

1 Tuesday, 20th October 2020
 2 (10.00 am)
 3 SIR BRIAN LANGSTAFF: This morning and tomorrow we have
 4 Professor Lee.
 5 MS RICHARDS: That's right, sir.
 6 PROFESSOR CHRISTINE ANNE LEE, affirmed
 7 Questioned by MS RICHARDS
 8 MS RICHARDS: Professor Lee, I'm going to start by asking
 9 a few questions about your career. You studied
 10 medicine at Oxford; is that right?
 11 A. Yes.
 12 Q. Then you held various house officer posts in the early
 13 1970s?
 14 A. Yes.
 15 Q. You began your haematology training in September 1974;
 16 was that at St Mary's, London?
 17 A. Yes, St Mary's, Harrow Road, London, yes.
 18 Q. And you were a registrar there and the consultant was
 19 Dr Fielding; is that right?
 20 A. Yes.
 21 Q. And that was something that you did until 1976. You
 22 then moved to St George's as a senior registrar in
 23 November 1976?
 24 A. Yes.
 25 Q. You remained there until December 1982?

1

1 A. Yes.
 2 Q. You told the Lindsay Inquiry that it was at
 3 St George's you became particularly interested in
 4 haemophilia; is that right?
 5 A. Yes.
 6 Q. Now, you spent, during that time, I think, some
 7 ten months or so at the South London Transfusion
 8 Centre?
 9 A. Yes, I was working part-time. So I was working two
 10 and a half days a week there for my training, for
 11 MRC Path.
 12 Q. And that was the Tooting centre?
 13 A. Sorry?
 14 Q. Was that the centre in Tooting, the transfusion
 15 centre?
 16 A. Sorry, yes.
 17 Q. Can you recall who the director was of the transfusion
 18 centre?
 19 A. No.
 20 Q. You've said in your statement that you would have
 21 understood, at that time, the risks of transfusion
 22 acquired infection. I'll come on to knowledge of
 23 risks of infection in more detail later but can you
 24 recall what, if anything, was discussed or talked
 25 about that issue at the transfusion centre?

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1 A. It would have been the generality of the infections
 2 that were known at that time.
 3 Q. Do you recall any particular impression of the centre
 4 at Tooting and how it was run?
 5 A. No.
 6 Q. Do you recall whether there were any shortages or
 7 supply issues? We've heard from Dr Winter that by the
 8 time he was dealing with the Tooting centre, there
 9 were difficulties because they were covering both the
 10 south east and south west regions; were you aware of
 11 that?
 12 A. No.
 13 Q. You then moved to the Royal Free Hospital at the end
 14 of 1982 and beginning of 1983; is that right?
 15 A. Perhaps I should explain. I was given the appointment
 16 at the end of 1982. I actually took up the
 17 appointment at the end of January 1983.
 18 Q. The post was entitled "Research Senior Registrar"; is
 19 that correct?
 20 A. That's right.
 21 Q. How did you come to apply for that job?
 22 A. The job was advertised by being sent to all the
 23 haematologists in the London region. And Peter Flute,
 24 Professor Peter Flute, gave me the description of it,
 25 and that has been submitted in the papers.

3

1 Q. Yes, we'll look at that in a moment. Had you known or
 2 worked with Dr Kernoff or Dr Howard Thomas before?
 3 A. Sorry, had I?
 4 Q. Had you known or worked with either Dr Peter Kernoff
 5 or Dr Howard Thomas before?
 6 A. When I did a neurology SHO post, in 1971, for
 7 six months, at the Churchill Hospital in Oxford.
 8 I was doing neurology and Dr Peter Kernoff at that
 9 time I think was doing his MD on inhibitors with
 10 Dr Rizza, and the Haemophilia Centre at the Churchill
 11 Hospital -- which incidentally is where I trained, in
 12 Oxford Medical School -- and the Haemophilia Centre
 13 was on the same site. And occasionally, I would see
 14 him because we had ward rounds to train us to take
 15 membership of the Royal College of Physicians. So
 16 that was how I knew him at that time.
 17 Q. And had you known Dr Howard Thomas before you applied?
 18 A. Dr Howard Thomas was a colleague of my husband in the
 19 Department of Medicine at the Royal Free, when
 20 Dame Sheila Sherlock headed up that department, and he
 21 was a professional colleague of my husband, and
 22 I did -- we did know him socially.
 23 Q. We're just going to look at a couple of documents, the
 24 application Dr Kernoff made for a grant for the post
 25 that you took up, and the job description.

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1 Henry, could we have, please, WITN0644062, please.
 2 This is one of the exhibits to your witness
 3 statement, Professor Lee.
 4 If we see the whole page, please, Henry.
 5 This is:
 6 "A Grant Application to Action Research for the
 7 Crippled Child."
 8 Could you just explain what Action Research was?
 9 **A.** It was a charitable trust that awarded monies for
 10 research, and as you can see from the title there, at
 11 the time it was called Action Research for the
 12 Crippled Child, which is rather insensitive and that
 13 has now been dropped but, as I understand it, I think
 14 it still exists. And I imagine it was applied for
 15 because haemophilia before treating caused great
 16 disablement.
 17 **Q.** We can see that the application was -- this is
 18 November 1981, in fact. So obviously before you saw
 19 the post advertised and applied. It's called Aspects
 20 of the Natural History of Liver Disease and
 21 Haemophilia. I'm going to ask you to turn to a few
 22 pages. I want to get a sense of the work you were
 23 doing at the Royal Free under this post.
 24 If you go to page 4, please, Henry.
 25 We can see under the heading "Objectives" -- if

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1 you want to zoom in on that paragraph, please, Henry.
 2 You can see the whole paragraph under the heading
 3 "Objectives".
 4 Sorry, can we see the whole of that section.
 5 Thank you.
 6 So there are three objectives there set out as the
 7 objectives of the post:
 8 "To use a newly-developed radioimmunoassay for
 9 immunological markers of non-A, non-B hepatitis to
 10 study (a) the natural history of acute and chronic
 11 [non-A, non-B] hepatitis in haemophiliacs; (b) the
 12 antigen/antibody content of different preparations of
 13 clotting factor concentrates; (c) the transmissibility
 14 of [non-A, non-B] infection to household contacts of
 15 haemophiliacs; (d) the antigen/antibody content of
 16 different preparations of pooled immunoglobulin."
 17 Just pausing there, is that an accurate description
 18 of part of what you were doing when you took up the
 19 post?
 20 **A.** This work I was not doing. This work was conducted in
 21 the Department of Medicine on samples, and it --
 22 I wasn't involved in that.
 23 **Q.** At 2.2, were you involved in what's set out there,
 24 which involves an ultrasound scanning, or was that,
 25 again, in the Department of Medicine?

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1 **A.** No, I'm sure we're going to move on to this, but these
 2 were two ways in which progression of liver disease
 3 could be looked at by non-invasive methods, so
 4 avoiding liver biopsy, essentially. And there is
 5 a paper in my submission that records the results of
 6 this, but it was published much later, and it was
 7 effective to some extent.
 8 **Q.** Yes, we'll come on to look at that paper at a later
 9 stage of your evidence, Professor Lee. Just trying to
 10 get a sense of what the aim of the work was.
 11 2.3 was:
 12 "To make a detailed evaluation of patients treated
 13 with pooled immunoglobulin ..."
 14 And then:
 15 "To make a detailed evaluation of the response to
 16 steroid therapy and patients with severe chronic liver
 17 disease. If appropriate, to establish a multi-centre
 18 controlled trial to assess the possible benefits of
 19 steroid therapy."
 20 Was that part of the work which you undertook?
 21 **A.** No, I need to just take a little bit of time here.
 22 Most of the patients had been seen before I -- my
 23 post, essentially, was looking retrospectively at the
 24 data. The study that I analysed, obviously, was
 25 Dr Kernoff's supervision. The patients had been

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1 treated, and most of them had been treated actually
 2 before I even set foot in the centre, and I think this
 3 document you've got is the application.
 4 **Q.** Yes.
 5 **A.** And actually what was done was not necessarily in the
 6 application. I'm sure we're going to move on to
 7 discuss it, but the information in this significant
 8 paper that came out of the evaluation had largely been
 9 in the notes before I even started.
 10 **Q.** Yes. We will come on to the paper, but at the moment
 11 I'm just trying to get a sense of what the work was
 12 that you were asked to undertake?
 13 **A.** Yes, but I just want to emphasise again that this is
 14 the application for the grant, and actually what
 15 I ended up doing was not necessarily what's in this
 16 application.
 17 **Q.** Well, if we just look at a couple more passages in
 18 this and then we'll look at the job description, which
 19 was the job description that you answered.
 20 **A.** Yes, I think that's probably a better description,
 21 really.
 22 **Q.** If we look at the next page, please, Henry, before we
 23 leave this document, we can see -- if we have the
 24 first half of the page, please.
 25 We can see there there's a description of, at (c):

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1 "Patients to be studied are registered at the
2 Royal Free Hospital Haemophilia Centre."
3 You did some work at a later stage with Dr Rizza.
4 I'll come back to that. But for the purposes of this
5 study, and the work you were initially engaged to carry
6 out, it was all relating to patients at the Royal Free,
7 was it?

8 **A.** Yes.

9 **Q.** And we can see there it said:

10 "All age groups are represented. About 200
11 patients receive infusions of blood products in any
12 one year. All patients receiving infusion therapy are
13 reviewed at frequent intervals and detailed
14 information about types and amounts of blood products
15 given, and sequential changes in biochemical and
16 immunological tests, is available for a period of
17 several years in most patients, and a lifetime in
18 many."

19 If we skip down a few lines, it then says:

20 "A large bank of stored sera is maintained."

21 Is it correct that the stored sera had been
22 maintained since 1978?

23 **A.** Yes, the stored sera came into practice in 1978, when
24 Dr Kernoff took up his tenure as director of the
25 centre. And I think it's important to just expand on

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1 this a little. It had become reported, and people
2 were aware, that there was a transaminitis, abnormal
3 transaminases, in people who were having concentrates.
4 And Dr Kernoff had come from Oxford. He had done
5 research through Dr Rizza. And the idea of storing
6 sera was in order to, in the future, if a test became
7 available, be able to see what was happening.

8 I think at this stage, it might also be important
9 to make a point about the first paper which was
10 published, in the year of my birth, in 1943, by
11 Paul Beeson, who was the Professor of Medicine when
12 I was a student there. He, at the end of that paper,
13 which reported seven cases of people who had got
14 jaundice and the common factor was a blood
15 transfusion -- this is 1943, no tests -- and he said
16 it's important that doctors begin to understand this,
17 and they should note down the details of the
18 transfusion, and they should store a specimen of it
19 for future use.

20 So the idea was really to understand what was
21 happening, and it became a regular part of the whole
22 practice of treating and caring for people with
23 haemophilia at that time. And this went on, and it
24 proved extremely helpful in understanding these
25 diseases.

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1 **Q.** Again, we'll come back to that in more detail at
2 a later stage.

3 If we just go on to the next page, please, Henry.
4 Go to the bottom of the page under the heading
5 "Reasons for support requested".

6 We can see, again this is the grant application, but
7 what is said there is that:

8 "The medical registrar will be involved in the
9 day-to-day supervision of patients included in the
10 clinical studies, and in the collection and analysis of
11 clinical and laboratory data."

12 So that's a description of what was intended for the
13 post that you then took up. So you were involved not
14 simply in the collection -- or the intention was that
15 you would be involved not simply in the collection and
16 analysis of data but also day-to-day supervision of
17 patients. Is that right?

18 **A.** No, that's not true. What I was involved in, the
19 patients had already been treated in the context of
20 a bleeding episode. And I was involved in analysing
21 the liver function tests, the treatment they'd had,
22 and their clinical symptoms from the notes and from
23 the results in the notes. I can't remember the detail
24 of it, but I think there was only about one or two
25 patients within that short frame. The study, if you

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1 look, finished -- it was '78 to '83.

2 And the actual patients who'd had treatment
3 that I followed, there are about two, out of the --
4 over 58. These patients had all been treated for
5 something that was bleeding associated. They weren't
6 chosen. And the significant thing about this study is
7 that these people had not been treated a lot before,
8 so they were first treatment patients. So it was
9 possible, at that time, the only way you could
10 diagnose non-A non-B hepatitis was you had to have an
11 increase in the liver function tests within one month
12 of twice the normal level, plus exclusion of other
13 causes of hepatitis. And the medical feature of non-A
14 non-B hepatitis is that it could be asymptomatic, and
15 transaminases were essentially what's called
16 a yo-yo response; they went up and down. So unless
17 these tests were taken about every two weeks for
18 three months, you would miss it.

19 This is what had already been done in these
20 patients under Peter Kernoff's direction, and I took
21 up the remaining ones that were put into this paper,
22 and I analysed what had gone before. The reason for
23 stopping in '83 is because there was a lot of
24 information that needed to be got out there for the
25 benefit of the patients and people treating them.

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1 Q. Again, we'll come back to the details of the study.
 2 I'm just trying to get a sense of the work that -- the
 3 day-to-day responsibilities you had, Professor Lee.
 4 So if we look at the job description.
 5 WITN0644061. So if we go to the heading "Duties of
 6 the post", bottom half of the page, please. It says
 7 there:
 8 "The main duty of the post-holder will be to take
 9 a primary responsibility, under the direction of
 10 Dr Kernoff and Dr Thomas, for the implementation,
 11 coordination, follow-through and completion of the
 12 research projects which are described in the attached
 13 protocols. He/she will be located in the Haemophilia
 14 Centre and will need to acquire a thorough knowledge of
 15 the principles of diagnosis and management of patients
 16 with congenital coagulation disorders by involvement in
 17 the service and academic work of the centre. There will
 18 be a strong clinical component to the job which will
 19 include frequent contact with patients with liver
 20 disease and their relatives, making appropriate
 21 arrangements for their investigation follow-up and
 22 collection of necessary samples and possibly
 23 establishing combined 'haemophilia/hepatitis' clinics.
 24 He/she will be responsible for the collection, recording
 25 and analysis of data which will accrue as the studies

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1 progress and the final assembly of results for
 2 publication".
 3 If we just go to the next paragraph, please, Henry,
 4 it then continues:
 5 "An important component of the post will be to
 6 liaise between the Haemophilia Centre and the Liver
 7 Unit."
 8 Then various matters set out there, including:
 9 "It will be necessary for the post-holder to
 10 familiarise him/herself with aspects of liver disease
 11 and its management by participation in Department of
 12 Medicine meetings, seminars and ward rounds."
 13 Then if we just go over the page before I ask you
 14 a question. Sorry, if we can go to the next part of the
 15 document. Under the heading "Study and training":
 16 "The post-holder is expected to gain wide experience
 17 of clinical and laboratory aspects of bleeding disorders
 18 during the tenure of the post. And there will be many
 19 opportunities to participate in departmental activities
 20 which are not directly associated with the research
 21 projects."
 22 So is that an accurate description of the job that
 23 you took up, Professor Lee?
 24 A. Not entirely. I think the first thing that hits me
 25 that I would like just to make a comment about is the

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1 bit about liver biopsy.
 2 And before I took up this post, there had been
 3 a death from a liver biopsy. And that certainly was
 4 not part of what I took on. The only patient who, at
 5 that time, had a liver biopsy was the lady that is
 6 reported -- or who had fulminant hepatitis, and it
 7 was covered with cryoprecipitate. But I certainly was
 8 not trained to do liver biopsies. I never did liver
 9 biopsies.
 10 The detail of the extent to which I, in practice,
 11 got involved in all these things was quite -- was not
 12 quite as extensive as it would appear there, because
 13 I took over in the end of January in '83, and almost
 14 immediately we were consumed by the issue of HIV.
 15 Q. This document suggests that whilst the completion and
 16 analysis of the research project was an important part
 17 of -- a key part of the work that the person was being
 18 employed to undertake, it was also expected that there
 19 would be a clinical component, regular dealings with
 20 patients, and learning thoroughly the principles of
 21 the diagnosis and management of bleeding disorders.
 22 Was that part and parcel of what you did?
 23 A. I think -- I'm sure all the descriptions of the centre
 24 are there in my submissions, and almost by osmosis you
 25 had to get involved in this. It was a very big

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1 centre. So there were teaching sessions and meetings,
 2 planning, about what was happening and who was coming
 3 and things like that. But I would just emphasise that
 4 the main thing I was doing was analysing data, and
 5 I just got -- I know we're coming on to it, but it's
 6 relevant.
 7 The study was over a five-year period from
 8 April 1978 to March 1983. And this information was
 9 already in the patient notes, and the study was
 10 retrospective in the sense these people were not
 11 recruited to go into a study. They were people who
 12 came with a bleeding problem, and then they were
 13 retrospectively identified. And because there had
 14 been the collection of the samples and the results of
 15 the liver function tests, it was possible to
 16 retrospectively analyse that information.
 17 The five-year period went from April 1978, when
 18 Peter Kernoff was appointed, and it ended in March 1983
 19 for the purposes of this study. I don't recall exactly
 20 the number of patients that I was taking two weekly
 21 specimens from, but clearly it wasn't very many because
 22 there's only a month that they had their treatments.
 23 Q. I understand your evidence, but for the purposes of
 24 that study, the time period of the patients being
 25 treated was coming to an end at the point in time at

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1 which you took up your post in January 1983.
 2 But following that, what clinical role did you
 3 have at the Royal Free, 1983, 1984? Did you, for
 4 example, sit in with Dr Kernoff when he saw patients
 5 with bleeding disorders?
 6 **A.** No. No. I think it also has to be understood that
 7 the care at the centre was a multi-disciplinary team.
 8 So there were the consultants, the clinical assistant,
 9 Dr Eleanor Goldman, who I know is making a submission;
 10 there were the family therapists; there was a
 11 physiotherapist, there were the laboratory staff. And
 12 the main day-to-day clinical work was conducted by the
 13 senior registrar or registrar who was rotating through
 14 the department from the department of haematology who
 15 was learning about haemophilia. New patients who came
 16 were seen by Dr Kernoff. I didn't see new patients.
 17 **Q.** Could we have on screen, please -- this is your
 18 evidence to the Lindsay Tribunal, Professor Lee --
 19 LIND0000326. Could we please go to page 3. You'll
 20 see you were being asked, as I am, about the various
 21 posts you'd held, and then you give an answer a few
 22 lines down:
 23 "Essentially, I cared clinically for this group of
 24 patients really since the beginning of 1983."
 25 The evidence you gave to the Lindsay Inquiry

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1 suggests you had had a clinical role for patients with
 2 bleeding disorders from 1983 onwards.
 3 **A.** I think a clinical role of taking blood tests or
 4 discussing patients within a team is what I was
 5 talking about. But I was not the person who saw new
 6 patients. I was not the person who made the decision
 7 about what treatment should be given to a particular
 8 patient. Dr Kernoff was the director at that time,
 9 and I was doing research under him, under his
 10 direction. And clearly, I would help out if there was
 11 some -- somebody who needed to have blood taken or to
 12 be clerked, but I just emphasise that it was a team
 13 approach.
 14 I would also like to just put on record, when
 15 I gave information to the Lindsay Inquiry, it was
 16 20 years ago. I was working as the Director and
 17 Professor Of Haemophilia at that time. So I had
 18 access to documents. I was -- I knew my information.
 19 You are asking me about a period in 1983 which, on my
 20 account, is 37 years ago?
 21 **Q.** It is.
 22 **A.** And it's difficult to remember these things.
 23 **Q.** Do you have a sense or recollection of how often you
 24 had direct patient interaction, other than for the
 25 purpose of taking bloods, in the period 1983/1984?

