

Wednesday, 21st October 2020

(10.00 am)

PROFESSOR CHRISTINE ANNE LEE, on former affirmation

Questioned by MS RICHARDS (continued)

MS RICHARDS: Professor Lee, before we turn to look at HIV and AIDS, there is just one matter from yesterday I wanted to go back to first. You told the Inquiry yesterday, or your evidence may have given the impression that in the period '83 to '84 and up until the point, really, when you became a consultant, in 1987, at the Royal Free, you had very little day-to-day clinical contact with patients.

A. Yes. Obviously, I would have had contact with patients because we were in the centre, and there were some patients who needed to have blood tests. And I can particularly remember there was a patient who I described yesterday, an elderly gentleman who had an undiagnosable chest infection, that I did see. I remember that.

So I must have had an honorary clinical contract to work in the hospital, but that wasn't my primary role. The vast majority -- I spent four days a week -- I had no on call commitments, and the vast majority of my time was spent looking at notes and analysing all that.

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Q. Could we just look at what you said about your work in an interview you gave in 2015 as part of the Royal College of Physicians Oral History Project. So it's THOM0000001, please, Henry. If we go to the bottom of page 26, please, Henry. I just want to show you a handful of passages and check whether these accurately convey the balance of your workload. So the very bottom of the page starts:

"Now, my primary task when I went there was to follow up patients with haemophilia who'd had their first treatment ever with a large ..."

Sorry. I'll wait until we go to the top of the next page.

"... large pool clotting factor concentrate, that's Factor VIII or IX."

And that's the research work that you've described, I think. And then if we go a few lines down, about ten lines down, you should see a passage beginning:

"So my job was to follow up these patients, and they were quite well. They just -- you know, some of them had had an operation; some of them might have had some trauma, which was why they'd had it, but I used to see them take the blood, and then that was tested, and we also used to store it."

So there's that description of seeing patients

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taking bloods. And then if we go to page 28, please, Henry. About seven lines down from the top, there's a passage beginning this:

"Then alongside all this comes this strange immunological problem, and I used to look after the patients as they presented. You know, I was -- although I was a pathologist by training, I had done a lot of general medicine, and I was quite a good physician, and they were presenting with strange infections."

Then you go on to refer to the patient who I think is the one that you just mentioned. If we go a number of lines further down, so it's four lines up from the bottom of the screen as it currently is. If you leave it there, Henry, it says:

"So I was seeing these patients."

And then there's a reference to the Haemophilia Society. Then if we go to the very bottom of this page, you say this:

"So to go back to my patients with haemophilia in these two years, I was looking after them clinically, but also, I was doing the research."

So the two years there are 1983 and 1984, aren't they?

A. Yes. I think I would like to just set this in context a little. This is 2015. I'd been retired ten years,

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and basically I hadn't done any clinical work for ten years. The Royal College of Physicians' history project was actually to lay down a history archive, and they were particularly interested in the position of women in medicine in the 1960s. You know, when I was at Oxford doing my undergraduate degree towards medicine, there were ten women. You weren't allowed to have any more than ten women in the whole university doing medicine. So that was the basic thrust of it.

The interviews were done by an oral historian, and I think in total in this oral history project, there were three days of continuous -- she was asking the questions, and I would dictate on the phone.

I would also like to stress that, you know, in no way was this saying under oath; I was just reminiscing in my own house. And what has happened in this Inquiry is that I've actually read all the papers and begun to remember more. It's quite -- it's really very difficult, you know, remembering back 1983, 37 years now. Then it would have been 32 years, I think.

So I think what I would say now, in memory, is that my -- most of my four days -- I would say 80% of my four days was spent looking at information and analysing information. I wasn't -- I didn't have clinical

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1 responsibility in the sense of decision-making, but
 2 I was in the department, I was a qualified doctor, and
 3 I had an honorary contract. So if there was a problem,
 4 I could be asked to see that person.

5 The main clinical care, the first person of contact,
 6 as I explained yesterday, was the junior doctor rotating
 7 through the department who was a senior registrar in
 8 haematology, and he or she was there to train in
 9 haemophilia care. So if he or she didn't know anything,
 10 or had a question or a query, who would they come to in
 11 the department who knew something about this strange
 12 condition that was coming? Who in the department would
 13 they ask about the hepatitis? The hepatitis, by the
 14 time -- and I think I explained this to you yesterday --
 15 the study was from April 1978 to March 1983, and
 16 I actually took up my job at the end of January '83.
 17 And as I recall -- and I'm just recalling, trying to
 18 remember 37 years ago -- I think there were about two
 19 patients left who still required to be seen every two
 20 weeks to take their blood sample.

21 So I hope that answers your question.

22 **Q.** Just two follow-up questions, if I may. The first is,
 23 in your answer a moment ago you posed a question,
 24 a rhetorical question: the senior registrars who would
 25 be seeing patients --

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1 **A.** Sometimes it was a registrar. It wasn't always a
 2 senior registrar.
 3 **Q.** -- and you posed a question: if they needed to speak
 4 to someone or discuss something, who would they ask?
 5 Is the answer to that question that they might come
 6 and talk to you about this strange new condition or
 7 about hepatitis?

8 **A.** They might come and talk to me, but clearly the -- and
 9 I tried to explain this yesterday. The Haemophilia
 10 Centre worked as a multi-disciplinary team. It had to
 11 because there was so much work coming and so many
 12 disciplines that we interacted with. You know, there
 13 were -- as I said yesterday, there were the nurses,
 14 there were the counsellors, family therapists, there
 15 were the junior doctors, there was the
 16 physiotherapist, there was the people that we
 17 interacted with, like the orthopaedic surgeon, the
 18 liver doctors, and later the HIV.

19 So when I say they came and asked me, they came and
 20 asked me probably primarily, but clearly the person who
 21 had the clinical decision-making around that patient was
 22 Dr Kernoff.

23 **Q.** Yes, and I'm not trying to requite your role in any
 24 respect with the role of Dr Kernoff. I'm just trying
 25 to understand roughly -- and I know I'm asking you

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1 about events a long time ago -- how much time you
 2 spent seeing patients, because your answers here
 3 suggest that you did at least spend some time with
 4 patients.

5 **A.** Yes, I just said. I spent four days a week. I'm
 6 sorry to bore you with domestic things, but it just
 7 gives you an idea of the fact that I was
 8 semi-part-time. I used to deliver my children to
 9 school. I used to get to the Royal Free at
 10 ten o'clock in the morning, Monday to Thursday, and
 11 I used to leave at five o'clock.

12 So, you know, that's not a very big clinical
 13 responsibility. And I had a desk in the corner of one
 14 room, and I spent most of the day sitting at this desk
 15 looking through notes, looking at results and things.
 16 Just remember, we did not have a computer. It was quite
 17 detailed sorting through numbers and things that you had
 18 to do.

19 **Q.** You gave an estimate -- and I understand it's only an
 20 estimate -- that about 80% of your time was spent on
 21 the research work. So would it be fair to infer that
 22 approximately 20% of your time may have been spent in
 23 more direct patient interaction?

24 **A.** It may have been. I think the other thing that should
 25 be recorded here is that the organisation of the

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1 Haemophilia Centre -- I did say yesterday that
 2 Dr Kernoff was really rather ahead of his time, having
 3 a management committee that managed, but what he also
 4 did -- we had lunchtime meetings.

5 On a Tuesday, there was a lunchtime meeting of
 6 appropriate people to discuss -- it was called
 7 a social work meeting. But essentially, it was to
 8 discuss the needs and requirements of -- as the time
 9 went on, of people with, as it turned out, HIV
 10 infection or AIDS, and hepatitis or haemophilia
 11 problems. You know, people had to have cars and
 12 sorting out that. There were little children where
 13 maybe the school was being difficult, about the child
 14 keeping -- going there and keeping treatment there.
 15 And the nurses would be at that meeting. And, you
 16 know, we had a nurse that went into the community to
 17 train the parents, and that might be something that we
 18 would discuss at that meeting because, clearly, and as
 19 many people in this room will know, it's not easy
 20 injecting yourself, and it's certainly not easy for
 21 parents to have to inject children, and it takes a lot
 22 of time to do that training.

23 So this meeting was a clinical meeting, if you like
 24 to call it that way. So that was on a Tuesday
 25 lunchtime. And on a Thursday lunchtime, we had almost

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1 a total department business meeting. And the important
2 thing about that meeting was that in the week ahead, we
3 would be seeing people, and the laboratory, particularly
4 if we had -- you know, we were having new referrals all
5 the time, so somebody had a bleeding disorder in some
6 small district general hospital in Essex. That
7 haematologist would refer that patient for investigation
8 in our centre.

9 So this lunchtime meeting on a Thursday, we would
10 have a sheet of paper telling us what was happening next
11 week because the laboratory had to do these tests, and
12 we had to make sure that they weren't going to have
13 a problem with the tests. And we also needed to know
14 whether everything was organised for the clinics.

15 So it was a total comprehensive care, and a whole
16 team were involved, not least the receptionist. You
17 know, there was no computers, so she's got a book where
18 she's having to book people's appointments and know
19 who's coming or is not coming, and there are telephone
20 appointments. So it's very difficult to -- it wasn't
21 like -- you know, I think probably you may have a sort
22 of idea of a regular outpatients, you know: the doctor
23 sitting in a room and receptionist here. It wasn't like
24 that at all. The centre was self-contained with the
25 whole team in it, and everybody knew what was going on.

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1 Communication was essential. We had a little ward area
2 where people were seen. There was a children's room.
3 There was a room where the family therapists could talk
4 to patients. So I don't know if that helps.

5 **Q.** And where physically was Dr Kernoff located --

6 **A.** He had his own room.

7 **Q.** But as part of the -- (overspeaking) -- self-contained
8 centre --

9 **A.** And ultimately, he had -- we all -- he had his own
10 room in the centre. I explained yesterday, in 19 --
11 the last thing he did before sadly he had this huge
12 myocardial infarction, he had got agreement from the
13 hospital to have an extension built, and that was paid
14 for by what was called the Katharine Dormandy Trust,
15 which was money that Katharine Dormandy had put in
16 trust that was given mostly by a property development
17 developer who was the father of somebody who had
18 severe haemophilia. And that agreement was there.

19 So after that extension was built, the
20 extension -- I think I said this yesterday -- the
21 extension provided consultant rooms, a room for the
22 family therapist, and the notes were put in a huge
23 area in filing cabinets, and the secretaries would sit
24 between the filing cabinets. And at that point --
25 Dr Kernoff wasn't there any more, clearly. I had

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1 a room at the back of the centre, a windowless room,
2 and I moved to the front.

3 Dr Kernoff's room became the children's room, and it
4 was set up as a special room where children could be
5 treated. That's going forward to 1994.

6 **Q.** Yes.

7 **A.** But the period you're talking about, 1983, he had his
8 own room.

9 **Q.** Thank you. I wanted to then move to the question of
10 the risk posed by AIDS to haemophiliacs. You've said
11 in your witness statement, and indeed in your Lindsay
12 evidence, that your first awareness of this may have
13 been a Lancet article in April 1983.

14 **A.** Sorry, what?

15 **Q.** I'll find the reference in your statement for you,
16 Professor Lee. So if you look at paragraph 37 of your
17 statement. It's page 28. Henry, it's WITN0644058.
18 And if you could go to page 28, please, Henry. Bottom
19 half of the page. In answer to the question "How and
20 when did you first become aware that there might be an
21 association between AIDS and the use of blood
22 products?", you refer to your answer in your evidence
23 to the Lindsay Tribunal, and then effectively you
24 replicate that answer, so:

25 "As far as I was aware, the first indication of the

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1 transmission by blood transfusion of what later became
2 known as AIDS or HIV was a publication in The Lancet on
3 30 April."

4 Then you say you don't think you were aware of the
5 publication by the MMWR of 10th December 1982.

6 Can I just look with you at a couple of documents
7 between December 1982 and 30th April.

8 Henry, could we have PRSE0002410, please.

9 This is an article in the New England Journal of
10 Medicine, 13th January 1983, "AIDS and Preventive
11 Treatment of Haemophilia", and it's by Jane Desforges.
12 And I'm fairly confident you're familiar with it because
13 you cited it in later articles that you wrote.

14 Did you read this at the time, Professor Lee?

15 **A.** I think I must have done but I don't remember.

16 **Q.** We know also, if we have on screen, please --

17 **A.** I think this is January 19 --

18 **Q.** 83.

19 **A.** Yes. I think I'd like to go back to something you
20 said at some point, maybe it was questioning
21 Dr Colvin, but you rather suggested that everybody
22 knew that AIDS was a problem in January 1983, and
23 I don't think that is true. It is certainly true that
24 there were cases of AIDS that had been reported in
25 people with haemophilia, but there was still debate

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1 about whether those cases were a problem because of
2 the immunological damage -- that concentrates had come
3 and made some people more sensitive to AIDS.

4 To go back to this paper you're referring to in
5 The Lancet, which was actually July 16th, 1983, if
6 that's the one you're referring to?

7 **Q.** No January 13th, 1983, the Desforges article.

8 **A.** Okay, sorry, that's this one. Okay.

9 Well, I just want to go back on my comment
10 about -- there was a suggestion that, you know, it was
11 all cut and dried, that we all knew that people with
12 haemophilia had got AIDS from treatment. It is
13 certainly true that there were people with haemophilia
14 who had got AIDS, but it was still being debated about
15 whether the immunological change in some people had
16 made them more sensitive to getting it.

17 And in the original presentation of HIV, people had
18 what was called a lymphadenopathy syndrome, and if you
19 go back to this paper, my paper, that was published in
20 May 1983, that -- those data I presented in a session at
21 the World Federation of Haemophilia in Stockholm in
22 1983, and there was an emergency meeting in the
23 lunch hour, an hour's meeting of haemophilia treaters
24 from all over the world, and of course patients were
25 there, because the World Federation of Haemophilia has

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1 treaters, patients and doctors, and there was a huge
2 discussion about lymphadenopathy syndrome.

3 When these data that I presented were shown, we had
4 shown that people who had haemophilia A
5 had immunological change, and that's the change -- at
6 that time how we measured it was T4/T8 ratios. They're
7 now known as CD4 counts, the T4 count. And when that
8 became low, that was -- represented immunological
9 depression.

10 The people with Factor IX deficiency did not have
11 this in our patients, and we didn't know why that was,
12 and the suggestion was it was the manufacturing process
13 of the Factor IX. And in fact there had -- so this is
14 June 1983, these data are being presented in a room of
15 international haemophilia treaters. There was still
16 debate in that presentation, because I only had two
17 slides -- everybody was asked to bring slides so that
18 people could understand what was happening.

19 So there was still debate going on about this
20 immunological change, and certainly, in the patients
21 themselves, they presented with immunological change.

22 The other thing I would like to comment on --
23 I think you commented on it yesterday, or maybe it was
24 when Brian Colvin was giving evidence -- but there was
25 a paper by Armen(?) where a child had got HIV from

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1 platelets. That paper was passed around numerous
2 journals and they turned it down. The head of the
3 Transfusion Service in America actually wrote a leader,
4 and I don't have it at hand now but I can certainly pass
5 it on to the Inquiry afterwards, where he disputed any
6 notion that blood transfusion could transmit AIDS and it
7 wasn't until a paper was published in the New England
8 Journal 1984 that definitive proof came that blood
9 transfusion caused AIDS.

10 And I just -- I'm sorry to go on about this, but
11 it's important. If you would like to get -- can I do
12 this? Can I interrupt this?

13 **Q.** Certainly but I do want to take you back afterwards,
14 please, to January of 1983.

15 **A.** Yes, that's fine. That's fine. The paper is --
16 I think this is your number, 644090.

17 **Q.** What's its called, please, Professor Lee?

18 **A.** It's called "Relationships between blood product
19 exposure and immunological abnormalities".

20 **Q.** No, it's 06 -- so WITN0644064, please.

21 This is your reach with Dr Rizza; is that right?

22 **A.** Yes.

23 **Q.** Yes, we are going to come on to this, but please do
24 make the observation you want to make.

25 **A.** What I just want to make the point is if we turn to

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1 page 170, which is the last page.

2 **Q.** The page before that, please, Henry.

3 **A.** This a discussion -- actually, before I say that, this
4 paper was received by the British Journal of
5 Haematology in June '84. It was accepted on
6 17th October 1984 and published in May 1985. But what
7 it's discussing here is that immune suppression
8 produced by repeated exposure to clotting factor
9 concentrates lowers the threshold for infection. It's
10 throwing that out. Now, at the time this was written,
11 the knowledge was accruing, but I can tell you that in
12 1983 there were big debates around lymphadenopathy
13 syndrome.

14 So there was an emerging experience but it certainly
15 wasn't cut and dried.

16 **Q.** Yes, I think -- Professor Lee, I don't think I've ever
17 put to Dr Winter or Dr Colvin that anything was cut
18 and dried in 1983; the proposition I put to them,
19 which they assented to, was that by January 1983,
20 clinicians involved in the care of patients with
21 haemophilia should that have realised that there was
22 a significant risk that blood products might transmit
23 AIDS.

24 Would you disagree with that proposition?

25 **A.** I think "disagree" is probably a too strong a word.

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1 I don't think it was cut and dried.
 2 **Q.** Would you agree that by January 1983, there was
 3 evidence that blood products might transmit AIDS?
 4 **A.** There was some evidence certainly. If you -- you
 5 know, if you have people with haemophilia having this
 6 strange syndrome.
 7 **SIR BRIAN LANGSTAFF:** I don't know if it's any help but,
 8 in either your presentation on the knowledge of risk
 9 or on Oxford, you told me that in December 1982, Rizza
 10 had observed that all HCO directors knew that there
 11 was a real risk that AIDS could be transmitted by an
 12 infectious agent carried by blood products.
 13 That appears to have been his view at any rate at
 14 the end of 1982, if that helps.
 15 **A.** I think -- I think what ...
 16 If you turn, on that same paper, the Rizza paper,
 17 to page 168, it's the beginning of the discussion, and
 18 I'm sure we're coming on to this because you're going
 19 to be discussing the document:
 20 "The recognition that many asymptomatic patients
 21 have laboratory abnormalities resembling those
 22 detectable in AIDS has raised the possibility that
 23 these patients may have a condition representing
 24 a prodromal or forme fruste of AIDS ... Whether or not
 25 this is the case, it seems beyond doubt that the

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1 abnormalities we and others have found in
 2 haemophiliacs without AIDS are caused by exposure to
 3 blood products."
 4 What that's telling you is that our experience at
 5 that stage was that a large number of people were
 6 demonstrating immunological abnormalities, but whether
 7 they were all going to go on to developing
 8 a form -- real AIDS, was debatable, and people were
 9 debating it. It's a bit like saying whether everybody
 10 who got non-A, non-B was going to get liver cancer.
 11 And I think I would also like, while we're on that
 12 page, so that we don't -- just to give you an idea of
 13 the people here, the patients -- can we?
 14 **MS RICHARDS:** Yes, of course.
 15 **A.** So this was our experience at the time that this paper
 16 was submitted, in June 1984. This was clinical
 17 experience of the patients. So we had patients with
 18 lymphadenopathy, the lymph nodes, which is this idea
 19 of a lymphadenopathy associated syndrome, we had
 20 somebody with an opportunistic infection, somebody who
 21 had lost weight, somebody with septicaemia and another
 22 one with herpes zoster. What that is showing us is
 23 that there is undoubtedly immune abnormality in these
 24 patients, but as the knowledge was emerging through
 25 that time, it wasn't entirely clear whether this was

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1 going to be something that transmitted into full-blown
 2 AIDS. We didn't know.
 3 **Q.** Before we return to January 1983, whilst we're on this
 4 paper, Professor Lee, is it then your evidence that as
 5 at June 1984, when this paper was submitted to the
 6 British Journal of Haematology, you and your
 7 co-authors had still not reached the conclusion that
 8 what you're describing here was most likely to be
 9 AIDS?
 10 **A.** I think you could say that at that stage.
 11 **Q.** We'll come back to --
 12 **A.** I just would remind you again of the patient that I
 13 saw in 1983, the elderly gentleman. He died at home.
 14 His chest X-ray was complete whiteout. And in
 15 retrospect there's no doubt that that was
 16 Pneumocystis carinii. So that was AIDS. The other
 17 thing that, you know, was happening at this time, we
 18 didn't have a test, so the definition of AIDS was very
 19 vague, in a way. There were these -- lymphadenopathy,
 20 a wasting syndrome, opportunistic infections like
 21 shingles, that is herpes zoster, septicaemia, and
 22 those things were added up and saying: well, you know,
 23 this looks like immunodeficiency, this looks like
 24 AIDS. But it wasn't really we got a test that you
 25 could definitely say that somebody had got HIV

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1 infection and AIDS, really.
 2 **Q.** If we return to January 1983, could we please have on
 3 screen PRSE0002647. These are a notes of a meeting
 4 attended by a number of Haemophilia Centre directors,
 5 not attended by you, Professor Lee, including
 6 Dr Kernoff, on 24th January 1983.
 7 And to provide you with some context, it was
 8 a rather unusual meeting, it took place at a hotel at
 9 Heathrow Airport.
 10 **A.** That is not unusual, because many meetings were held
 11 at airport hotels because it enabled -- you know,
 12 because haemophilia was rare -- this not in the
 13 context of this meeting, but many meetings were held,
 14 of European treaters or American treaters, they would
 15 fly in to a meeting and fly out. So having a meeting
 16 at a hotel is not at all unusual.
 17 **Q.** If we can just turn to the last page we can see who
 18 was there. If you very quickly cast your eye down the
 19 list of names, you'll see it involved the reference
 20 centre directors at the time, including Dr Kernoff,
 21 but also a number of other Haemophilia Centre
 22 directors who were not reference centre directors,
 23 together with Dr Craske and Professor Zuckerman, and
 24 the author of these notes is Dr Boulton, we think, and
 25 then there were representatives from Immuno.

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1 I'm not going to trouble you with the first part
 2 of the meeting minutes, just the second part, which
 3 looked at AIDS.
 4 Can we go to the previous page, please, Henry.
 5 So you'll see under the heading "Acquired
 6 Immunodeficiency Syndrome", there's a summary by
 7 Dr Craske of the current position. There's
 8 a description two paragraphs down of possible clinical
 9 features, including herpes viruses. And then it says:
 10 "Up to 10 December 1982, some 800 people had been
 11 reported as suffering from the AIDS, and there was a 45%
 12 mortality."
 13 Then it says this:
 14 "Ten haemophiliacs in the US have been affected,
 15 five have died. The youngest was aged 7. All cases
 16 have had prolonged treatment with Factor VIII, but there
 17 is no specific implication of one particular product or
 18 batch. Other cases involving blood and blood product
 19 transmission have included platelets transfused in three
 20 cases. In one of these cases, one of the donors was
 21 a young New York man in his twenties. A second case was
 22 a 20-month year old child with Rhesus HDN who had
 23 received several units, including platelets known to
 24 have come from a homosexual donor ..."
 25 **A.** That case was the case I was talking about.

