16 way the additional question at the end of the long
17 list of questions for my rule 9 response.

18 The additional question of is there anything
19 further that I'd like to add, and I note that today
20 much of what I put in to this invitation has been
21 considered, and I thank the Inquiry for doing so.

22 I don't think I've got anything further to add
23 than what I did in that -- in the paragraphs I put
24 into that response to the offer, and I appreciated the
25 invitation.

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1 The only other thing I think I would say is
 2 I wish the Inquiry well, I look forward to seeing the
 3 report and I hope it is of help to everyone who's been
 4 affected by these terrible tragedies. Thank you.
 5 **SIR BRIAN LANGSTAFF:** Thank you for those words and I'd
 6 like to thank you also for your evidence, which is not
 7 so much slow, I think, as the word Richard Tedder used
 8 "pensive" on occasions, perhaps. You understand how
 9 sometimes oral evidence can be of real importance, and
 10 yours, if I may say so, has been, for much of the
 11 time, riveting, certainly revealing, in a way that the
 12 printed page of the witness statement cannot easily
 13 be, and certainly informative, particularly for
 14 someone who has been at the helm in Edinburgh
 15 throughout much of the period with which the Inquiry
 16 is focused.
 17 I'm sorry we made you work overtime today, but
 18 I thank you for having done so, and you are the first,
 19 I think, witness who has, as it were, had a week to
 20 yourself, so it's a long and gruelling time, I'm quite
 21 sure. Thank you very much.
 22 **THE WITNESS:** Thank you, Sir Brian.
 23 **MS RICHARDS:** Sir, we resume on Monday at 10.00 with the
 24 evidence of Dr Pettigrew, we will then continue on
 25 Tuesday with the evidence of Professor Hann, which may

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1 continue onto Wednesday morning and then we have the
 2 evidence of Professor Lowe for the remainder of the
 3 week.
 4 **SIR BRIAN LANGSTAFF:** Yes, so it's ten o'clock on Monday
 5 morning. Thank you very much.
 6 **(4.53 pm)**
 7 **(The hearing adjourned until 10.00 am on Monday)**
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