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1 **A.** No, I don't have a recollection of the complete number
 2 of cases, but I can tell you that once HIV infection
 3 began to impact -- for example, I can remember
 4 a patient. He was the oldest patient who died of HIV
 5 infection, and I did look after him when he came up to
 6 the centre because we were totally confused about what
 7 he had. So we had to think of all the possible things
 8 to test. In retrospect, what he had was Pneumocystis
 9 carinii, but we didn't know that.
 10 So that was the kind of situation that I might be
 11 called upon to do clinical work. But the
 12 practicalities and organisation at that time was:
 13 Peter Kernoff was the director. He made the
 14 decisions. And there was a junior -- well, not so
 15 much junior, really; it would be a senior
 16 registrar/registrar -- in the department so that when
 17 the patients came up, as they could do at any time,
 18 that would be the first person who saw them and
 19 reviewed the problems, and they would probably discuss
 20 with Dr Kernoff what should be done.
 21 **Q.** So a new patient typically would be seen by
 22 Dr Kernoff. Existing patients who were returning for
 23 review appointments would be seen ...?
 24 **A.** It would depend on what the clinical problem was.
 25 You also probably need to know that there was

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1 a very well-trained senior nurse. And at that time,
 2 I can't remember how many, exactly, nurses there were,
 3 but certainly one who very sadly died two years ago.
 4 But the nurses also would be very involved in the
 5 first -- seeing the patient as they came in.
 6 For serious situations which the patients, many of
 7 the patients -- all the patients who were treated in
 8 this paper, I'm quite certain Dr Kernoff will have
 9 seen them.
 10 I think it's also important that you know -- you
 11 know, I was working part-time. I wasn't on call.
 12 I didn't -- I was working four days a week then,
 13 I think.
 14 **Q.** And you --
 15 **A.** So I think it's very difficult for me to know what
 16 Dr Kernoff was doing 24 hours of the day.
 17 **Q.** Yes. I'll take you through some documents in due
 18 course and ask you about them which show some of
 19 Dr Kernoff's thinking at the time. But just going
 20 back to the question of how the care was organised and
 21 structured at the Royal Free in this 1983/1984 period.
 22 You've mentioned team discussions. Was that
 23 a regular occurrence, that there would be what would
 24 now be known probably as multi-disciplinary team
 25 meetings to discuss patient care?

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1 A. Can I just refer to a document here --
 2 Q. Yes, of course.
 3 A. -- which you have. This is on record.
 4 In order to just give you an idea of the sort of
 5 team working we had --
 6 Q. Sorry. Can I just stop you, Professor Lee, so others
 7 can follow? Is that the document: "Haemophilia centre
 8 haemostasis unit"?
 9 A. That's right.
 10 Q. Henry it's WITN0644069.
 11 A. This was actually written in 1987 when I returned as
 12 a consultant, but it gives a description of the
 13 centre. Like, for example, by 1970, the centre had
 14 180 patients, and this was housed in a prefabricated
 15 extension and the end of a ward at the old Lawn Road
 16 Hospital.
 17 In 19 -- in 1972, they've got 220 patients. The
 18 present director, Dr Kernoff, took up post in 1978. And
 19 I think to give you an idea of the growth is important,
 20 because that was also reflected in the team that came
 21 together. So this is -- by 1987, you've got 981
 22 patients in the period 1987-88. And this required more
 23 staff, so you've got Dr Kernoff and now
 24 Professor Tuddenham, who mainly was in the laboratory
 25 doing research, trying to purify Factor VIII. You had

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1 an associate specialist, Dr Eleanor Goldman who tended
 2 to see mostly the children, and she was a trained family
 3 therapist. You have Riva -- she was 90 two weeks ago,
 4 and I think is giving evidence to you. And Riva Miller,
 5 who was called a social worker, but she was a trained
 6 family therapist and went on to develop the same-day
 7 testing clinic for HIV in the hospital, and also to
 8 advise the Blood Transfusion Centre in North London
 9 about HIV.
 10 There was also a full nursing team. There was the
 11 nurse manager, she was called -- there was Patricia
 12 Lilley. There was a data processing officer, because
 13 Peter had a computer put in in '79/'80. There was an
 14 office manager. There were secretaries. There was a
 15 reception coordinator, and there was a full laboratory
 16 that did all the specialised tests for our patients and
 17 also had to do the specialised haemostasis tests for the
 18 whole hospital. We had a renal unit. We had a big
 19 transplant unit, and we had a big emergency department,
 20 so that was a big part of it.
 21 In terms of the team -- would you like me to tell
 22 you about the teamworking?
 23 Q. I'm interested in particular in the years 1983 to 1984
 24 for the purposes of my current questions.
 25 I understand that most of the people that you've

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1 mentioned would have been in post then -- so
 2 Riva Miller, Dr Goldman, Dr Kernoff,
 3 Professor Tuddenham.
 4 In terms of the clinical decisions that were being
 5 taken about, for example, what treatment a particular
 6 patient should receive, was that something that was
 7 discussed in team meetings, in some sense?
 8 A. I don't recall that, no. I think those decisions were
 9 made by Dr Kernoff.
 10 Q. We'll come back to a number of these matters,
 11 Professor Lee, but just completing the basic
 12 chronology of your career, in November of 1984, you
 13 worked -- went to work at the Charing Cross and
 14 Westminster Medical School and Queen Mary University
 15 Hospital; is that right?
 16 A. I hope it's possible to put this into context.
 17 I think it's important because you might wonder why
 18 I left something that was very important to me, and I
 19 really cared for those patients. I had two young
 20 children. I lived in Richmond which, for those of you
 21 who live in London may know, is very close to Queen
 22 Mary's Hospital, Roehampton, which was then a district
 23 general hospital that was a university hospital. And
 24 there was a post of a senior lecturer in haematology
 25 at Charing Cross medical school but essentially taking

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1 up the single-handed haematology post at Queen Mary's
 2 Roehampton. And the previous consultant in
 3 haematology had been a laboratory-based haematologist,
 4 and I was to change the service because this was
 5 happening in haematology for it to be a clinical and
 6 a laboratory service. It was a very attractive post
 7 to me because there was no definite post at the
 8 Royal Free. I was doing research. And it was
 9 actually quite difficult for me to make this decision,
 10 but I did it for family reasons and proximity reasons,
 11 really.
 12 So I applied for the post, and I became the
 13 consultant. I was there for three years, and during
 14 that time, because I was a senior lecturer, the head
 15 of the department very kindly -- this is at Charing
 16 Cross -- the professor at Charing Cross very kindly
 17 let me go on secondment for one day a week back to the
 18 Royal Free, essentially to try and write up
 19 information that we had because it was very important
 20 to get this into the public domain for the patients
 21 and the people caring for these people.
 22 So I think that was 1986, as I remember it, that I
 23 started going a day off a day a week. And then, during
 24 that time, the workload of HIV and non-A non-B hepatitis
 25 was becoming enormous, and Peter Kernoff made the case

1 within the Royal Free for a consultant where the -- most
2 responsibilities would be to manage this group of
3 patients. And he eventually succeeded in getting the
4 funding for that, and I applied for it and took it up in
5 November '87.

6 I think -- will you enable me now to just sidetrack
7 a little bit to what I was doing in this post about HIV?
8 Because it is relevant.

9 **Q.** Yes.

10 **A.** Or would you prefer me to keep that --

11 **Q.** No, I'll ask you about that in a moment. Can I just
12 ask two questions before you do that?

13 **A.** Yes, sure. Sure.

14 **Q.** The first is: in relation to the period 1984 to 1987
15 when you were at Queen Mary, my understanding from the
16 evidence you've given elsewhere is that you were
17 working initially one day a week at the Royal Free?

18 **A.** Yes.

19 **Q.** Then from 1986, you did two sessions per week at the
20 Royal Free; does that sound right?

21 **A.** One day I did. I used to drive over from Richmond to
22 Hampstead. And maybe that was called two sessions, I
23 don't know.

24 **Q.** It's simply the terminology --

25 **A.** I don't think I was paid. I wasn't paid for that. It

25

1 may be that -- because of the regulatory thing within
2 the hospital, Peter had to put in -- because I was
3 working there, he might have had to put some kind of
4 documentation into the hospital, because, you know,
5 hospitals don't let people just go and work in
6 a department without the authority. So I imagine
7 that's where the two sessions came. But I was not
8 paid. My salary was as a senior lecturer at Charing
9 Cross Hospital.

10 **Q.** And in terms of the work you were undertaking at
11 Charing Cross or Queen Mary University Hospital, did
12 you have any responsibility during that period for the
13 care of patients with bleeding disorders?

14 **A.** I think -- you know that -- well, I'm sure you'd
15 know -- haemophilia occurs in 1 in 10,000 people.
16 During the three years I was there, there was one
17 little boy who presented, and I actually referred him
18 to Peter. That was the only person. But, of course,
19 you know, haematologists, bleeding disorders aren't
20 just haemophilia. And, of course, also, that time --
21 we're talking about '84 -- our knowledge was perhaps
22 rather rudimentary about other inherited clotting
23 factor deficiencies.

24 But we -- at that time, I didn't have anybody
25 specifically with haemophilia, but because I was the

26

1 consultant haematologist, if anybody bled in the
2 hospital, I was responsible for trying to diagnose it
3 and organise -- tell the laboratory what they should
4 test for. But again, the laboratory at Queen Mary's,
5 Roehampton, was nothing like the laboratory at the
6 Royal Free. So we were not doing -- we did very
7 simple screening tests for bleeding disorders.

8 **Q.** So you were a general haematologist --

9 **A.** Yes.

10 **Q.** -- in a district general hospital --

11 **A.** -- I looked after the whole of the haematology. And
12 as I say, it was quite a challenging post because
13 haematology was changing. You know, we're doubly
14 trained in haematology. We have what's called MRCP,
15 Membership of the Royal College of Physicians, so we
16 have to have done medicine, and we have to have done
17 a very full laboratory training which is medical --
18 MRC Path.

19 And at about that time -- previously, haematology
20 had been within pathology, had been a pathological
21 discipline, but now we were moving to a situation,
22 actually like Scotland had always had, where the
23 haematologist was a clinician and a laboratory person.
24 And I had to change that hospital laboratory to that.

25 **Q.** You had wanted to make an observation about the work

27

1 you did in relation to HIV and AIDS?

2 **A.** Yes. We'll be talking about this, I'm sure, but
3 the -- as I remember it, the National Blood
4 Transfusion Service wanted to -- clearly wanted to
5 test blood for HIV, and this became possible in the
6 beginning of 1985. They were very concerned that
7 people would therefore go and give blood in order to
8 get a test. And in order for that not to happen, in
9 every -- I think every region or district general
10 hospital, I'm not quite sure of the size of the areas,
11 they appointed two AIDS counsellors, and they were to
12 provide a testing service for HIV, as it were, in the
13 community. And because, when I went to Queen Mary's,
14 they knew that I'd had some experience, I was
15 appointed one, and I had an HIV testing clinic that I
16 had to see people with.

17 The other quite extraordinary thing, and I think
18 this is important because it does set the scene of how
19 AIDS and HIV really overwhelmed not just haemophilia,
20 where it was quite tragic, but it overwhelmed the whole
21 country. And I was told to go and address every
22 secondary school in the borough of Richmond upon Thames
23 to educate them about AIDS.

24 **Q.** You returned to the Royal Free full-time at the end of
25 1987, November 1987 --

28

1 A. Yes.
 2 Q. -- as a consultant?
 3 A. Yes.
 4 Q. And then you took over as acting director in around
 5 April of 1991 after Dr Kernoff was taken suddenly ill?
 6 A. That's right.
 7 Q. And you then became the director of the centre in
 8 April 1992 until your retirement at the end of 2005.
 9 A. Yes.
 10 Q. We'll come on to these in more detail, to some extent
 11 at, a later stage, but you were a member of the UKHCDO
 12 from 1991 to 2005?
 13 A. Yes.
 14 Q. Or before 1991?
 15 A. 1991 to 2005.
 16 Q. And you sat on various working parties and groups?
 17 We'll look at couple of those.
 18 A. Yes.
 19 Q. And you were on the medical advisory panel of the
 20 Haemophilia Society between 1993 and 2005.
 21 A. Yes. I think I was asked in my statement about this.
 22 I think what I remember is that David Watters used to
 23 phone me periodically, but I can't remember regularly
 24 going to meetings of that.
 25 Q. I want to ask you a few questions about St George's,

29

1 first of all, before we turn to look in more detail
 2 again at the Royal Free.
 3 So you were at St George's between 1976 and 1982,
 4 with the exception of the time you were on secondment
 5 for training purposes to the Regional Transfusion
 6 Centre. That's --
 7 A. Can I interject a little bit? And I'm sorry to get
 8 personal about this, but I was actually working
 9 part-time, so 6/10ths I was working, and it was under
 10 a scheme called the Married Women's Scheme. And I had
 11 two pregnancies during that time, so I was on
 12 maternity leave at two stages during that time.
 13 Q. St George's was a designated Haemophilia Centre, not
 14 a reference centre, but a small Haemophilia Centre at
 15 the time?
 16 A. I don't know about that because Peter Flute,
 17 Professor Peter Flute was the Professor then. I don't
 18 have knowledge of that.
 19 Q. I just want to get a sense of the number of patients
 20 and the kind treatments used there. And we can do
 21 that, I can prompt your memory, Professor Lee, by
 22 looking at the annual returns. It's HCDO0000143_003,
 23 please, Henry. If we go to the next page, please.
 24 This is just to get an idea, because we may not
 25 have anybody else that I can ask anything about

30

1 St George's of. This is the 1983 return, so you'd
 2 still have been there in 1983 -- no, I'm sorry. You'd
 3 moved on at the beginning of 1983, but this may give
 4 us a flavour. You'd been there in 1982.
 5 We can see there 31 haemophilia A patients and 4
 6 von Willebrand patients, so a much smaller centre than
 7 the Royal Free.
 8 A. Mm.
 9 Q. If we look at the products that were used, we can see
 10 a small amount of cryoprecipitate, some NHS human
 11 Factor VIII concentrate used both in hospital and for
 12 home treatment, and then the predominant product used
 13 there was Armour Factor VIII. And we can see the
 14 quantities there: 270,755 per hospital treatment;
 15 309,680 per home treatment.
 16 Decisions as to what concentrates to use at
 17 St George's, were those taken by Professor Flute?
 18 A. I do not know.
 19 Q. Do you have any recollection of what the treatment
 20 policies were at St George's at that time?
 21 A. No. I could just comment on these figures.
 22 Q. Yes.
 23 A. I saw them for the first time, I think, last evening.
 24 You see that there's NHS Factor VIII and commercial
 25 here. It's roughly a third was NHS, and two-thirds

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1 was commercial, and the national figures were similar
 2 to that. But I have never seen that document before.
 3 I would have no part in any decisions that
 4 Professor Flute made, and of course --
 5 **SIR BRIAN LANGSTAFF:** If you look at the figures, it looks
 6 more like a fifth.
 7 A. Sorry?
 8 **SIR BRIAN LANGSTAFF:** If you look at the figures, the
 9 total there for NHS, as opposed Armour, it looks to me
 10 to be something more in the region of a quarter or
 11 a fifth.
 12 A. Yes, maybe. I mean, I think it's not really
 13 appropriate for me to comment on Peter --
 14 Professor Flute's figures, you know. I wouldn't have
 15 had anything to do with this.
 16 I mean, I suppose, to follow up on that comment,
 17 I mean, it just emphasises that much more commercial
 18 Factor VIII was being used than NHS Factor VIII.
 19 **MS RICHARDS:** As senior registrar and completing your
 20 training, effectively, under Professor Flute, you
 21 would presumably -- I appreciate what you said about
 22 periods of maternity leave and being part-time, but
 23 when you were there, you would presumably have been
 24 involved in the clinical care of patients?
 25 A. Yes, but not an awful lot, actually. A lot of -- to

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1 do MRC Path training, you had to rotate through
2 various specialities. So some of the time would be
3 spent -- as we've seen from the transfusion centre,
4 there was a whole big several months spent at the
5 Royal Marsden to learn about leukaemia, and within
6 St George's, I would occasionally have seen a patient.
7 But my main clinical contact with patients was
8 actually at a district general hospital that was part
9 of the St George's network, St James', Balham, which
10 was general haematology, and there I would see
11 patients on the wards, and I ran an outpatient clinic,
12 but I didn't do those things at St George's. And, of
13 course, there was a large amount of microscope work to
14 screen films.

15 I also, at St George's, was very involved in being
16 trained in the laboratory to do Factor VIII assays and
17 things that are relevant to haemophilia. But that
18 wasn't in the context of doing work for patients; it
19 was to actually learn how to do it, because when we
20 did our MRC Path exam, we had a three-hour practical
21 session doing such tests.

22 **Q.** And which year did you undertake the MRC Path exam?

23 **A.** I finally achieved the MRC Path exam in 1982, so then
24 I was fully accredited as a haematologist, but before
25 that time I wasn't accredited.

33

1 **Q.** If we then move on to the Royal Free.

2 If we could have up on screen, please, Henry
3 RLIT0000022.

4 Put this up as much as anything as an aid to memory,
5 Professor Lee. This is a seminar you participated in,
6 or helped organise, I think, in 1998. So that's when
7 events would have been fresher in your mind.

8 **A.** I didn't just participate in it. I actually helped
9 organise it.

10 **Q.** If we go to page 34, Henry -- oh, I'm sorry, I'm using
11 the internal pagination, so can you go on 10 pages.
12 Thank you.

13 I just want to get a sense of practices at the
14 Royal Free in the 1970s. Obviously aware that you
15 weren't there, Professor Lee, but you've talked about
16 it in this seminar.

17 So we can see you ask a question:

18 "Was it right to think that cryoprecipitate was
19 a thing that really pushed home treatment?"

20 And then you go on to say, after Dr Matthews'
21 response:

22 "In our own Centre [Royal Free], Katharine Dormandy
23 really made a major contribution. I think I am right in
24 saying that she made cryoprecipitate in the old hospital
25 at Lawn Road in the labs there, and that the patients

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1 were actually started on home treatment with
2 cryoprecipitate. In fact, if you go back and look
3 through the notes of some of our older patients, the
4 social work contribution was to raise the money to buy
5 the deep freezers enabling them to have it at home."

6 Then if we just go to the top of the next page
7 before I ask the question, you then --

8 **SIR BRIAN LANGSTAFF:** Just give Professor Lee a moment --

9 **MS RICHARDS:** I'm so sorry, Professor Lee.

10 **SIR BRIAN LANGSTAFF:** She's trying to follow it both in
11 the document and on the screen.