21

1 **Q.** The San Francisco baby case --
 2 **A.** When it was written, up, the paper itself, I think
 3 this is very clearly shown in the book called And The
 4 Band Played on by Randy Shilts, where he really
 5 exposes the transfusion head-up in America, but that
 6 paper was sent around various journals and turned
 7 round because people didn't believe it.
 8 **Q.** Yes, but --
 9 **A.** I'm saying that because there was debate. You know,
 10 people who reviewed papers are experts.
 11 **Q.** The child, it's described, has developed a possible
 12 AIDS case. That's a 20-month old child.
 13 Over the page:
 14 "The incubation period for the syndrome appears to
 15 be six months to two years.
 16 "In the UK, so far only one or two cases have been
 17 reported ...
 18 "The infectious precautions include ..."
 19 Then the various protocols in relation to donation
 20 are discussed.
 21 Then:
 22 "The attention of the meeting was then drawn to the
 23 two articles on the editorial in the New England Journal
 24 of Medicine ..."
 25 We've looked at one of those.

22

1 And reference there expressly to the T4/T8 ratios,
 2 and issue about donor pools.
 3 Now that's an update, as at 24th January, about
 4 cases in the States, including the case of the baby that
 5 you've referred to. Was that information, as far as you
 6 can recall --
 7 **A.** I think you've missed out the critical line in this,
 8 actually.
 9 **Q.** Which line is that, Professor?
 10 **A.** The second line:
 11 "In the UK, so far only one or two cases have been
 12 reported from the communicable diseases centre."
 13 I presume that's talking about haemophilia people,
 14 with AIDS.
 15 **Q.** No, not at that stage. And I don't think I did miss
 16 it out. I think I read it out, Professor Lee --
 17 **A.** Okay --
 18 **Q.** In any event -- no, not haemophiliacs at that stage in
 19 the UK.
 20 **A.** Okay, well, it was during that year.
 21 **Q.** Yes, it was. Would you agree that the information set
 22 out there about the numbers of cases in the States and
 23 the cases from platelet transfusion was significant
 24 information which would support the idea of a link
 25 between transfusion and AIDS? Not prove but support.

23

1 **A.** Well, I think -- I think, probably, yes. It's not
 2 proof.
 3 **Q.** Did Dr Kernoff report this information at one of the
 4 meetings you have described? This is about the time
 5 you're joining the Royal Free.
 6 **A.** This is January 1983. I'm not even there.
 7 **Q.** 24th January 1983.
 8 **A.** Yeah, I'm not there. I said the end of January
 9 I started there.
 10 **Q.** Yes, forgive me Professor Lee --
 11 **A.** I also don't -- I really don't think it reasonable to
 12 ask me about a meeting in 1988 -- what is it --
 13 **Q.** January 1983 --
 14 **A.** -- that I wasn't at.
 15 **Q.** I'm trying to show you, Professor Lee, the state of
 16 knowledge as at January 1983 that would have been
 17 shared with Dr Kernoff, and the question is: was that
 18 information that was disseminated by Dr Kernoff
 19 amongst the staff at the Royal Free?
 20 **A.** I have no idea. And what I would also say to you is
 21 to go back to -- I would like to tell this Inquiry
 22 about things I know about. I don't want to tell this
 23 Inquiry about what Dr Kernoff was thinking. I don't
 24 know what he was thinking. But what I do know what he
 25 was thinking when I was working with him.

24

1 And I would go back to The Lancet paper in
2 May 1983. And what I can remember -- and this is
3 a very clear memory -- is before that letter was sent
4 to The Lancet, he had a very clear discussion with me
5 about what this means. That's after this paper. So
6 what I'm trying to get over to you is that that was
7 not the only view. I would also -- it was emerging
8 experience.

9 **Q.** What discussions, if any, did you have with
10 Dr Kernoff, or Dr Kernoff have with you, about AIDS in
11 the first half of 1983?

12 **A.** We were continually talking about it because we were
13 trying to understand what was going on.

14 **Q.** So it's like --

15 **A.** But what I'm saying to you is the idea that everybody
16 knew everything at that stage is wrong. And I'm
17 trying to also -- you know, the memory, the really
18 powerful memory I have, mainly because it was the
19 first international meeting I'd ever been to in my
20 life, was this meeting in Stockholm where it was an
21 ad hoc meeting. It wasn't even in the programme.
22 Because people were trying to report their ideas. And
23 these data were presented there and accepted. And
24 people were still discussing: is everybody going to
25 get it? There was no doubt that some people had got

25

1 it, but it -- (overspeaking) -- certainly not clear
2 that everybody was going to get it.

3 **Q.** Professor Lee, at no point have I suggested to you, or
4 to any witness, that everybody knew everything in
5 1983, in January 1983 -- (overspeaking) -- or that
6 everyone --

7 **A.** Well, I'm getting the feeling that that's what you are
8 suggesting.

9 **Q.** No. I'm trying to understand, and ask you to explain,
10 what discussions took place in the early part of 1983
11 at the Royal Free Hospital. You are one of the few
12 witnesses that we can ask that question of. If you
13 cannot remember, then you cannot remember.

14 **A.** All I can say is, I sat at this desk in my room, and
15 I'm looking at this information and trying to analyse
16 it, talking with Dr Rizza maybe on the phone
17 occasionally. And Peter is in his room down there,
18 managing the department, and he clearly would come and
19 see me and discuss things and, "What's the findings?
20 What have you got here?"

21 So, insofar as that, we were discussing AIDS. He
22 also -- as I said yesterday, he had this collection of
23 references, this filing cabinet that he -- anything that
24 was a reference, he would stick the title, or have the
25 title stuck on a file card so that he can access

26

1 references. So he would say, you know, "You ought to
2 read this." So, you know, we were discussing it.

3 But I would also like to emphasise again, 37 years
4 ago, you're trying to ask me what conversations I had
5 with Professor Kernoff, Dr Kernoff. And as I said, I
6 have this very clear conversation about the data that
7 was going to be put in two slides in Stockholm because,
8 you know, this was a memorable thing for me. And he was
9 quizzing me on, you know, "Are we sure? You know,
10 what's this all about?" And we were kind of batting
11 ideas around. You know, that's the kind of thing we
12 did.

13 **Q.** In the course of 1983, the UKHCDO Reference Centre
14 directors met. Information was sent to directors by
15 Professor Bloom and Dr Rizza. Information was sent to
16 Dr Kernoff, and he was part of their decision-making
17 process.

18 Was that information that, as a matter of general
19 practice, Dr Kernoff would circulate amongst the
20 department or summarise for the benefit of the
21 department?

22 **A.** Well, we did have -- every Thursday morning for an
23 hour, we had what was called a teaching session, and
24 so that would be the kind of meeting where information
25 was presented. So the laboratory might be talking

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1 about a meeting they'd been to, and they'd give
2 feedback of new tests or something. And it might have
3 been something he might have discussed then, but
4 I don't recall. And I think, also, it's a little
5 unfair asking me about meetings at which I wasn't at.

6 **Q.** I wasn't asking you about meetings at which you
7 weren't at then, Professor Lee. I was asking you what
8 information was shared by Dr Kernoff with those at the
9 centre.

10 **A.** About a meeting at which I wasn't at.

11 **Q.** No, about the advice that was provided by UKHCDO
12 Reference Centre Directors. Was that information --

13 **A.** I can't remember. It's 37 years ago.

14 **Q.** One of the -- I won't take you to the documents of the
15 meetings that you weren't at, Professor Lee, but one
16 of the things which Reference Centre Directors asked
17 directors to do in March of 1983 was to look out for
18 signs of AIDS and to set up a reporting system so that
19 that information was fed back to Dr Craske. As far as
20 you can recall, was that something Dr Kernoff asked
21 you to do?

22 **A.** No. Don't think so.

23 **Q.** Just before we get to the World Federation of
24 Haemophilia meeting, which I think was 27 June to 1
25 July 1983, could we look at PRSE000372.

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1 This is a document from the Council of Europe's
 2 Committee of Ministers. If you look at the heading,
 3 it was:
 4 "Recommendation of the Committee of Ministers to
 5 Member States on preventing the possible transmission
 6 of acquired immune deficiency syndrome (AIDS) from
 7 affected blood donors to patients receiving blood or
 8 blood products".
 9 And you can see from the italicised bit in
 10 brackets, it was adopted by the Committee of Ministers
 11 on 23rd June 1983.
 12 So this was just a few days before the World
 13 Federation of Haemophilia meeting in Stockholm which you
 14 attended.
 15 If we go to the second page, please. Could we zoom
 16 in on the top half of the page? This is
 17 a recommendation at national level from Europe to
 18 Member States, and you may not have seen it at the time,
 19 Professor Lee, but you'll see it says this:
 20 "Recommends the governments of Member States take
 21 all necessary steps and measures with respect to AIDS
 22 and, in particular, to avoid wherever possible the use
 23 of coagulation factor products prepared from large
 24 plasma pools. This is especially important for those
 25 countries where self-sufficiency in the production of

29

1 such products has not yet been achieved."
 2 Then the second is:
 3 "To inform attending physicians and selected
 4 recipients, such as haemophiliacs, of the potential
 5 health hazards of haemotherapy and the possibilities of
 6 minimising these risks."
 7 So you'll see there, Professor Lee, that a few days
 8 before this World Federation meeting in Stockholm, the
 9 European Committee of Ministers recommended the
 10 avoidance, where possible, of the use of coagulation
 11 factor products from large plasma pools, and that not
 12 just doctors but also haemophiliacs, patients, be
 13 informed of potential health hazards of haemotherapy.
 14 Was that something, as far as you can recall, that
 15 was discussed at the World Federation of Haemophilia in
 16 Stockholm a few days later?
 17 A. I don't recall it.
 18 Q. Your evidence to the Lindsay Tribunal was that there
 19 were no changes to the approach to treatment at the
 20 Royal Free Hospital in 1983 or 1984, save that in 1984
 21 there was at some point adopted, and you couldn't
 22 recall when, a policy in relation to deferring
 23 elective surgery.
 24 As that was your evidence to the Lindsay Tribunal,
 25 as you've said when events were still fresher in your

30

1 mind, is that likely to be correct?
 2 A. I think that probably is correct, yes.
 3 Q. So --
 4 A. I think also, as I said yesterday, the evidence I gave
 5 to the Lindsay Inquiry 20 years ago, I was a working
 6 director of the Centre and Professor of Haemophilia,
 7 and I actually had access to documents or treatment
 8 records, and so I think it was accurate. But again, I
 9 would emphasise that, you know, I wasn't in the
 10 business of the decision-making process through that
 11 period.
 12 Q. The discussion that took place that you refer to, the
 13 debate at the World Federation of --
 14 A. It wasn't a debate; it was people from all over the
 15 world. It was an hour at lunchtime. It was chaired
 16 by Dr Margaret Hilgartner, who was -- she's died now,
 17 but she was a famous paediatrician in New York who had
 18 looked after people -- children with haemophilia.
 19 And before the meeting -- and this request would
 20 have gone to Dr Kernoff, not to me. He didn't go to
 21 the meeting. A request was made that if you had
 22 information to share, would you take information on no
 23 more than two slides. And the reason for that is,
 24 again, I would pick up a point that I made yesterday.
 25 You know, the dissemination of information now is

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1 instant. Then, it was very, very slow, and so -- and
 2 you may pick up on this in a later discussion about
 3 London. You know, meetings were instant, and that was
 4 where the information was being shared. So it wasn't
 5 a debate; it was a presentation. And what I was
 6 trying to say -- that there were different views
 7 presented.
 8 Q. Can you recall whether there was a majority view that
 9 the condition was likely due to an infectious agent?
 10 A. It wasn't -- there wasn't a vote taken or anything.
 11 What I do remember -- one, I remember I got my slides
 12 upside down, which was -- which is perhaps why I do
 13 remember it. But I also remember, right at the back
 14 there was a Canadian physician -- I think he was
 15 called Tsoukas, T-S-O-U-K-A-S, and he talked at great
 16 length about lymphadenopathy syndrome, and that was
 17 quite a dominant part of that meeting.
 18 Q. Can we move on to 1984 and a document that you
 19 authored. Could we have on screen, please, Henry,
 20 WITN1003018, please. This is a Haemophilia Centre
 21 publication: "Haemofact. AIDS. Release number 3".
 22 It says:
 23 "This fact sheet contains important information
 24 concerning AIDS. 11 May 1984."
 25 If we go over the page, we can see that the leaflet

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1 is authored by you. Can you recall how you came to
 2 write this? Who asked you to write it?
 3 **A.** I think -- I don't know, but I think the -- certainly,
 4 the request came from The Haemophilia Society. And
 5 I would imagine it must have gone to Peter, because
 6 they wouldn't come directly to me, and that Peter
 7 passed it on to me. And it's certainly -- what
 8 I wrote would have been reviewed by Peter.
 9 **Q.** As far as you can recall, were you given any kind of
 10 brief from The Haemophilia Society as to the kind of
 11 message they wanted to convey?
 12 **A.** No. They wanted information.
 13 **Q.** If we look at what you wrote here, you said:
 14 "The occurrence of AIDS in haemophiliac patients has
 15 strongly suggested transmission of disorder by blood
 16 products. Epidemiological studies have suggested it may
 17 be related to a transmissible agent."
 18 Then you make reference to scientific developments
 19 in the States and in Paris. You say this:
 20 "These reports should be received with optimism.
 21 The obvious benefits from such findings would be the
 22 provision of a blood test for both affected persons and
 23 donated blood and, in the long-term, the development of
 24 a vaccine."
 25 You then say:

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1 "In Great Britain, the number of haemophiliacs who
 2 have been reported with AIDS remain at two. Thus, the
 3 incidence is less than 1 in 1,000 patients at risk."
 4 I'll come back to that. You say:
 5 "The relationship of immunological abnormalities
 6 found in many heavily treated haemophiliacs throughout
 7 the world is uncertain."
 8 Then refer to studies in Scotland, Australia and
 9 America. You say:
 10 "It's possible that the immune suppression produced
 11 by repeated exposure to clotting factor concentrates
 12 lowers the threshold for infection with a putative AIDS
 13 agent."
 14 And there is then further discussion about that.
 15 And you suggest that:
 16 "This is a function of the characteristics of the
 17 final product and the fractionation methods used to make
 18 it. Thus, prospects for resolving these problems are
 19 brighter for haemophiliacs than for other high-risk
 20 populations, since improvements in plasma fractionation
 21 are likely to make it possible to remove or inactivate
 22 causal agents from the therapeutic products."
 23 And you say:
 24 "The heat treating clotting factor concentrates
 25 which have been manufactured by many commercial

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1 companies in the NHS may be an advantage."
 2 Then you talk about:
 3 "The really good news."
 4 And you refer to work at the Royal Free, Speywood,
 5 and in San Francisco about the synthesis of the gene --
 6 sorry, the cloning of the gene for Factor VIII.
 7 Now, it could be said -- and this is what I'm
 8 inviting you to comment on, Professor Lee -- that this
 9 is an article which has a rather upbeat, positive,
 10 reassuring tone. Was that what it was designed to
 11 convey: to reassure patients?
 12 **A.** No. It was written to convey what the knowledge was
 13 at that time. And the number of cases of AIDS in
 14 people with haemophilia in the UK at that date, at
 15 that time, was two, and this had come from the Oxford
 16 records, as you said. The people had to let Oxford
 17 know for the database -- not the database; the
 18 records.
 19 And when I write in here that the number at risk was
 20 2,000, this was the number of people in the UK who had
 21 been treated with clotting factor concentrate at that
 22 time. So the incidence was 1 in 1,000.
 23 And in terms of the immunological change, I think
 24 I would like you, if possible, if that's allowable, to
 25 pull up a paper. I'm afraid the number I've got is my

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1 witness statement which is 655086 --
 2 **Q.** -- (overspeaking) --
 3 **A.** -- and this was published in 1996.
 4 **Q.** Is that comparison of immunodeficiency
 5 -- (overspeaking) -- conditions?
 6 **A.** Yes.
 7 **Q.** Yes, it's WITN0644086.
 8 **A.** I think the reason I want to just put this up is
 9 because the discussion around immunological
 10 abnormalities caused by blood transfusion and
 11 concentrates was quite significant in the time period
 12 that we're talking about. And indeed, it didn't go
 13 away in North America. There was a Professor Duesberg
 14 who was still promoting this idea, and we had to
 15 publish a paper in 1996 to dispel it. What we did was
 16 we compared a group of our patients who were
 17 HIV negative -- we had a test then -- and group who
 18 were HIV positive, and it was quite difficult -- it
 19 was quite difficult, sadly, to find number of
 20 HIV negative people who had had a large amount of
 21 treatment at that stage, but we did manage to find it
 22 so that the two groups could be compared. And we
 23 showed that, you know -- I'm sure we would all think
 24 that that was what would happen, that people who were
 25 HIV positive were the people who got AIDS and the

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1 people who were HIV negative didn't.
 2 Even so, when you read -- I don't want to prolong
 3 this here now but if you read the paper, this Duesberg
 4 is still saying -- but even so, you know, he's not
 5 believing it.

6 So this is published in the BMJ, so it's been
 7 subjected to peer review, so the BMJ are not going to
 8 publish a paper about something that is not an idea.
 9 And that's 1996, when we've got tests for it. In 1983
 10 we didn't have any tests. So I don't think I should be
 11 representing somebody who is putting rose-coloured
 12 spectacles on what was a terrible health problem.

13 What I was doing in this pamphlet was stating the
 14 facts and the view that was held at that time.

15 **Q.** We know that --

16 **A.** And, you know, I would add that -- you keep asking me
 17 what Peter -- Professor -- Dr Kernoff thought, and did
 18 I have discussions with Dr Kernoff. He certainly
 19 would not have let this go to the Haemophilia Society
 20 without, you know, looking at it.

21 I would also, you know, go back to the earlier
 22 discussion we had about the paper, looking at
 23 immunological abnormality, of these strange
 24 opportunistic infections and lymphadenopathy that we
 25 were seeing, but it was still discussing about whether

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1 it was immunological or whether we were going to
 2 see AIDS, or whether those people were going to go on
 3 to AIDS. It was still not clear.

4 And the other thing that's quite interesting here --
 5 I mean, there is such a parallel with Covid-19, isn't
 6 there, because we're talking about there may be
 7 a vaccine. Well, of course there never was a vaccine
 8 because it's a carrier state. But we never had any idea
 9 of that then. So I don't think -- you know, people now,
 10 with Covid, are talking about we'll have a vaccine by
 11 Christmas maybe. We don't know. And I really do think
 12 it's important to try to understand that -- it's very
 13 easy with -- looking retrospectively, but it's very
 14 difficult to remember the confusion, the lack of
 15 knowledge, at that time.

16 **Q.** Do you think there might have been a risk that those
 17 reading this material might have felt reassured from
 18 reading it that very few people were likely to develop
 19 AIDS and that it was safe to continue taking factor
 20 concentrates?

21 **A.** Well, I guess, on the face of it, there may be. But
 22 that -- you know, that ...

23 Because you present facts as you know it, and
 24 that's how they're interpreted, I don't think one
 25 should massage facts, you know. These are facts.

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1 There are two people in the UK who have got AIDS.
 2 There are 2,000 people who have been treated.
 3 Therefore, the incidence is 1 in 2000. And then I go
 4 on to talk about the immunological changes, which
 5 undoubtedly there were. We were sitting there
 6 recording them. People, because their lymphocyte
 7 count went down to less than a thousand, they got
 8 these strange things -- like shingles and
 9 streptococcal pneumonia in a young man was, you know,
 10 unheard of, but if you've got immunological
 11 abnormality it's there. And so we were learning. We
 12 were so learning.

13 **Q.** Telling a lay audience, in the sense of
 14 non-clinicians, although no doubt many of those
 15 reading this were experts in their own care, as
 16 haemophiliacs, but telling a lay audience that the
 17 incidence is less than one in 1,000 patients at risk,
 18 the number of haemophiliacs remain at two, may be
 19 factually correct, but what you don't go on to set out
 20 here is what the risk might be from factor
 21 concentrates of others, having transmitted to them
 22 what was, by now, surely thought likely to be, if not
 23 proven to be, yet, a transmissible infectious agent?

24 **A.** I would take issue with you. Patients with
 25 haemophilia are pretty expert because they go to

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1 meetings, they have bulletins from the Haemophilia
 2 Society, so, you know, there was a lot of knowledge
 3 circulating around, so I think it's a bit patronising,
 4 really, to -- well, not patronising, but it's -- of
 5 all the patients you have, they're probably the most
 6 educated about their condition, because it's so rare,
 7 it's lifelong, and so they learn about it and they get
 8 information from the Haemophilia Society.

9 **Q.** Yes, absolutely right about their bleeding disorder.
 10 They wouldn't be experts in AIDS or viable
 11 transmission --

12 **A.** But they were getting as much information as was
 13 coming out by the Haemophilia Society. That's why
 14 they produced this bulletin: to send stuff out. They
 15 were sending anything that came their way about this
 16 strange condition.

17 **Q.** Can we just look before we break at one further
 18 document, which is the haemofact that followed up
 19 this. It's at WITN1003019. This is
 20 24th September 1984, so the next release.

21 And this was at the time the Haemophilia Society's
 22 chosen method of communicating information to its
 23 members, through these leaflets.

24 This is authored by Dr Kernoff, if we go to the
 25 next page, and I'll just ask, if we go to the page

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1 after that, please -- so he talks on the first page
2 about the identification of LAB and HTLV-III, and then
3 at the top of the page he says:

4 "The presence of antibodies is usually taken as
5 evidence of immunity to infection, and perhaps one
6 reason why the risk of AIDS in haemophilia is so low
7 (around 1 in 1000) is that many patients are immune to
8 it."

9 Now, he's not there talking about incidence; he's
10 talking about risk.

11 **A.** Well, I think that is incidence. That's the same
12 figure I had. I mean, I think you're playing with
13 words.

14 **Q.** Words can be rather important, Professor Lee, when
15 they're the means by which patients understand if
16 they're being exposed to the risk of a fatal
17 condition.

18 **A.** All I can say is that, in this context here, he is
19 meaning incidents. It's the same, you know, the risk
20 of AIDS. You know, those are words he crafted but he
21 is meaning this as incidence, one in a thousand.

22 **Q.** He says in terms:

23 "... the risk of AIDS in haemophilia is so low ..."

24 **A.** Yes.

25 **Q.** What's the basis upon which he could reasonably say

41

1 that, in September 1984 --

2 **A.** Because --

3 **SIR BRIAN LANGSTAFF:** I think I've got that. What he's
4 saying is we have seen two cases, or something of that
5 region, of AIDS, despite the number of haemophiliacs.
6 I think you're right, Professor, that he uses the word
7 "risk" where he ought to have used the word
8 "incidence", and it may be, it's a matter of comment
9 and a matter of conclusion for me, that -- whether
10 I come to the view that, really, the risk of AIDS is
11 something very different from the incidence of AIDS.
12 And it may be that somebody reading it without having,
13 as it were, a dictionary to one side, might have said,
14 "Well, the risk to me is very, very small."

15 And that might be the way that somebody might read
16 it, I suppose. But that's a matter for me ultimately.

17 It's time for a break, I think.

18 **PROFESSOR LEE:** Before we go for a break, can I just
19 comment on what's written here?