12 **A.** Page 34 I've got ...

13 **MS RICHARDS:** I'm so sorry.

14 So you asked a question about cryoprecipitate
15 being a thing that really --

16 **PROFESSOR LEE:** Which page is that, please?

17 **MS RICHARDS:** It's page 34, using the pagination at the
18 bottom left-hand of the page. It is on the screen.

19 **PROFESSOR LEE:** Yeah, okay, sorry.

20 **MS RICHARDS:** You asked a question about
21 cryoprecipitate --

22 **SIR BRIAN LANGSTAFF:** Just a moment.

23 You may find it easier to look at the screen.

24 I don't know if it's easier -- you're working with.

25 **PROFESSOR LEE:** I think I will use this.

35

1 **SIR BRIAN LANGSTAFF:** Okay.

2 **PROFESSOR LEE:** As long as I have the page numbers, I'm
3 fine.

4 **MS RICHARDS:** So you asked that question, Dr Matthews, who
5 was at Oxford, responds about cryoprecipitate making
6 a big difference because it was easily made, although
7 he observes it wasn't the ideal material but many
8 centres found it a very useful material for home
9 treatment.

10 Then you made an observation about
11 Katharine Dormandy, who had been the director at the
12 Royal Free in the 1970s. And you observed that
13 cryoprecipitate was made in the labs at the Royal Free,
14 patients were started on home treatment with
15 cryoprecipitate. And you refer to the notes of some of
16 your older patients showing social work efforts to raise
17 money to buy deep freezers.

18 Then if we go to the top of the next page, so it's
19 the top of page 35, you then say that:

20 "In our Centre we were a bit slow to use large full
21 clotting factor concentrate because it wasn't really
22 until you [Professor Tuddenham] and Peter Kernoff came
23 that people were started on this treatment, because
24 Katherine had been so taken up with the
25 cryoprecipitate."

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1 Now, I can obviously ask Professor Tuddenham about
2 this as well but your understanding was that
3 cryoprecipitate had been a significant part of the
4 treatment policies of the centre in the 1970s under
5 Dr Dormandy?
6 **A.** Yes, I think I would like you to refer to this paper.
7 I can give you the number if you like. Do you want
8 the number now?
9 **Q.** Yes, please.
10 **A.** It's the history paper that was written for the
11 50th anniversary of the KD Trust, and it's on the --
12 it's 644061.
13 **Q.** I'm not sure it is, I'm afraid.
14 **A.** All right, well, on my witness statement --
15 **Q.** Not your fault at all, Professor --
16 **A.** On my witness statement it's 0655067.
17 **Q.** Yes.
18 **A.** Okay.
19 **Q.** "Blood borne infections and haemophilia: the worst
20 of times."
21 **A.** Yes, and this --
22 **Q.** Professor Less, can I ask you just to pause for a
23 moment so we can get it up on the screen so others can
24 follow?
25 **A.** Sure.

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1 **Q.** Henry, it's WITN0644067.
2 Which page would you like to refer to?
3 **A.** I think the first page is talking about
4 Katharine Dormandy, and the references are very
5 relevant and you have these in my deposition.
6 Katharine Dormandy pioneered making
7 cryoprecipitate at the old Lawn Road Hospital. And
8 the paper that describes that is Bennett et al, in
9 1967, referenced in this paper. I was actually
10 working at the renal unit at the Royal Free when the
11 old Lawn Road Hospital was there, so -- and it was
12 a two-storey old Victorian hospital, and she
13 commandeered the whole of a haematology ward, the old
14 haematology ward, to make the cryoprecipitate on site.
15 And then eventually the North London Blood Transfusion
16 Service took it over. And she pioneered home
17 treatment with cryoprecipitate. And at that stage the
18 Haemophilia Centre was a caravan that had been paid
19 for by the Haemophilia Society in 1965, and she had
20 about six beds at the end of a ward bay on the ground
21 floor, and people -- the patients with haemophilia
22 would come up to that place if they needed treatment,
23 or bleeds or whatever, but they also came up,
24 eventually, when it went on to home treatment, to
25 collect cryoprecipitate.

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1 If you read in some of these -- this paper of hers,
2 she describes how, in order to take the cryoprecipitate
3 home, it needed to be kept cool, and she had card ice,
4 you know? And that was given to the patients and they'd
5 have cardboard boxes to kind of insulate this
6 cryoprecipitate, because the problem with
7 cryoprecipitate is that, you know, Factor VIII decays
8 over 12 hours. So if you have cryoprecipitate, the
9 actual amount of Factor VIII in it depends on, one, the
10 speed with which you get the blood that's taken out of
11 the patient, to centrifuge it, to get off the plasma, to
12 freeze that plasma down to a low temperature, and then
13 warm it up to a slightly -- sort of 4 degrees, and then
14 decant that over to another bag. This is a process.
15 And she had this going in this haematology ward at
16 Lawn Road. And then those bags have to be put in a deep
17 freeze.
18 And all this time, every time that material is out
19 of freezing, the Factor VIII is decaying. And then the
20 patients who have driven -- often those patients came
21 from quite a distance to the Royal Free -- they have to
22 take this home to put in their own deep freezers, if
23 they've got a deep freeze.
24 And they had these boxes, the home-made boxes that
25 would be -- card ice put in and insulated to take them

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1 home. And all the time the Factor VIII is decaying.
2 And I think that is very well described in the paper,
3 Bennett.
4 **Q.** Thank you.
5 So throughout the 1970s, Dr Dormandy essentially
6 establishing and operating a home treatment programme
7 using cryoprecipitate?
8 **A.** Actually, I'm sorry to -- you asked me another
9 question, didn't you, before that? About that she was
10 using cryoprecipitate, and Dr Kernoff and
11 Dr Tuddenham --
12 **Q.** I'm just going to come to that.
13 **A.** Oh, sorry. I'm sorry.
14 **Q.** Don't worry.
15 So Dr Dormandy's post was taken over by Dr Kernoff
16 and Dr Tuddenham in 1978. They were appointed
17 co-directors of the Royal Free at that point?
18 **A.** Well, that's not entirely true. Peter Kernoff was
19 initially appointed director, and I think he was
20 interviewed by Katharine Dormandy, and then he took up
21 a research -- he was doing research, I think, in
22 North America. And in the interim, Katharine Dormandy
23 was diagnosed [redacted] and she had a terminal
24 illness, and they then managed to get a senior
25 lecturer post to be her replacement, although she

40

1 hadn't actually died yet.
2 And Dr Tuddenham, you can ask him about this
3 tomorrow, but it's my understanding, and this
4 understanding comes from Peter Kernoff, Dr Tuddenham was
5 appointed by the new Professor of Medicine,
6 Professor Hoffbrand, and he was made co-director in
7 Peter Kernoff's absence. He was actually appointed as
8 a senior lecturer.

9 So I think, at that stage, Peter Kernoff's
10 understanding was he was director, and when he came back
11 from America he found out he was co-director.

12 Q. If we look at your evidence to the Lindsay Tribunal
13 again, LIND0000362, please.

14 If we go to page 5 please, Henry.

15 Actually, we'll just pick it up -- to put it in
16 context -- the bottom of the previous page, the second
17 page.

18 So if we pick it up down there, Professor Lee, we
19 can see, just about halfway down the page, you were
20 talking about Dr Dormandy and the use of
21 cryoprecipitate, and you referred to the notes and
22 there being records of letters from social workers
23 trying to get deep freezers and patients talking about
24 having that treatment at home.

25 And then you were asked the question at the bottom

1 of the page:

2 "For how long would the patients have continued to
3 use cryoprecipitate for home treatment at the
4 Royal Free?"

5 If we go to the next page, you say:

6 "... at the Royal Free, they went on using it
7 probably for longer than other places."

8 And you've explained why: Dr Dormandy was very
9 enthusiastic about cryoprecipitate. And then you say:

10 "[The] two co-directors were put in ... they were
11 young doctors, and they came in in 1978 and very rapidly
12 changed everybody to concentrate. There had been some
13 people who had had concentrate before then, but I would
14 think that up until 1978, the majority were still
15 probably still on cryoprecipitate."

16 Then you're asked about this being a change of
17 policy, and you answer yes.

18 What understanding did you have, from subsequent
19 conversations or discussions or however you gained it,
20 about the reasons for this change of policy? Why did
21 they switch very rapidly to concentrates?

22 A. I think you should ask Professor Tuddenham that
23 question tomorrow. I just need to just go back a bit
24 about Katharine Dormandy. And why she was so
25 enthusiastic about continuing cryoprecipitate was

1 because she had made it, and she had pioneered home
2 treatment. And also, she -- and this is listed in the
3 blood-borne infections paper, she'd done a study with
4 some American workers in North America, in Worcester
5 in the United States, and they were treated
6 exclusively with the new concentrates, whereas
7 Katharine Dormandy was treating people with
8 cryoprecipitate.

9 And what she found was that while both groups of
10 patients, so that's the people on the concentrates in
11 North America and the people just receiving
12 cryoprecipitate at the Royal Free, while both groups of
13 patients had raised transaminases, that's a liver
14 function test, this was more common in those treated
15 with concentrate. This was consequently shown to be due
16 to be due to hepatitis C.

17 And in the comment at the end of this paper,
18 published in 1977, Dormandy noted:

19 "The long-term significance of the various
20 abnormalities recorded here is unknown. Aggressive
21 therapy should continue."

22 And I don't know, I think you'd have to ask
23 Professor Tuddenham, but I think it was probably the
24 convenience and the efficiency. And so when you treat
25 people with the concentrate -- I described this fall of

1 the Factor VIII, making cryoprecipitate, let alone
2 everything you needed to use this at home and also to
3 draw it up in hospital. I'm sure that it was the much
4 more effective treatment for bleeding. And that's
5 probably what drove them to changing people. And it
6 wasn't just them, it was the patients asking for it and
7 the whole of the treatment community.

8 I am going to -- I think it's important to go
9 through this again, if you will allow me. I just want
10 to expand a bit about cryoprecipitate.

11 It comes in a plastic bag, and it's a very sticky
12 solution. And when people treated themselves at home,
13 if they, say, had a bleed, they would need probably ten
14 bags of this. So the process of this was using two big
15 syringes and having to draw this stuff into a syringe.
16 And the volume that the patient had to then -- they were
17 taught how to self-in fuse, and you imagine trying to --
18 it's not easy. The volume is enormous. Not only was
19 the volume enormous but the efficiency, the amount of
20 Factor VIII in it, you didn't know exactly how much
21 Factor VIII was in it. It depended on how long that
22 whole process I've described to you took.

23 You know it also depended on the Factor VIII, the
24 original donor, and some transfusion centres even got
25 people running up stairs to raise the Factor VIII in the

1 plasma.
 2 So when the concentrates came, you had two little
 3 bottles, and it was a very small -- much smaller volume,
 4 and you actually knew how much was being given. So you
 5 knew how much the patient would have in his bloodstream.
 6 It also meant that people could take the bottles to
 7 work, or they could go on holiday. You know, this had
 8 been virtually unheard of because you had to have a deep
 9 freeze full of cryoprecipitate.
 10 So I think that that was the reason that there was
 11 the complete change, and I don't think they could be
 12 criticised for that at that time.
 13 **MS RICHARDS:** Okay.
 14 I note the time, sir, is this a convenient point
 15 to take a break?
 16 **SIR BRIAN LANGSTAFF:** It is, yes.
 17 We take a break in the mornings. It will be
 18 45 minutes. That allows everyone to have a proper
 19 socially distanced refreshment. So we start again,
 20 shall we, at 12 o'clock.
 21 **MS RICHARDS:** Yes, and if you could give --
 22 **SIR BRIAN LANGSTAFF:** Professor Lee, you're giving
 23 evidence. The rule is that in a break, you must not
 24 discuss your evidence, either the evidence you have
 25 given, or you suspect you may be asked to give, with

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1 anyone. That includes those near to you and it
 2 includes counsel, it includes family, but you can talk
 3 about anything else you like. I'll see you at 12.
 4 **(11.15 am)**
 5 **(A short break)**
 6 **(11.59 am)**
 7 **MS RICHARDS:** Professor Lee, I was asking you about
 8 arrangements at the Royal Free Centre. The Royal Free
 9 was part of the North East Thames region but also,
 10 I think, to some extent, part also of the
 11 North West Thames region; is that right?
 12 **A.** Yes. This was, of course, prior to us becoming
 13 a trust in 1991, but there were two regions and
 14 patients came from both areas.
 15 **Q.** We know that there were regular meetings of
 16 a haemophilia working party of the North East Thames
 17 region which were attended by Dr Colvin and
 18 Dr Kernoff. What regional transfusion centre or
 19 centres did the Royal Free predominantly deal with in
 20 the eighties?
 21 **A.** The North London.
 22 **Q.** Was that the one in Edgware?
 23 **A.** Yes.
 24 **Q.** Okay.
 25 In your evidence to the Lindsay Tribunal, you

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1 described Dr Kernoff as a real stickler for detail.
 2 Could you just expand upon that?
 3 **A.** He -- well, I suppose he -- everything he did needed
 4 to be recorded. And I suppose it's really underscored
 5 with the fact that one of the very early things he did
 6 at the Royal Free in 1979/80 was that he recruited
 7 a computer person to get a computer that could record
 8 all the treatments that patients had, and the numbers
 9 of the batches of concentrate.
 10 And, you know, to set that in context, nowadays
 11 all of us computers in our hands, mobile phones.
 12 I didn't have a computer on my desk at the Royal Free
 13 until 1994. The idea that there was a computer in
 14 1980 is quite extraordinary.
 15 So that was one area, that he was a stickler for
 16 detail. The other thing which I was on the receiving
 17 end, and we're going to go on to talk about the way we
 18 disseminated the information that we were finding,
 19 I wrote a lot of that, and he would go through it with
 20 a fine-tooth comb, and make sure that the facts were
 21 right, the dates were right, and I suppose that's
 22 stickler for detail, really.
 23 He also -- it's quite extraordinary. I mean,
 24 these days we have clinical governance, everybody
 25 talks about governance. Dr Kernoff, as early,

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1 I think, as 1980, actually set up a management
 2 structure in the Haemophilia Centre and had regular
 3 management meetings of the key individuals who were
 4 leading each section, so the laboratories the nursing,
 5 the medical, the counselling. And I think that was
 6 also kind of reflection of his stickler for detail.
 7 The other thing that I think is also reflects it
 8 is that, you know, these days we can go online and get
 9 any kind of information, through PubMed or anything
 10 like that. In those days it was all paper bound. And
 11 in his office, he had a filing cabinet and he had file
 12 cards, and any publication that he was aware of, or
 13 that was important, it was put on this file card,
 14 and -- so that he had a kind of almost -- a very
 15 primitive kind of PubMed, if you like.
 16 So he was a stickler for detail.
 17 **Q.** Do you happen to know what became of that card file?
 18 **A.** No.
 19 **Q.** If we have up on screen, please, Henry, again the
 20 transcript of Professor Lee's evidence to the
 21 Lindsay Tribunal, LIND0000326.
 22 And if we could go to page 15, please, Henry.
 23 Just picking it up halfway down the page you, were
 24 asked questions -- and I'm going to ask you similar
 25 questions in a few moments, Professor Lee -- about the

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1 treating practice at the Royal Free, starting with
2 1983. And you explained that you were working very
3 closely with Peter Kernoff and you say this:

4 "... I was party to his thoughts. And we used to
5 discuss these things in that period.

6 "But it was his clinical decision ..."

7 And that's correct?

8 **A.** Yes.

9 **Q.** Before we look, then, in a little more detail at the
10 treating practices, just one further question about
11 Dr Kernoff.

12 You've mentioned that he worked in Oxford under
13 Dr Rizza or worked with Dr Rizza. What, if anything,
14 can you tell us about the relationships he had with
15 other reference centre directors, in particular
16 Dr Rizza and Professor Bloom?

17 **A.** Professor who?

18 **Q.** Bloom.

19 **A.** I know particularly about Dr Rizza, I don't know
20 that I know about his relationship with
21 Professor Bloom.

22 And the relationship with Dr Rizza was that -- you
23 know, Oxford was the pioneering centre in the UK for
24 haemophilia, with Rosemary Biggs and MacFarlane, and
25 then the UKHCDO was set up, initially as group of

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1 doctors in the country who knew about haemophilia.
2 Because it's so rare, she had recognised your average
3 GP or even hospital haematologist was unlikely to see
4 a person with haemophilia, and therefore it was
5 important to bring together people who had knowledge
6 in order to be able to know what was the best
7 treatment for people.

8 She was at Oxford with MacFarlane, and then
9 MacFarlane retired, and then she retired, and Dr Rizza
10 came down from Scotland to be the director. And
11 Dr Kernoff, as I understand it, was doing work towards
12 an MD at London -- for London University -- which is
13 where he trained, at the London. And I think initially
14 his topic was to look at why people with haemophilia had
15 haematuria, blood in their urine, but actually he
16 changed, because it became quite a problem, an emerging
17 problem, I suppose, in haemophilia, and that was
18 inhibitors. He did a thesis on inhibitors.

19 And Dr Rizza was his supervisor, and I'm sure that
20 Peter, Dr Kernoff, learnt about haemophilia through
21 Dr Rizza.

22 Oxford at that time was beginning to make
23 concentrates. MacFarlane had realised that if you were
24 going to provide enough blood to make concentrates for
25 the haemophilia population of the UK, which then,

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1 I think, had been -- approximately 500 had been
2 identified, patients, you would need an enormous amount
3 of blood, and therefore they started making concentrates
4 from bovine concentrates, animal concentrates.

5 And in fact, the very first tooth extractions for
6 haemophilia were actually done under bovine concentrate.
7 And, you know, for a patient with haemophilia, your
8 teeth -- if you had a tooth out, it was terrible. And
9 people could bleed to death with that, so this was quite
10 remarkable.

11 One of the problems about that early concentrate,
12 bovine concentrate, is that it developed inhibitors,
13 antibodies. So Peter, Dr Kernoff, had moved in towards
14 trying to look at what are these antibodies about,
15 because of that experience. And Dr Rizza had clearly
16 been the clinical person looking after such patients and
17 involved in the development of these concentrates
18 following on from MacFarlane and Biggs.

19 So I think the relationship was really like an
20 apprentice, really. And, you know, I think in that
21 history document, Dr Rizza describes about sitting by
22 patients' bedsides transfusing cryoprecipitate. So
23 Peter, Dr Kernoff, would have learnt about haemophilia
24 from Rizza.

25 And, you know, clearly, certainly in my own career,

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1 those of my teachers who are still alive, you go on
2 having a respect and a collaboration with them in the
3 sense of maybe asking them for advice or whatever. So
4 I think that explains their relationship.

5 But I do not know the relationship between
6 Professor Bloom and Dr Kernoff.

7 Of course I knew Professor Bloom. Extraordinary
8 physician. And he -- I mean, his contribution to people
9 with bleeding -- inherited bleeding disorders, was that
10 he began to understand about von Willebrand disease.
11 I can remember in my training, and revision for
12 MRC Path, there was still an idea that von Willebrand
13 factor, they didn't -- the idea that it was separate and
14 was significant was ill understood, and it was largely
15 Arthur Bloom who understood that. And he actually came
16 and taught us on that training course in London at that
17 time.

18 But to go back to your first question, I don't know
19 about Dr Kernoff and Professor Bloom.

20 **Q.** I'm going to ask you about the treatment policies at
21 the Royal Free, largely from around 1983 onwards. And
22 similar question to those you were asked at the
23 Lindsay Tribunal, but before we do that, I just wanted
24 to look at one earlier document with you. It
25 pre-dates your time at the Royal Free, Professor Lee.

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1 I just want to go through it with you.
 2 It's BART0000913, please.
 3 You'll see, Professor Lee, this is a letter from
 4 Dr Kernoff to the local Health Authority, Camden and
 5 Islington Health Authority, in June of 1980, and it
 6 gives -- it's a discussion about what are going to be
 7 the purchasing relations in terms of the commercial
 8 concentrate.
 9 So we see the first paragraph refers to:
 10 "... the views of the medical members of the
 11 adjudication panel -- [himself] and Dr Colvin -- on the
 12 tenders submitted for this contract."
 13 Now you've described how, when you became director,
 14 you didn't have a role in contractual relationships or
 15 choice between tenders, and we'll look at that later.
 16 Were you aware of this adjudication panel system?
 17 Was it a system still in operation when you took over as
 18 director?
 19 **A.** I don't know. This was 1980. I wasn't there. I don't
 20 know.
 21 **Q.** By the time you took over as director, was it a panel
 22 that you had to dismantle, or was it something that
 23 you knew nothing about?
 24 **A.** When I became -- I had nothing to do with the
 25 purchasing or the decision about which concentrate to

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1 make -- to have -- until 1991 when I became director.
 2 And when I became director, I -- it was the same time
 3 as the Royal Free became a trust, so there's no more
 4 North East Thames and North West Thames. There was a
 5 completely different -- the Royal Free had to get its
 6 own money in. And from that point onwards, the
 7 purchasing was actually done by the supplies
 8 department. And then it was changed to the chief
 9 pharmacist, but largely, actually very good advice
 10 I had from my husband, that I should never get
 11 involved in negotiations about which pharmaceutical
 12 company, or those kind of negotiations.
 13 There was a manager -- he was the chief scientist --
 14 called Angus McGraw, and he -- eventually, they changed
 15 from supplies to the pharmacist of the hospital, and
 16 together with Angus McGraw, they did all the
 17 negotiating. And the only decision-making, from the
 18 point that I was making the decisions, was that I would
 19 make a decision about which was the right type of
 20 concentrate. So the types of concentrate were: is it
 21 going to be plasma derived? Is it going to be high
 22 purity? Is it -- later is it going to be recombinant?
 23 And that, as far as I was able, was done through what
 24 was the guideline from the UKHCDO at that time. So it
 25 was a type. I didn't have anything to do with the

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1 decision as to which company to go with --
 2 **Q.** If we go back to --
 3 **A.** -- or the prices, which was -- I think I should
 4 just -- I think it's important, if you'll allow me, to
 5 just talk a little bit about what I know from 1991
 6 about buying.
 7 The Royal Free, when it became a trust, was very
 8 clear that managers looked after money, doctors look
 9 after patients, which is probably how it should be.
 10 So the contracts were not in the medical hands. And
 11 other institutions, other hospitals, who weren't
 12 actually trusts yet, but then they became trusts, some
 13 of the directors actually had the ability to choose
 14 which concentrate to have, which company to go with.
 15 And there was a deal of profit that could be made
 16 by the hospital, because the -- there's one particular
 17 trust that I know of that the purchasers would pay
 18 a price for the concentrate, and the director of that
 19 trust -- and I think it would be inappropriate of me
 20 to name names. I'm just explaining the system that
 21 could have gone on. The director of that trust had
 22 negotiated a price A. The purchaser was asked to pay
 23 a price A plus something or other, so that trust or
 24 that hospital made enormous profits out of
 25 haemophilia.

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1 **Q.** There maybe some --
 2 **A.** I have to say that, and that was not the case at the
 3 Royal Free, but the negotiation of contracts was very
 4 difficult because they had to negotiate with GPs
 5 sometimes, or small health authorities.
 6 And there was -- I remember we had a -- this is
 7 moving on a bit, but I think it's relevant. We had
 8 a little boy who sadly had an inhibitor, and the cost
 9 of his recombinant -- they were treated with a thing
 10 called recombinant 7A for inhibitors. I'm moving on
 11 a bit. But the cost of that child's care, which was
 12 totally appropriate and enabled that child to go to
 13 school and to do things which, you know, you hoped all
 14 children with haemophilia would be able to do,
 15 completely wiped out the whole budget of the authority
 16 that he lived in. And in my -- which maybe we're
 17 moving on to, but that was the reason I wrote probably
 18 to the BMJ leader about the economics of haemophilia
 19 care, that a single institution like the Royal Free,
 20 that had a tenth of all the people with inherited
 21 bleeding disorders in the country -- the Royal Free
 22 was having to negotiate these concentrates in order to
 23 get the money in to pay for the concentrate. It was
 24 very, very difficult. And it was a poor management
 25 system that had been brought in by the

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1 purchaser-provider divide that happened in the '90s.
 2 **Q.** I'm going to come on to that, but I'm going to take
 3 you back to the first half of the 1980s,
 4 Professor Lee.
 5 We can see from this letter, and there are plenty
 6 of other examples of it, that Dr Kernoff, in contrast
 7 to what you've described of your own practice, and
 8 Dr Colvin, were actively involved in decisions about
 9 which concentrates to use. But I just want to explore
 10 with you some of the points he makes about the
 11 treatment policies at the trust in this letter.
 12 So we can see in the second paragraph:
 13 "The present buying policy of the Royal Free and
 14 London hospitals" --
 15 **A.** Can you --
 16 **Q.** Yes, it's the second paragraph. It begins "In
 17 essence". We can see that that --
 18 **A.** No, it's not -- is this a letter to Mr Jones?
 19 **Q.** Yes.
 20 **A.** Well, I've only got the first line, is it?
 21 **Q.** Ah. I'm sorry.
 22 **A.** And the number 2:
 23 "We feel rather strongly that the contract should
 24 be shared."
 25 **Q.** Is that the only thing you can see on your screen?

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1 **A.** Yes. I've only got down to that.
 2 **Q.** Ah, I think the other screens have the --
 3 **A.** Okay, now I've got the full --
 4 **SIR BRIAN LANGSTAFF:** Mine doesn't. Mine has exactly what
 5 Professor Lee has.
 6 **MS RICHARDS:** Mine has the whole second half of the
 7 document. Are you able to read it in that form?
 8 **A.** No. It's just -- the letter only has page 1.
 9 **Q.** Yes, we'll start with page 1 and move on.
 10 **SIR BRIAN LANGSTAFF:** I now have the whole.
 11 **MS RICHARDS:** If we pick it up in the second paragraph, we
 12 can see there that the present buy-in policy --
 13 **A.** No, I still haven't got it. It just says:
 14 "We feel rather strongly that the contract should
 15 be shared between two companies" --
 16 **SIR BRIAN LANGSTAFF:** No, I think the second paragraph,
 17 Professor Lee, on the page. It begins "In essence".
 18 **A.** I hadn't got that. It's now come up.
 19 **SIR BRIAN LANGSTAFF:** You may have if you go back -- have
 20 you got the start of the --
 21 **DR LEE:** Oh, I see. Sorry. I was looking at number --
 22 it's got numbers 1 and 2. I'm sorry. "In essence."
 23 Okay, sorry.
 24 **MS RICHARDS:** So we can see there:
 25 "The present buy-in policy at the Royal Free was

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1 described as sharing purchased between Immuno and
 2 Armour."
 3 That's as at 1991. And then if we go back to the
 4 full letter, please, Henry, the next paragraph says:
 5 "We had taken account of several factors other than
 6 the tender prices alone."
 7 So we can see the price was a factor for Dr Kernoff.
 8 But then he says this, and I wanted to ask you about
 9 this:
 10 "There is generally considered to be a medical
 11 hazard in exposing patients to a brand of concentrate
 12 which they have not previously received in that the
 13 likelihood of contracting hepatitis seems to be
 14 increased. Our policy has therefore been to attempt to
 15 maintain individual patients on particular brands."
 16 Now, were you aware, when you joined the Royal Free,
 17 that that was the policy at the Royal Free?
 18 **A.** Yes, that certainly was the policy, and the idea
 19 behind that policy was that maybe you could limit
 20 exposure. And throughout, we always had a policy that
 21 patients were kept on the same batch, the same number
 22 of concentrate, until that batch ran out.
 23 **Q.** And then if we could go on to the third page of the
 24 letter, please, Henry. We can see in the paragraph
 25 that's numbered 6, so towards the top of the page,

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1 Dr Kernoff says this:
 2 "In common with the directors of most other large
 3 Haemophilia Centres in the UK, I have in the past both
 4 sought and accepted financial support for research and
 5 educational purposes from all the companies now making
 6 tenders. We're currently receiving support from Immuno,
 7 who paid the publication costs of the Royal Free
 8 'Haemophilia Centre Handbook' which we're now selling to
 9 augment our research funds. The maintenance of our
 10 academic programme has always depended to some extent on
 11 assistance from commercial companies, and it is my
 12 intention to continue to seek such support and, if funds
 13 are offered, to accept them."
 14 Again, dealing with the period in the first half of
 15 the 1980s, so in terms of your work there -- it would
 16 have been 1983 and 1984 predominantly -- are you aware
 17 what funding was received from pharmaceutical companies
 18 by the centre or by Dr Kernoff in that period?
 19 **A.** No. I think the description in this letter I am sure
 20 is true, but I didn't know the detail of it. This is
 21 1980, isn't it?
 22 **Q.** It is. I'm just seeking to --
 23 **A.** I wasn't there.
 24 **Q.** I understand that, Professor Lee. I'm just seeking to
 25 establish from this what the position was in 1980 --

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1 **A.** I think it's highly likely, and again, I said that
 2 Dr Kernoff was pretty much, as we said, a stickler for
 3 detail, and I'm sure he provided the information which
 4 this document is based.
 5 **Q.** Then if we go to the next paragraph, please, Henry.
 6 Just have the whole of the next paragraph. If we pick
 7 it up about halfway down, he says this:
 8 "I do not view Factor VIII simply as a commodity
 9 which forms part of a general hospital supplies list.
 10 It is an essential human blood component whose use is
 11 accompanied by serious risks to patients and whose
 12 methods of production by commercial companies are the
 13 subject of intense medical, ethical, and political
 14 controversy."
 15 Are those issues about medical, ethical, and
 16 political controversy, are those matters which you and
 17 Dr Kernoff ever discussed?
 18 **A.** I don't know that I specifically discussed with him,
 19 but I can understand from this letter, and I think
 20 what's also happening here, is that we're in
 21 a transition period. The reason that initially the
 22 contracting was done through suppliers, you know, who
 23 did everything from toilet papers to, I don't know,
 24 soap or whatever, was because it was blood, cryo. And
 25 all the blood went -- it was suppliers that did it.

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1 I mean, actually, I don't know when you had to start
 2 paying for blood. I'm sure you had to start paying
 3 for it by the time you became a trust.
 4 But what's happening is that you're transitioning
 5 into a drug, a therapeutic product, from blood. And
 6 I think the managerial and financial implications of
 7 that changed. That's why gradually, and by the time
 8 I got there, it changed from supplies to a pharmacy
 9 because you've got a drug.
 10 So I think what is written in this letter is true,
 11 but what you're asking me is: was I aware of that in
 12 1980? No.
 13 **Q.** Really more, were you aware of it from your
 14 interactions with Dr Kernoff from 1983 onwards when
 15 you were working with him?
 16 **A.** I don't know that we would have had discussions about
 17 purchasing products. It was, as you like, below my
 18 pay grade. I wasn't a consultant; I was a senior
 19 registrar, so I don't think I would have had any
 20 discussions with him.
 21 **SIR BRIAN LANGSTAFF:** I don't think the question is really
 22 about purchasing; it's about the nature of the
 23 commercial product. So the issue, I think, is whether
 24 you may or may not have discussed at any stage with --
 25 **A.** You mean whether it's Immuno or Armour or what --

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1 **SIR BRIAN LANGSTAFF:** Whatever. Just call it "pharma", if
 2 you like. Pharmaceutical. Commercial companies.
 3 **A.** No, I wouldn't have had those discussions in 1983.
 4 **MS RICHARDS:** Did you ever have discussions with
 5 Dr Kernoff, whether in 1983 or later on during the
 6 1980s, about what he talks there of the intense
 7 medical, ethical and political controversy? Methods
 8 of commercial production of concentrates?
 9 **A.** I don't think so. I don't recall anything.
 10 **Q.** When you arrived in 1983 -- I'm just going to ask you
 11 for your assistance on, in broad terms, the treatment
 12 policies --
 13 **A.** Sorry. In broad terms?
 14 **SIR BRIAN LANGSTAFF:** You're moving away from the
 15 microphone.
 16 **MS RICHARDS:** I'm so sorry. My apologies, Professor Lee.
 17 I'm going to ask you in broad terms about the
 18 treatment policies of the Royal Free in 1983/1984. So
 19 the matters that you were able to assist the
 20 Lindsay Tribunal on I'm going to ask you about.
 21 **A.** Could we have that -- the Lindsay Tribunal statement
 22 that I made --
 23 **Q.** Absolutely.
 24 **A.** -- because that was made 20 years ago, and at the time
 25 that I made that, I also had access to information

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1 within the centre, and I -- you know, it's very
 2 difficult for me to recall that now, so I'd be
 3 grateful if you would put up what I said to the
 4 Lindsay Tribunal.
 5 **Q.** Yes. I should say, we don't have the written
 6 statement you provided to the Lindsay Tribunal, but we
 7 do have the transcript of your oral evidence, and we
 8 can have that on screen. It's LIND0000326. If we go
 9 to page 15. I'm not going to ask you at the moment
 10 about specific parts of the transcript, but if we need
 11 to look at it, or you need to look at it to refresh
 12 your memory, we can find any useful sections.
 13 Do you have any recollection of, broadly speaking,
 14 the proportion of patients in 1983 who would have been
 15 on home treatment at the Royal Free Centre?
 16 **A.** No.
 17 **Q.** Do you know whether home treatment at the Royal Free
 18 Centre by '83/'84, was that for adults and children or
 19 just adults?
 20 **A.** Both, I think.
 21 **Q.** Do you know whether it was -- a home treatment was
 22 only used for patients with severe haemophilia A?
 23 **A.** Yes. I know that because it's mostly the practice
 24 still today. You have to train somebody to treat
 25 themselves, and as many people in this room will

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1 attest, it's not easy, and if you're not doing it
2 regularly -- so somebody with mild haemophilia would,
3 you know, maybe not have a bleed or a problem; they'd
4 have it very infrequently. So they would lose their
5 practice. So you trained up the patients, and of
6 course the parents, which was not so easy.

7 So the question you're asking me, whether it was
8 the same for all patients, I think it was the severe
9 patients who were on home treatment.
10 **Q.** And then dealing first with adults with severe
11 haemophilia as a cohort, what products -- I don't mean
12 the specific pharmaceutical companies, unless you can
13 remember those. What products were used for the
14 treatment predominantly of adults with severe
15 haemophilia A? Was it commercial concentrate, or NHS
16 concentrate, or something else?

17 **A.** It's very difficult for me to be precise about this,
18 but the generality of my memory, and I think what's
19 recorded here, we were very fortunate to be able to
20 have all our children on NHS concentrate, and that was
21 really, I suppose, for two reasons. One is they're
22 small, so there was not a supply problem. And the
23 other is that, although at that time there wasn't any
24 evidence that NHS product was to be preferred, we
25 didn't have any evidence that commercial concentrate

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1 transmitted more than NHS concentrate, but many
2 parents had an instinct that they would prefer NHS
3 concentrate for their children. And that was done,
4 and we were able to maintain that.

5 And, you know, in retrospect, it was fortunate,
6 because I think the only child we had to care for with
7 HIV actually acquired his infection, I think, abroad
8 somewhere when he was given commercial concentrate.

9 As far as the adults were concerned, I believe it
10 was a mixture. But again, it's very difficult for me
11 because I -- you know, I didn't make the decisions, and
12 that wasn't my day-to-day work.

13 **Q.** Again, this is territory you largely covered in your
14 Lindsay Tribunal evidence --

15 **A.** Yes.

16 **Q.** -- so that's one of the reasons why I'm asking you.

17 **A.** I would just remind you that at the time I gave the
18 Lindsay Tribunal evidence, I actually was able to have
19 access by telephone to the people within the centre to
20 review the treatment records. And that information
21 was not information that I remembered or information
22 that -- in that time period, or information that had
23 been because of my decision, but I was able to get the
24 evidence from records. And so that's -- I hope I'm
25 not appearing to be difficult, but I would really

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1 prefer for the -- what I said then to be taken as what
2 was happening because, you know, I can't remember
3 after 20 years.

4 **Q.** Yes. You'll appreciate not everyone will have had the
5 opportunity of looking at the Lindsay transcript --

6 **A.** Yeah, sorry.

7 **Q.** -- which is one of the reasons for asking you in this
8 forum.

9 So children, NHS Factor VIII; adults with severe
10 haemophilia, commercial concentrates, or NHS
11 concentrates or both.

12 **A.** Yes.

13 **Q.** In terms of adults with moderate or mild haemophilia
14 -- you said in your Lindsay evidence it was difficult
15 to distinguish between the two, not diagnostically but
16 in terms of your recollection of treatments --

17 **A.** Yes. I think just to clarify that, I mean, severe
18 haemophilia is less -- it's defined as less than 2%,
19 but basically it's nothing, and non-severe haemophilia
20 is above 2%.

21 **Q.** So for adults with non-severe or mild or moderate
22 haemophilia, what was the general approach to
23 treatment for those adults?

24 **A.** I think we're talking about 83, so by then, we did
25 have access to DDAVP, I think.

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1 **Q.** Yes.

2 **A.** Professor Mannucci's paper was published in '77, and
3 I was actually quizzed on it during my MRC Path exams,
4 so -- in the early 80s, so I think we had DDAVP by
5 then.

6 And DDAVP you can give to people who have
7 non-severe Factor VIII deficiency. You can't, of
8 course, use it for anybody with Factor IX deficiency.
9 It acts by raising the Factor VIII. You can also use
10 it for people with von Willebrand's disease, but at
11 that time we hadn't worked out what it was all about,
12 von Willebrand's disease. And some people didn't
13 respond and some people did respond, and it was only
14 later that the different types emerged because we had
15 molecular diagnosis.

16 So DDAVP was beginning to be used where it was
17 possible, but if -- particularly in the context of
18 von Willebrand's disease, I would say, if a patient had
19 an enormous bleed, like, you know, some of the
20 nosebleeds that people had, which are called epistaxis
21 in the papers, it could be torrential. So to use DDAVP
22 was just totally inappropriate. And there were also
23 people who just didn't respond to it.