20 **SIR BRIAN LANGSTAFF:** Yes, of course.

21 **PROFESSOR LEE:** I mean, what is interesting is -- the
22 presence of antibodies is usually taken as evidence of
23 immunity to infection, and perhaps one reason why the
24 risk of AIDS in haemophilia is so low is that many
25 patients are immune to it. When we come -- well,

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1 I don't think you'll be questioning me on this because
2 I never gave results out and I think you have
3 a statement being made by Dr Eleanor Goldman, who was
4 a specialist in the centre -- and it's my
5 understanding, I think I put this in my statement,
6 that when patients were given the result of their
7 HIV test, that some of them were -- or they've maybe
8 all been told, I don't know because I didn't do it,
9 but that they might be immune. And of course now we
10 know that there's a carrier state. So it doesn't mean
11 you're immune.

12 **SIR BRIAN LANGSTAFF:** It may be thought it's something
13 paradoxical about it, there being a disease of the
14 immune system or a disease which results in immune
15 misfunction which also produces an immunity to
16 something else, but that's for others to perhaps
17 consider, and perhaps for me to consider. But let's
18 take a break, shall we? And let's come back at ten to
19 12. Ten to 12.

20 (11.08 pm)

(A short break)

22 (12.00 pm)

23 **MS RICHARDS:** Professor Lee, I want to ask you next about
24 some correspondence you had with Dr Rizza and some
25 work you undertook with Dr Rizza in the course of

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1 1983. If we have up on screen, just to put this in
2 context, WITN0644065. If we just zoom in a little bit
3 on the text, please, Henry. This a letter from The
4 Lancet July 16 1983, and it's authored by you and
5 others at the Royal Free.

6 It talks about a study of 64 patients with
7 haemophilia A. And as I understand it, this was the
8 examination of the T cells, in the way that you've
9 referred to already, and consideration of whether
10 fractionation methods were a cause. So a somewhat crude
11 summary, but is that right?

12 **A.** Yes.

13 **Q.** At this stage, the patients that you had looked at
14 were all Royal Free Centre patients?

15 **A.** Yes.

16 **Q.** If we could have on screen, please, 0XUH0002971_006.
17 We can see this is a letter which you wrote to
18 Dr Rizza in July 1983. It refers to a telephone
19 conversation the two of you had had, and then you set
20 out in writing the plan. And you talk about how the
21 technician will receive specimens, and you suggest it
22 would be helpful if some serum could be stored for
23 future use. And then you say in the concluding
24 paragraph:

25 "I look forward to receiving the specimens.

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1 I think it will be a very valuable contribution to
 2 have these results in a population of patients treated
 3 with non-commercial Factor VIII."
 4 Could you just explain what it was you were asking
 5 Dr Rizza to do and what the two of you had discussed?
 6 **A.** I already talked about this. Basically, that letter
 7 that you just put up, in our patients we had found
 8 that patients treated with Factor IX concentrate did
 9 not have abnormalities, but the patients treated with
 10 Factor VIII concentrate did. And our speculation in
 11 that letter was that we thought it was the
 12 manufacturing process of the Factor IX and -- which
 13 was different to the Factor VIII. But there remained
 14 the possibility that it might be something to do with
 15 the donor pool.
 16 And although we had all our patients with Factor IX
 17 NHS concentrate because they're a smaller number -- they
 18 were all on NHS -- our patients with Factor VIII
 19 deficiency had a mixture of commercial and NHS.
 20 So what we wanted to do was to expand the population
 21 of patients with Factor VIII deficiency who had NHS
 22 concentrate so that we could compare the two.
 23 Now, Oxford had a long tradition of making
 24 concentrates, and they had tended to keep more of their
 25 patients on -- the fractionation moved from Oxford to

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1 the fractionation plant later. But they had a tendency
 2 all the way through to keep more patients on NHS
 3 concentrate than we did. So the idea was to expand the
 4 number of patients with Factor VIII deficiency who'd
 5 been treated exclusively with NHS product and compare
 6 the two.
 7 **Q.** So an arrangement was made between you and Dr Rizza
 8 that he would take samples of serum from his patients,
 9 and those would be sent to the Royal Free, and then
 10 tested in the Royal Free's laboratories; is that
 11 right?
 12 **A.** That's right. And the comment here, "Our technician
 13 here feels he can cope with five or six specimens",
 14 that was because the immunology laboratory, it's quite
 15 -- it was quite an intensive test to do. And I think
 16 they were sent by a car to the Royal Free because the
 17 other issue about these T4/T8 ratios was that it was
 18 important that the blood was tested as quickly as
 19 possible.
 20 **Q.** Before we look at the rest of your correspondence or
 21 some other bits of your correspondence with Dr Rizza,
 22 could we have on screen OXUH0002245_007.
 23 This is a letter not sent by or to you,
 24 Professor Lee; it's from Dr Rizza to the Regional
 25 Medical Officer within his own health authority. And

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1 it's May 1983. You can see if you look at the last
 2 sentence of the first paragraph, he's saying he thinks
 3 it's important to act quickly to set up screening
 4 tests to detect patients who might be at risk of
 5 developing the full-blown condition. And then he goes
 6 on in the next paragraph to talk about the fact that
 7 Oxford has many patients who have received only NHS
 8 Factor VIII and says:
 9 "It should be possible to find out if patients on
 10 NHS concentrates are immunosuppressed to the same degree
 11 as those on US concentrates."
 12 So was the work that you and Dr Rizza were doing in
 13 any respect connected with what's identified here as the
 14 importance of screening tests to detect patients who
 15 might be at risk of developing AIDS, or was that
 16 something separate?
 17 **A.** What was the date of this?
 18 **Q.** 11 May 1983.
 19 **A.** I think it probably was to do with our tests.
 20 **Q.** Did you see the tests that you were doing in any
 21 respect as a means of detecting people who might be at
 22 risk of developing AIDS?
 23 **A.** To the extent that we were considering whether the
 24 immunological changes were going to lead on to AIDS,
 25 yes. We had this discussion before the break. It

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1 would be helpful, but we didn't really know for
 2 certain. And, you know, we at that stage were still
 3 speculating whether it was the manufacture of the
 4 Factor IX that had made the ratios normal, compared to
 5 the manufacture of Factor VIII. But clearly, another
 6 possibility that was being considered then was whether
 7 it was the donor pool.
 8 **Q.** In terms of those patients where -- and I'll just ask
 9 you here to deal solely with the Oxford patients, not
 10 the Royal Free patients. The Royal Free patients
 11 where you identified the immunological abnormalities,
 12 was that information, to your knowledge, shared with
 13 patients at the time?
 14 **A.** I don't know. I think -- we certainly were -- it was
 15 being done as a screening test so that we knew -- we
 16 did a total lymphocyte count which demonstrated
 17 immunological damage, and you'd have a count less than
 18 1,000. But it also -- the T4/T8 ratio allowed us to
 19 identify patients who were particularly at risk. And
 20 I can't remember whether we specifically said what the
 21 result of their T4/T8 ratio was. I suppose because we
 22 didn't entirely know, but I can't remember.
 23 **Q.** Okay. Then if we go on to your correspondence with
 24 Dr Rizza, OXUH0002972, this is a letter of
 25 3 October 1983, and it says:

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1 "Dear Dr Rizza, I'm setting out below our plan for
 2 the joint study which we discussed at Oxford and by
 3 telephone last week.
 4 "The aims of the study are:
 5 1. To establish the degree of immunological
 6 abnormality in a population of heavily treated
 7 haemophiliacs treated exclusively with NHS concentrate.
 8 2. To confirm the differences in T subset
 9 distribution we have found between patients with
 10 haemophilia A and haemophilia B."
 11 Pausing there. That's the same study that the
 12 earlier letter also refers to?
 13 **A.** Yes.
 14 **Q.** If we go down, we can see various blood specimens were
 15 required. And then if you go over the page, please,
 16 Henry, can I ask you to look at the last paragraph.
 17 You say:
 18 "I hope this covers all the details, and we look
 19 forward to the study becoming a reality. I hope you're
 20 not all worn out telephoning patients your end. If we
 21 manage to obtain this data, it should make a valuable
 22 contribution and perhaps even silence the Daily Mail."
 23 Just dealing, first of all, with the sentence in the
 24 middle of that paragraph, "Not all worn out telephoning
 25 patients your end." What was that a reference to? Are

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1 you able to say?
 2 **A.** I imagine he actually phoned patients to ask them to
 3 come in to have blood taken, I would imagine.
 4 **Q.** Then you say:
 5 "If we manage to obtain this data, it should make
 6 a valuable contribution and perhaps even silence the
 7 Daily Mail."
 8 What was the reference to silencing the Daily Mail?
 9 **A.** I can't remember what the particular headline was, but
 10 the Daily Mail was making really awful headlines about
 11 AIDS at this time, but I can't remember the specific
 12 headline. No, I can't remember.
 13 **Q.** You then -- if we go on to OXUH0002971_001, this
 14 a letter from you to Dr Rizza, 16 November 1983. You
 15 refer in the first paragraph to results for
 16 a particular set of specimens, I think. Again,
 17 they're very normal. And then in the next paragraph,
 18 you say:
 19 "It's noticeable how normal your patients are, but
 20 apart from the problem of dose, younger patients seem to
 21 be normal in other studies, so we must be cautious and
 22 look at more patients before we can find any comment
 23 about NHS concentrate."
 24 Then you say this:
 25 "I do have a nasty feeling that NHS concentrate is

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1 going to turn out safer!"
 2 What was that nasty feeling? Can you explain that
 3 comment, please?
 4 **A.** Well, the nasty feeling was that I then realised that,
 5 or began to realise, that we may maybe have a large
 6 number of Factor VIII deficient patients who have got
 7 this problem. That's what it's about.
 8 **Q.** The problem meaning the immunological abnormalities,
 9 or that you were realising that it was the donor pool
 10 and not fractionation methods?
 11 **A.** Yes.
 12 **Q.** So --
 13 **A.** Yes, so this would -- the donor pool was the problem,
 14 rather than the fractionation process. That was --
 15 and it was that realisation that -- it was the nasty
 16 feeling, you know, that we were going to have a large
 17 number of patients with illness.
 18 **Q.** So --
 19 **A.** And the other issue about this is that one of the
 20 things about "younger patients seem to be normal",
 21 well, later on, we found that the normal CD4 count is
 22 800, and early on, we began to realise that, actually,
 23 children have higher counts than adults. So that's
 24 what that comment is about.
 25 **Q.** Could we then just look at the published article

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1 briefly. We've already looked at it this morning.
 2 WITN0644064, please. So this is the article
 3 ultimately published in 1985, but we can see from the
 4 dates received on 4 June 1984, and co-authored,
 5 amongst others, by you and Dr Rizza.
 6 If we go to the last page, please, Henry. Go
 7 two pages before that. If we see in the
 8 acknowledgments, we can see:
 9 "This study was supported by Action Research, the
 10 Medical Research Council, the Haemophilia Society, and
 11 the Armour Pharmaceutical Company."
 12 "Supported by" presumably means "funded by"? Is
 13 that right?
 14 **A.** Yes.
 15 **Q.** And what was the particular interest of Armour in
 16 funding this study; can you recall?
 17 **A.** No.
 18 **Q.** We've looked at this already, but if we just go back
 19 to the first page, if we look in the summary -- that's
 20 the first paragraph, please, Henry. So if we just
 21 look at the last sentence of the summary:
 22 "Fractionation procedures used to prepare clotting
 23 factor concentrates, and the amounts of concentrate
 24 used, are more likely to be causally related to these
 25 immunological abnormalities than the origins of source

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1 donor plasmas."
 2 I just wanted to ask you about that conclusion,
 3 Professor Lee, because you've explained in relation to
 4 the correspondence with Dr Rizza that the nasty feeling
 5 was because the NHS results, if I can put it in that
 6 abbreviated way, were coming back relatively normal, and
 7 you were beginning to sense that it was not
 8 fractionation methods but the plasma pools that were the
 9 problem. But in an article submitted approximately six
 10 months later, the conclusion is still there that
 11 fractionation procedures are the likely cause. Why was
 12 that?
 13 **A.** I think that must have been the predominant conclusion
 14 at that time.
 15 **Q.** Are you able to assist us with what the basis was for
 16 the conclusion that it was -- these abnormalities that
 17 you were detecting were more likely to be due to the
 18 fractionation procedures than the donor pools?
 19 **A.** Well, I think it was still going back to the -- there
 20 was a question about Factor IX. I can't remember the
 21 detail of this.
 22 **Q.** Can I ask you then, next, just briefly about what, if
 23 any, information may have been provided to patients
 24 about the risk of AIDS in 1983 and 1984.
 25 Whose responsibility within the Centre would it

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1 have been to provide information or advice to patients
 2 about the possible risk of AIDS at that time?
 3 **A.** I think probably Dr Kernoff. I can't actually
 4 remember, but I would imagine. The other thing that
 5 we had in the Centre was a -- people waited in
 6 a waiting area in the Centre. And there was a wire
 7 basket with all sorts of information put in, and you
 8 put the information from Haemophilia Society or
 9 anything that -- and that would be one way of
 10 disseminating information. But I don't know.
 11 **Q.** Do you know, as a matter of fact, whether information
 12 or warnings about the risk of AIDS was provided to
 13 patients at the Centre in '83 or '84?
 14 **A.** No.
 15 **Q.** So you don't know?
 16 **A.** I don't know.
 17 **Q.** Can you recall if, whether in the regular meetings
 18 you've mentioned or otherwise, whether there were any
 19 discussions within the Centre at that time on the
 20 issue of what information to provide to patients?
 21 **A.** Did you say "do I remember"?
 22 **Q.** Do you remember if there were any discussions?
 23 **A.** No.
 24 **Q.** So you don't remember?
 25 **A.** No.

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1 **Q.** It appears that there was some -- Dr Kernoff
 2 contemplated some trials of heat-treated products in
 3 late '83. I just wanted to ask you to look at
 4 a couple of documents and see if it was something you
 5 had any involvement with. Henry, it's RFLT0000019.
 6 So we can see this is an application to the
 7 Ethical Practices Subcommittee, I think, at the
 8 Royal Free. It's dated 1 December, and it's signed by
 9 Dr Kernoff. And you'll see the subject of it is:
 10 "To assess whether heat-treated human Factor VIII
 11 concentrate or PE-fractionated porcine Factor VIII
 12 concentrate are less likely to transmit hepatitis than
 13 routinely used human Factor VIII concentrates."
 14 Then if we just skip over of the next paragraph. In
 15 the paragraph beginning "A major effort is being made",
 16 Dr Kernoff says:
 17 "We've been offered two commercial heat-treated
 18 products for clinical assessment. Both have been
 19 granted clinical trials exemption."
 20 And he sets out what they were: Hemofil T and
 21 Factor VIII heat-treated.
 22 Did you have any involvement with these trials?
 23 **A.** No.
 24 **Q.** Do you know if they actually happened at the
 25 Royal Free?

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1 **A.** I don't think the heat-treated trials took place, but
 2 what I do know is that there was a publication of
 3 porcine Factor VIII that was published, in blood, that
 4 was authored -- I think you should probably ask
 5 Professor Tuddenham tomorrow. What I also know is
 6 that I doubt whether heat-treated Factor VIII was used
 7 at this time because quite clearly stated in one of
 8 these papers is that it says that heat-treated
 9 Factor VIII was used in the late part of '84, I think.
 10 But I think the answer should be no.
 11 **Q.** Okay.
 12 Now, we know, and you refer to it in your
 13 statement, that in December 1984, the Haemophilia
 14 Centre reference directors produced an AIDS advisory
 15 document. I'm not going to ask you to look at the
 16 details of that but it contained recommendations for
 17 the use of heat-treated products. You were asked
 18 about what the Royal Free then did at the
 19 Lindsay Tribunal. I can take you to it if need be,
 20 but your evidence was that there was a phased
 21 introduction of heat-treated products over
 22 a three to six-month period, so that would have been
 23 the first half of 1985. Can we take that as being
 24 your best evidence on that point, as it was given at
 25 the Lindsay --

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1 A. Yes, I think it's important to remember that I left
 2 the Royal Free in -- I'd started at the Queen Mary's
 3 and at Charing Cross at the beginning of November --
 4 sorry, did you say '83 or '84?
 5 Q. The AIDS advisory document was December '84, so --
 6 A. Yes.
 7 Q. So you were --
 8 A. Yes, so I'd started working at Charing Cross and
 9 Queen Mary's at the beginning of November '84. I do
 10 remember when I gave that evidence to the Lindsay
 11 Tribunal, I cross checked with -- I think in
 12 particular, I cross checked with Sister Patricia
 13 Lilley, who was the clinical nurse specialist who had
 14 worked alongside Dr Kernoff at that time, so that's
 15 where that fact came from. But I was then working at
 16 Queen Mary's, Roehampton.
 17 Q. Yes, I'm not suggesting that these were decisions for
 18 which you were responsible, Professor Lee, it's simply
 19 because they were matters that were looked at at the
 20 time of the Lindsay Tribunal through your evidence.
 21 So the position, as I understand it from your
 22 Lindsay evidence -- and it's really to ensure that
 23 this information is heard by others -- there's a three
 24 to six-month period in relation to patients receiving
 25 Factor VIII where some would continue to receive

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1 unheated concentrate, some received heated
 2 concentrates on a phased basis, and in relation to
 3 Factor IX, what you told the Lindsay Tribunal was that
 4 it was unheated NHS Factor IX until the beginning of
 5 May 1985, then Alpha heated Factor IX for a short
 6 period of time, and then, from July onwards, heated
 7 NHS Factor IX.
 8 And that's likely to be correct, is it, on the
 9 basis that's what you told Lindsay?
 10 A. I think so.
 11 Q. I want to ask you next about the arrangements that
 12 were made for the testing of patients for HIV/HTLV-III
 13 once a test became available. Your statement says the
 14 last thing you did before you left in November 1984
 15 was to take samples from all the patients and send
 16 them to Professor Tedder. As I understand it from
 17 what you've said elsewhere, Professor Lee, what was
 18 actually done was that the stored samples were used;
 19 is that correct?
 20 A. Yes.
 21 Q. And if we just look at the way in which you put it in
 22 the oral history project interview.
 23 It's THOM0000001, please, Henry. And if we go to
 24 page 29, please.
 25 If we look down about eight lines from the top, it

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1 begins:
 2 "And then towards -- the HIV virus was not
 3 identified until I think May or June '84 and we didn't
 4 have a test until the November of '84 and we had access
 5 in a research capacity, and I mean now it's horrific
 6 what we did but it was okay at that time -- I can't even
 7 remember -- we must -- yeah, we used gloves, but we
 8 actually decanted from our stored specimens -- because
 9 we had 600 patients we didn't know who was positive and
 10 who was negative, and we decanted the stuff into little
 11 test tubes and sent them down to Richard Tedder at the
 12 Middlesex Hospital for testing ..."
 13 So is this right, that as a matter of fact, patients
 14 at the Royal Free, all the patients at the Royal Free,
 15 were tested for HIV without their knowledge and consent?
 16 A. Yes.
 17 Q. In terms of the numbers who were infected, who were
 18 HIV positive, you've told us in your witness
 19 statement, and you told the Lindsay Tribunal, it was
 20 111 patients, I've seen reference, Professor Lee, in
 21 some places to 112; is that because there was
 22 a partner?
 23 A. Yeah, the 112 initially -- this information was --
 24 I think I should just expand a bit here.
 25 Richard Tedder had a test in advance of there

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1 being a test available. And so the reliability of
 2 that test was not entirely sure. Peter -- Dr Kernoff
 3 had obviously -- must have had conversation with
 4 Richard Tedder, and he asked me to decant samples into
 5 test tubes, and I did that alongside
 6 Dr Elizabeth Miller, who was going to take over my
 7 post. So I had no further involvement in that.
 8 I'm sorry, I've lost the thread.
 9 Q. You were --
 10 A. What did you ask me?
 11 Q. I had asked you about the numbers who tested positive.
 12 A. Yes, sorry. The 111 and 112.
 13 Q. Yes.
 14 A. It was only much later that we realised that one of
 15 the 100 -- the 112th, if you like, was an individual
 16 who actually had -- he had HIV for other reasons. And
 17 not -- he had never received clotting factor
 18 concentrate.
 19 Q. The majority of those who tested positive were those
 20 with severe haemophilia A, and I think the figures you
 21 put in your statement, and which you gave the
 22 Lindsay Tribunal, were: 101 patients who had severe
 23 haemophilia A, seven who were mild or moderate, one
 24 haemophilia B, and a possible von Willebrand's.
 25 As I understand it, no children who had been

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1 treated solely at the Royal Free were HIV positive?
 2 **A.** That's right.
 3 **Q.** And that is presumably because they had been treated
 4 solely with NHS concentrate?
 5 **A.** Yes. And the individual -- one individual with --
 6 who'd been treated with Factor IX concentrate, it was
 7 unheated NHS concentrate that he had.
 8 **Q.** And --
 9 **A.** And he acquired HIV from it.
 10 **Q.** That was the haemophilia B patient?
 11 **A.** Yes.
 12 **Q.** And that was in the course of the first part of 1985?
 13 **A.** Yes, because the -- there was a lag in time between
 14 the BPL treating -- heat-treating Factor VIII
 15 concentrate and Factor IX. I -- my memory was that --
 16 I may be wrong but it may not have been until August
 17 of '85, but that's a --
 18 **Q.** I think there's certainly one place in the papers
 19 where you've said July --
 20 **A.** And I've expanded on this in my statement, that it was
 21 because -- and, you know, this is picked up in
 22 Mannucci's commentary -- that we still didn't know for
 23 certain whether heating would fix it. It wasn't
 24 entirely clear, and Dr Kernoff took the decision that
 25 the NHS donor pool at that stage was more likely to be

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1 safer than the American donor pool and therefore he
 2 continued those Factor IX patients on NHS treatment.
 3 And it was a wrong decision, but it was made with the
 4 right logic, I suppose, at the time.
 5 **Q.** You also told the Lindsay Tribunal that there were
 6 a few adults who'd been treated solely with NHS
 7 Factor VIII, and none of those were infected with HIV?
 8 **A.** That's right.
 9 **Q.** You may not be able to answer this, but was there any
 10 particular feature of that cohort of patients who had
 11 only been treated with Factor VIII? Was that just
 12 happenstance? Or was that a particular type of
 13 patients who only got NHS Factor VIII?
 14 **A.** I can specifically remember two of them, why they did
 15 it. You remember yesterday I talked about
 16 a carrier lady who had fulminant hepatitis from
 17 cryoprecipitate, and she was a very -- she was very
 18 protective of her son and she had always insisted,
 19 although actually there wasn't necessarily
 20 a scientific reason at the time, but she had always
 21 insisted he had NHS product, and that was the way it
 22 was. And there was another patient who insisted on
 23 having it.
 24 **Q.** Is it right that there were children who had been
 25 treated elsewhere than the Royal Free, so treated