24 **Q.** So for the patient who is a non-severe haemophiliac,
25 and for whom you've judged that DDAVP would not be

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1 appropriate in those particular circumstances, what
 2 would be the next line treatment in 1983/84?
 3 **A.** Factor VIII.
 4 **Q.** Concentrates?
 5 **A.** Yes.
 6 **Q.** Not cryoprecipitate?
 7 **A.** No.
 8 **Q.** You told the Lindsay Tribunal, and we can look at this
 9 if we go to the next page, we pick it up at out of the
 10 third of the way down, you were asked the question --
 11 this here was about children, but you were asked the
 12 question:
 13 "... were any of your children receiving
 14 cryoprecipitate as distinct from concentrate?"
 15 You said:
 16 "No ... I have carefully checked on that issue, and
 17 the only person with severe Haemophilia A who received
 18 cryoprecipitate during that period was, if you like,
 19 a kind of conscientious objector who didn't want to have
 20 concentrate."
 21 Pausing there, what did you mean by "conscientious
 22 objector"?
 23 **A.** It was somebody who didn't want to have blood
 24 products. I don't think -- is "conscientious
 25 objector" the right word, actually? The parents

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1 didn't want any blood product.
 2 **Q.** You describe it there as a patient who received
 3 cryoprecipitate. So someone who didn't want
 4 concentrates.
 5 **A.** Yeah, I -- quite honestly, I think it's very difficult
 6 for me to remember precisely what that means.
 7 **SIR BRIAN LANGSTAFF:** Let me tell you how I read it.
 8 Somebody who on principle -- I think is the words
 9 I would replace "conscientious objector" by, but on
 10 principle didn't want to have concentrate. It doesn't
 11 say what the principle is but that's the sense of it
 12 that it conveys to me at the moment.
 13 Is that about right, do you think?
 14 **A.** Yes, I really -- I do remember when I was giving the
 15 Lindsay Tribunal evidence actually phoning back to the
 16 Royal Free for them to check, I think probably either
 17 the treatment records, the Oxford returns, you know,
 18 or to find out that fact, because I was being asked
 19 that fact, and that was the information I got at the
 20 time, I think.
 21 **MS RICHARDS:** So that was the use of cryoprecipitate for
 22 a single severe haemophiliac. You were then asked:
 23 "Whether for children or for adults, the choice
 24 was if somebody was a person with mild haemophilia and
 25 who could be treated with DDAVP, that was done [which

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1 is the answer you gave me a few moments ago] if not,
 2 they were treated with concentrate, either NHS or
 3 commercial --"
 4 And you answered "Yes".
 5 Do you know why cryoprecipitate was not used as the
 6 second line treatment for a mild haemophiliacs if DDAVP
 7 was not an option?
 8 **A.** Well, I think I partly have rehearsed the answer to
 9 this question in that the practicalities were very
 10 difficult. But more than that is the issue of
 11 exposure, that to treat a bleed you need ten -- what
 12 are we talking about? We're talking about --
 13 **Q.** Mild haemophilia.
 14 **A.** Mild haemophilia ... no, I think it's more about the
 15 risk of not getting the right level and not having
 16 effective treatment, I think, is probably the
 17 decision-making process here.
 18 And, you know, it relates to the fact that the
 19 Factor VIII in the cryoprecipitate was not known, in
 20 that you couldn't measure it, and it would probably
 21 have had a fall-off by the time you got it into the
 22 person. And also, it may also have been the issue of
 23 the bleed they got, you know. The treatment just
 24 wouldn't be so effective.
 25 But, you know, again, the decision-making process is

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1 Dr Kernoff's. It's very difficult for me to know
 2 exactly how he came to that decision. And I -- I think
 3 it would have been very difficult, in some situations --
 4 in many situations -- to use cryoprecipitate effectively
 5 and to stop the bleeding, and to prevent the problem.
 6 **Q.** Was prophylaxis a feature of treatment at all at the
 7 Royal Free in the first half of the 1980s or was that
 8 something that only came later?
 9 **A.** No, prophylaxis, we started prophylaxis at the
 10 Royal Free in 1994. It depends, in a way, what you
 11 call prophylaxis. You know, regular prophylaxis for
 12 children was begun in 1994, where you gave three
 13 treatments a week to keep the level up to a certain
 14 level, to stop bleeds, but sometimes there was
 15 a certain kind of prophylaxis used if people had
 16 a particularly important day, you know, that was -- in
 17 their life, that they needed cover. I'm trying to
 18 think of an example.
 19 I mean, for example, I suppose if you had a job
 20 interview or something like that. But it wasn't used
 21 widespread in the sense that we now know about
 22 prophylaxis.
 23 **Q.** Haemophilia B was the predominant treatment NHS
 24 Factor IX concentrate?
 25 **A.** Yes. And the reason for that is that it's sixth less

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1 common than haemophilia A, and there was not a supply
2 problem.

3 **Q.** And then you've touched on this already, but
4 von Willebrand's disease, what was the predominant
5 mode of treatment in 1983/84?

6 **A.** Well, it depended what the bleed was, but if it was
7 a severe bleed it would be concentrate. And you'd try
8 and use DDAVP if you felt that that was going to be
9 effective.

10 **Q.** Just look at the 1983 returns for the Royal Free which
11 would have been completed by Dr Kernoff and/or
12 Dr Tuddenham.

13 Henry, it's HCDO0000184_006, first of all, please.

14 We can see here it's the annual return for 1983,
15 the directors are identified as Drs Kernoff and
16 Tuddenham. Total number of haemophilia A patients
17 treated during the year, 128; carriers of haemophilia
18 A treated during the year, 4; total number of
19 von Willebrand's disease patients treated during the
20 year, 24.

21 Then if we look for the haemophilia A patients, we
22 can see for hospital treatment, there's an amount
23 1,443 bags of cryoprecipitate which someone has
24 translated into units.

25 Then we can see NHS Factor VIII concentrate at

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1 193,965 units for the hospital treatment.

2 And then the total use for home treatment that's
3 given there, would that have been predominantly
4 children, in all likelihood?

5 **A.** No, I don't think it would necessarily be all used for
6 children. That seems quite a lot. I think there
7 would have been adults who were on home treatment with
8 NHS, not necessarily all of them. I don't know.

9 **Q.** Then we can see the figures for use of commercial
10 products, so in that year, Factorate, Koate, Hemofil
11 and Kryobulin were all used, and the concentrate used
12 most was Factorate, just over a million units of
13 hospital treatment and 1.2 million for home treatment.
14 And then Koate, 1.2 million for home treatment.

15 If we go further down that, we can see "Porcine
16 Factor VIII". I'll ask you a little more about
17 porcine later, but what, at that time, was porcine
18 Factor VIII predominantly used for?

19 **A.** Inhibitor treatment. And it's important, I talked
20 a bit about -- or do you want to leave this for later,
21 about porcine?

22 **Q.** We'll come back later to porcine and one of the papers
23 you wrote about it later, if we may, Professor Lee.

24 Then we can see reference to some other products,
25 including DDAVP.

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1 And then von Willebrand's disease we can see
2 cryoprecipitate was still being used for
3 von Willebrand's disease, it would appear, in
4 hospital, and then smaller amounts of NHS treatment
5 used, hospital and home.

6 If we can then go to HCDO0000184_051, please.

7 I won't go through the details of the inhibitor
8 treatments, Professor Lee, but we'll just look at
9 haemophilia B.

10 So this is the annual return for 1983 in relation to
11 haemophilia B treatment. Thirty-one patients treated
12 throughout the year, one carrier treated, and we can see
13 there that the bulk of the material used there is
14 NHS Factor IX concentrate.

15 Are you aware of 1983 representing any particular
16 change in approach to treatment or, as far as you know,
17 was this broadly consistent with what had been the
18 treating practices at the Royal Free?

19 **A.** No, I -- you know, I just say again that I was
20 a senior registrar in the department. These decisions
21 and what was going on with the treatment was managed
22 by the directors. So I think what is here is here,
23 and I'm sure it's true.

24 **Q.** If we just look at WITN0644070, please, Henry.

25 This is a document from much later, it's

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1 a 1995 document that you prepared.

2 If you could just go to page 20, which is the last
3 page of this document, please.

4 You provide there a table showing "Clotting factor
5 concentrate obtained 'free' in the context of
6 therapeutic trials", and that gives figures from 1988
7 onwards to 1995, which was the date of the document,
8 with a total value attributed to it of £1,572,000.

9 Do you know what the position was at all pre-1988?
10 Were clotting factor concentrates provided free to the
11 Royal Free for therapeutic trials?

12 **A.** No, this is -- covers the time period that I was in
13 charge. I was a consultant. I became a consultant
14 in 1987. So prior to that, I didn't -- I don't know
15 what was obtained.

16 **Q.** Do you know at all -- and again, I'm asking you now,
17 again, about 1983/84, what the arrangements were at
18 all for obtaining NHS concentrates?

19 **A.** No.

20 **Q.** You don't? You don't know whether that was from the
21 Regional Transfusion Centre or directly from BPL?

22 **A.** No, I don't know.

23 **Q.** You've alluded to the fact that there were possibly
24 supply issues in relation to NHS concentrate because
25 you focused the supplies you had on children and then

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1 some for adults. Do you recall any more detail about
 2 what those supply issues were? Was it something you
 3 discussed with Dr Kernoff or he discussed with you?
 4 **A.** No. I do have memory that he tried to save up
 5 concentrate if he knew somebody had got to have an
 6 operation. That's the vague memory I have.
 7 **Q.** NHS concentrate?
 8 **A.** I don't know which particular one it was. I just know
 9 that he would do that, because I think there was
 10 a supply problem in general sometimes. But I think
 11 it's probably not appropriate that I make statements
 12 about this period because I would say again that I
 13 wasn't responsible for making any of these decisions,
 14 I wasn't looking after the patients that needed to
 15 have an operation. It wasn't my job, you know. So
 16 I think what we have to do is rely upon what's in the
 17 returns and things --
 18 **Q.** And your evidence to the Lindsay Tribunal, which
 19 you've said --
 20 **A.** -- yes, yes -- (overspeaking) -- what is said in the
 21 Lindsay Tribunal, which, as I say, I said it 20 years
 22 ago, at the time that I said that, I cross checked
 23 with people who were then alive, like the chief nurse
 24 in the unit, who -- and she -- I phoned up and
 25 cross-referenced, and she checked out things. But

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1 I think it's very difficult for me now to give
 2 reliable information about that period. I'm quite
 3 happy to give you the detail for when I was in charge,
 4 in 1991, and how it was done. But I think it's
 5 unfair, it's probably unfair for Dr Peter Kernoff, to
 6 say why the decisions were making what he was doing,
 7 you know, because I don't know.
 8 **Q.** Professor Lee, to make it clear, I'm not asking you to
 9 speculate.
 10 **A.** Yes, well, that's why -- I don't want to speculate.
 11 **Q.** The reason I'm asking these questions is because you
 12 told the Lindsay Tribunal that these were matters that
 13 you discussed, that you were to some extent privy to
 14 Dr Kernoff's thinking, and you did give evidence to
 15 the Lindsay Tribunal about what the treatment policies
 16 were, in broad terms, in 1983 and 1984.
 17 **A.** Yes, but what I would also say is that we are now in
 18 2020, so this was 20 years ago. And I think the
 19 information that I provided for the Lindsay Tribunal
 20 at that time was what I remembered 20 years ago from
 21 17 years before that. We're now 37 years, and I'm
 22 sorry, I think that what I said in the
 23 Lindsay Tribunal was as true as I knew at that time,
 24 and from my standpoint now, I stand by what I said.
 25 But I don't think it's fair for me to speculate, in

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1 a way, because trying to remember back 37 years, when
 2 I've been retired 15, is quite difficult for me. But
 3 what I said to the Lindsay Tribunal was true at that
 4 time.
 5 **SIR BRIAN LANGSTAFF:** Not only at that time, so far as you
 6 know, you've just said that you think it's -- that you
 7 have no reason to think that anything said there was
 8 inaccurate?
 9 **A.** No.
 10 **SIR BRIAN LANGSTAFF:** Thank you.
 11 **MS RICHARDS:** You've said Dr Kernoff was a stickler for
 12 detail and for records. What, if any, policy or
 13 practice was in operation at the Royal Free during the
 14 1980s for recording what particular products patients
 15 received and what particular batches patients
 16 received?
 17 **A.** This is the 1990s?
 18 **Q.** 1980s. You returned as a --
 19 **A.** 1980s, okay. Well, I have explained to you that there
 20 were the beginnings of a computer in '79/'80, but
 21 every patient had a treatment record which was in
 22 addition to the medical record, and all the notes and
 23 all the treatment records were all kept in the
 24 Haemophilia Centre. And in those treatment records,
 25 which the patients had at home, and we had access to

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1 them in the centre, they had to record the date, the
 2 type of bleed, the number on the concentrate bottle,
 3 and how much used.
 4 They had those forms at home. Initially, they would
 5 post them back, and within the centre, they were filed
 6 in this treatment file. And of course, if we were
 7 administering treatment in the centre, because sometimes
 8 a patient might come up with a problem and they needed
 9 treatment in the centre, we would record in those
 10 treatment files. And gradually, from 1980 onwards, that
 11 treatment was put on a -- on the computer, which was a
 12 pretty primitive computer to start off with.
 13 And you showed us the records that were sent to
 14 Oxford. We called them the Oxford returns. And there
 15 are a large number of patients we looked after and
 16 a large amount of treatments. So that detail eventually
 17 was -- we were able to put the numbers down because we
 18 had a computer. But it was still there in the records,
 19 and the data manager within the centre,
 20 Francoise Kendall, one of her big jobs was to go through
 21 these records and, you know, add it all up.
 22 Gradually, we were able to appoint additional people
 23 in the centre. I think we had two people eventually.
 24 We had a -- we were so lucky because we -- the patients
 25 were so lucky. We had a big cold room where all the

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1 concentrate was kept, and eventually we had a good stock
2 control, so there was a record of what's here, what
3 numbers are here, what's gone. So I think that answers
4 your question, does it?

5 **Q.** Yes. The treatment records from the 1980s that you've
6 described --

7 **A.** Yes.

8 **Q.** -- so the physical treatment records, and leaving
9 aside whatever there might have been transposed to the
10 computer --

11 **A.** Yes, yes.

12 **Q.** -- were they part of the patient's medical records, or
13 were they kept separate?

14 **A.** No. They were -- the medical record was, you know,
15 like we all remember medical records, was a big file.
16 And then there was a separate folder which had these
17 sheets of paper in. And within the centre, initially
18 when I went there in '83, when there were less
19 patients, we actually had a whole bank of filing
20 cabinets, alphabetical filing cabinets, where these
21 records were kept together.

22 When we were able to have the new extension opened
23 in 1994 by the Duchess of Kent -- and, in fact, just to
24 add in, that was the last decision Peter was able to get
25 out of the Trust before he was ill. It wasn't a Trust

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1 then, but the hospital was to go forward with this
2 extension. We were able to put in that extension, a
3 huge area -- it was about the size of this platform
4 here -- where the notes were put in filing cabinets,
5 hanging in filing cabinets, but the notes were with the
6 treatment folder. So if you saw a patient, anybody saw
7 a patient within the centre, they had those notes.

8 **Q.** And when you retired in 2005, did those hard copy
9 treatment recordings still exist?

10 **A.** Yes, I think -- it's a tragedy, actually. Those
11 treatment records enabled us to have an enormous
12 information about haemophilia, which wasn't just so
13 that you would get publications; it was so that you
14 could inform your care and understand what was
15 happening. It was there on paper. Sadly, I think
16 the -- certainly, the hospital record has now been
17 computerised because I know my rule nine request,
18 we've had to, you know, get them. I don't know what's
19 happened to the treatment records. And I tell you, it
20 is a real tragedy. I mean, maybe they've been
21 digitised. I don't know.

22 **Q.** Well, we can no doubt ask that question of the
23 Royal Free.

24 Sir, I'm about to move on to a topic that won't be
25 capable of being resolved within the next two to three

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1 minutes, so shall we break for lunch now?

2 **SIR BRIAN LANGSTAFF:** Yes, let's break for lunch until
3 two o'clock. So an hour for lunch. Back at
4 two o'clock. The same rules apply as they do at any
5 break.

6 **(12.59 pm)**

7 **(Luncheon Adjournment)**

8 **(1.58 pm)**

9 **Q.** Professor Lee, I'm going to ask you about the
10 developing knowledge of risk of non-A non-B hepatitis
11 as the next topic.

12 First of all, as part of your general medical
13 training and then your haematology training, what do
14 you recall you learnt about the risks of viral
15 transmission from blood and blood products?

16 **A.** Sorry, the risk of?

17 **Q.** The risks of transmission of virus through blood and
18 blood products, to what extent did that feature in
19 your medical training?

20 **A.** Well, going back to when I was a house officer --
21 sorry, a medical student at the Radcliffe, at Oxford,
22 Professor Paul Beeson was the Professor of Medicine.
23 And I remember very distinctly going on ward rounds,
24 almost the first ward round we went with him as
25 a student, he would -- he asked us what the risks of

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1 blood transfusion are. And we very quickly learnt to
2 say hepatitis.

3 And of course the reason he focused on that was
4 because he was -- I said earlier, he was the man who
5 in 1943, as probably a very junior doctor, had noticed
6 that seven patients he wrote up who had become
7 jaundiced, there seemed to be a common feature that it
8 was due to transfusion.

9 And he was the person at the end of that report that
10 said that it was very important that doctors recognised
11 this problem, and recorded details of what they'd had
12 transfused. I think scientifically speaking, looking at
13 it, you could argue, you know, maybe it was hep B. But
14 it was probably more likely that it was non-A non-B
15 hepatitis. And of course, you know, there were no
16 tests, at that time. I suppose that was my first
17 knowledge.

18 Then, of course, the Australia antigen, as it was
19 called, was identified in 1965, and I remember this was
20 the measure of hepatitis B, it was called
21 Australia antigen because it was first identified in
22 Aboriginal people. I can remember as a medical student,
23 we had -- he's died now -- we had a professor -- no, he
24 wasn't a professor, he was
25 a gastroenterologist/hepatologist, Ralph Wright, and

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1 I can remember going with a bottle to get a patient's
2 blood who had come in, when I was a house physician, for
3 access to this Australian antigen which he had in his
4 laboratory.

5 I think my knowledge -- I think, if I remember
6 rightly, and maybe I don't need to remember the details
7 of this, and we can refer to it, but the test for
8 hepatitis B came in 1973, so by the time I did my blood
9 transfusion training, which is 1979, I think I would
10 have certainly been aware of hepatitis B. But of course
11 by then, we had a blood test for it, so ...

12 In terms of -- of course I knew about hepatitis A,
13 because it's orally -- you know, it's a problem not
14 necessarily from blood transfusion, although later it
15 transpired that one of the concentrates transmitted it.
16 I think non-A non-B hepatitis, to be perfectly honest,
17 I don't think I was particularly aware of it until I was
18 aware of this research post. I think that's probably
19 true.

20 **Q.** I'm going to ask you in a moment to look at a small
21 number of papers from the 1970s.

22 **A.** Yes.

23 **Q.** You may not have seen them at the time but they're
24 a set of articles that we've asked other clinical
25 witnesses to look at so far.

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1 **A.** Yes.

2 **Q.** Before I do that, generally speaking, in the 1970s and
3 1980s, what journals or periodicals, magazines, would
4 you read in order to keep yourself up to date with
5 medical developments?

6 **A.** I think for the most part, in that time, I would more
7 read textbooks. You know, there was a particular
8 volume for haematology called Postgraduate Haematology
9 that was the sort of bible, if you like, for MRC Path.

10 In terms of journals, I mean, we -- my husband and
11 I -- had a life subscription to New England Journal, so
12 that would have been in the house. British Medical
13 Journal was also in the house, I would that have read.
14 Lancet also. We took Lancet at home, I think. And in
15 terms of other relevant journals for haematology, I
16 would have read the British Journal of Haematology.
17 That would have been in the library at St George's
18 Hospital.

19 Again, I think what's really changed so much over
20 this time is the -- you had to go to paper journals.
21 I mean, now you go straight into the Internet and can
22 find anything. And the other thing, I suppose, is
23 really the delay in publication. So sometimes you would
24 rely on hearing things at meetings, and sometimes there
25 would be departmental meetings, but it wasn't really

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1 very focused, really. When I did blood transfusion
2 I think hepatitis B I would have really known about, and
3 hepatitis A to a certain extent, but that was it.

4 I think the other thing to say just about blood
5 transfusion, when we did our training in blood
6 transfusion a lot of it was on the basis of looking --
7 doing the laboratory things of looking at antibodies and
8 antigens. You know, you had to identify whether
9 somebody had an antibody to a certain blood antigen, so
10 it was quite complicated and we spent a lot of time
11 doing that. So, I think --

12 **Q.** Okay.

13 You've already indicated, I think in the responses
14 you gave this morning and just now, that it had
15 generally been known, certainly from the 1940s
16 onwards, that hepatitis was a major risk of blood
17 transfusion. I'm going to ask you to look at -- it's
18 four or five short articles.

19 If we could first of all, please, have, Henry,
20 PRSE0001431.

21 I'm going to show these to you or extracts from
22 them, they're all fairly short, Professor Lee, then
23 ask you some questions about them.

24 The first is a Lancet article from August of 1974,
25 it's:

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1 "Long-incubation post-transfusion hepatitis
2 without serological evidence of exposure to
3 hepatitis B virus."

4 There are just two passages, I think that will
5 suffice for current purposes.

6 The summary explains that:

7 "An agent other than hepatitis B virus seems to be
8 the cause of 36 (71%) of 51 cases of post-transfusion
9 hepatitis identified during prospective biweekly
10 serological follow-up of 204 cardiovascular-surgery
11 patients. The sera of the 36 cases showed no evidence
12 of the antigen or antibody response expected to
13 accompany response by HB virus and to be detectable by
14 the assays used. Incubation periods and clinical and
15 epidemiological features were inconsistent with
16 hepatitis A. Cytomegalovirus-associated seroconversion
17 was no more common among the HB-negative cases than
18 amongst HB-positive cases or amongst patients who did
19 not develop hepatitis. The data suggest that a large
20 proportion of long-incubation post-transfusion hepatitis
21 is unrelated to hepatitis B and that control of
22 post-transfusion hepatitis will require identification
23 of a hepatitis virus(es) type C."

24 Then if we go to the last page, please, Henry,
25 left-hand column, towards the top of the page, the first

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1 main paragraph beginning, "The fact that":
 2 "The fact that non-B hepatitis cases are less
 3 frequently associated with serious acute illness does
 4 not imply that such cases are of lesser importance.
 5 Long-term complications of acute hepatitis B infection,
 6 such as chronic hepatitis, cirrhosis, and hepatoma, have
 7 been reported to follow mild anicteric infections more
 8 frequently than severe icteric cases; consideration must
 9 thus also be given to the possibility that
 10 non-B hepatitis may play a role in the aetiology of some
 11 forms of chronic liver disease."

12 Pausing there, Professor Lee, first of all, I'm not
 13 expecting you necessarily to remember if you read this
 14 at the time, but would you have been reading the Lancet
 15 at the time? Is this the kind of material you're likely
 16 to have come across in 1974?

17 **A.** I think no is the answer, because I was just reviewing
 18 my CV and trying to -- in 1972 to '73, I was
 19 a research registrar in renal medicine to now Sir
 20 Keith Peters, and then, for domestic reasons, really,
 21 I left that post, I had an MRC training fellowship but
 22 I left that post-to work as a general practitioner,
 23 because I thought that would fit in with my domestic
 24 responsibilities.

25 I think it's very important -- and this is in the

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1 College of Physicians recordings that I made, which
 2 were essentially to look at how women went into
 3 medicine in that period, early sixties, early
 4 seventies. There was no opportunity, really, to have
 5 children in creches or nurseries and things, and so my
 6 husband and I felt that it might be a better career
 7 path for me. And I actually trained in general
 8 practice for a year, until September 1974. And then
 9 I realised that general practice wasn't for me. I'm
 10 very privileged to have had that experience because
 11 I think it helped me understand people and patients
 12 and other concerns. I went back into my first love,
 13 really, which was haematology, because before I went
 14 to university, I'd worked for eight months in the
 15 post-graduate medical school in the haematology
 16 laboratory.

17 So I went into haematology, and that was when
 18 I started at Harrow Road, so St Mary's Hospital,
 19 Harrow Road, with Dr Jack Fielding. And that was
 20 a district general hospital, September 1974. I don't
 21 think we had any patients with haemophilia. And
 22 I certainly would not have been aware of that article
 23 then. But I know the article and I probably, I think,
 24 became aware of it when I took up the research post
 25 in 1983.

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1 I think it's also important to -- for me to remember
 2 and to let people know what the knowledge was and --
 3 around about that time.

4 I was a Senior Registrar, part-time Senior Registrar
 5 at St George's, and then I said I'm going to take this
 6 post to look at non-A non-B hepatitis. And amongst my
 7 colleagues, there was almost a universal thing: what is
 8 that? Why are you doing that?

9 So, to answer your question, I probably became first
 10 aware of this paper when I took up the research, because
 11 it's a very significant paper, but up until then,
 12 I would not have seen it, and probably very few of my
 13 colleagues would have been aware of it.

14 **Q.** Well, I understand the basis for the first part of
 15 your answer, Professor Lee, that you wouldn't have
 16 seen it at the time. What's the basis for your
 17 suggestion that your colleagues, in haematology, would
 18 not have seen it at the time?

19 **A.** The basis is my personal memory of when I said I was
 20 leaving to go and do this research. So I'm talking
 21 about the group of doctors that I worked with --

22 **Q.** At St George's?

23 **A.** -- at a very significant department of haematology,
 24 headed by somebody who worked -- who specialised in
 25 haemostasis.

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1 **Q.** You rightly said that this was a significant piece of
 2 work, something which you realised later. It's
 3 significant because it's one of the first articles
 4 which identifies the existence of what then, over the
 5 next few years, became referred to as non-A non-B
 6 hepatitis, isn't it? So that's its key significance:
 7 that this is the emergence of non-A non-B hepatitis,
 8 and an understanding that there was some other form of
 9 post-transfusion hepatitis. Would you agree?

10 **A.** Yes.

11 **Q.** And the second part of its significance is that
 12 observational warning on the last page, that -- I'm
 13 going to paraphrase and put it in perhaps more
 14 colloquial terms: that clinicians shouldn't assume
 15 that non-A non-B hepatitis is going to be something
 16 mild or insignificant. Would you agree?

17 **A.** Well, I agree what's written there, yes.

18 **Q.** If we could then have up on screen, please, Henry,
 19 PRSE0001794.

20 This is an article by Craske, Dilling and Stern in
 21 August of 1975 in The Lancet:

22 "An outbreak of hepatitis associated with
 23 intravenous injection of Factor VIII concentrate."

24 We can just, again, look at two passages. I think
 25 this is one, again, that you're familiar with,

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1 Professor Lee.
 2 So the summary tells us there was:
 3 "An outbreak of jaundice associated with three out
 4 of four batches of a commercial brand of freeze-dried
 5 Factor VIII concentrate ... at the Bournemouth
 6 Haemophilia Centre between April and June, 1974. Seven
 7 cases of non-B hepatitis and four of hepatitis B
 8 occurred within 6 months of the first use of this
 9 product. Two patients contracted both types of
 10 hepatitis ... nine ... became ill out of a total of
 11 twenty regularly seen at the centre, eighteen of whom
 12 received commercial Factor VIII concentrate."
 13 So here we have a report of non-B hepatitis in
 14 haemophiliacs published in The Lancet.
 15 And if we go on, please, Henry to page 3, and look
 16 towards -- in the left-hand column, second half of the
 17 page, towards the bottom of the page, please, Henry, the
 18 paragraphs numbered (1), (2) and (3), we can see that
 19 Dr Craske and his colleagues say this:
 20 "In the meantime, some or all of the following
 21 measures might help to lessen the frequency of jaundice.
 22 "(1) Commercial Factor VIII concentrates should be
 23 reserved for the treatment of life-threatening bleeds in
 24 all haemophiliacs and for covering major operations."
 25 And then it goes on to make two other observations.

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1 Is this is an article that you think came to your
 2 attention at the time?
 3 **A.** In 1975, I think, did you -- wasn't it?
 4 **Q.** Yes, it's August of 1975.
 5 **A.** In 1975 I was working for Jack Fielding, I think, and
 6 I was also pregnant with our first son, and I don't
 7 think I would have been aware of this article then.
 8 I certainly, of course, became aware of it as soon as
 9 I started looking at this problem, and again, I would
 10 remind you, in 1975, I think that was when
 11 Katharine Dormandy was in charge of haemophilia.
 12 **Q.** Yes.
 13 **A.** And of course, if you read -- subsequently I read her
 14 articles, and it was quite clear that she must have
 15 been aware of that and she must also -- because she
 16 wrote that paper where she compared the rate of
 17 transaminitis in her patients treated with
 18 cryoprecipitate, and the American, but I don't --
 19 I certainly wasn't aware of this paper in 1975.
 20 **Q.** I absolutely understand that, Professor Lee. I'm
 21 trying to explore these papers to some extent
 22 generally with you but drawing on the fact that you
 23 consequently specialised in haemophilia. Would you
 24 agree that this is a report that ought to have been
 25 given serious consideration by those caring for

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1 patients with bleeding disorders in 1975?
 2 **A.** I don't know, really, I don't think I can comment --
 3 I think what it says I agree with.
 4 The question you're asking me is if everybody caring
 5 for people with bleeding disorders would have known
 6 this. I don't know. You know, I wasn't involved in
 7 that at that time.
 8 **Q.** Yes. My question is not whether they would have known
 9 it as a matter of fact, because obviously you can't
 10 speak to that, but whether you would accept that they
 11 should have known it. This was a significant
 12 publication in terms of haemophilia and non-A non-B
 13 hepatitis.
 14 **A.** I think that's probably right. But, you know, I think
 15 it's very difficult for me to comment on those people
 16 at that time because, you know, knowledge moves, and I
 17 don't know how long -- I mean, this kind of
 18 information might have been presented at meetings. I
 19 don't know. I wasn't -- you know, I wasn't at those
 20 meetings.
 21 **Q.** No, and we have access to meetings such as those of
 22 UKHCDO.
 23 Do you recall whether -- later, once this became an
 24 issue that you were going to be researching with
 25 Dr Kernoff, do you recall ever discussing with him the

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1 recommendation that we see here from Dr Craske and
 2 others that commercial Factor VIII concentrate should be
 3 reserved for the treatment of life-threatening bleeds
 4 and for covering major operations?
 5 **A.** I don't remember specifically discussing it with him
 6 because, as I said, you know, my responsibilities were
 7 not in deciding what should happen; it was trying to
 8 find out what was happening at that time.
 9 **Q.** If we could then have, please, PRSE0000381. This is
 10 a publication in the Yale Journal of Biology and
 11 Medicine in 1976 by Purcell, Alter and Dienstag. If
 12 we just have, please, Henry -- to page 246. So it's
 13 the fourth page.
 14 There's just one passage I wanted to invite your
 15 attention to, Professor Lee. And we see, by this time,
 16 the terminology of non-A non-B hepatitis is being used.
 17 Third paragraph down:
 18 "Although type non-A non-B hepatitis is associated
 19 with less severe acute illness than type B disease, the
 20 long-term prognosis for the two diseases may be
 21 similar."
 22 And then the passage goes on to discuss transaminase
 23 elevations. I just invite you perhaps to read that to
 24 yourself, Professor Lee, and then I'm going to pick it
 25 up in the last sentence of that paragraph:

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1 "Chronic non-A non-B hepatitis is not necessarily
 2 a benign infection and may be the cause of a significant
 3 proportion of chronic hepatitis" --
 4 **A.** I haven't got there.
 5 **Q.** I'm so sorry, I'm going too fast.
 6 So that others can follow, I'll read the whole
 7 passage:
 8 "Thus elevation of transaminase values persisting
 9 for six or more months has been observed more frequently
 10 following non-A, non-B hepatitis than following type B
 11 hepatitis. Others have reported similar results.
 12 Transaminase elevations have been documented for several
 13 years in some patients. Three such patients at the NIH
 14 underwent liver biopsy. Two had histopathologic changes
 15 in the liver compatible with chronic active hepatitis,
 16 and the other was diagnosed as having chronic persistent
 17 hepatitis. Thus, chronic non-A non-B hepatitis is not
 18 necessarily a benign infection and may be the cause of
 19 a significant proportion of chronic hepatitis not
 20 identifiable as type B disease."
 21 This a publication 1976. I'm afraid I don't know
 22 the month without --
 23 **SIR BRIAN LANGSTAFF:** It's a bit of a publication in
 24 February.
 25 **MS RICHARDS:** Yes.

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1 **SIR BRIAN LANGSTAFF:** And that's the best we can do.
 2 **MS RICHARDS:** I'm sure we can find the precise date, but
 3 in any event, it's published in the Yale Journal of
 4 Biology and Medicine. 1976, I think, was the year you
 5 moved to St George's. You've described the broad
 6 nature of the work you undertook there.
 7 Do you think you would have come across this article
 8 at the time?
 9 **A.** 1976 is a very significant time in my life because our
 10 elder son was born on [redacted] 1976, and I was on
 11 maternity leave, and I spent the time trying to
 12 negotiate a part-time post. I had no job, and in
 13 those days it was quite difficult if you wanted to
 14 have a part-time post. And I think I eventually
 15 started at St George's Hospital on October 14, 1976.
 16 So I certainly was not aware of this paper then, but
 17 I did become aware of it, of course, because it's a
 18 very significant paper and, you know, I knew
 19 Harvey Alter, eventually, and I think this last
 20 sentence is very important. It says, you know:
 21 "Thus, chronic non-A non-B hepatitis is not
 22 necessarily a benign infection and may be the cause of
 23 a significant proportion of chronic hepatitis not
 24 identifiable as type B disease."
 25 The significant word is "may". May. And the whole

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1 point of studying this -- there was no test -- was to
 2 find out more about it. I mean, the whole -- all people
 3 at that time, and this was knowledge that I would have,
 4 you know, become aware of as I started doing the --
 5 putting the data together. People were aware of these
 6 transaminitises. There was an idea that it might be
 7 some kind of metallic thing in the concentrates. But
 8 they were aware of the transaminitis, but the knowledge
 9 of what was going to happen was just not there. Indeed,
 10 even the acute infection, until we published our very
 11 detailed follow-up, the -- what happened when you have
 12 an infection was not so clearly defined.
 13 You know, a lot of people who have their first
 14 attack, it was asymptomatic, and as I think I said
 15 earlier, the only way, at the time that we were doing
 16 this, to prove as best you could that somebody had had
 17 it was to do sequential transaminases. And to have
 18 a baseline, you needed to know what the level was before
 19 somebody had the treatment. And, of course, we didn't
 20 know the long-term consequences really until -- I would
 21 suggest the knowledge didn't really become defined as to
 22 long-term consequences until the 1990s. And perhaps our
 23 long-term study in 2000 actually was very significant
 24 because what it showed was that for people who didn't
 25 have HIV co-infection, the progression rate was very

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1 slow.
 2 So I hope that answers your question.
 3 **Q.** Yes. Would you agree that, whilst you're right to
 4 point out the use of "may" and to observe that there
 5 was still much that was unknown --
 6 **A.** Yes.
 7 **Q.** Would you agree that, again, for clinicians practising
 8 in the field by 1976, this, from a very authoritative
 9 source, should have been, at the very least, a warning
 10 against any assumption that non-A non-B hepatitis was
 11 somehow mild or insignificant?
 12 **A.** No.
 13 **Q.** Why?
 14 **A.** Because I don't think they would have read this
 15 journal. Sorry, this is the Lancet one?
 16 **Q.** No. This is the Yale Journal of Biology and Medicine.
 17 **A.** Yes. I mean, I doubt whether anybody in this country
 18 reads the Yale journal. I don't think they would have
 19 been aware of this.
 20 **Q.** How would important research such as this from the
 21 States have been disseminated in the United Kingdom,
 22 then, in the late 1970s?
 23 **A.** I would think that somebody like Dame Sheila Sherlock
 24 would have probably attended the American association
 25 meetings of hepatology. That's probably how it would

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1 have got disseminated. But I don't think this would
 2 necessarily have been disseminated amongst haemophilia
 3 physicians, this particular paper.
 4 **Q.** Let's look at one more from Harvey Alter which is now
 5 the following year, 1977. Henry, this is NHBT0000092_
 6 002, please. This is headed "International forum".
 7 It's published in Vox Sang 32 in 1977, and it appears
 8 to be an address by Harvey Alter. I'm just going to
 9 ask you to go to the end of it, to the second page,
 10 please, Henry. Last paragraph of the paper, so the
 11 bottom right-hand column:

"Although non-A non-B hepatitis is, on the average,
 12 less acutely severe than type B hepatitis, it can cause
 13 severe acute disease, and, more disturbing, it appears
 14 to have considerable propensity to progress to chronic
 15 hepatitis."

16 Then he says:

"The main thrust of post-transfusion hepatitis
 17 research must now be directed at developing detection
 18 methods for the non-A, non-B agent or developing some
 19 reliable method of viral inactivation or removal which
 20 would be independent of testing."
 21

22 Were you familiar, first of all, with this journal?

23 **A.** Sorry, what was the journal?

24 **Q.** If you go to the first page, it's Vox Sang.

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1 **A.** No, I didn't read Vox Sang.
 2 **Q.** Would you expect haematologists to be broadly familiar
 3 with research or --
 4 **A.** In 1977?
 5 **Q.** -- advice of this kind?
 6 **A.** I doubt whether -- not every haematologist would have
 7 read Vox Sang. I think it might be quite helpful, if
 8 I am allowed, for us to -- am I allowed to do this --
 9 to help answer these questions about what people were
 10 thinking and what they knew around this time because,
 11 you know, it was 1977. I wasn't moving in these
 12 circles.
 13 **Q.** No, but I'm very keen to keep this chronological,
 14 Professor Lee --
 15 **A.** Yes, but can I --
 16 **Q.** Materials from the 1970s, absolutely.
 17 **A.** I just -- you've had this article, and I just feel
 18 it's important for people to get a feel for what
 19 people knew and didn't know. Haematologists, I'm
 20 talking about, and haemophilia physicians. In fact,
 21 the most -- the person who has contributed the most to
 22 haemophilia care in the whole world, I would say, and
 23 that's Professor Pierre Mannucci, who is now 80. And
 24 you have this.
 25 **Q.** Yes. What's the reference, please?