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1 I think specifically at Great Ormond Street Hospital,
 2 who had received commercial concentrates there and
 3 then had transferred their care to the Royal Free?
 4 **A.** Yes, I can't -- I can't remember how many there were.
 5 I can remember specifically that there was a child
 6 whose parents had worked in the Middle East and he'd
 7 had concentrate, and so he was a child with infection.
 8 But I don't think -- you see, the children from --
 9 there may have been children who'd been treated as
 10 children at the Royal Free -- is that what you're
 11 saying? The children who had been treated as children
 12 at Great Ormond Street who then came to the Royal Free
 13 because they'd had commercial -- yes.
 14 **Q.** It wasn't entirely clear from the Lindsay evidence
 15 whether that was the position or not.
 16 **A.** Yes, it was -- Professor Hardisty was the haematology
 17 professor at Great Ormond Street then, and they had
 18 used commercial concentrate, I think. But they came
 19 to us as adults. They didn't -- we didn't -- we had
 20 our own children and Great Ormond Street had their own
 21 children, and our children were treated with NHS
 22 concentrate.
 23 **Q.** Whose decision had it been to use the stored samples,
 24 to send those off for testing without patients being
 25 told in advance? Would that have been Dr Kernoff's

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1 decision?
 2 **A.** Yes.
 3 **Q.** It would have been Dr Kernoff?
 4 **A.** Yes. And I think it needs a bit of qualification
 5 because there was a bit of concern about public health
 6 risk and things as well. Because, you know, although
 7 universal precautions became adopted gradually soon
 8 after that, the nurses were handling needles and doing
 9 treatments, the laboratory were handling the samples,
 10 and indeed the surgeons might be operating on these
 11 people, these patients. And so I think although
 12 basically it was to find out who was infected, there
 13 was also that issue. There was also, I think, the
 14 issue that we had, I think, about 500 patients then,
 15 and we needed to focus our clinical care on people who
 16 were infected. I mean -- you know, I'm doing what
 17 I said it's difficult to do: I'm reading Dr Kernoff's
 18 decision-making process to do that.
 19 **Q.** You observed in the oral history project, in the
 20 passage that we've got on the screen, you said:
 21 "... now it's horrific what we did but it was okay
 22 at that time ..."
 23 And in your statement you say, in relation to this
 24 issue, the issue of samples having been tested without
 25 the patient's knowledge or consent, you say you abided

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1 by the relevant ethical principles as you understood
 2 them to be at the time.
 3 I'm conscious this was not, on the evidence you've
 4 just given, your decision, it was Dr Kernoff's
 5 decision, but can I just ask for your understanding of
 6 what the relevant ethical principles were at the time
 7 regarding issues of consent for testing?
 8 **A.** Well, what I -- essentially there weren't really big
 9 issues of consent until HIV came along, and then we
 10 started taking consent before testing that.
 11 I went very thoroughly through your expert
 12 document on the ethics and consent, and it's
 13 a wonderful document, but I mean the bottom line is
 14 that until the Data Protection Act in 1998, which
 15 became law in 2000, taking samples or using stored
 16 samples of blood or specimens, if it was anonymous and
 17 it was used for audit or epidemiological reasons,
 18 there was no need. This is before -- sorry, the Data
 19 Protection Act in 1998, which became law in 2000,
 20 states that you have to get ethical consent for
 21 a study, but you do not have to ask the individual
 22 patients' consent for testing stored serum or
 23 specimens, but it's recommended that you get -- if
 24 it's anonymous, you don't have to get the patient's
 25 consent but you should get ethical consent. This is

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1 in 2000.
 2 At this time, there wasn't any ethical issues around
 3 this, or consent.
 4 **Q.** We do have various materials which I think have been
 5 sent to you in advance, Professor Lee, which are BMA
 6 Medical Defence Union materials really from the 1950s
 7 onwards. I can ask you about those if it would assist
 8 or if there's anything you want to say about them. Do
 9 you know whether any express consideration was given
 10 within the Centre at the time to the -- whether there
 11 was an ethical component to what you were proposing to
 12 do?
 13 **A.** No.
 14 **Q.** As in there was no express consideration or you don't
 15 know?
 16 **A.** No.
 17 **Q.** Sorry, forgive me, Professor Lee, but --
 18 **SIR BRIAN LANGSTAFF:** There are two questions.
 19 **MS RICHARDS:** Yes, it's my fault entirely.
 20 Was there any ethical consideration or
 21 discussion -- was there any discussion or
 22 consideration of the ethical dimensions of what was
 23 proposed?
 24 **A.** No.
 25 **Q.** Okay.

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1 Then, as I understand it, the arrangements for
 2 telling patients the result was the responsibility of
 3 others within the Centre, and you by this time were
 4 now back down to working only one day a week at the
 5 Royal Free?
 6 **A.** I wasn't there.
 7 Can I go back to what I was doing and what
 8 I wasn't doing? I started at Queen Mary's and
 9 Charing Cross at the beginning of November, and
 10 I didn't start going back for a day a week, I think it
 11 was, until '86.
 12 **Q.** Okay, so in any event I won't ask you about --
 13 **A.** But I mean I sometimes feel -- it was very difficult,
 14 I'm sure, for those who had to give results. I never
 15 had to do it ever. Ever.
 16 **Q.** So by the time you had rejoined the centre as
 17 a consultant, full time in '87 --
 18 **A.** '87.
 19 **Q.** -- all the patients as far as you are aware had been
 20 told their diagnosis?
 21 **A.** Yes. And the people concerned, I think, were -- it's
 22 in my statement -- were Dr Eleanor Goldman and I think
 23 she's making a statement for you, I imagine, and
 24 Mrs Riva Miller, who -- the family therapist, and
 25 I think the person who took over from me,

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1 Dr Elizabeth Miller. I think they were the three
 2 people. I don't know whether Dr Kernoff himself gave
 3 results. I don't know.
 4 **Q.** Okay.
 5 Work was undertaken to try to establish the date
 6 of seroconversion at a later stage.
 7 And if we have up on screen, Henry, please,
 8 WITN0644083.
 9 This is a 1989 publication, "The natural history
 10 of [HIV] infection in a haemophilic cohort", and
 11 again, you were one of the authors of this. And if we
 12 just look down the bottom of that page, we can see it
 13 says:
 14 "112 anti-HIV positive patients were entered into
 15 the study using data from records and samples from the
 16 period 1 December 1979 to 30 November 1988."
 17 Then you give various statistics in relation to
 18 that.
 19 If we go over to the next page, please, Henry.
 20 If we look first of all towards the bottom of the
 21 page, under the heading "Results", we can see there
 22 were:
 23 "... 59 patients for whom a previously negative
 24 anti-HIV result was available ..."
 25 So that's doing a retrospective exercise going back

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1 to the stored samples -- (overspeaking) --
 2 **A.** Yes, I think it might be helpful --
 3 **Q.** The table at the top?
 4 **A.** -- to take you through the diagram about --
 5 **Q.** Yes. Top of the page, please, Henry.
 6 **A.** This doesn't show 112 patients. And, again, actually,
 7 that's a slight mistake. It should be 111. I was
 8 telling you about the von Willebrand's -- subsequently
 9 was found not to have had concentrate.
 10 This is looking at people for whom we had
 11 a specimen that was negative. And then we had
 12 a specimen that was positive. So each line represents
 13 a patient. And you see the seroconversion for the
 14 first patient was in 1979, and then gradually there's
 15 a transition over these years. And you see the last
 16 patient was the haemophilia B patient I told you about
 17 who seroconverted in 1985. From the beginning of
 18 1985, as we've already discussed, there was heated
 19 concentrate, so there were no more seroconversions.
 20 And I think what is really sad is that -- well, if
 21 I look at the time that I started at the beginning of
 22 '83 and you draw a line up, most patients had actually
 23 been infected by then, and unwittingly, we watched
 24 some people being -- moving into HIV positivity, being
 25 infected. Of course, we didn't know.

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1 The epidemic of HIV and haemophilia is short because
 2 it ended with heating, and also, in this country ...
 3 well, actually, in this country it tended to come over
 4 later in the general population, but that was when it
 5 emerged in the American population, donor population.
 6 **Q.** Just so that I can ensure I've correctly understood
 7 the table, Professor Lee, the open circle, as it were,
 8 or the white circle represents the last negative --
 9 **A.** That's right.
 10 **Q.** -- result, the black circle represents the first
 11 positive result, and the line is a line -- and it's
 12 any point between those two points where the
 13 individual may have zero converted?
 14 **A.** Yes.
 15 **Q.** And for the purposes of the analysis you do in the
 16 paper, certain assumptions are made -- I don't use
 17 that word critically -- about taking a median point;
 18 is that right?
 19 **A.** Well, it means the middle.
 20 **Q.** Yeah.
 21 **A.** You take the time here and the time there, and you
 22 take the middle point, and I think the middle point
 23 was the beginning of '83, yeah.
 24 **Q.** Do you know whether the information that that table
 25 reveals about the time periods within which these 59

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1 individuals would have seroconverted, was that
 2 information that was ever shared with the individual
 3 patients themselves?
 4 **A.** I doubt whether it was. By the time this paper was
 5 written, the patients were on heat-treated concentrate
 6 that -- so we knew it was safe. And these data, I --
 7 we wouldn't have had early on. But at the time that
 8 the people were giving the test results, we wouldn't
 9 have had these data. They were -- I mean, I think
 10 when they gave the test results, they had who was
 11 positive from Richard Tedder's results, but these data
 12 were assembled later.
 13 **Q.** I understand that this would have been information
 14 available only potentially as at 1989 when the
 15 analysis was done.
 16 **A.** Yes.
 17 **Q.** And my question -- and it's a question that I've been
 18 asked by others, in fact, to enquire as to -- was: at
 19 that point in 1989 when for some patients -- only
 20 some; you had a time period within which they'd
 21 seroconverted -- was that information given to them at
 22 that point?
 23 **A.** I doubt whether it was done routinely, no. To be
 24 perfectly honest, I don't know. I think one would
 25 have to refer back to the contemporaneous note that

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1 was made.
 2 **Q.** Can I turn, then, to the question of testing and
 3 diagnosis for hepatitis C. Before we look
 4 specifically at the hepatitis C testing arrangements
 5 in the Royal Free in 1990/1991, can I just ask you
 6 about the practice in relation to non-A, non-B
 7 hepatitis.
 8 You -- 1986, you returned part-time; 1987 you
 9 become a full-time consultant at the Royal Free.
 10 Presumably there were patients who the Centre believed
 11 to have non-A, non-B hepatitis. Was that information,
 12 as far as you know from your patient dealings and
 13 patient records -- was that information and that
 14 diagnosis shared with patients at the time?
 15 **A.** Well, the particular patients that I can remember
 16 that I was testing for -- I told you that it was the
 17 end of -- or the beginning of 1983, it was the end of
 18 the study period. Certainly, when I took blood from
 19 them, I discussed what we were doing and why we were
 20 doing it and what we understood. And before that, I
 21 imagine Dr Kernoff must have done that. But -- and
 22 certainly, if you look back in the notes when we did
 23 reviews later on, I mean, we talked about what had
 24 been shown in their liver function tests and what we
 25 understood, but -- yes.

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1 Q. Your statement refers to then the process for testing
 2 for HCV once the hepatitis C tests became available.
 3 We'll look at a couple of documents in a moment, but
 4 before we do that, what can you recall -- you were
 5 a consultant at the Centre by now, 1990/1991. What
 6 can you recall about how testing for hepatitis C was
 7 undertaken at the Centre?
 8 A. Well, it was my responsibility to look after the
 9 patients with HIV and hepatitis C, and by 1990, I was
 10 the kind of more knowledgeable one, I suppose. So the
 11 liver unit and the virology unit had got an in-house
 12 test for antibody, I think, and then later they had
 13 what's called a PCR test for antigen.
 14 And we knew -- you know, the virus was identified
 15 in the world in 1989. And we had the test available,
 16 and therefore we tested our patients with -- to see if
 17 they had antibody. By that stage, the patients would
 18 have been regularly reviewed, and their liver function
 19 tests had been discussed with them, and those who had
 20 abnormal ones would have been discussed. And we
 21 sent -- I sent a letter of the results. I think we
 22 initially tested about 80, and you probably have the
 23 letter there.
 24 Q. Yes, we'll have a look at the document. It's
 25 BART0000668. If we go to the next page first, please,

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1 Henry. So if we look at both this page and the next
 2 page on screen together. It's just easier to see the
 3 document as a whole.
 4 So we can see this is headed "HCV Policy Document
 5 for the Haemophilia Centre", and if we look on the
 6 right-hand side, we can see it's authored by you.
 7 It's dated 4 May 1990.
 8 We can -- then if we look in "Introduction", you
 9 talk about the agent having been identified. And then
 10 if we go on to the heading "Studies at the Royal Free
 11 Haemophilia Centre", you say this:
 12 "We've been able to study the longitudinal behaviour
 13 of antibody to HCV using the Ortho HCV antibody assay
 14 and testing stored sera from patients who developed
 15 non-A, non-B hepatitis following exposure to unheated
 16 pooled factor concentrates. All such patients have been
 17 found to be seropositive for anti-HCV. We have thus
 18 demonstrated reliability of the Ortho anti-HCV assay.
 19 In our haemophiliac population, HCV accounts for the
 20 non-A, non-B hepatitis seen, and in the majority of
 21 patients the antibody is long-lasting and may reflect
 22 virus replication," et cetera.
 23 Just pausing there. This would appear to suggest
 24 that by this time -- this is 4 May 1990 -- at the
 25 Royal Free, all patients believed to have non-A, non-B

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1 hepatitis had been tested for HCV using the particular
 2 test --
 3 A. No, that's wrong. It may read as if that's the case.
 4 I think this was using the samples from the
 5 retrospective study that showed that a first exposure
 6 had a 100% risk. And so we were able -- because we
 7 had longitudinal samples of that and we knew the
 8 incubation period from the transaminases, we were able
 9 to use those samples. This is from the 1985 paper on
 10 non-A, non-B. Those samples -- we used those samples
 11 to test that antibody test.
 12 Q. Okay. So just trying to understand. So is it only
 13 a subset of patients?
 14 A. Yes, at that stage because -- I think the question was
 15 whether this was reliable or not.
 16 Q. And that testing was undertaken on the stored sera --
 17 A. Yes.
 18 Q. -- so you, or whoever it was, took the sera from
 19 storage --
 20 A. Yes.
 21 Q. -- for this subset of patients.
 22 A. It's the patients who are in the first exposure --
 23 Q. Yes, which we'll look --
 24 A. -- in that table --
 25 Q. We'll look that up this afternoon. But you test them

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1 for -- their samples for hepatitis C using the new
 2 test that was now available, so for that cohort of
 3 patients, is this right, that that first test was
 4 undertaken without their knowledge and consent?
 5 A. Yes.
 6 Q. If we then go to the previous page.
 7 A. I mean, I just go back -- without their knowledge and
 8 consent. Of course, all those patients will have been
 9 told that they -- back in '78, '83, they will have
 10 been told at that stage that they had had non-A, non-B
 11 hepatitis, so they knew that. And every time they
 12 came for their review, they would be reminded of that.
 13 **SIR BRIAN LANGSTAFF:** Just let her run, if you please.
 14 **MS RICHARDS:** That, I think, is an assumption you're
 15 making because as you rightly --
 16 A. Sorry?
 17 Q. Is it fair to say that what you've just said, which is
 18 that patients between 1978 and 1983 would have been
 19 told they had non-A, non-B hepatitis, that's an
 20 assumption you're making because, of course, as you
 21 have told us, you only came in at the end of
 22 January 1983 --
 23 A. Yes, okay, it's an assumption that Dr Kernoff would
 24 have told them that.
 25 Q. And could we go to the first page of this document,

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1 which is the letter. So this is a letter dated
 2 4 June 1990. And it's obviously a standard form
 3 letter, but we have seen it crop up in individual
 4 patient records from the statements that the Inquiry
 5 has received.
 6 "Dear [blank], I'm writing to tell you about the new
 7 anti-HCV test. Many haemophiliacs who have been treated
 8 in the past with unheated clotting factor concentrates
 9 or other blood products have been exposed to the non-A,
 10 non-B hepatitis virus, so-called because it's unrelated
 11 to hepatitis A and unrelated to hepatitis B. One agent
 12 responsible for non-A, non-B has now been identified.
 13 We have a new test available which measures antibody to
 14 HCV (anti-HIV) and shows past infection. Your anti-HCV
 15 was positive on [blank]."
 16 Now, the way this letter might read or might be said
 17 to read is: it's simultaneously telling the patient
 18 about the new test and telling them their result, which
 19 would suggest they hadn't been told in advance of the
 20 testing that the testing was going to take place.
 21 **A.** Yes.
 22 **Q.** Is that what happened then for all patients? Was this
 23 the model that was adopted for all patients --
 24 **A.** I think ultimately, yes, and I go back to what I said
 25 before, that the patients will have been regularly

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1 reviewed through all these years. And we had a review
 2 pro forma, and one of the sections that patients were
 3 asked about and discussed was hepatitis. So the
 4 transaminase results would be discussed through all
 5 those years. And as information emerged, it probably
 6 would have been more detailed information about what
 7 the nature of non-A, non-B was, as far as we knew it.
 8 **Q.** Do you think there's a difference between the process
 9 of telling a patient that -- what their liver function
 10 test results are and whether they have elevated
 11 transaminases and so on and actually testing them for
 12 hepatitis C once the test was available?
 13 **A.** Yes.
 14 **Q.** Is there any particular reason why patients were not
 15 called in and asked whether they consented to being
 16 tested for hepatitis C before the tests were
 17 undertaken?
 18 **A.** I think it wasn't thought necessary at that stage, you
 19 know, it wasn't -- you see the last paragraph of this
 20 letter, that the idea was that it would be discussed
 21 at their next review, and if they wanted to come and
 22 discuss it, they were very welcome to, earlier than
 23 that.
 24 **Q.** Was this the method by which patients were intended to
 25 be given their hepatitis C result? It was by letter?

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1 **A.** At this stage -- I mean, I think the original -- the
 2 first batch -- I had 80 patients to do this. It's,
 3 you know, the context of a busy department doing all
 4 sorts of other things. If we had pulled up
 5 80 patients at that stage it would have been very
 6 difficult. And the reason for putting that last
 7 paragraph in is to encourage patients who wanted to
 8 come and discuss, to come and discuss earlier. And
 9 the whole working of the Centre also was that people
 10 could walk in if they wanted, they could phone up,
 11 they could phone directly to nurses, the consultant
 12 haemophilia nurses.
 13 **Q.** Do you think -- and whether with the benefit of
 14 hindsight or otherwise -- do you think that was the
 15 right way to tell patients that they had tested
 16 positive for hepatitis C, known to be a serious
 17 disease with long-term consequences?
 18 **A.** Yes, because they had been -- it had been discussed
 19 over many years about non-A, non-B transaminitis, so
 20 I do think so.
 21 **Q.** And the onus then was on the patient to make the
 22 appointment to come in and be given further
 23 information if they sought it?
 24 **A.** Yes.
 25 **Q.** Can we go back --

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1 **A.** I can't exactly recall the number but it was a handful
 2 that did that. Most patients discussed it at their
 3 next review appointment.
 4 **Q.** Can we go on to the second page again, Henry.
 5 Can we look at the paragraph below the paragraph
 6 we looked at previously. It begins:
 7 "We have also demonstrated a 7% seropositivity rate
 8 in 30 female sexual partners of 30 anti-HIV and
 9 anti-HCV positive haemophiliacs. In other studies the
 10 seropositivity rate amongst sexual partners has been
 11 higher. It seems likely, therefore, that sexual
 12 transmission of HCV may occur."
 13 I just wanted to ask you about that first sentence.
 14 How was it that the Centre had stored sera for the
 15 sexual partners of a number of its patients?
 16 **A.** I think very early on there had been a concern that,
 17 you know, because people were treating at home and
 18 sometimes families were -- it wasn't necessarily the
 19 patient; sometimes other members of the family, like
 20 a wife, might be doing it, I think that's how that had
 21 been there.
 22 I think Dr Eleanor Goldman had looked at this,
 23 because the other issue that is sort of slightly tied
 24 up about this was that hepatitis B itself, not non-A,
 25 non-B, but hepatitis B, was very -- you could easily

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1 get it from people you were living with. And I have
 2 a feeling that there was a study to look and see
 3 whether family members had abnormal transaminases,
 4 but -- this -- there is a publication from this,
 5 I think.
 6 **Q.** The 30 female partners whose sera has obviously been
 7 tested if one looks at this, would it be right to
 8 infer from this that their sera had been tested also
 9 without their -- them expressly being told that that
 10 was happening?
 11 **A.** It's very difficult to remember precisely. I think
 12 there is a -- we did look at HIV seropositivity in
 13 partners, because obviously, you know, it's very
 14 important. And of course what we haven't talked about
 15 here at all is that everybody who has -- who got
 16 infected with HIV must have been infected with
 17 hepatitis C either at the time they got infected with
 18 HIV or before, and I think this may have been the
 19 blood samples from looking at whether spouses were
 20 infected with HIV. I can't remember.
 21 **Q.** That might be why you had the stored samples --
 22 **A.** Yes, I think that was probably why. I can't actually
 23 remember. And -- yeah, well, that's ...
 24 **Q.** Is it right to understand from this that, as with the
 25 patients themselves, the samples were tested and only

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1 after that the patients were informed of that fact?
 2 **A.** I think --
 3 **Q.** That the partners were informed of that fact?
 4 **A.** I think the -- I think we -- I would have to go back
 5 to the publication of the HIV in partners, because
 6 I think by that -- that's published, by the time that
 7 was done, you know, consent for HIV testing came in
 8 quite early. I mean it's something that really moved,
 9 consent for that, I think in '85. And so those
 10 partners would have consented for the HIV test. And
 11 those specimens would have been stored. But the
 12 partners weren't asked, I don't think, for their
 13 anti-HCV, no.
 14 **MS RICHARDS:** Okay.
 15 Sir, I note the time. Is this a convenient point
 16 to stop?
 17 **SIR BRIAN LANGSTAFF:** Yes, it is. So let's meet again,
 18 then, at five past two. Five past two.
 19 **(1.04 pm)**
 20 **(The Short Adjournment)**
 21 **(2.04 pm)**
 22 **MS RICHARDS:** Henry, could we have up, please THOM --
 23 **SIR BRIAN LANGSTAFF:** Just one moment.
 24 **MS RICHARDS:** Sorry.
 25 **SIR BRIAN LANGSTAFF:** We're just a little early.

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1 **MS RICHARDS:** Sorry.
 2 **SIR BRIAN:** No, it's my fault for starting just a bit
 3 early, don't worry. Right.
 4 **MS RICHARDS:** THOM0000001, please. This is the oral
 5 history project again, Professor Lee. Could we go to
 6 page 27, please, Henry. Just look at the bottom six
 7 or seven lines. You're talking here about hepatitis C
 8 testing -- sorry, hepatitis C testing coming in, and
 9 you say:
 10 "So in the context today, we have patients going
 11 around saying, 'They never told us anything. They never
 12 told us, but they knew, and we weren't told until 1991.'
 13 And, of course, it's very difficult for them to
 14 remember. We would have been talking about them having
 15 abnormal liver function tests, but we don't know what
 16 this means, and you're very well, and all the rest. And
 17 it wasn't until 1991 that we actually told them, 'Well,
 18 actually, you've been infected with hepatitis C.'
 19 Now, were you saying there that the information
 20 given to patients, as far as you know prior to the
 21 availability of the hep C test, was about them having
 22 abnormal liver function tests, rather than specifically
 23 being told they had non-A, non-B hepatitis?
 24 **A.** Yes.
 25 **Q.** If patients were told prior to 1991 at the Royal Free

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1 that they had non-A, non-B hepatitis, would you expect
 2 that to have been recorded in the notes of the
 3 relevant individual patient consultation?
 4 **A.** Probably depends who saw them. Mostly I saw them, but
 5 not always. Some reviews were done by other doctors.
 6 I think I probably would have done. I don't know.
 7 **Q.** So that I understand this correctly, if you had been
 8 seeing a patient and telling them about non-A, non-B
 9 hepatitis -- so this is before the HCV test. If you
 10 told them that you had, or you believed they had,
 11 non-A, non-B hepatitis, you would have expected that
 12 you would have recorded that in the notes?
 13 **A.** Probably, yes.
 14 **Q.** And you can't necessarily speak for others?
 15 **A.** No. Of course, the importance of the review and the
 16 importance for considering the abnormal liver function
 17 tests and the liver was because if we sensed there was
 18 any abnormality or things were not going well -- and
 19 then, of course, when we move on and we've got
 20 treatment, we can actually refer them to the Joint
 21 Liver Clinic which I established when I became the
 22 director, where I think they roughly, or about every
 23 month, it rather depended when the consultants,
 24 hepatologists, could come down to the clinic. And
 25 I would sit alongside him in that clinic, to review

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1 him from a hepatological point of view.
 2 **Q.** When did that start?
 3 **A.** I think it was after I became -- there were joint
 4 liver clinics, but I set a regular basis certainly
 5 when I became director.
 6 **Q.** So that would have been after April 1991?
 7 **A.** It was probably before then, because the first liver
 8 consultant that I worked with was somebody called
 9 Dr Geoffrey Dusheiko who ultimately was the world
 10 authority on hepatitis C. And he came in 1988 from
 11 South Africa. And what I remember is that we tried
 12 very, very hard at that stage to try and access
 13 treatment for these patients, and that was before
 14 I was director.
 15 **Q.** Yes. Just sticking with the question of notes and
 16 what you might or might not expect to be recorded in
 17 the notes, if at a patient consultation a patient was
 18 given information about the risks of non-A, non-B
 19 hepatitis or the risks of AIDS, would you expect that
 20 to have been documented in the notes of the
 21 consultation?
 22 **A.** What do you mean by "risk"?
 23 **Q.** If there was any discussion, whether by Dr Kernoff or
 24 a registrar or anybody else in, say, 1983 with
 25 a patient, in which that patient was given information

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1 about what was known about the risks of AIDS at the
 2 time, would you, based on your knowledge of practices
 3 and looking at the notes of subsequent years, would
 4 you expect that to be recorded in the notes of the
 5 consultation?
 6 **A.** I don't know about '83. I can't remember. I don't
 7 know.
 8 **SIR BRIAN LANGSTAFF:** You've said that Peter Kernoff was
 9 a careful and meticulous, I think --
 10 **A.** Yes.
 11 **SIR BRIAN LANGSTAFF:** Looking at his practices, as far as
 12 you knew them -- you may not have known -- would you
 13 expect him to record it if that had been said by him?
 14 If you can't answer it -- (overspeaking) --
 15 **A.** I can't answer it.
 16 **MS RICHARDS:** Then, again, just while we're talking about
 17 notes, as the '90s went, the issue of vCJD arose. I'm
 18 not going to ask you in detail about that because
 19 that's fairly well documented in what you've provided
 20 to the Inquiry and in some of your publications. But
 21 in terms of any conversations you had with patients
 22 specifically about vCJD, would you have recorded that
 23 in their notes?
 24 **A.** Yes.
 25 **Q.** Going back to the question of the testing for

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1 hepatitis C, 1990 onwards, we've looked at that
 2 letter, the model letter, June 1990. Over what period
 3 of time, as far as you can recall, did the process of
 4 testing the Royal Free's patients for hepatitis C take
 5 place?
 6 **A.** I don't know precisely, but I would have thought
 7 within a few months.
 8 **Q.** Of the test becoming available?
 9 **A.** Yes. We actually had -- I mean, on records, sadly
 10 some people had died. We had 310 patients who'd been
 11 infected with hepatitis C, and I think 30 of them had
 12 actually cleared it. So you're talking about a vast
 13 number of patients that we had to tell, although some
 14 of those patients would have been -- have died by
 15 1990.
 16 **Q.** And so the -- did you test the samples of every one of
 17 the patients who you knew had received blood products?
 18 **A.** Ultimately, yes.
 19 **Q.** When you say "ultimately", was that a --
 20 (overspeaking) -- period that took some time?
 21 **A.** Well, the Natural History paper published in 2000 was
 22 clearly dependent on that and, because we had such
 23 meticulous records, we could actually look at the
 24 dates of when patients had a first infusion, and we
 25 knew from the previous study that if you had a first

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1 infusion, there's 100% chance of getting infected. So
 2 in that paper, the 310 were identified because we
 3 looked back at the records to see when they had
 4 a first infusion, and we tested those sera. Some
 5 of it had already been tested, so that was how they
 6 were identified.
 7 **Q.** So for the purpose of that study, perhaps we should
 8 just briefly look at it, it's WITN0644088.
 9 **A.** I think the other thing that perhaps I ought to just
 10 interject is that -- is the convention of writing
 11 papers.
 12 This paper, which is the first author, Dr Yee,
 13 because she analysed the information. And she
 14 actually, I think, put this in towards an MD on the
 15 side effects of therapy. She has the first author
 16 here. My name at the end here is because I was in
 17 overall in charge of the study. And Anja Griffioen is
 18 an epidemiologist who looked after the data. And by
 19 this stage, although the Data Protection Act actually
 20 hadn't kicked in, we had already moved to a position
 21 that all data on computers was totally anonymised with
 22 codes. And Caroline Sabin, who is now
 23 Professor Caroline Sabin, was also an epidemiologist,
 24 and by this stage she had moved to the AIDS unit,
 25 looked at their epidemiological issues. And I've

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1 already talked about Dr Dusheiko, who by then was
2 beginning to be the most eminent hepatologist looking
3 after non-A, non-B.

4 Q. So every patient should -- well, presumably before
5 this time should have been told their hepatitis C
6 results?

7 A. Yes.

8 Q. There is a reference, if you just go to page 2, under
9 the heading "Results", on the bottom half of the page,
10 right-hand column, you refer there in the last
11 sentence of that paragraph, under the heading
12 "Results" to there being 27 individuals who were
13 consistently HCV PCR negative, they:

14 "... were thought to have cleared the virus and
15 were studied in more detail."

16 Are you able to say what the more detailed study
17 entailed?

18 A. Yes. The specimens were re-tested, I think, to
19 check -- when -- what you're dealing with here is
20 you've got a positive antibody test, and they're PCR
21 negative, so they haven't got the virus anymore.
22 And -- so they had cleared it.

23 And interestingly -- I think this is important --
24 those patients who were co-infected with HIV, there
25 were three out of that 100 who had cleared

1 hepatitis C, which is quite extraordinary.

2 Q. The reference to further study there is a reference to
3 repeat testing, is it?

4 A. I think so, yes.

5 Q. And when you first saw a patient after they tested
6 positive for hepatitis C, whether it was because
7 they'd asked to come and see you on receipt of
8 a letter or at a consultation that was taking place in
9 any event, what information do you recall providing to
10 patients at that stage in the early part of the 1990s
11 about their diagnosis?

12 A. Well, it would be the equivalent message that was in
13 that letter, really. We would explain that the virus
14 had been identified in 1989 and it was now possible to
15 actually test and confirm that they had this
16 infection. And I think certainly if I saw such
17 a patient, I probably would have referred to the fact
18 of when they first got it, that they got it when they
19 would have had their first infusion.

20 And of course, when we reviewed them, we had the
21 hospital notes, we had all the notes in the Centre,
22 and we had the separate folder with the treatment
23 records in, so you could find that out very easily.

24 Q. And what was the system in place at the Royal Free for
25 the ongoing monitoring of patients with hepatitis C?

1 A. Well, the patients -- all patients with severe disease
2 were ideally reviewed every six months, but of course
3 that depends on patients coming. Sometimes patients
4 didn't take up their appointments, so -- mainly they
5 did. And certainly at their review they would have
6 had liver function tests done, and we -- when we had
7 the facility for doing testing, we would -- when we
8 could do the antigen testing, we began to look to see
9 who had the antigen and probably those people, once we
10 began to have treatments, would certainly be reviewed
11 at the Joint Liver Clinic. And more importantly, we
12 became available -- became available to actually do
13 the genotype of the hepatitis C, and again, this was
14 information that would be passed with some -- when
15 they were seen in the Joint Liver Clinic. And the
16 significance of that was that once we had treatment,
17 if you had what's called genotype 1, it was more
18 difficult to treat. If you had genotype 3, it was
19 more easy to treat with interferon and, later, with
20 combination therapy. So that information was very
21 important for the hepatologist and that would have
22 been shared with the patient.

23 One of the other things I would say, and I don't --
24 I can't precisely say the date that I started doing
25 this, but it became my habit to copy the letter that was

1 sent to the GP to the patient. The letter from the
2 Liver Clinic, there was a dedicated secretary who did
3 the special clinics, she would -- the doctor, the
4 hepatologist who was doing the clinic would review the
5 patient, talk to the patient, and he dictated the
6 summary then, and that summary was sent to the GP, and
7 I would countersign it to make sure that, you know,
8 there hadn't been any mistakes. But I don't know at
9 what stage I started copying it to the patient. And
10 I also did that for reviews.

11 Q. In terms of the Joint Liver Clinic, was that something
12 that would be offered to all patients in the early
13 1990s who had been diagnosed with hepatitis C, or only
14 a subset of those patients?

15 A. No, it would be -- as soon as we had treatments
16 available, all patients would be referred, because
17 hepatitis C essentially could be cured. But this was
18 very slow. I mean, it wasn't really -- we had in the
19 interferon first of all, which didn't have such
20 a good, success rate for genotype 1. It was quite
21 good for genotype 3.

22 And later, when we had better treatments, the people
23 who hadn't succeeded in clearing would be referred.
24 I think that's the answer.

25 Q. In terms of treatment with interferon, you referred in

1 your statement to a study of 20 patients, and you
 2 said -- well, sorry, I don't want to misquote you so
 3 let's see exactly what you say. It's paragraph 97.
 4 No, it's not that paragraph but there is a question
 5 about that paragraph.
 6 If we can have up on screen WITN0644058, please,
 7 and if we could go first of all to page 56.
 8 So this is paragraph 95 of your statement. And
 9 you refer, third paragraph, to two studies, the second
 10 which is a controlled trial of interferon, in
 11 20 haemophiliac patients where you say this:
 12 "... where we describe side effects as:
 13 "Fever malaise, lethargy, poor concentration and
 14 irritability were reported as troublesome in 16 (80%) of
 15 patients."
 16 Then you said this:
 17 "But we found these tended to lessen as treatment
 18 continued and were generally tolerable when paracetamol
 19 was taken with the interferon injections".
 20 Then you go on to say:
 21 "Side effects were very common as is usual with
 22 interferon, and although only temporary in the majority
 23 of cases, may deter patients from adhering to the
 24 demanding treatment regime."
 25 Was your assessment, that the side effects of

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1 interferon were generally tolerable when paracetamol was
 2 taken, based on the trial of those 20 patients or your
 3 broader patient experience?
 4 **A.** I think at the time this was written, it was in the
 5 context of that trial. I think it's important at this
 6 point to say how we were able to access this
 7 treatment. When Dr Dusheiko came to the Royal Free,
 8 it began to be more common to treat patients -- as
 9 soon as we had a test, to treat patients with
 10 interferon, but it was extremely difficult to get
 11 interferon for people with haemophilia. There was
 12 a reluctance to treat such patients. Before this
 13 trial we had an experience with interferon, because --
 14 we had a patient who had HIV infection. And, as
 15 I said earlier, everybody with HIV infection had
 16 hepatitis C. And one of the fairly rare complications
 17 of HIV infection is thrombocytopenia, a very low
 18 platelet count, and you can imagine a low platelet
 19 count in somebody with a bleeding disorder is pretty
 20 hazardous. And there had been a case report, I think
 21 in the American literature, that intravenous
 22 interferon would be successful in treating such a side
 23 effect.
 24 And this patient who's actually reported in the
 25 British Medical Bulletin review -- and there's a picture

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1 of it -- was started on intravenous interferon,
 2 essentially for the low platelet count. And what is
 3 quite extraordinary, he went on with this -- it was
 4 given intravenously which also was unusual because that
 5 was done because he had haemophilia. People who didn't
 6 have haemophilia were given interferon by, I think,
 7 subcutaneous injection. And his platelet count became
 8 normal, and ultimately, he actually -- he was a carrier
 9 of hepatitis B e-antigen. He converted, and because --
 10 there's another agent called delta agent that you get
 11 only if you have hepatitis B e-antigen.
 12 So he had HIV. He had HCV. He had HB -- delta
 13 agent. And all those were cleared completely with the
 14 intravenous interferon. And he went on having that for
 15 some time. And I think, you know, it's anecdotal, but
 16 there's no doubt that -- well, maybe it's anecdotal so
 17 there is doubt, isn't there. His CD4 count didn't
 18 decline at the rate of other people with HIV infection,
 19 so that was one experience we had.
 20 The lady who I keep describing, who had
 21 cryoprecipitate and got acute fulminant hepatitis C and
 22 was on ITU and things -- a carrier of haemophilia --
 23 she -- I looked after her, and I think it was Dr Thomas
 24 who suggested that perhaps she would benefit from
 25 interferon. And she was on a really tiny, tiny dose for

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1 many years, and her transaminases went to a very low
 2 level. Ultimately when, you know, learning in
 3 hepatology, they realised what was the right treatment,
 4 she had a proper course of interferon. She had type 1,
 5 genotype 1, and she cleared it completely. And her son,
 6 who had severe haemophilia, who'd actually been somebody
 7 who had NHS concentrate, so he didn't have HIV -- and he
 8 cleared it.
 9 So that was the previous experience going into when
 10 we tried to get this trial going.
 11 **Q.** You'll appreciate that the experience of many patients
 12 who subsequently were on interferon was that the side
 13 effects were very far from tolerable and were
 14 intolerable.
 15 **A.** Were very what?
 16 **Q.** Were very far from tolerable --
 17 **A.** It depended who the patient was. Some people did
 18 tolerate it; some people had very bad side effects.
 19 It was -- I mean, I think what is written here was the
 20 experience of these patients, some of whom were
 21 Dr Colvin's patients. It wasn't -- you know, you can
 22 see the results of the study. It wasn't at all
 23 successful, but we needed to move into a situation of
 24 trying to provide some treatment.
 25 **Q.** Can you recall what information or advice you gave

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1 your patients in the 1990s about the potential side
 2 effects of interferon?
 3 **A.** Well, this study had ethical approval, and I'm sure
 4 there was a patient information sheet for it, talking
 5 about the side effects.
 6 And the patients, when we moved on and the treatment
 7 of hepatitis C was really clarified within the
 8 hepatology world and we could genotype the patients and
 9 it was really under the direction of hepatologist, the
 10 person administering the interferon -- the patients
 11 would come up -- was a nurse specialist, and she would
 12 discuss the side effects.
 13 **Q.** Can we just go to the next page of the statement,
 14 please, Henry. The first main paragraph. You talk
 15 there about your natural history of HCV paper and what
 16 you describe as:
 17 "The lethal combination of HCV and HIV
 18 co-infection."
 19 And then you said this:
 20 "Hepatitis C is a very slowly progressive disorder
 21 with a 3% progression rate to a liver-related death from
 22 the time of HIV infection in 1985."
 23 I think you probably didn't mean HIV infection in
 24 the last --
 25 **A.** Sorry, what?

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1 **Q.** If you look at the extract of the statement --
 2 (overspeaking) --
 3 **A.** Yes, I've got the paper here. It comes from --
 4 **Q.** It's not the paper, I'm sorry. I wanted to ask --
 5 (overspeaking) --
 6 **A.** No, it comes from the e-paper. This is from the
 7 e-paper.
 8 **Q.** Could I ask you just to look at the statement for a
 9 moment, though.
 10 **A.** Yes.
 11 **Q.** It should come up on the screen in front of you. That
 12 last sentence there says:
 13 "For those HCV positive individuals without HIV
 14 infection, we have shown that hepatitis C is a very
 15 slowly progressive disorder with a 3% progression rate
 16 to a liver-related death."
 17 Then it says:
 18 "From the time of HIV infection" --
 19 **A.** Yes.
 20 **Q.** -- that must be HCV infection?
 21 **A.** No. The significance of this is that we were
 22 demonstrating that HIV is a lethal combination. We
 23 had already, in 1994, identified that the people who
 24 had progressed to cirrhosis were the -- the majority
 25 were co-infected. There were one or two people who

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1 drank a lot of alcohol, but mostly it was
 2 co-infection.
 3 This paper here is analysing the progression rate
 4 after they've got HIV infection to compare the people
 5 who were co-infected with the people who were not
 6 co-infected.
 7 **Q.** So for those who had hepatitis C but not HIV --
 8 **A.** Yes.
 9 **Q.** -- that's the cohort in respect of whom you're saying
 10 there's a 3% progression rate to a liver-related
 11 death?
 12 **A.** Yes.
 13 **Q.** Can I --
 14 **A.** This is 2000, so you're talking about the time they
 15 would have got ... the HIV was sort of '70/'90, '83 --
 16 '85, sorry. So that's why the analysis was done from
 17 '85, if you're comparing these two groups of patients.
 18 **Q.** Can I just ask you to explain, and again, this is
 19 a question I particularly have been asked to ask you:
 20 what's meant by the "3% progression rate to a
 21 liver-related death"? How should that be understood
 22 on a year-by-year basis?
 23 **A.** You mean why is -- how do you explain what 3% means?
 24 Is that what you mean?
 25 **SIR BRIAN LANGSTAFF:** If I may just intervene for a

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1 moment?
 2 **PROFESSOR LEE:** Sorry?
 3 **SIR BRIAN LANGSTAFF:** If I may just intervene. A rate
 4 depends -- (overspeaking) -- on what you're measuring
 5 against --
 6 **PROFESSOR LEE:** I think probably could we look -- I think
 7 in order to explain this, the question you're asking
 8 me, could we look at the Yee paper which -- well, my
 9 number is 655088. Or the other number I've got is
 10 655084. I'm not sure which one it is do you have got.
 11 **MS RICHARDS:** I'm not sure either.
 12 **A.** It's the 2000 paper from --
 13 **Q.** So it's WITN0644088, yes. Thank you.
 14 **A.** If you turn to the fourth page. I mean, this becomes
 15 rather like the familiar graphs we keep seeing on our
 16 television screens from Covid. It's epidemiological,
 17 the way epidemiologists present data. And if you look
 18 at the lower graph ... if you look at the lower graph,
 19 that's progression rates to liver-related deaths from
 20 1985 in HIV positive and negative patients, and you
 21 see this very slow progression. Then the top one is
 22 any death; do you see --
 23 **Q.** Yes.
 24 **A.** -- at the top? And, of course, the difference between
 25 those is that, very sadly, those individuals who are

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1 HIV positive have died from -- a lot of them have died
 2 from the HIV, although they might have been
 3 co-infected with whatever they were co-infected with;
 4 HCV.
 5 Is that clear, or have I completely bamboozled
 6 everybody?
 7 **Q.** We probably have enough evidence from elsewhere,
 8 including from the Inquiry's own experts, about the
 9 progression --
 10 **A.** Yes.
 11 **Q.** -- so I don't need to ask you more about that.
 12 Can I move to a slightly different topic and just
 13 ask you briefly about the use of porcine products.
 14 We looked earlier at an application that Dr Kernoff
 15 had made in December 1983 for a clinical study in
 16 relation to porcine products. I'm not going to go back
 17 to that or go to, I think, your own publications on it,
 18 but you did, I think, for example, publish a case report
 19 about successful long-term treatment with porcine
 20 Factor VIII.
 21 **A.** Yes.
 22 **Q.** At the Royal Free, was porcine used solely for those
 23 with inhibitors?
 24 **A.** Yes. Yes.
 25 **Q.** Was consideration -- would it have been suitable at

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1 all for use for those without inhibitors, and do you
 2 know whether consideration was ever given to that?
 3 **A.** I don't think so. I go back to what I said yesterday.
 4 The reason for making porcine in the beginning was: in
 5 Oxford, they realised there wasn't enough human blood
 6 to make human Factor VIII at that time, and Macfarlane
 7 suggested making bovine Factor VIII. They made bovine
 8 Factor VIII. They took, I think, three patients'
 9 teeth out, and they got antibody afterwards. So he
 10 said, "Oh, we can't make bovine Factor VIII," so
 11 I think they made sheep Factor VIII, and they made
 12 porcine Factor VIII. And subsequently, it became
 13 an extremely useful drug for treating inhibitors, not
 14 only in inherited haemophilia, but there is
 15 a condition called acquired haemophilia that
 16 predominantly occurs in elderly people, and it's an
 17 autoimmune condition, and it proved very valuable for
 18 that group of patients. And then subsequently, as
 19 time went on, Professor Ulla Hedner did a lot of
 20 research work, and ultimately, there was a product
 21 called recombinant VIIa, which was a most wonderful
 22 drug, extremely expensive, that we used to treat
 23 inhibitors. And it was first used in the war
 24 situation, or it was used in the war situation in
 25 Iraq, because you could use it to treat haemorrhage

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1 from wounds. And it slowed down the time to -- you
 2 know, if you had people killed in the -- injured in
 3 the battlefield, you could give them a shot of
 4 recombinant VIIa, and then get them to the field
 5 situation. It was a very, very useful drug.
 6 So the answer to your question, we used -- we used
 7 then at the Free porcine Factor VIII for inhibitors, and
 8 then latterly, we moved to a recombinant product.
 9 **Q.** And could, in principle, porcine have been used for
 10 the treatment of haemophilia more broadly in those who
 11 did not have inhibitors?
 12 **A.** I suppose it could have been, but you might have got
 13 inhibitors from it.
 14 I think probably tomorrow, you're questioning
 15 Professor Tuddenham, and Dr Kernoff and
 16 Professor Tuddenham published a paper in blood
 17 describing the first use of porcine Factor VIII, and
 18 I think he can answer these questions --
 19 **Q.** I'll take that up with him.
 20 **A.** -- better than I can.
 21 **Q.** Can I just ask you briefly about Factor XI deficiency,
 22 not what it is; the Inquiry has heard evidence in
 23 relation to that. But the Royal Free, as I understand
 24 it, treated more patients with Factor XI deficiency
 25 probably than any other centre in the United Kingdom.