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1 **A.** The reference is witness 755071, and --
 2 **Q.** So that reference -- could you give me the title
 3 of it?
 4 **A.** It's "AIDS, hepatitis and haemophilia in the 1980s:
 5 memoirs from an insider".
 6 **Q.** If you give me a moment, Professor, I. Know we have
 7 it, but it's not necessarily --
 8 **A.** I may be able to give you a different reference
 9 that is -- your references are all different.
 10 **Q.** It's WITN0644071, please, Henry.
 11 **A.** This is wonderful. Thank you very much.

To answer your question, really, you were asking
 12 about what would you expect people to know? And
 13 I think what Mannucci's writing here really
 14 encompasses it, really, that through the 1970s it was
 15 recognised that the use of concentrates -- coagulation
 16 factors made from plasma pools -- were associated with
 17 hepatitis. And then it goes on to talk about the
 18 first tests of liver function tests, and I think it
 19 quotes the Alter paper. And then I would just point
 20 you to the second page, the next page, and I think
 21 it's important that -- that sentence that he writes:
 22

"It was only in the mid-1970s it became clear that
 23 hepatitis was frequent in haemophiliacs and it was only
 24 in mid-'80s that it was shown to be progressive and
 25

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1 severe in one-sixth of patients."
 2 **Q.** If we look at the -- it's right to note this was an
 3 article written by Professor Mannucci, I think, in
 4 2003, or published in 2003. I'm going to ask you some
 5 more about this later.
 6 **A.** You've got the wrong one. That's why, is it?
 7 **Q.** The top of the first page, to cite this article, and
 8 then we see the date --
 9 **A.** Okay.
 10 **Q.** -- 2003. But if we go to the second page which you
 11 were referring to, Professor Lee, you'll see in the
 12 paragraph above there, he talks about:
 13 "A relatively benign picture of non-A non-B
 14 hepatitis initially emerging from studies being
 15 questioned by three subsequent studies published in
 16 1985 and 1986."
 17 **A.** Yes.
 18 **Q.** The issue I'm exploring with you, or seeking to
 19 explore with you, Professor Lee, is whether it's right
 20 to characterise the understanding of non-A non-B
 21 hepatitis in the second half of the 1970s as being
 22 a relatively benign condition.
 23 **A.** I think, for some people, it was a benign condition.
 24 It probably was, and it was probably right to
 25 characterise it. I think the whole problem was that

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1 it was very difficult to sort out who was going to
2 have a benign prognosis and who was going to progress
3 quickly to liver disease. And that only really
4 evolved later.

5 **Q.** We'll look at some of your later studies in due
6 course, Professor Lee, but if I can return you to the
7 second half of the 1970s, there are just two further
8 documents I'm going to ask you to look at.

9 RLIT0000228, please, Henry. This a publication by
10 Hoofnagle and others called "Transmission of non-A
11 non-B hepatitis", and the date is 1977. This from the
12 Annals of Internal Medicine. If we could go, please,
13 Henry, to page 6. It's the long paragraph in the
14 right-hand column, beginning "Several clinical and
15 epidemiologic features of non-A non-B hepatitis".
16 Thank you. I'm just going to read certain parts of
17 this, Professor Lee, and then ask you about it.

18 "Several clinical and epidemiologic features of
19 non-A non-B hepatitis have become clear from studies
20 such as the present one. First, non-A non-B hepatitis
21 closely resembles type B hepatitis. The incubation
22 period, the clinical symptoms and signs, and the
23 potential for chronicity appear to be similar to type B
24 hepatitis. Undoubtedly, what was once referred to as
25 serum hepatitis included both type B and non-A non-B

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1 hepatitis."

2 That's the first point. Second:

3 "Non-A non-B hepatitis appears to be spread
4 predominantly by the parenteral route. Most cases have
5 been described in association with transfusion,
6 intravenous drug use or serum inoculation."

7 Then we can skip to the third point:

8 "Third, non-A non-B hepatitis appears to be
9 associated with a chronic carrier state and chronic
10 liver disease."

11 Then it goes on to talk about the particular study.

12 "These 'implicated' blood donors were, for the most
13 part, asymptomatic, although liver function tests and
14 liver biopsy examinations frequently showed evidence of
15 underlying chronic hepatitis."

16 Then:

17 "Finally, non-A, non-B hepatitis appears to be
18 common. Three of the five infectious donors studied
19 here transmitted this non-A, non-B hepatitis."

20 Then it goes on to talk about the screening of blood
21 donations.

22 If we can just go a little further down, Henry.

23 Then goes on to say:

24 "... at the present time, more than 90% of
25 post-transfusion hepatitis is due to non-A non-B

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1 hepatitis."

2 Professor Lee, this doesn't appear to be consistent
3 with Professor Mannucci's description of a benign
4 picture in the 1970s of non-A non-B hepatitis, does it?

5 **A.** Well, I would just comment, and I think we need to
6 perhaps talk about the work that I did for -- with
7 Dr Kernoff and Dr Thomas, and that is that certainly
8 the acute attack in some of those patients was totally
9 asymptomatic.

10 And I would also like to fast forward to tell you
11 that come the year 2000, so we're talking 30 years
12 after, there was a very low number of people who had
13 progression of their hepatitis in those who were not
14 infected with HIV. HIV was a terrible co-infection
15 that speeded up the progression of this condition.

16 I think it's also quite difficult, in 1977, to talk
17 about progression when there is not a test, and in
18 certain -- I think it's very difficult. And, you know,
19 I think it's very important to understand that part of
20 the rationale, if you like, of trying to understand what
21 happened following concentrate treatment -- which had
22 been given because it was necessary because the patient
23 had some kind of life-threatening bleed or needed an
24 operation or whatever, acute operation -- it's important
25 to understand that we needed to know what was happening,

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1 you know.

2 And I don't -- I've got a bit lost with your
3 question, actually. I'm getting tired.

4 **SIR BRIAN LANGSTAFF:** Would you like a break?

5 **PROFESSOR LEE:** I think I probably would like a bit of
6 a break, if that's possible. Just five minutes or
7 something.

8 **MS RICHARDS:** Or we could take the half hour break now,
9 sir.

10 **SIR BRIAN LANGSTAFF:** That would be a good idea, I think.

11 It's not an endurance course; it's evidence. So by
12 all means, if you feel tired, you just let us know,
13 and you've done that.

14 So take a break now for half an hour. Allow
15 everyone to get a cup of tea. A bit earlier than
16 usual, but that's what we'll do. So be back, please,
17 at 20 past 3.

18 (2.42 pm)

(A short break)

20 (3.16 pm)

21 **MS RICHARDS:** Professor Lee, there's one further article
22 from the 1970s I want to ask you to look at.

23 It's PRSC00003622. And this is The Lancet,
24 September 1978. It's a report by a Professor Preston
25 and others, "Percutaneous liver biopsy and chronic

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1 liver disease in haemophiliacs".
 2 If we look at the summary, and this should come up
 3 on the screen in front of you, Professor Lee, the
 4 summary says:
 5 "Systematic screening of forty-seven haemophiliacs
 6 in Sheffield revealed abnormal liver function tests in
 7 thirty-six (77%), with a tendency for these
 8 abnormalities to persist. To assess the importance of
 9 these abnormalities, percutaneous liver biopsy was
 10 carried out on eight symptom-free patients under
 11 Factor VIII cover. A wide spectrum of chronic liver
 12 disease was demonstrated, including chronic aggressive
 13 hepatitis and cirrhosis. The liver pathology bore no
 14 relation to clinical history or to biochemical findings.
 15 Hepatitis B virus markers were common, but evidence
 16 suggests that this is not the only factor contributing
 17 to the development of liver disease. The high incidence
 18 of chronic liver disease seems to be a recent
 19 development and is probably related to
 20 factor-concentrate replacement therapy."
 21 Then if we go to the third page, please, Henry,
 22 under the heading "Discussion", we see -- a little
 23 closer.
 24 We can see it starts by saying that:
 25 "77% of our treated haemophiliacs had abnormal liver

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1 function tests and a history of a hepatitis-like illness
 2 was listed in 50%."
 3 And then this contrasted with earlier reports.
 4 Then if we go to the next paragraph, please, Henry,
 5 we can see it talks about biopsies, and then halfway
 6 down the paragraph it says:
 7 "We also found a wide spectrum of chronic liver
 8 disease including benign self-limiting chronic
 9 hepatitis, potentially treatable aggressive hepatitis,
 10 and established cirrhosis. All our patients were
 11 symptom-free at biopsy and it was impossible to
 12 differentiate between the different forms of liver
 13 disease on the grounds of biochemical abnormalities.
 14 Since the patients undergoing biopsy had been
 15 arbitrarily selected it is reasonable to conclude that
 16 in a large proportion of haemophiliacs receiving
 17 treatment with Factor VIII have important chronic liver
 18 disease."
 19 Then one final paragraph.
 20 Next column, please, Henry. Go up a bit.
 21 Picking it up six lines down into the first main
 22 paragraph, Professor Lee:
 23 "In addition, non-A non-B hepatitis may well be an
 24 important factor and observations in four of our eight
 25 patients support this possibility."

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1 And then that is developed in the rest of that
 2 paragraph. And then we have the conclusion that
 3 histological liver disease is common in haemophiliac
 4 patients, and then again it goes on to talk about
 5 assessment by use of biopsy.
 6 Now I'm not at the moment asking you about the
 7 practicalities or, indeed, the risks of liver biopsies,
 8 which you've already alluded to and we may come back to,
 9 but just in terms of the importance here of the findings
 10 of evidence of chronic liver disease, would you agree
 11 that this was a significant paper?
 12 A. This was a significant paper, but I think it's
 13 important that it's realised that there were other
 14 studies.
 15 I think the other thing I've had time to reflect on
 16 when I was -- had the break, is I don't think this is
 17 a memory test, and I am a great believer in looking at
 18 documentation. And if I'm allowed, could we look at
 19 what Mannucci writes on this matter.
 20 Q. Is that the same document we were looking at before?
 21 A. Yes, it's --
 22 Q. Yes. So Henry, it is WITN0644071.
 23 A. I would -- the next page, please. I'd point you to
 24 the second paragraph. As we've discussed, it talks
 25 about, you know, unequivocal evidence of the existence

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1 of structural liver disease in people with haemophilia
 2 and elevated transaminases, we've talked about that.
 3 But I think what's important is the bottom of that
 4 paragraph where he talks about:
 5 "A prospective biopsy study was undertaken by me
 6 with hepatologists Colombo and Rizzetto in
 7 10 haemophiliacs with non-A, non-B chronic hepatitis
 8 followed up for more than 6 years. The study, published
 9 in 1982, demonstrated no case ..."
 10 No case.
 11 "... of progression towards cirrhosis or
 12 hepatocellular carcinoma."
 13 So that was that his experience. I'm not saying
 14 this is universal; what I'm trying to show is that
 15 different patients were showing different progression
 16 rates and not everybody was showing every kind of
 17 abnormality.
 18 And then I think the other significant thing that he
 19 states here is:
 20 "The relatively benign picture of non-A non-B
 21 hepatitis initially emerging from these studies was
 22 questioned by three subsequent studies published in 1985
 23 and 1986."
 24 So.
 25 "A large retrospective study of liver biopsies

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1 collected by Aledort ... provided histologic [change]
 2 ... in 15% of cases."
 3 So 15% of the total. And it's worth noting that
 4 within that worldwide collection of liver biopsies, one
 5 of his patients had died of the liver biopsy.
 6 Then I think this is the study you're talking about,
 7 isn't it? I think?
 8 **Q.** No --
 9 **A.** Well, this is from the same group:
 10 "In an 8-year prospective study conducted in
 11 Sheffield, histological signs of cirrhosis were found
 12 in nine of 79 haemophiliacs (12%) ..."
 13 I mean, what I'm trying to show you is that there
 14 was a realisation this was a problem, but there was
 15 debate at that time as to how severe this problem was,
 16 and what was happening. And some of the papers
 17 published, who had done biopsies, showed abnormalities.
 18 Some of the studies did not show abnormalities.
 19 And of course the other issue, which I think I took
 20 up with Professor Preston in the debate over doing liver
 21 biopsies, because it is relevant, is that liver biopsies
 22 were very often done on more severe patients. So it
 23 wasn't at all clear as to how many of the patients were
 24 progressing. There was no doubt there was some kind of
 25 problem. And some of the experience at this time --

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1 and, you know, Mannucci's study was showing that.
 2 What these people were looking at is, you know, when
 3 you treat a patient with clotting factor concentrate,
 4 you're doing it for a reason. You're doing it to stop
 5 severe bleeding. And what they were weighing up is how
 6 severe is this transaminitis, or non-A non-B hepatitis?
 7 We don't know. And is the risk of not treating them, of
 8 them not receiving concentrate, is that risk worth
 9 taking? That was the debate.
 10 And I think the other important thing in this paper
 11 that he writes is on two pages, 2068, it's on the paper.
 12 **Q.** It's two pages further on, Henry.
 13 **A.** And this called "The fallacy: a retrospective
 14 knowledge". And he sets out in the table --
 15 **SIR BRIAN LANGSTAFF:** Just a moment. I think it's at the
 16 bottom of the --
 17 **DR LEE:** Yes, but I think we need --
 18 **SIR BRIAN LANGSTAFF:** You're looking at your paper --
 19 (overspeaking) --
 20 **DR LEE:** No, no, no. There's a table at the top.
 21 **SIR BRIAN LANGSTAFF:** I see.
 22 **DR LEE:** Can we just see the table at the top first? He
 23 sets out in this table a very good chronological order
 24 of how knowledge developed, both for hepatitis and
 25 AIDS. Now can we go back to the bottom which you --

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1 and it's talking about:
 2 "The fallacy of retrospective knowledge. Table 1
 3 summarises the chronology of the development of
 4 knowledge about hepatitis and AIDS in haemophiliacs.
 5 To sum up, even though the problem of hepatitis was
 6 known since the 1970s, there was no reason to believe
 7 that this adverse effect of haemophilia care was
 8 heralding the much more ominous AIDS. On the whole,
 9 everybody was muddled in the period between the early
 10 1980s and the first cases of people with haemophilia
 11 and AIDS were reported."
 12 Now, I know you're talking here -- you've separated
 13 off hepatitis, but there is absolutely no doubt at that
 14 time that there was a debate going on about how severe
 15 these changes were. Was everybody going to get this?
 16 Was it vastly progressive? And that was being weighed
 17 about -- it's all a balance of risk. It was being
 18 weighed up about whether treating the patient -- it was
 19 important to treat the patient, to give effective
 20 treatment.
 21 I mean, some of the reasons -- people would have
 22 died of bleeding if they hadn't had these concentrates.
 23 So it's a balance of risks.
 24 **MS RICHARDS:** I'll come back to balance of risks,
 25 Professor Lee, but first of all, Professor Mannucci

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1 entitles this "The fallacy of retrospective
 2 knowledge". He is, of course, writing retrospectively
 3 at this point.
 4 **A.** Sorry. He's writing what?
 5 **Q.** He's writing retrospectively in this article. If we
 6 look at his table at the top of this page and we just
 7 look at hepatitis, because we're going to come on to
 8 AIDS separately, we can see, for example, none of the
 9 materials which I've just referred you to are there
 10 set out in his chronology of the main events in
 11 hepatitis. He refers to some early reports, '70 to
 12 '72. 1975, he cites his own piece of work. 1977, he
 13 cites liver biopsy. And the reasons you've explained,
 14 liver biopsies were not something that could be
 15 frequently undertaken. And then he goes on to
 16 desmopressin, DDAVP, and then to the 1980s. So it's
 17 not, by any stretch of the imagination,
 18 a comprehensive chronology of the development of
 19 knowledge of non-A non-B hepatitis, is it?
 20 **A.** I really find that very difficult, what you've just
 21 said. This man lived through treating his patients
 22 through all of that period. And there is absolutely
 23 no doubt around this time that there was a debate as
 24 to what transaminitis meant. There is no doubt that
 25 it was clearly stated in some of these papers that

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1 this hepatitis occurred, but the debate was also about
2 how serious the transaminitis was. Was it worth
3 stopping the treatment because it was terrible, or was
4 it more important to go on using the treatment?

5 And, you know, as things transpired, the later
6 information we had showed that, actually, for many
7 patients, it was a very, very slow progression. And,
8 indeed, for some patients -- quite a few, actually --
9 they lived through an era where we had treatment for
10 hepatitis, so it could be cleared. So are you saying
11 that in this period, that treatment should have been
12 stopped because they get hepatitis and maybe they have
13 the problem of bleeding?

14 **Q.** Professor --

15 **A.** And these people -- can I just finish? I'm sorry.

16 **Q.** Of course.

17 **A.** But these people benefited from the clearing of their
18 hepatitis in the end. And I just will emphasise again
19 that in this time there was debate about the
20 seriousness of the transaminitis. I don't think
21 anybody doubted it was there, but there was debate
22 about the progression and the seriousness. And
23 I would say again, Preston's paper where he
24 biopsies -- he worked alongside a very able
25 hepatologist called Dr David Trigger -- it's more

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1 likely they were biopsying the patients who looked as
2 if they were more badly affected.

3 **Q.** Yes.

4 **A.** So you have a skewed vision.

5 **Q.** You and Professor Preston I think have crossed swords,
6 if I may put it that way, in relation to that issue in
7 the past --

8 **A.** I don't think it's a question of crossing swords.

9 **Q.** I disagree --

10 **A.** I'm sorry, I don't like that. I am a physician.

11 I cared desperately about my patients. They're not my
12 patients; it's the patients. And throughout my
13 career, I have wanted to do the best for those
14 patients. And for me, the best I can do for patients
15 is based on evidence and also safety and efficacy.
16 And I do not -- and the reason you're using this term
17 "cross swords", which I don't really like because it
18 was just showing our experience and questioning
19 whether it was right to risk death from a liver biopsy
20 and provide cover to cover the biopsy. I don't think
21 that's crossing swords. It's trying to fight for care
22 and investigation of patients to be relevant.

23 **Q.** Would you accept that you and Professor Preston
24 disagreed about whether his was effectively
25 a selection of the most serious cases?

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1 **A.** I think what I would say is that I put into the public
2 domain the experience we had had. And as a physician,
3 the way I have approached looking after and caring for
4 patients has been that I need to know what is going
5 on, but I need to know in a way that is not risky for
6 them. And what I have -- we're going to perhaps talk
7 about it, I don't know, but what I wrote up in that
8 letter was an experience -- it wasn't when I was there
9 that the person died of the liver biopsy. It was
10 during the time that Dame Sheila Sherlock was
11 investigating these patients with liver biopsy.