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1 **A.** Yes, and this reflected our situation in North London
 2 where there's a large Jewish population, and it has
 3 a very high frequency in Jewish people.
 4 **Q.** And in the '70s and 1980s, how -- if we take it up to
 5 about 1985, 1986, what were the treatments that were
 6 used for those with Factor XI deficiency?
 7 **A.** Initially, fresh frozen plasma was used, and then
 8 a plasma-derived Factor XI concentrate was used. It
 9 was produced by BPL and it was heated, so there's not
 10 an issue about transmitting viruses.
 11 One of the issues which -- I don't think you were
 12 planning to talk about variant CJD, but it's relevant
 13 to CJD. When this became an issue, the thing about
 14 Factor XI deficiency, it -- you don't tend to get
 15 spontaneous haemorrhages. It particularly affects
 16 women with their periods and post-partum haemorrhage.
 17 And we looked after women who were pregnant with
 18 Factor XI deficiency. And sometimes it -- we used to
 19 do it -- I worked -- we had another joint clinic which
 20 was a joint women's clinic for inherited bleeding
 21 disorders which I started in 1995 with an obstetric
 22 gynaecology colleague.
 23 And for the pregnant women with Factor XI
 24 deficiency, she would write a birth plan, and that
 25 birth plan would require Factor XI to be given, maybe.

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1 And the ladies, quite rightly, said they didn't want
2 it because it was plasma-derived; they might get
3 variant CJD. And we did a study which is in my list
4 of publications in my CV, we covered them with
5 recombinant VIIa to stop their risk of bleeding.

6 I think it's important to know that, you know,
7 Factor XI doesn't go up in pregnancy, but Factor VIII
8 does, and von Willebrand factor does. So it was quite
9 a serious problem for those ladies.

10 **Q.** The practical arrangements that were made at the
11 Centre for the treatment of patients with HIV, when
12 you rejoined full-time in 1987, what was the position
13 in terms of how patients with HIV at the Centre were
14 being cared for?

15 **A.** I had a weekly clinic on Monday morning, and depending
16 on their medical condition, I would either review them
17 monthly or sometimes it might be weekly when -- if
18 they were becoming ill. And just to kind of give an
19 idea of what that clinic was like, it wasn't until
20 we'd identified that people were getting opportunistic
21 infections when their CD4 count reached 200 -- the
22 normal is 100 -- we realised that that was when they
23 were getting the opportunist infection, so we were
24 able to give septrin to cover Pneumocystis, we were
25 able to give drugs to stop the Candida in their mouth,

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1 and drugs to stop CMV, and that was done on a -- and
2 also for tuberculosis. So that prophylactic treatment
3 was done when they reached the CD4 count of -- of 200.

4 So basically, I suppose the way I reviewed those
5 patients and I saw those patients, and I can tell you,
6 it was such a sad period. Between 1987 and '92, on
7 average we were losing about eight young men, and
8 sometimes not so young, a year. And the only thing we
9 could offer these people was prophylactic treatment,
10 to begin with. So we would use the CD4 count as
11 a monitoring. And you don't want me to digress, but
12 the way we arrived at that information was from the
13 1989 cohort study where we realised that the CD4 count
14 goes down in a line, and at the line of 200, that's
15 the point at which these opportunistic infections are
16 coming in.

17 So I was seeing patients and clearly, if somebody
18 was ill, supposing, for example, they'd -- I don't know,
19 recently had a septicaemia or something, you would put
20 the closer follow-up.

21 **Q.** You described how in relation to hepatitis C care
22 there was -- there were arrangements for joint
23 clinics --

24 **A.** Yes.

25 **Q.** -- with liver specialists. What, if any, arrangements

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1 were there for bringing in others to the care of those
2 with HIV? Did it fall to you to start with?

3 **A.** Well, Professor Margaret Johnson, who ultimately
4 headed up the Ian Charleson Centre, the AIDS unit at
5 the Royal Free, because there was an enormous AIDS
6 unit eventually, but in the beginning, she was
7 appointed in 1989, and she was a senior registrar in
8 chest medicine, because initially the problem that was
9 hitting was Pneumocystis carinii, and patients were
10 given pentamidine inhalations, and she, as a senior
11 registrar, was beginning to develop that.

12 In terms of expert input, to begin with there was
13 a joint ward round on ward 11, which was where
14 non-haemophilia patients were admitted, and the patient
15 care was discussed. As soon as she became a consultant,
16 we set up her coming to do a joint clinic with me, but
17 clearly, you know, we had a communication, and if
18 I needed advice or help, I got it from her. But there
19 was a formal -- she would sit in on the clinic.

20 There was another person who was very involved, and
21 his name appears on some of the reports, and he's now
22 Professor Seng Lim, in Singapore, a professor of
23 medicine there, and he was employed as a research
24 student under me, paid for by the MRC to run the concord
25 trial of zidovudine. And he became quite involved and

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1 quite expert clinically with these patients. So ...

2 **Q.** The Inquiry is aware from other information that there
3 were patients at the Royal Free who were filmed during
4 consultations, certainly consultations with Mrs Miller
5 and Dr Goldman. Was that something you were aware of?

6 **A.** Yes, I was aware of it. Dr Goldman, who I would
7 emphasise is 90, and Riva Miller, who's dead, were
8 both trained family therapists in the Milan method,
9 and they did video consultations with signed consent,
10 and occasionally I would sit in, but not always.
11 I think you are going to have a statement from her,
12 probably, and I imagine you will ask her those
13 questions.

14 **Q.** The consultations you undertook, as a consultant,
15 would not have been filmed?

16 **A.** No, I didn't initiate it. It wasn't my practice. But
17 I had sat in on consultations.

18 **Q.** You referred in your evidence yesterday several times
19 to the balance of risk, and the choice between what
20 you described as "life-saving treatment and the risk
21 of infection with non-A, non-B hepatitis". It was
22 during the course of your evidence yesterday afternoon
23 when I was asking you about risks of non-A, non-B
24 hepatitis.

25 **A.** Yes.

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1 Q. What would you define as "life-saving" treatment?
 2 A. Well, I think perhaps I would like to give you an
 3 example. Can I do that?
 4 Q. Yes, of course.
 5 A. The very first treatment with Factor IX concentrate,
 6 which was developed in Oxford, was in 1961. And
 7 a little boy of four, who I think came from Edinburgh,
 8 had had a venipuncture, blood taken from his arm. And
 9 he developed a haematoma, big, big clot. And that got
 10 infected. He then got osteomyelitis and gangrene of
 11 his fingers, this is in 1970 -- 61, and he was going
 12 to die unless he had an amputation. And the only way
 13 he could have an amputation was to have Factor IX
 14 concentrate.
 15 And fortunately for him, Dr Rizza, who got phoned
 16 up because he'd been a senior registrar or something
 17 in Edinburgh I think, where this child was, the child
 18 was flown down, and he was given this Factor IX
 19 concentrate and had an amputation. The reason I know
 20 this so well is because when I was the editor of The
 21 Journal of Haemophilia, I ran a series of historical
 22 accounts to show how the treatment of haemophilia had
 23 developed and improved, and I asked Dr Rizza if he
 24 would write a commentary. The description of the
 25 amputation had been extremely successful, he survived,

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1 and it was published in a journal. And Dr Rizza wrote
 2 a commentary about this case. And, you know, Dr Rizza
 3 was another one who was very thorough, very detailed.
 4 He phoned up the patient. And the patient I think by
 5 then, you can check in the publication, was about
 6 36 years old. And he was very well. He must have had
 7 hepatitis C unless he'd cleared it. And he played
 8 one-armed golf very successfully. That's really such
 9 an illustration of risk of the treatment versus the
 10 ability to save a life, really.
 11 Q. Would you accept that there will be many bleeds
 12 experienced by an individual with haemophilia where
 13 that bleed couldn't be described sensibly as
 14 endangering their life?
 15 A. Yes.
 16 Q. And the balance might -- could potentially be struck
 17 differently in such cases?
 18 A. Well, it depends what you call a risk. And I know
 19 that you criticised me yesterday for quoting
 20 Carroll Birch and said, "Oh, this is 37 years ago,
 21 what kind of relevance has that got". I've got
 22 a facsimile of that original book, or report, which
 23 I had copied from the British Library, and I tell you,
 24 to look at that book is horrendous. The poor disabled
 25 people, it's awful. And, you know, you're not -- you

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1 don't have a life-threatening thing if you're disabled
 2 and have to limp and you have painful joints, but
 3 I think, if you talk to patients, they would have
 4 appreciated, perhaps, having regular treatment and
 5 having treatment as soon as a bleed occurs.
 6 If you don't treat a bleed, it damages the joint,
 7 and ultimately the joint becomes bent. And, you know,
 8 we still had one or two patients at the Royal Free whose
 9 life was in a wheelchair. And with the advent, the
 10 gradual advent of concentrate, not only could you let
 11 the little boys have prophylaxis so that they didn't get
 12 deformity as they grew older, but you were able to offer
 13 some patients joint replacements, so that instead of
 14 being in a wheelchair they might be able to actually
 15 walk. And certainly their pain would be reduced.
 16 So when you're talking about risk, it may not just
 17 be, you know, stopping a cerebral bleed; it may be
 18 giving somebody a better quality of life.
 19 Q. I just wanted to ask you a little more about how
 20 decisions about risk would be taken or might be taken.
 21 Your evidence to the Lindsay Tribunal -- and I'll just
 22 call it up -- find the reference.
 23 It's LIND -- you're ahead of me, Henry, thank you.
 24 Go to page 28 and 29. If we look just almost
 25 halfway down the page -- well, we pick it -- thank

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1 you, Henry.
 2 There's a question there:
 3 "You indicated this morning that the parents of
 4 children with haemophilia opted for [NHS] concentrate as
 5 a preferable treatment option. Was that a matter that
 6 would have been discussed with their medical advisors as
 7 to the appropriateness of [NHS] product versus
 8 commercial product at that time?"
 9 "No."
 10 Then your answer went on to say:
 11 "It wasn't at that time the practice to discuss the
 12 treatments that were being used with patients. Times
 13 have changed."
 14 And I just wanted to ask you a little about the
 15 approach to patient involvement in decision making.
 16 As I understand that evidence, but please correct me
 17 if this is wrong, the decision as to which form of
 18 treatment would be used was regarded at the time you're
 19 describing there as a matter for the doctor rather than
 20 for the patient.
 21 A. Yes.
 22 Q. You're there talking about the choice between NHS or
 23 commercial product, but the same -- would that apply,
 24 whether it was a choice between concentrate or
 25 cryoprecipitate, or concentrate or DDAVP, it would be

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1 the doctor's decision, not the patient's?

2 **A.** No, I think what was more relevant is the type of

3 concentrate. So what we're talking about is

4 plasma-derived versus the high purity concentrate.

5 I mean, that's -- that was the decision that had to be

6 made. And it was -- when I'm talking about type -- it

7 depends, of course, what period you're talking about.

8 I'm now talking about type when I'm there, and the

9 type was defined by the doctor according to the

10 recommendation of UKHCDO, actually. You would go by

11 guidelines. The type. That's not talking about the

12 manufacturer.

13 And of course, by then, they're all heated anyway.

14 **Q.** I don't know whether you can answer this because it's

15 a time before you're director that I'm really asking

16 you about, but to the best of your understanding, what

17 would -- or what would your expectation have been of

18 the patient's involvement, in the late 70s, first half

19 of the 80s, in decisions about their treatment?

20 **A.** I can't answer that. That was not my decision making.

21 **Q.** Would you agree with this, and this is a general

22 question rather than specific to any particular point

23 in time or any particular centre, that the question

24 of -- that that balance of risk question that you

25 identified, may depend upon the level of risk that the

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1 individual patient is willing to accept?

2 **A.** Well, when we look at risk, it's partly how much the

3 patient is going to accept, but it's also what is

4 likely to happen after this first presentation, what

5 the risk is going to be. And often, you don't know.

6 **Q.** The clinician's role may be to advise, to inform the

7 patient, but ultimately, the judgment as to whether

8 the patient wants to run the risk of being exposed to

9 a virus or run the risk of sustaining damage to their

10 joints or limitations upon their lifestyle, would you

11 agree that that ultimately is a decision for the

12 patient?

13 **A.** I can't answer that question.

14 **Q.** If we move, then to -- sorry, just in relation to

15 stored samples. The practice of storing samples at

16 the Royal Free began, you've told us, in 1978,

17 obviously well before you arrived there. But your

18 statement explains why you say those samples were

19 stored. And if we look at the bottom of page 5 of

20 your statement, sorry, Henry it's WITN0644058, page 5,

21 you say towards the bottom of that page:

22 "I think it is important to add that samples used

23 were stored for clinical management and treatment of

24 patients with haemophilia."

25 We know they were used subsequently for testing,

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1 analysed for the purposes of the research studies you

2 describe. What did you mean by "clinical management and

3 treatment"? In what sense were the stored samples used

4 for those purposes?

5 **A.** Exactly what you've just said. You said -- say what

6 you just said again.

7 **Q.** The samples were ultimately, a number of years later,

8 used for testing.

9 **A.** Yes.

10 **Q.** Was that the purpose, in part, of storing them, in

11 case a virus was identified in future?

12 **A.** I think it depends how you define "clinical

13 management".

14 **Q.** But they were your words, Professor Lee --

15 **A.** Well, I know, clinical management was everything to do

16 with managing that patient, and knowing what was

17 happening was part of that management.

18 The only way that we could find out about the fact

19 that 100% of people got hepatitis following exposure

20 to concentrate, and that commercial concentrate was

21 just as much risk as NHS concentrate, the only way we

22 could find that out is by using stored samples.

23 I would think that knowing that information was part

24 of clinical management.

25 **Q.** Okay. And do you know, as a matter of fact, what

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1 information was provided to patients about the purpose

2 for which the samples were being stored, or indeed the

3 fact that the samples were being stored?

4 **A.** They were told that the samples were being stored.

5 The blood -- in the Centre, we had a dedicated

6 four-bedded area, and the people who took the blood

7 were the nurse specialists, and they would say that

8 that was included in the spectrum of samples that were

9 taken. But you can't say what it's going to be used

10 for when, for example, it was ultimately used to tell

11 the genotype or the fact that somebody had got an

12 antibody to hepatitis C when in this stage you don't

13 even know that there's going to be hepatitis C

14 identified.

15 I would also say that the clinical management of our

16 patients with HIV was tremendously helped by the fact

17 that there were stored samples. So, uniquely, we could

18 find out when people had been infected, and later on,

19 with the help of the regular assessments we made of

20 immunology -- that wasn't for research, that was to know

21 whether somebody needed drugs or were getting ill. The

22 studies on that information was so valuable to clinical

23 management, not just for people with haemophilia but

24 dare I say it, and it may sound terribly conceited, but

25 worldwide, because I think nowhere in the world did we

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1 have such a regular assessment of patients. And we were
 2 able to demonstrate that the opportunistic infections
 3 came at a CD4 of 100 -- 200, and later, in one of the
 4 papers that I've submitted to you, in 1994, we were able
 5 to show that some 25% of people, 20 years after they got
 6 infection, would not have AIDS. And that was an
 7 important, you know -- clinical management is not just
 8 doing drugs and things, it's important to tell people
 9 their prognosis.

10 And again, that was information that was important
 11 for the patients that we were caring for. It was also
 12 terribly important in the world, you know.

13 And the other thing about knowing that when the
 14 CD4 count reached the 50, patients were very vulnerable.
 15 So, you know, we might bring them up more regularly to
 16 follow them up.

17 So I think -- you know, clinical management is the
 18 whole patient and what is happening physiologically and
 19 pathologically to them.

20 **Q.** Were those samples ever made available to anybody or
 21 any organisation outside the Royal Free Haemophilia
 22 Centre?

23 **A.** The only thing I can think of was, after I retired,
 24 they were offered outside. And I'm sure you've got
 25 all of the references to that. I was very cross about

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1 it.

2 **Q.** Yes, and that's an issue I will explore with
 3 Professor Tuddenham tomorrow.

4 **A.** Sorry?

5 **Q.** That's an issue that I may need to explore with
 6 Professor Tuddenham tomorrow.

7 **A.** I think, in all fairness, since I'm here, could
 8 I comment on it?

9 **Q.** Yes, certainly.

10 Yes, I think --

11 **A.** Could we have it up?

12 **Q.** Are you talking about the newspaper article?

13 **A.** Yes, the newspaper --

14 **Q.** Let me see if I can find the reference.

15 **A.** I think I've probably got the number.

16 **Q.** You've got it somewhere, WITN064410 -- no, that's the
 17 wrong one, forgive me.

18 HSOC0021123. Is this the newspaper article you
 19 were referring to Professor Lee? "Patients' fury over
 20 blood test 'betrayal'?"

21 **A.** Yes. And the date of this is 3rd June 2007.

22 Are you going to talk about variant CJD today or
 23 not?

24 **Q.** It rather depends on how much time we have, because
 25 there are some other issues I need to cover first.

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1 **A.** Well, In that case, I'll just very briefly make
 2 a comment.

3 This is 2007. I retired in 2005. The Data
 4 Protection Act was 1998; made into law in 2000. So
 5 the first thing to say is that I knew you needed
 6 ethical approval for any kind of thing like this.
 7 That was the first thing to say.

8 The second thing to say is that, because of my
 9 involvement with the Transfusion Transmitted Working
 10 Party -- and as you know, for two years, I had
 11 constant contact with the Department of Health in
 12 order to get a multi-centre ethical approval for
 13 follow-up of patients -- I actually became quite
 14 knowledgeable about variant CJD.

15 The National Institute for Biological Standards and
 16 Control was almost as it says: in the world of
 17 haemostasis, you need control bottles of Factor VIII so
 18 that, you know, a lab in London is measuring the same
 19 thing as a lab in Edinburgh, so controlled samples.

20 A scientist from the -- as I understand it,
 21 a scientist from the National Institute of Biological
 22 Control was at a meeting in America about variant CJD.
 23 And somebody, I don't know who, at that meeting must
 24 have heard him say, "Oh it's possible to access
 25 specimens at the Royal Free," and he'd had

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1 a conversation with Professor Tuddenham, presumably.

2 I was very cross about this because, you know,
 3 although you might say, you know, I was testing people
 4 without consent in 1983, things have changed, and
 5 actually, we're being told not to do that now. But even
 6 more importantly -- it's more important than the
 7 consent -- was: there wasn't a reliable test. We didn't
 8 know whether people were at risk or not at risk. So
 9 here's these specimens being offered to this scientist
 10 at the National Institute of Biological Control to do
 11 tests that then you're going to tell a patient that
 12 they've had this test. You don't know whether it's
 13 really sensitive. You don't know what it means.

14 I get phoned up. I was -- I feel very cross about
 15 it. I was actually on holiday in Ireland. I got phoned
 16 up by a journalist saying, "You've been testing
 17 patients," and it was wrong, and that's why.

18 **Q.** And you're reported in this newspaper article as
 19 saying:

20 "You can't just go around just grabbing stored
 21 samples."

22 Then it says:

23 "Acknowledging that she had used samples for
 24 hepatitis and HIV infection research at an earlier time,
 25 she said that attitudes had changed. You can't go ahead

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1 and test people without their knowledge. It's just not
 2 on."
 3 Is that an accurate summary -- (overspeaking) -- of
 4 what you said?
 5 **A.** Yes, it is, and you know, that's what I said. But
 6 I think it's more than that. When those patient --
 7 well, it's not more than that, actually, because the
 8 initial tests for HIV, we didn't necessarily know that
 9 they were sensitive or whatever.
 10 So we're talking about from 1984 to 2000 and, you
 11 know, 2007, actually. So what's that?
 12 **SIR BRIAN LANGSTAFF:** 23 years.
 13 **A.** Yes.
 14 **MS RICHARDS:** Sir, I note the time. I still have some
 15 further questions for Professor Lee and also,
 16 obviously, recognise the legal representatives' need
 17 to have the opportunity to suggest any further
 18 questions that they would wish to have asked. So is
 19 it sensible to take a break now? It might mean,
 20 obviously, sitting a bit late tonight in order to
 21 complete Professor Lee's evidence.
 22 **SIR BRIAN LANGSTAFF:** Well, let me ask Professor Lee.
 23 I saw you looking at your watch a moment or two
 24 ago, so I suspect you could probably do with a break.
 25 **PROFESSOR LEE:** I think so.

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1 **SIR BRIAN LANGSTAFF:** Very well. Let's do that.
 2 **MS RICHARDS:** And sir, can I suggest, so that I have time
 3 to consider any questions proposed, that we take
 4 40 minutes, 45 minutes?
 5 **SIR BRIAN LANGSTAFF:** Yes. Well, let's say we'll come
 6 back at four o'clock, shall we? That gives us plenty
 7 of time, I would hope.
 8 **MS RICHARDS:** Thank you.
 9 **(3.09 pm)**
 10 **(A short break)**
 11 **(3.59 pm)**
 12 **MS RICHARDS:** Professor Lee, hepatitis B briefly, if
 13 I may.
 14 How frequently did you come across cases of
 15 hepatitis B infection at either St George's or the
 16 Royal Free?
 17 **A.** I think, when we did that study in 2000 -- so we that
 18 the data -- there were actually six patients who'd had
 19 it. I particularly was involved with one patient who
 20 sadly went on to get hepatitis -- cancer. Cancer of
 21 the liver. So there were six altogether, but I was
 22 particularly -- actually, two, because I talked about
 23 the one who had the interferon.
 24 **Q.** What was the severity of the hepatitis B cases? Or
 25 was there a spectrum with some mild, some severe?

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1 **A.** Well, two were severe. The other thing I should add
 2 is that we did immunise patients against hepatitis B
 3 as soon as a vaccine became available, and that was
 4 1984. And when we did that, clearly, we had to see
 5 who'd had it, and many people had had it, so they had
 6 antibody.
 7 **Q.** Parvovirus. We've got two documents from you. I'm
 8 not proposing to display either of them, but we have
 9 a letter from you to The Lancet in 1995 which was
 10 a case report about a life-threatening human
 11 parvovirus B19 infection in a haemophiliac, and then
 12 a more in-depth study that you've provided to the
 13 Inquiry.
 14 Can I just ask you perhaps to deal with parvovirus
 15 more generally. How frequent an occurrence was it
 16 that patients treated with blood products developed
 17 parvovirus?
 18 **A.** I think it was probably very rare. The whole
 19 significance of that was to point out that, in spite
 20 of having what we perceived was safe plasma products,
 21 they weren't entirely safe, and indeed, one of those
 22 patients had quite a severe septicaemia, and the other
 23 was a woman carrier who had parvovirus. So it was
 24 more we were disturbed that parvovirus had caused
 25 illness in these patients.

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1 **Q.** Were patients routinely tested for parvovirus at the
 2 Royal Free?
 3 **A.** No.
 4 **Q.** So they would be tested only if there was a reason to
 5 believe --
 6 **A.** No, it was only -- it was only two cases that we
 7 encountered. But it was important to point it out to
 8 people because of the fact that they received what was
 9 perceived to be safe plasma dried concentrate.
 10 **Q.** And that was then part of the debate that you were
 11 involved in, in relation to the funding of
 12 recombinants?
 13 **A.** Yes. And you sent me last week the correspondence
 14 within the Department of Health that I had not seen
 15 before and many of the comments from the Chief Medical
 16 Officer about that case.
 17 **Q.** Yes, and I'm not proposing --
 18 **A.** No, okay.
 19 **Q.** -- to ask you, not least because there's a lot of
 20 documentation which tells the story --
 21 **A.** Yes.
 22 **Q.** -- in relation to recombinant and the various efforts
 23 that you made in that regard.
 24 **A.** Yes.
 25 **Q.** So we have the correspondence for that.

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1 Pharmaceutical companies and relationships with
2 pharmaceutical companies. You mentioned advice that you
3 received from your husband about involvement with -- or
4 not getting involved with contracting arrangements or
5 tendering arrangements. What precisely was the advice;
6 can you recall?

7 A. Well, the advice was not to. And so what I practised
8 was advising on the type of product, you know, whether
9 it was plasma derived, high purity, recombinant,
10 whatever. And that would be -- accord with what
11 guidelines were around. But I was not involved in
12 financial matters, apart from -- I think this is
13 important for the Inquiry to know about, actually,
14 that the financial matters when we moved to becoming
15 a Trust became extremely difficult. And when I first
16 took over as director -- you showed earlier these
17 concentrates that had been commercial that we had used
18 so that there could be a product licence got. So many
19 people had to be treated. They were safe, but so many
20 people had to be treated for them to get the product
21 licence, and I think there was £1.5 million worth.

22 And when we became a Trust, that had happened, and
23 they tried to -- they put their budgets in order, and
24 they suddenly realised that they were this money short.
25 And haemophilia was regarded as a liability within the

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1 Trust. And it was being said that -- they had a new
2 management structure of specialty groups, and it was
3 being discussed at specialty groups that: oh, well,
4 the Trust, you know, is not doing so well. It's
5 2 million over, but that's because of haemophilia. It
6 was a very difficult time.

7 And I think this is important for the Inquiry to
8 know. You have the document, and I won't -- you don't
9 need to go into it, but we were being challenged about
10 the amount of concentrate that was being used, and
11 a tremendous amount of increase was for two main
12 reasons: one was prophylaxis in children, so giving
13 regular treatments, and the other was doing
14 operations, where we need a lot of treatment. And
15 then there was one particular case of a patient with
16 von Willebrand's disease who had his tonsils taken
17 out, and he had horrendous, horrendous bleeding
18 afterwards. So there was an enormous amount being
19 used.

20 And I'm -- maybe I shouldn't do this. There was
21 one particular manager who said -- she'd been on
22 a management -- an MBA course, and she said, "Well,
23 I think what we should do is ask the manufacturers",
24 and she actually went to ask the manufacturers, or
25 somebody went to ask the manufacturers -- the bottles

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1 used to come in 1,000 units or 500 units, and you
2 would probably need maybe 2,000 units to treat
3 a bleed, maybe less. And she said, "If we had bottles
4 of 250 units, they wouldn't use so much."

5 So I had terrible trouble trying to explain to her,
6 number one, they needed -- patients needed to use the
7 amount that was right to stop the bleeding or to prevent
8 the bleeding or whatever it was, but also, the idea that
9 instead of having two bottles, you got four bottles. It
10 was absolutely extraordinary.

11 And I don't know whether you're going to talk about
12 this today, but that moved -- you've got all the
13 documentation. That moved on into the recombinant era.
14 And the -- and it's partly tied up with the parvovirus,
15 as well, that we as Haemophilia Centre Directors, we
16 really wanted to have our patients on recombinant
17 Factor VIII.

18 And you'll be talking to Professor Tuddenham
19 tomorrow. We had had the first patient in Europe in
20 1988 have recombinant Factor VIII in a trial. And when
21 the trial finished, it had to be stopped. He had to go
22 back on plasma-derived concentrate.

23 We didn't get a -- the negotiations were going on
24 about recombinant, and we said, "Well, you know, at
25 least we should have our children on it." And the

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1 parting shot of this particular manager, as she left on
2 maternity leave, was, "No way are those boys going to
3 get recombinant."

4 In my papers, there is a newspaper article, and
5 there was a child who needed his grommets repaired.
6 And, you know, I had been lobbying the Chief Executive
7 explaining about the safety of products, and, you know,
8 we never know, there might be an unknown virus, and
9 I use the parvovirus also as a marker. Anyway, this
10 little boy who was having his grommets done, his mother,
11 who was a very nice articulate lady, she said to me
12 before he was having it, "I assume he's having
13 recombinant?" And I said, "No, I'm sorry. We're not
14 allowed to treat our children with recombinant."

15 And she naturally was upset about it, and I did
16 something -- perhaps I am a little bit indiscreet.
17 I had written a very clear letter to the chief
18 executive, explaining why people should have
19 recombinant, and in particular children should have
20 recombinant. And I said, "Well, look. This is a letter
21 I sent to our chief executive." Really to inform her.
22 And she said to me, "What do you want to do about it?"
23 And I said, "I don't mind what you do about it." But
24 I just wanted to explain that I wanted this child to
25 have the right treatment.

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1 Anyway, I was actually away at a meeting at the time
2 that it struck, but this lady had a friend who was
3 a journalist on The Independent, and she showed her the
4 letter. And there was this double page spread in The
5 Independent with photographs of the child and the
6 mother, and actually, it was -- you know sometimes
7 journalists don't write well, but it was a very good
8 article about the problem, with many quotations from my
9 letter.

10 Now, it didn't do me much good, but I'm pleased to
11 say that overnight a decision was made to let the
12 children have recombinant.

13 **Q.** You've said in your statement that you personally
14 received no money directly from any pharmaceutical
15 companies. Did the Haemophilia Centre receive funding
16 from pharmaceutical companies from time to time?

17 **A.** Yes, I think -- we had a charitable trust, as I told
18 you, called the Katharine Dormandy Trust. And
19 particularly when we were building the extension,
20 which was opened in 1994, we needed -- it sounds
21 extraordinary, but it only cost half a million then,
22 but we were fundraising for it, and I think
23 pharmaceutical companies paid into the
24 Katharine Dormandy Trust for that.

25 And if we did -- if we did trials -- for example,

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1 I know in detail about the Kogenate -- the first
2 Kogenate trial of recombinant. There would be a medical
3 advisory board, an international medical advisory board,
4 and I was on that. I didn't receive specific payment,
5 but clearly -- you know, mostly the meetings were in the
6 United States, so they would pay the airfare. And
7 I think -- and maybe Professor Tuddenham can talk about
8 this more. As we were moving forward with the
9 Katharine Dormandy Trust, he became the chairperson of
10 it. He left the Royal Free in 1986, and he went to set
11 up his MRC research unit at the Royal Postgraduate
12 Medical School. But he came in as the chairman of the
13 Katharine Dormandy Trust as somebody who knows about
14 haemophilia, and, if you like, was sort of objective;
15 you know, away from what was going on.

16 So they moved into a process of trying to raise
17 money for gene therapy, which eventually was developed
18 at the Free and jointly with UCH. And I think there
19 were commercial monies that went into the KD Trust to
20 help support research people.

21 **Q.** I will ask Professor Tuddenham about that, then.

22 In terms of your own practice, did any
23 pharmaceutical companies ever suggest to you that you
24 should use specific products for specific cohorts of
25 patients, or try and influence your clinical

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1 decisions?

2 **A.** No.

3 **Q.** And did pharmaceutical companies ever request you to
4 provide particular data or information to them about
5 patients?

6 **A.** Well, I suppose in the context of the -- not the
7 patients, but certainly in the context of the Kogenate
8 study, I was asked to lecture in Greece. And I was
9 also -- and that was, I think, a meeting that was
10 sponsored by the manufacturers of the recombinant
11 product.

12 **Q.** I wanted to ask you, in terms of your research, just
13 about the study that you've referred to a number of
14 times in your evidence but we've not looked at in
15 detail. It's PRSE0003439. So this is your 1985 paper
16 with Dr Kernoff: "High risk of non-A, non-B hepatitis
17 after first exposure". And I just have a handful of
18 questions relating to that study.

19 You've already pointed out that it was a study that
20 took place over a five-year period from April 1978 to
21 March 1983, so I'm not going to ask you -- I'm going to
22 try not to ask you, in any event, questions about how it
23 was set up because you weren't obviously there in 1978.
24 But do I take it from the fact -- well, your name
25 appears second on the list of authors. So it's

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1 Dr Kernoff, then you, then two others. You would have
2 had a role at least in the writing up of this paper?

3 **A.** Yes, I -- when I went there in '83, I was handed
4 a graph paper strip about this long, and what
5 Dr Kernoff had done from the time he became appointed
6 in 1978 -- because he had come from Oxford where he
7 realised about hepatitis, every time any patient
8 needed treatment for the first time, he wrote down
9 their name, what was the problem, and what they had.
10 So I was handed this sort of long scroll.

11 And what I did was go to the notes and find out, you
12 know, who they were, what they presented with, look at
13 all the liver enzymes and try and work out -- and
14 whether they were symptomatic when they had this
15 treatment, and to try and work out -- you could work out
16 the incubation period from when you got the peak of the
17 transaminases. And that's -- the information that is in
18 the table, which is on page 474, which is EPU --

19 **Q.** The sixth page, please, Henry.

20 **A.** Page 6, isn't it? All that information on the
21 table -- it's got the concentrate they had, the batch,
22 the dose. And then this previous exposure, the
23 significance of the previous exposure, this previous
24 exposure in cryoprecipitate. And then you see the
25 incubation period, the peak ASTs, and whether they

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1 were symptomatic or not. So this long scroll of graph
 2 paper that I'm telling you about, the reason it was
 3 presented to me like that was, you can imagine, if
 4 he's busy in a centre and he's just started, he had
 5 a lot of other things to do. So he was just, you
 6 know, writing this down.
 7 And that was compiled from the hospital notes of
 8 these patients. And then, you know, this graph of
 9 incubation periods was calculated from this information.
 10 In terms of authorship and writing this paper, the
 11 reason Dr Kernoff's name goes first is clearly it was
 12 his idea, and his enthusiasm for it. The reason
 13 Howard Thomas's name goes at the end is because in
 14 practice, that's usually the author who's a sort of
 15 lead person, and what was happening here was
 16 Howard Thomas had been very advisory about liver disease
 17 with Dr Kernoff at that stage, and -- he was working
 18 under Professor Sheila Sherlock -- and clearly, he saw
 19 the drafts of the paper and things, but actually, he did
 20 nothing to get the information.
 21 Peter Karayiannis was the laboratory scientist with
 22 Professor Thomas, Dr Thomas, and they were trying to get
 23 an assay of the antigen of non-A, non-B and it was
 24 totally unsuccessful. But because he had been
 25 supportive and was in the group, that's why his name was

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1 on the paper.
 2 My name is on the paper because I looked out all the
 3 information and also I wrote quite a lot of it. My
 4 recollection is that I wrote the patient's methods
 5 because that's factual, that's not opinion.
 6 I think Dr Kernoff wrote the introduction, and
 7 I think the conclusion, he -- I think -- I can't
 8 remember whether I wrote the first draft and he,
 9 you know, corrected it or something, and of course
 10 I would have researched the references, which was not --
 11 it was quite a difficult task in those days, as you
 12 know, getting the precise title of the patient and the
 13 volume and all the rest of it, you had to go to the
 14 library and look it all up and everything.
 15 **Q.** The bit I want to ask you about particularly is under
 16 "Patients and Methods", I'm hoping you can help. It's
 17 really just some factual questions. So if we go to
 18 page 2 please, Henry -- it's page 470 if you have the
 19 paper copy -- and we go, towards the bottom of the
 20 page, "Patients and Methods". Just enlarge that so
 21 people can see.
 22 It describes 58 patients receiving 60 first
 23 exposures. I'm not quite sure I follow that but I
 24 don't think that matters. And then 31 of those
 25 exposures prospectively studied, 29 retrospectively

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1 studied. And then you go on to say, towards the
 2 bottom of the page, or you and your co-authors:
 3 "... a minority of the patients were 'virgin' ..."
 4 So there were a handful of patients who had not
 5 previously received any form of blood, plasma or
 6 cryoprecipitate therapy.
 7 Do you have the page I'm looking at?
 8 **A.** No, I'm fine.
 9 **Q.** Then:
 10 "... most [of them] needed infrequent
 11 treatment ..."
 12 That would tend to suggest, would it, that they
 13 were predominantly not severe haemophiliacs but
 14 non-severe?
 15 **A.** Yes, I was just looking if, in this table, it
 16 actually -- in some way it describes who they were.
 17 But -- I thought it was on this table. Hang on
 18 a minute.
 19 There were a number of people who had
 20 von Willebrand's disease. Surely it's here somewhere.
 21 **Q.** Yes, if you go to the next page.
 22 So it's page 471, or page 3 please, Henry.
 23 **A.** Yes, here we go.
 24 So 13 had haemophilia A, four had haemophilia B,
 25 ten had von Willebrand's disease, three were female

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1 carriers, and the three female carriers, two carried
 2 haemophilia A and one carried haemophilia B. And it
 3 says five patients, six exposures, were less than
 4 5 years at the time of exposure.
 5 Yeah, okay.
 6 **Q.** And then of the patients with haemophilia A or B,
 7 seven were classed as haematologically severely
 8 affected.
 9 **A.** Yes, I would think the most -- likelihood is --
 10 I can't remember now, but, it's most likely they were
 11 the children.
 12 **Q.** Those who were severely affected?
 13 **A.** Yes, because the adult patients who were severely
 14 affected most likely were -- certainly would not be
 15 untreated -- you know, virgin patients ... I don't --
 16 the term "virgin" is awful, and I make apologies for
 17 that. It was the convention at that time to call
 18 people "virgin patients". Unfortunately the North
 19 Americans found it wrong, which I think is right, it
 20 was wrong. And so it was changed to "previously
 21 untreated patients" which I think is rather a more
 22 respectful way of talking about patients.
 23 **Q.** Just in the same paragraph it says in the last two
 24 sentences:
 25 "Duration and dosage of therapy, and choice of

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1 therapeutic product, were influenced by clinical
2 circumstances, local availability of products, and
3 departmental policies which operated at the time
4 treatment was given."

5 What's meant there by "clinical circumstances"? Are
6 you able to cast any further light on that?

7 A. I think it was the nature of the bleeding episode,
8 whatever it was.

9 Q. Um --

10 A. I mean, I -- because I had a Rule 9 request, I know
11 certainly, I think, three people had von Willebrand's
12 disease, and there was epistaxis. I thought the
13 clinical thing was listed here, but I can't see it at
14 the moment. So that's what it means, it's: what was
15 their bleeding? Why did they need to have this
16 treatment?

17 Q. Okay, and "local availability of products" I think is
18 probably self-explanatory.

19 "Departmental policies which operated at the time
20 that treatment was given."

21 That is going to, presumably, predate your
22 arrival, and I've asked you already about what you
23 were able to assist with in terms of policies.

24 A. Yeah, I mean, it's what you've been discussing about
25 Dr Kernoff and what he was using. I mean, these

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1 patients were being treated from the time he started
2 in '78, through that time.

3 Q. And it says, and again it was really whether you can
4 throw any light on this, it then says:

5 "These policies changed over the period of the
6 study, as it became appreciated that the risk of [non-A,
7 non-B] hepatitis after concentrate therapy was very
8 high."

9 A. Well, I think that possibly relates -- well, I don't
10 know, because it wouldn't have DDAVP in it. I don't
11 know what specifically that's referring to. It may --
12 I don't know.

13 Q. And in terms of the products that were used for the
14 purposes of this, we can see those, can we, from your
15 table on page 474?

16 A. Yes.

17 Q. Then if I can just ask you to look at the bottom of
18 page 472 -- it's page 4, Henry -- under the heading
19 "Ethical and legal considerations", if we just -- it's
20 the last paragraph, Henry.

21 A. No, I've got it.

22 Q. It's just for the benefit of others to be able to see.

23 It talks about ISG and Kryobulin-G being used on
24 a named patient basis. I wonder, could you just
25 explain what they were used for.

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1 A. This was the only part of the study that needed
2 ethical approval because it involved giving a product
3 immunoglobulin, and the idea was to try and see, if
4 you gave immunoglobulin, whether it would protect
5 against non-A, non-B.

6 It's a bit akin to the Covid-19 patients -- and
7 indeed, Donald Trump, I think -- having antibody
8 given. And because it was a commercial product and it
9 was done in the context of a study, it had to have
10 ethical approval.

11 This was completed before -- the accrual of the
12 information was completed before I started. And as it
13 happens, one person did not get non-A, non-B. But it
14 was only five -- out of five people, so whether that was
15 significant or not, I don't know. I think it's shown in
16 the table there's a -- yeah, the cross in the table --

17 Q. Page 6, Henry.

18 A. -- indicates the ones that had the immunoglobulin, and
19 you see this person with Factor IX deficiency -- I
20 have a feeling it was a carrier, actually -- where,
21 with Factor IX deficiency, it was NHS Factor IX
22 deficiency, did not get non-A, non-B. And I think in
23 the paper we speculate why that might have been or why
24 ...

25 Q. If we just go back to the bottom of page 472, sorry,

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1 Henry, back to the bottom of page 4, what's said there
2 under "Ethical and legal considerations" about
3 information to patients and Ethical Committee
4 approval, do I understand that that relates solely to
5 the use of the ISG and the Kryobulin-G?

6 A. Yes, yes.

7 MS RICHARDS: Sir, before I turn to another project, was
8 there anything you wanted to ask Professor Lee about
9 this paper?

Questioned by SIR BRIAN LANGSTAFF

11 SIR BRIAN LANGSTAFF: Well, I do just want to ask a couple
12 of things.

13 If I can just go back to the point which raised
14 your own eyebrows, Ms Richards, at the very start,
15 under "Patients and Methods" --

16 A. Yes.

17 SIR BRIAN LANGSTAFF: -- it says:

18 "58 patients with congenital divisions of
19 coagulation factors VIII or IX received 60 first
20 exposures ..."

21 Now am I right or wrong in thinking that first
22 exposure generally in this paper meant first exposure to
23 concentrate? Or did it mean first exposure to any
24 treatment?

25 A. Yeah, I think -- I agree, yes, it's rather confusing.

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1 I think possibly it refers to the two -- no, I don't
 2 know. I'm sorry it's a bit pathetic, isn't it, but
 3 I --
 4 **SIR BRIAN LANGSTAFF:** There may be some help. If you go
 5 back to the table at 474, one of the curiosities, if
 6 you look at the numbers which go down from 1 to 30, 16
 7 appears twice, between 24 and 25, and in its normal
 8 numerical order. And it may well be the same person,
 9 a baby or infant, at 19 months and at 27 months,
 10 I don't know, but it's the same patient number.
 11 **A.** I'm lost, I'm sorry. Oh I see, okay. Ah, I know --
 12 **SIR BRIAN LANGSTAFF:** Does that help?
 13 **A.** Yes, it does. I think it's ... I think, yes, it's --
 14 it's because they had -- I think it's because they had
 15 cryoprecipitate on two occasions, probably.
 16 **SIR BRIAN LANGSTAFF:** But that's what I thought might be
 17 an answer, but then I don't really understand if you
 18 go back to page 470 -- so we go back to that, please,
 19 Henry.
 20 Right down at the about of the page, page 470, you
 21 say this:
 22 "Only a minority of the patients were 'virgin' ..."
 23 You've rightly put that in inverted commas.
 24 "... although most needed infrequent treatment,
 25 a majority had received blood, plasma or cryoprecipitate

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1 that way before."
 2 **A.** Yes, um --
 3 **SIR BRIAN LANGSTAFF:** So it's a definition of what
 4 a previously untreated patient was --
 5 **A.** I think in the context here it was, strictly speaking,
 6 the concentrate. But what you -- you raise a very,
 7 very interesting point here, because if you look at
 8 the NHS patients, there are 12 of them, and ten get
 9 hepatitis and two don't, and as it happens, the two
 10 that don't had had enormous quantities of
 11 cryoprecipitate. And I think we speculate in the
 12 discussion that maybe they were immune. And indeed,
 13 that is so, because when we were able to have the
 14 test, they actually had antibody.
 15 And I think -- yeah, I think that underscores the
 16 fact that if you have vast amounts of cryoprecipitate,
 17 you could have got it.
 18 **SIR BRIAN LANGSTAFF:** The next thing which I would just
 19 like to understand is you set out, in previous
 20 exposure, going back to the table -- I'm sorry, Henry,
 21 to ask you to dodge around -- back to page 474.
 22 **A.** Yeah, I've -- now I've got it.
 23 **SIR BRIAN LANGSTAFF:** Under "Dose", well, that's
 24 international units per kilogram, presumably.
 25 **A.** Yeah.

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1 **SIR BRIAN LANGSTAFF:** And that would prefer to dose of
 2 concentrate, would it?
 3 **A.** Yes, yes, that's right.
 4 **SIR BRIAN LANGSTAFF:** And that explains why, when we come
 5 down to the 22 to 25, the unit is donor units, and
 6 donor units are donations?
 7 **A.** No, this is the bags of cryoprecipitate.
 8 **SIR BRIAN LANGSTAFF:** Yes.
 9 **A.** So I think what we've done there -- I can't remember,
 10 I don't -- no, we wouldn't have -- what you could do
 11 with cryoprecipitate is you could actually take
 12 a sample out and measure it in the lab, but I don't
 13 think that was done. I think what was done was
 14 looking at the literature of where people had done
 15 that, and so, you know, the average bag of
 16 cryoprecipitate contains this much. And then you can
 17 put the unit --
 18 **SIR BRIAN LANGSTAFF:** Well, just stopping you there,
 19 because I think the unit of comparison is rather
 20 different.
 21 One is international units per kilogram, the other
 22 is donor units. And I think in the text you define
 23 donor units as the number of donations.
 24 **A.** Yes, but I think -- no, it -- let's take patient
 25 number 22, who's the female aged 40, and she has

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1 NHS cryo. And we've got this column saying, "Units
 2 per kilogram", and she's had -- so that essentially is
 3 84 units per kilogram. And that's been worked out
 4 from the -- I think the average content of
 5 a cryoprecipitate bag is something like 30 units,
 6 something like that, or 60 units. It's very variable.
 7 And so that -- so you'd multiply 70 by 60. Would that
 8 work it?
 9 **SIR BRIAN LANGSTAFF:** No, it wouldn't.
 10 **A.** Well, she weighs --
 11 **SIR BRIAN LANGSTAFF:** 84 is 12 times 7.
 12 **A.** Yes, but she weighs 50 kilograms, doesn't she?
 13 **SIR BRIAN LANGSTAFF:** Ah, yes, so that then might. But
 14 then the 70 donal units is -- (overspeaking) -- dose
 15 per kilogram.
 16 **A.** -- (overspeaking) -- 70 times 60 is -- you're better
 17 at maths than me, 4,200. If you divide that by 50,
 18 does that work out? Yes, it does.
 19 **SIR BRIAN LANGSTAFF:** Yes.
 20 **A.** Yes.
 21 I'm sorry, I --
 22 **SIR BRIAN LANGSTAFF:** No, no, that's fine. I just wanted
 23 to understand what it was telling me, really.
 24 **A.** If you'd asked me this in 1983 I probably would have
 25 been able to tell you very quickly.

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1 **SIR BRIAN LANGSTAFF:** Please understand I don't expect
2 people ever to remember every detail of everything
3 that happened years ago. I couldn't, I'm sure nobody
4 here could, unless they're remarkable. So don't worry
5 about it.

6 So if we're looking at the paper, on one view, it
7 would say -- in the summary, at the start of the paper,
8 please, Henry.

9 There are 21 patients who had Factor VIII
10 concentrate. It's describing nine out of nine British
11 patients treated with USA commercial products developed
12 non-A, non-B. And ten out of 12. There's 85% treated
13 with NHS products, non-A, non-B.

14 **A.** Yes.

15 **SIR BRIAN LANGSTAFF:** So that could be read as suggesting
16 that the British product was less likely to develop
17 non-A, non-B.

18 **A.** It could be read like that but, as we say in the
19 discussion, these two patients had had vast amounts of
20 National Health Service cryoprecipitate. But you're
21 right, I mean, it could be read like that. But
22 subsequently, when we were able to measure it, there's
23 no doubt that these people had been immune.

24 **SIR BRIAN LANGSTAFF:** Part of the significance, perhaps,
25 of this study and the Fletcher study which came before

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1 it, is that until this time, 1983, 1985 -- 1985 for
2 this study, it had been, I think, thought that those
3 who received cryoprecipitate and nothing -- no
4 concentrate, were much less likely to develop
5 hepatitis, and that NHS concentrate was much less
6 likely to develop hepatitis because the donor pool was
7 less infected. And you were showing, I think, you
8 say --

9 **A.** No, the data at the time which came out of blood
10 transfusion data in a cardiac surgery unit, I think in
11 Scotland, was that the infection rate of hepatitis C,
12 or the transmission rate, was 1 in 300 of the
13 population. And so, in theory, once you reached 300,
14 it was almost inevitable you would get hepatitis C.

15 **SIR BRIAN LANGSTAFF:** Just dealing with the donor pool
16 size, do you know how the donor pool size for
17 commercial concentrate or NHS concentrate worked?

18 **A.** I think at that time the NHS product -- I'm a bit sort
19 of rambling numbers -- but I think it was something
20 like 4,000, 5,000, and the American pool size was
21 sometimes bigger.

22 But the other thing that happened in America much
23 faster than here, and I'm sorry I can't give precise
24 dates, was that in America, in order to get plasma,
25 they used the technique of plasmapheresis, where they

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1 would use a single donor and that donor, you know, in
2 a year would give more donations.

3 So that inevitably, you know, cut down the risk
4 of it, didn't it, because you've got one person giving,
5 say, four --

6 **SIR BRIAN LANGSTAFF:** Unless he was giving infected
7 -- (overspeaking) --

8 **A.** But I think it's right to say that the commercial
9 products were a bigger pool size, but I think the
10 significance of this was, one -- I mean, I understand
11 your criticism, but the significance of this was that
12 non-A, non-B hepatitis approached 100% in NHS, when
13 previously it had been suggested it was safe.

14 The interesting thing is that it probably is right
15 to say that the viral load might have been bigger in
16 the commercial concentrate because if you look at the
17 lower diagram and you look at the days to the
18 incubation period, you see for the commercial
19 Factor VIII, it's about three weeks, whereas for the
20 NHS Factor VIII it's about seven weeks. And it has
21 been suggested that that might be because of viral
22 load.

23 And the other thing that I think came out of this
24 study which is true is that when you look at the
25 symptomatology, there were many asymptomatic people, but

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1 there were some who were quite symptomatic, and I think
2 they were more likely to have received commercial
3 Factor VIII, and that may have been because it was
4 a bigger viral load. The analogy to Covid-19 is quite
5 remarkable, actually.

6 **SIR BRIAN LANGSTAFF:** I was just wondering if -- let me
7 put it in context. The Inquiry is yet to have a full
8 report -- given to me, anyway -- of the relative pool
9 sizes that were used for commercial concentrate on the
10 one hand.

11 **A.** Yes.

12 **SIR BRIAN LANGSTAFF:** -- and NHS concentrate on the other.
13 Such information as I currently have, and it is by no
14 means the last word, suggests that NHS concentrates
15 were initially made from very small pools.

16 **A.** Yes.

17 **SIR BRIAN LANGSTAFF:** And very little infectivity was
18 reported. It may have happened, but very little was
19 reported. And later on, particularly around about the
20 1980s, they became very much larger. Now, that may or
21 may not be right, but it does give rise to the
22 question whether infectivity may, in part, be
23 a consequence of the pool size, or whether there's
24 any -- you weren't studying that at all in this paper,
25 were you?

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1 A. No, um, but what I can say is, in all my experience of
2 looking after this large number of patients during the
3 years, I never encountered a patient who had not got
4 infected.

5 **SIR BRIAN LANGSTAFF:** I see. Well, that's all I --

6 A. I think the other thing to say about this. I don't
7 know ... I don't know. Probably not, actually,
8 because what I was about to say is whether any of
9 these -- no, they wouldn't have been. I was thinking
10 about co-infection. No, forget it.

11 **SIR BRIAN LANGSTAFF:** That's all that I wanted to ask you
12 about this paper. Thank you very much.

13 **Further questions by MS RICHARDS**

14 **MS RICHARDS:** Professor Lee, just a very small number of
15 final questions, I've been asked to ask you.

16 You referred in your evidence yesterday to
17 a Haemophilia Centre profiteering through the purchase
18 of commercial Factor VIII concentrate. Do you know
19 which pharmaceutical company or companies were involved
20 in relation to that?

21 A. I don't know. I suspect many.

22 Q. And which Haemophilia Centre?

23 A. I don't know. I feel a bit bad about -- I know who it
24 is. I know the centre, but I feel rather embarrassed
25 about saying these things. I don't --

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1 **SIR BRIAN LANGSTAFF:** I don't think you should be
2 embarrassed. We are, after all, inquiring into
3 something which is of public importance, so the public
4 interest, I think, suggests that you should tell us --

5 A. Can I then rehearse what I was saying yesterday?

6 The contracting at the Royal Free, when I was
7 director, was that the managers did that contracting.
8 And as I understand it, whatever they paid for the
9 concentrate was passed on to whoever was buying it,
10 and the people who were buying it would be sometimes
11 a district, but I think there were occasions when
12 there was a GP practice that had a patient who were
13 the contractors.

14 And there wasn't profiteering, if you like, but at
15 St Thomas', where Professor Geoffrey Savidge was the
16 director -- and he was a very good physician. He'd
17 trained in Sweden. He looked after his patients
18 extremely well. And I am not suggesting for one moment
19 that he put any money -- he took any money. I don't
20 think he did. But what he did was he would negotiate,
21 and I think he did the negotiation. He's died now, so
22 he can't confirm this or not. He would do the
23 negotiation directly with the drug company, and he
24 would -- so they paid A plus B for a unit, or whatever
25 it was. When the purchasers -- when the contract was

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1 made with the purchasers, there would be added on,
2 I don't know, 2p a unit or 3p, I don't know, but there
3 would be added on something. And that meant that St
4 Thomas' Hospital had all this extra money because they
5 were buying the factor at one price, and then they were
6 getting money from the purchaser at another price.

7 And I hope I'm not being libellous or something
8 because -- I mean, this is -- this is the truth as
9 I know it.

10 Within the hospital, he became a kind of king, if
11 you like. And I'm not criticising any way he treated
12 his patients. He was excellent, and I think he cared
13 very much for the organisation and the clinical care of
14 his patients, but he was making a kind of profit for the
15 hospital. And it almost became that he was kind of
16 handing out, you know, money to different departments,
17 or different departments were benefiting from this.

18 And I'm certainly not going to tell you the detail
19 of something further I know, but there was a difficulty
20 relating to Professor Savidge, and I knew the details of
21 this difficulty. And I spoke to the Dean in the medical
22 school about this difficulty, and he said he would
23 investigate it. And he didn't investigate it because he
24 said, "I can't investigate this because the hospital is
25 benefiting from this finance."

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1 But again -- I would say, again, that
2 Professor Savidge I don't think was benefiting himself;
3 he was benefiting the hospital. And I think also it
4 benefited his centre. His centre was very nice. But it
5 wasn't the right thing to do, I don't think, but it was
6 a consequence of this change in contracting. And it was
7 this change in contracting that, in the end, compelled
8 me to start looking at the economics of all this,
9 because it seemed wrong that the Royal Free was
10 a wonderful hospital, and it had got this wonderful
11 Haemophilia Centre who were very expensive. And, you
12 know, they needed this expensive treatment, but a tenth
13 of the haemophilia treatment of the UK was being --
14 having to be provided by the Royal Free in this
15 purchaser-provider contract. And in that leader that
16 I wrote for the BMJ, I was saying, look, there needs to
17 be some kind of national thing here.

18 I think -- I haven't really kept up with what's
19 happening now, but I think that has largely happened.
20 It's -- you know, it's the problem of a very expensive
21 specialty which is of low volume.

22 **MS RICHARDS:** So that there's, I hope, no great mystery
23 about these matters, the difficulty you refer to about
24 Dr Savidge, Professor Savidge, was not connected to
25 his care of patients?

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1 A. No. It was nothing to do with haemophilia. Well, it
 2 kind of was, but it wasn't.
 3 Q. I'm not proposing at the moment to ask you any more
 4 about that.
 5 A. Indeed, I think -- I don't know if there were other
 6 centres that that's how the money was managed.
 7 Q. Again, arising out of some evidence you've given
 8 either yesterday or today, you talked about the
 9 convenience and practical advantages of concentrate
 10 over cryo. I'm not asking you to go over that again,
 11 but you talked about how the patients wanted
 12 concentrates for that reason.
 13 As far as you know, from your own direct personal
 14 knowledge only, was any patient actually presented
 15 with that choice at the Royal Free in the first half
 16 of the '80s?
 17 A. I don't know.
 18 Q. And then we talked about the storage of samples of
 19 serum. I don't need to ask you about that again.
 20 Was there ever any storage, to your knowledge or
 21 understanding your directorship, of any other tissue
 22 samples from haemophiliac patients post-mortem?
 23 A. Yes, I -- the only thing I'm particularly aware of,
 24 the post-mortem samples were stored anyway -- biopsy
 25 specimens were stored -- and I think it wasn't until

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1 the Alder Hey problem that these all had to be
 2 destroyed.
 3 In 1998, we did a study jointly with Edinburgh and
 4 Oxford and the CJD unit in Edinburgh, because there
 5 was a big, big worry and concern as to whether
 6 patients with haemophilia were going to get variant
 7 CJD. And what we did, we knew that we had a group of
 8 patients between these three centres who had had
 9 nothing but NHS concentrate for the years. You know,
 10 the BSE came into cows in '80, and the idea was that
 11 people ate the meat, and they were blood donors and
 12 contributed to the concentrate which then went into
 13 people with haemophilia.
 14 It was really a big concern, so we identified
 15 a number of patients. And, actually, I was going to
 16 send the paper and I never got around to it -- it's
 17 here -- but I will do it after the Inquiry. And this is
 18 before 1998, so it's -- and 2000; it's before the Data
 19 Protection Act. And there were specimens from the
 20 brains of people who had died, and they were looked at
 21 in the new variant CJD centre in Edinburgh. And there
 22 was no prion agent, and this was very reassuring.
 23 The only -- the only evidence that there has been
 24 transmission is that there was a post-mortem done in
 25 Oxford much later, I think, 2003, for other reasons in

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1 a patient who had haemophilia, and prion agent was found
 2 in the spleen. That's the background to that, and
 3 I will send the paper.
 4 Q. Thank you. There's just one further matter. I wanted
 5 to ask you about two comments that you made. Again,
 6 I've been asked to ask this question, Professor Lee.
 7 I'm sure you'll understand why.
 8 Could we have up on screen, first of all, Henry,
 9 JEVA0000009. This is an interview that you and
 10 Dr Rizza conducted with Dr Biggs, and if we could just
 11 go to page 4, please.
 12 A. This was done for the historical --
 13 Q. Yes.
 14 A. -- Wellcome Trust document, and because Rosemary Biggs
 15 was quite elderly then, that's the reason it was done
 16 as an interview.
 17 Q. Yes, I understand that. It's the highlighted passage
 18 towards the bottom. And if we just pick it up before
 19 the highlight with -- can we go to the passage just
 20 above that, Henry, to put it in context. This is --
 21 Dr Biggs, says:
 22 "The next thing that started to crop up was that
 23 patients started to get jaundice, and we felt at the
 24 time that they were better alive and having jaundice
 25 than dead with haemophilia."

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1 And then your response was:
 2 "That's the most amazing comment. I get very
 3 irritated with patients now who are demanding
 4 compensation because they have got hepatitis C from
 5 concentrate, but they wouldn't be alive to make those
 6 kind of complaints if they hadn't been treated."
 7 That's the first I wanted to draw to your attention.
 8 I then want to draw another, and then I want to just ask
 9 you a question if that's okay.
 10 A. Yes. You kindly sent this to me last week. And when
 11 I read that now, I think perhaps the word "irritated"
 12 is strong, and I think what I was really trying to
 13 express there was frustration. And let me explain.
 14 Dr Biggs made this quite brutal statement -- I've
 15 written about this; it's in many of my papers -- that
 16 patients were better getting jaundice than being dead.
 17 And it's presented very harshly, but what it's saying
 18 here is what we've been discussing throughout. And
 19 it's a balance between risk and the necessity of
 20 treating. And what she's got on her scales is the
 21 risk of treatment, which at the time she was working,
 22 there were patients getting jaundice, and the -- if
 23 you don't give the treatment, there's the possibility
 24 of dying.
 25 And I would take you back to the fact that in 1937,

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1 the life expectancy was 20 years. Towards, I would say,
2 the beginning of the '90s, it was approaching 70. And
3 this was at the cost of having hepatitis and sadly, for
4 many people, HIV. But the other side of it was people
5 lived a life. And, indeed, as early as 1981, there was
6 an anonymous leader in the BMJ, which I think was
7 probably written by Peter Jones who I think you may be
8 talking to, and he makes the point that the side effect
9 of hepatitis may be the cost of having this very
10 effective treatment.

11 I think the other issue that I would just say about
12 this is that I think the Macfarlane Trust and the
13 Skipton Fund are wonderful. And I believe, truly
14 believe, that any patient who has any treatment for
15 which they have really severe side effects should have
16 financial support, as far as possible, to make their
17 life better.

18 But what I don't like about the idea is the idea of
19 compensation because what compensation does, it suggests
20 liability. And I truly believe that people at that time
21 were doing what they thought was the best, and the side
22 effects were really not at all clear, and certainly HIV
23 was a tragedy that nobody could have foreseen. And of
24 course, the other thing that we haven't really talked
25 about at all is this lethal combination of HIV and HCV.

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1 And many of our patients, and I think this probably goes
2 for the majority of patients who had HIV, they
3 progressed so fast to liver failure, and we couldn't
4 have seen that.

5 And, you know, it's very easy retrospectively to
6 say, "Ah, but the HIV all came from America," and that's
7 true up to a point, but there were occasional donors who
8 had it here. The infection in Britain came much -- sort
9 of a year later. We were lucky we could do de-referral
10 at Blood Transfusion Centres which mitigated it to
11 a certain extent.

12 So I suppose, you know, when I read this, when you
13 sent it, I just felt that my choice of words was not
14 very good and rather insensitive in this interview. But
15 I think what I was irritated about was that I had not
16 been able to explain or convince people that what we did
17 was in good faith, if you like. For the knowledge at
18 the time.

19 Q. The second document is from the oral history
20 transcript. It's THOM000001. If we go to page 35,
21 please, Henry. If we go to the bottom half of the
22 page, so it's about ten lines down from what we can
23 see on the screen. You say this:

24 "And in the context of today, you know, there are
25 one or two haemophilia patients who are really driving.

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1 They want compensation, and their argument is that
2 Britain didn't get self-sufficient. Well, that is an
3 argument we didn't get self-sufficient, but, on the
4 other hand, they were -- in the period that -- well,
5 self-sufficiency would not have done anything about
6 hepatitis. From the point of view of HIV, the
7 fractionation and the ability to provide enough was just
8 not there, and the patients were actually champing at
9 the bit. You know, they wanted it. They wanted to have
10 regular treatment. They wanted to be able to have their
11 operations, and that's kind of forgotten. You know, you
12 may be able to blame America for HIV. You certainly
13 can't blame it for hepatitis, and personally -- but, you
14 know, maybe I would say that, wouldn't I?"

15 Then you say this, Professor Lee:

16 "Personally, I don't think that faults can be
17 attributed. And, you know, that recent Inquiry in
18 Scotland, the Archer Inquiry, fortunately did kind of
19 sort of come to that kind of conclusion, but it kind of
20 rumbles on. I mean, cynically, I think the patients,
21 the few patients driving this, are probably after money,
22 actually. There was quite a big payout. Not payout,
23 but there is a fund -- I've forgotten the name of it for
24 a minute -- for hepatitis [that's obviously Skipton],
25 and it's done on health grounds and also on whether

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1 you've got families and dependents."

2 I asked to show you that, Professor Lee, and I just
3 wanted to ask you whether, on reflection, you stand by
4 those comments, or if there is anything further you want
5 to say about them?

6 A. It's a similar reflection that I have for the Rosemary
7 Biggs comment, or in that article, in that I really
8 supported and continue to support the idea of the
9 Macfarlane Trust and Skipton Fund which is giving
10 support for hardship, but I think that compensation is
11 the wrong thing to do because it suggests liability.

12 And I think at the time I conducted this, I was
13 feeling particularly aggrieved, and I think it would
14 not be appropriate to tell the Inquiry who this
15 patient was. But I was particularly aggrieved because
16 a patient had received -- and this was hearsay of the
17 amount -- but had received £80,000 as an out-of-court
18 settlement. And I had been asked about this case, and
19 I had seen the notes, and if that had gone to court,
20 I think it wouldn't have shown any liability. And
21 I was feeling aggrieved that the National Health
22 Service had paid out this money really that was
23 unjustified.

24 I think it is right for any medical treatment, if it
25 causes harm that wasn't expected, the patient should be

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1 supported. But I think the idea that we would -- anyone
2 who is a decent person would give somebody some
3 treatment that they knew would cause harm is frankly
4 ridiculous. And it's actually quite hurtful for those
5 people, those many people who cared for patients.

6 I mean that's -- I really don't want people to think
7 I'm a hard, unsympathetic person because I'm not. These
8 people have always been part of my life. They're still
9 part of my life. I sometimes see them. I've got an
10 ornament of a Greek student who died on my shelf. Every
11 day I see that, and I see this man. It was the saddest
12 tragedy of all, but I think to suggest culpability is
13 wrong. Sorry, my speech is over, but I -- it does upset
14 me.

15 **Q.** Professor --

16 **A.** I've been -- one of my rule nine things said I killed
17 somebody, and that is -- it is so hurtful. And then
18 I think, well, I'm pathetic. These patients have got
19 far more problems than me. Why should I feel pathetic
20 about that? But I do. I feel totally hurt.

21 **Q.** Professor Lee, those are the questions I have for you.

22 Sir, are there any questions that you have?

23 **SIR BRIAN LANGSTAFF:** No, I don't, thanks. I've asked all
24 that I've needed to, and you've answered the others
25 with what you've been saying.

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1 **MS RICHARDS:** Is there anything else, Professor Lee, that
2 you wanted to add?

3 **PROFESSOR LEE:** Yeah, I would just like to say something.
4 We've talked a lot about risk, and, you know, whether
5 treatment was necessary, but one of the things I was
6 thinking a lot about last night is: one of the things
7 treatment has done for a lot of patients is it had
8 given them some better quality of life. And I just
9 want to give you three examples of patients who
10 I cared for, where the concentrates really had made
11 a dramatic difference.

12 One had had prophylaxis. He'd had prophylaxis since
13 a child. And he'd studied music, and he became
14 a composer who won a prestigious prize and performed
15 a work at the Barbican; somebody with severe
16 haemophilia. And that is just amazing.

17 And another patient, when we were -- when our
18 orthopaedic surgeon was able to do -- he did double knee
19 replacements because it -- there was less concentrate,
20 and also the patients actually said that it was less
21 frightening having one operation than two. He had
22 double knee replacements, and his walking was completely
23 transformed. He had HIV and, of course, hepatitis C,
24 and he went on the Trans-Siberian Railway. And on the
25 border between Mongolia and wherever on this railway, he

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1 said he was stopped at three o'clock in the morning, and
2 they had some kind of inspection. And he said, "It was
3 really weird because they looked at passports, and then
4 they asked was I HIV positive?" They didn't know he had
5 haemophilia or anything.

6 And he said, "I thought it was probably better to be
7 economical with the truth at three o'clock in the
8 morning."

9 But, you know, that was somebody who had this
10 wonderful experience, and then the third patient
11 that I remember -- sadly he has died -- was an
12 Egyptologist, and he'd done most of his researching and
13 things at the British Museum, but when he got
14 concentrates, he could go to Egypt.

15 So that's to just reflect on the fact that life was
16 improved for a lot of people. And my personal first
17 memory of haemophilia was when I was doing orthopaedics
18 in Oxford, and there was this ward of little boys with
19 joints strung up to all sorts of things. So, you know,
20 it -- treatment has been good, despite these terrible
21 side effects.

22 And the last thing I really want to say is I want to
23 pay tribute to Dr Kernoff. It's very difficult. He
24 left treatment as a doctor when he was 40 years old,
25 I think, with this heart attack. He was the most

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1 amazing organiser and he cared for his patients, and he
2 set up a very good centre which I was lucky enough to
3 inherit. And I just think that he just needs to be
4 remembered. I think that's enough.

5 **MS RICHARDS:** Thank you, Professor Lee.

6 Sir.

7 **SIR BRIAN LANGSTAFF:** Well, it remains for me to thank
8 you, Professor, for coming to give your evidence.
9 You've given us a much greater understanding of what
10 life was like at the Royal Free, in particular, when
11 you were there, and what it was like to practice as
12 a researcher and as a clinician during the late 70s
13 and through the 80s, and since. And you'll
14 understand -- I know you understand -- how important
15 it was that we hear from someone with that experience
16 in your position.

17 And I'd particularly like to thank you because
18 it's common knowledge that concern about the -- "the
19 virus", as we might now call it -- Covid has been
20 heightening, particularly in London, and it makes me
21 all the more grateful that you were able to come in
22 person, as I want you to, but you did, and so thank
23 you for that.

24 **PROFESSOR LEE:** Thank you.

25 **MS RICHARDS:** Sir, tomorrow we have Professor Tuddenham,

1 so we continue with the Royal Free at ten o'clock
 2 tomorrow. And Professor Tuddenham is also here in
 3 person.
 4 **SIR BRIAN LANGSTAFF:** So, ten o'clock?
 5 **MS RICHARDS:** Ten o'clock tomorrow.
 6 **(5.09 pm)**
 7 **(The hearing adjourned until 10.00 am the following day)**

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