12 But having had that experience, there was no way
13 we were going to expose patients to the risk of death
14 from bleeding. And I do not like the idea that you
15 are suggesting that I crossed swords with somebody.
16 You know, I'm a doctor, and we're all in the thing
17 together. We're all trying to find out knowledge, to
18 find out what is best for our patients. We're not
19 fighting.

20 **Q.** Professor Lee, let's leave aside the term I used.

21 **A.** Sorry?

22 **Q.** Leave aside the term I used.

23 **A.** Thank you.

24 **Q.** The question I was simply putting to you is: are you
25 aware and do you accept that Professor Preston

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1 disagreed with your characterisation of his research?
2 That's all.

3 **A.** I think -- I didn't disagree with the results he got.

4 Not at all. Not at all. In fact, they were very
5 helpful. What I did disagree with was the approach of
6 doing unnecessary liver biopsies. And for the reasons
7 I've said. You know, there was a patient that died.

8 But what I would also say is that, as we went
9 through the '90s, and then we had CT scans and
10 imaging, the consultant hepatologists that I worked
11 alongside were able to do what's called transjugular
12 liver biopsies where the needle went down through the
13 vessel into the liver, and they could do that under an
14 image. They can see where the needle goes. When you
15 do a liver -- I've never done a liver biopsy. When
16 you do a liver biopsy, in the days that these were
17 being done, the needle goes into the liver. The liver
18 is an incredibly vascular organ, so you could hit
19 a vessel. It's quite dangerous. And also, each one
20 of those liver biopsies had to be covered with a large
21 amount of concentrate, so that's another issue.
22 That's probably a minor issue because, I think, you
23 know, that shouldn't be an issue, but it's the safety
24 issue.

25 And I think it's terribly important that we're

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1 pursuing science here, as applied to haemophilia care,
2 which then makes the care of those patients good and
3 safe, but you can't do anything unless you know what's
4 going on.

5 **Q.** Professor Lee, we may be slightly at cross-purposes.
6 I'm not seeking to challenge your view that liver
7 biopsies could be dangerous, or your view that they
8 are not something that should generally be undertaken.
9 That's not the purpose of my questions. I'm looking
10 simply at the question of what was known in the second
11 half of the 1970s and what was not known; the emerging
12 picture in relation to non-A non-B hepatitis.

13 Professor Preston's work was a part of that
14 picture. An important part of the picture. I'm not
15 suggesting it was a complete part of the picture, and
16 you pointed to some of the other studies here.

17 Can I ask you to look at two descriptions of non-A
18 non-B hepatitis --

19 **SIR BRIAN LANGSTAFF:** Before you do that, can I just ask
20 a couple of questions about this paper by Mannucci in
21 the 1990s? Can we go down to the bottom of the page,
22 please, Henry? Under "The fallacy of retrospective
23 knowledge", the second sentence:

24 "To sum up ..."
25 So what he appears to be saying, this sums up the

1 fallacy of retrospective knowledge:
2 "Even though the problem of hepatitis was known
3 since the 1970s, there was no reason to believe that
4 this adverse effect of haemophilia care was heralding
5 the much more ominous AIDS. On the whole, everybody was
6 muddled in the period between the early 1980s ..."

7 That muddling, as I read this -- and please tell me
8 if I'm reading it wrong. I read the muddling to be
9 about AIDS and the link between hepatitis and AIDS.
10 Because I think he's saying that hepatitis is one thing.
11 Put that on one side. AIDS is another. That's the way
12 it seemed. Have I got it wrong?

13 **A.** Well, not really wrong, but what he's trying to say is
14 that ... one of the big problems was that mostly --
15 and this was knowledge that was gained later. The
16 people who, mostly, who had big problems with liver
17 disease actually had co-infection with HIV. And we
18 now know that HIV was coming in, in '79. So I'm not
19 saying all these studies, but some of these studies
20 overlapped that period. So what he's saying is that
21 we had no reason to know that then. I don't know if
22 that explains it or not.

23 **SIR BRIAN LANGSTAFF:** I'm not sure it does because it's
24 really a question of how one reads the words.

25 But the second question I want to ask you -- can

1 we go back to the very first page of this article,
2 please, Henry. Just something that caught my eye at
3 the bottom of the page. It's the very bottom
4 right-hand side:

5 "Hepatitis. Emergence of the hepatitis problem."
6 This is what Mannucci says throughout the 19 --
7 through the 1970s:

8 "Recognised the use of concentrates of coagulation
9 factors made from plasma pooled from several thousands
10 of blood donations was often associated with hepatitis.
11 However, the first large study of liver function tests
12 was published in 1975."

13 Now, that's Mannucci's own study, I think, because
14 that's the reference. And:

15 "Our survey of 91 multi-transfused Italian
16 haemophiliacs found that 45% of them had elevated serum
17 transaminases. Although non-A non-B hepatitis ..."

18 Can we turn over the page?

19 "... was expected to be responsible for transaminase
20 abnormalities, a definite distinction between
21 transfusion associated hepatitis and transaminitis could
22 not be made at that time."

23 The last sentence:

24 "Our findings were subsequently confirmed and
25 extended by a joint American/English study that

1 demonstrated that transaminase abnormalities persisted,
2 supporting the views that they were a hallmark of
3 chronic viral hepatitis."

4 Now, what he appears to be saying is that his own
5 work in 1975 demonstrated that there was a condition
6 which was associated with factor concentrates made from
7 large pools and the development of chronic viral
8 hepatitis. It doesn't say how serious the chronic viral
9 hepatitis was, but that's what he appears to be saying.
10 And then what does it go on to say after that, Henry?

11 **A.** I think --
12 **SIR BRIAN LANGSTAFF:** "Unequivocal evidence."

13 So he's saying that what he had suspected in '75
14 was unequivocally confirmed in 1977, and on it goes.

15 Have I got that right? Is that the way it would
16 read?

17 **A.** Yes, but I think the other important thing in that
18 paragraph is what I said earlier: the thing about the
19 joint American/English study -- this was
20 Katharine Dormandy's study with Levine in Boston. And
21 I said earlier about this, that she had shown -- she
22 had been worried about transaminitis, and she compared
23 her patients who were treated with cryoprecipitate
24 with the American patients who had been treated with
25 concentrate. And transaminitis was in both, but there

1 was more transaminitis in the American patients. So
 2 this was a piece of information that was in
 3 circulation.
 4 The other thing that's not actually written here,
 5 but I can tell you that there was a view held by some
 6 people that transaminitis may be accentuated by metallic
 7 things in the fractionation process. So what I'm trying
 8 to do -- you know, it's quite clear that there was --
 9 they're descriptions of non-A non-B hepatitis. They're
 10 not really defined as non-A non-B, but going on -- but
 11 the extent of this problem and the rate of progression
 12 and the seriousness of it was not clear. There was
 13 evidences in both directions, and it was that kind of
 14 information that was informing the way people or
 15 haemophilia treaters were treating.
 16 **MS RICHARDS:** Dr Kernoff, in April 1979 -- perhaps we'll
 17 look at this, Henry. BART0002487. Go to the second
 18 page, please, Henry. You'll see there it's a letter
 19 to Dr Colvin, 27 April 1979. We go to the paragraph
 20 numbered 2 under the heading "Types of therapeutic
 21 material available", and we'll go halfway down the
 22 paragraph. He's talking about commercial versus NHS
 23 concentrates. I don't need to ask you about that, at
 24 least not at this stage. Then he says:
 25 "The clinical reason [referring to the NHS] is the

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1 growing awareness that the probability that commercial
 2 concentrates are the higher risk of transmitting non-A
 3 non-B hepatitis than NHS material."
 4 Then this the sentence, Professor Lee:
 5 "This is a serious disease with long-term
 6 consequences."
 7 I can take you to a reference the following month by
 8 Dr Kernoff and Dr Colvin which talked about it being
 9 serious with long-term sequelae and that the acute
 10 disease may sometimes be fatal.
 11 Would you agree with that characterisation, as at
 12 1979, recognising there's still much to learn, it was
 13 known that this was a serious disease with long-term
 14 consequences?
 15 **SIR BRIAN LANGSTAFF:** Shall we use the word "believed"?
 16 **MS RICHARDS:** It was believed.
 17 **A.** Yeah. Can we begin at the beginning of that
 18 paragraph? The paragraph you just had, it's
 19 disappeared, has it?
 20 **Q.** That's the paragraph:
 21 "Types of therapeutic material available."
 22 **A.** Saying that he wrote:
 23 "The clinical reason is the growing awareness that
 24 the probability that commercial concentrates have a
 25 higher risk of transmitting non-A non-B hepatitis than

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1 NHS material."
 2 Dr Kernoff wrote that. It later transpired that is
 3 not true, and we're going to go and discuss that paper.
 4 That came after that. So what I'm saying here -- this
 5 is 1979 -- that even Dr Kernoff clearly moved his view.
 6 **Q.** That wasn't, with respect, the question I was putting,
 7 Professor Lee, which is: do you agree with
 8 Dr Kernoff's characterisation, as at 1979, that non-A
 9 non-B hepatitis is a serious disease with long-term
 10 consequences? Is that a fair way of describing non-A,
 11 non-B in 1979?
 12 **A.** I think all I would say about that sentence, and this
 13 is written in 1979 by Dr Kernoff, okay, is that he
 14 writes: "As far as is known." And I think that is the
 15 qualification: as far as is known. And, as we know,
 16 subsequent work shows --
 17 **SIR BRIAN LANGSTAFF:** I think the "as far as it's
 18 known" is dealing with its prevalence, rather than the
 19 long-term consequences -- (overspeaking) -- if you
 20 just read it through:
 21 "As far as is known is, at present, much less
 22 common in the UK than in the USA, et cetera."
 23 **A.** Yes, okay. As far as is known: what I'd say to
 24 that is it is a qualification. This is written in
 25 1979. And if Peter had been -- Dr Kernoff had been

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1 alive in 2000 or 1994, he would have realised that,
 2 actually, there were some patients where the
 3 progression was very slow. Sadly, it was mostly the
 4 patients who had co-infection with HIV who progressed
 5 very rapidly. And, you know, we cared for those
 6 patients, and because all the clotting factors are
 7 made in the liver, it was very difficult.
 8 So I think -- I suppose what I'm trying to say is
 9 this is written in 1979, and Dr Kernoff is aware of
 10 all these publications that you've shown. And he's
 11 balancing those publications up, and he's saying that
 12 it's a disease with long-term consequences. Of
 13 course, that's '79. You know, the long-term
 14 consequences for many patients didn't come until 2000.
 15 That's what I'm trying to explain. Is that helpful?
 16 **SIR BRIAN LANGSTAFF:** Yes, thank you very much.
 17 **MS RICHARDS:** Would you accept, in light of the material
 18 that we've looked at and any other material that
 19 you're aware of from the second half of the 1970s,
 20 that it should have been appreciated by
 21 haematologists, by the end of the 1970s at least, that
 22 non-A non-B hepatitis was a clinically significant
 23 condition which carried a significant risk of causing
 24 liver disease?
 25 **A.** No.

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1 Q. Why?
 2 A. Because they weren't aware of that.
 3 Q. Well, Dr Kernoff is saying it in terms. It is
 4 a serious disease with long-term consequences.
 5 A. Yes, you asked me about all haematologists, didn't
 6 you? What was your question?
 7 Q. I'm asking you whether you would accept that, in
 8 general, haematologists should have known by the end
 9 of the 1970s that non-A non-B hepatitis was
 10 a clinically significant condition which carried
 11 a significant risk of causing liver disease?
 12 A. I think, I suppose what I would say in answer to
 13 that is, in an ideal world, they should have known,
 14 but what I would say is that they did not know.
 15 I don't think any of us really knew for certain what
 16 was going on. I mean that was why the study was being
 17 done: to understand it.
 18 So I think the idea that everything was understood
 19 by the end of the 1970s is wrong. There were all
 20 sorts of emerging knowledge coming out. And in
 21 parallel with that, there was treatment, remarkable
 22 treatment. And that's what people were weighing up.
 23 And they were -- you know, one of the reasons for this
 24 study, this retrospective study that Dr Kernoff wanted
 25 to be looked into, for the information to be assembled

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1 and published, was to find out more about what is
 2 happening, what is going on.
 3 And of course, the -- we're going to talk about
 4 it, I know, but the most important thing that that
 5 study showed, and the knowledge up to that date had
 6 been completely wrong on it, was that whether the
 7 concentrate was made from blood donors in America or
 8 anywhere, or the UK, everybody got non-A non-B
 9 hepatitis on their first exposure.
 10 And, you know, none of that knowledge was available
 11 in the late 1970s. That emerged and began to be
 12 presented at clinical meetings, I suppose, from 1983
 13 onwards. But what was known -- you've shown it -- was
 14 the Craske paper, and, you know, the knowledge was
 15 building up.
 16 Q. Professor Lee, you used the term "for certain", things
 17 weren't known for certain.
 18 A. Yes.
 19 Q. Professor Mannucci used the term "unequivocal" in the
 20 paper you've referred us to. Finding certainty,
 21 finding unequivocal evidence, may be something that
 22 might take many years of research and study.
 23 Clinicians will rarely have evidence of certain
 24 outcomes. They have to look at the risks. Would you
 25 agree?

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1 A. Yeah, and I think -- yes. And I think what is
 2 important when you're considering risk, the only risk
 3 that you are considering or you're throwing at me, is
 4 the risk of this emerging picture of transaminitis,
 5 non-A non-B hepatitis.
 6 Haemophilia treaters at that time, and indeed now,
 7 also have the risk to think about: what happens -- what
 8 happens -- if I don't give this patient treatment? What
 9 happens if this patient isn't having regular home
 10 treatment at home so that when he develops a knee bleed
 11 at home he can treat himself immediately so that that
 12 knee in future is not going to be a target joint and he
 13 becomes -- "crippled" is a word that I don't like
 14 using -- disabled.
 15 And I think always in this risk -- and, you know, it
 16 goes for the whole of medicine. You're balancing risk.
 17 You know, what were haemophilia physicians trying to do?
 18 They were treating people who had an inherited bleeding
 19 disorder, and they had to balance up what is the greater
 20 risk: that I risk this person being at home and getting
 21 a cerebral haemorrhage? Or -- you know, I'm sorry to
 22 labour this point but it really is important. And
 23 I just -- I think it's important.
 24 You've got this document somewhere, I've got
 25 a number. It's to try and convey what haemophilia is

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1 like untreated. And it is relevant.
 2 We're now in 2020, and what I want you to put up on
 3 the screen, if I'm allowed, is -- it's witness
 4 number 644002.
 5 Q. Sorry, could you tell me what the --
 6 A. The title of it is the -- it's from the textbook of
 7 haemophilia, it's a historical introduction
 8 that I wrote.
 9 Can you find it?
 10 Q. Unless it's exhibited to the long statement that you
 11 prepared for today, then it's not something
 12 that I can --
 13 A. All right, well, am I allowed to read from it and
 14 provide this to you afterwards? I think it is
 15 probably in one of my Rule 9s.
 16 Q. It's fine for you to read from it. We will have it
 17 but we don't have it electronically to display.
 18 A. Will you forgive me if I -- I won't read too much.
 19 What I was going to say was, this is 2020, and this is
 20 a publication that came in 1937 from America. And it
 21 was --
 22 SIR BRIAN LANGSTAFF: Is it the Birch paper?
 23 A. Sorry?
 24 SIR BRIAN LANGSTAFF: Is it the Birch paper?
 25 A. Yes, yes.

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1 So it was 113 people with haemophilia in 1937.
 2 And she -- actually, it's a he, with a strange
 3 spelling -- reviewed the causes of death from
 4 bleeding.
 5 Just to give you an example, 15 out of these people
 6 died from circumcision, six died from epistaxis, seven
 7 from central nervous bleeding.
 8 And what's even more awful was that most of these
 9 people died before the age of 15 years. I think only
 10 eight survived beyond 40. And what you're balancing is
 11 always risk of bleeding. I think we must not forget
 12 that people bleed. And it's often forgotten now because
 13 fortunately we now have recombinant products and our
 14 little boys can be treated with prophylaxis, and indeed
 15 now there's even gene therapy, so nobody ever sees
 16 a bleed. And of course cerebral bleeding was the most
 17 devastating thing of all. So that's what I'm trying to
 18 convey.
 19 **MS RICHARDS:** 1937 was not 1979, and the choice was not
 20 necessarily one of, in every case, treatment with
 21 concentrates or no treatment. Amongst other things,
 22 cryoprecipitate was available, and for non-severe
 23 haemophiliacs, DDAVP.
 24 **A.** Yes, let's go back to cryoprecipitate.
 25 We know, then, that the incidence of hepatitis in

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1 blood transfusions was one in 300. This was done from
 2 post-transfusion studies. If you treat somebody with
 3 cryoprecipitate, you very quickly accrue a large
 4 number of treatments. And indeed, the paper that you
 5 have here from the lady who was a carrier of
 6 haemophilia, you know, people -- women who are
 7 carriers of haemophilia, sometimes they have quite
 8 a low level of Factor VIII. And she had an operation
 9 on her knee, and was given cryoprecipitate. I'd need
 10 to get the paper, but I think in the end she had about
 11 300 units of cryoprecipitate. She developed fulminant
 12 hepatitis C. She was in intensive care and nearly
 13 died. That was from cryoprecipitate.
 14 And that lady went on with long-term hepatitis C,
 15 and indeed in the end she and her son both had
 16 type 1 hepatitis -- of course her son had severe
 17 haemophilia -- and they both cleared it with
 18 treatment, with interferon, later on.
 19 So the idea that you could go and treat everybody
 20 with cryoprecipitate, and it was safe and effective,
 21 because people had a transaminitis or a non-A non-B
 22 hepatitis for which we did not know the progression of
 23 the seriousness, was really not a correct idea.
 24 Furthermore, I followed your questioning of
 25 Dr Brian Colvin, and following that question, I went

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1 back to Katharine Dormandy's original papers, and
 2 I think it was the one in 1974 which shows in great
 3 detail what was needed to train people and to make
 4 cryoprecipitate.
 5 You're suggesting, I think, that in the late 1970s,
 6 that this concentrate is stopped being used, and we
 7 start going back to cryoprecipitate.
 8 Well, for a start off, if people are treating at
 9 home, they haven't got deep freezers anymore. In the
 10 hospital, the Blood Transfusion Service is not geared up
 11 to making this anymore. That's just a provision thing.
 12 But the most important thing, probably -- and, you know,
 13 there are many people in this room who were in receipt
 14 of concentrates, the convenience for the patients of
 15 these concentrates was extraordinary, because it was,
 16 you know, injecting -- I don't know, 20mls into your
 17 arm, having a little bottle that you shake up, that you
 18 can take when you go in your car somewhere, or you can
 19 go abroad or you go to work, the patients wanted it.
 20 You know, it ...
 21 And the other thing that we haven't talked about at
 22 all -- I mean, we have kind of talked about it,
 23 I discussed with you how bovine Factor VIII was
 24 developed and how in Oxford they were therefore able to
 25 take people's teeth out.

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1 As things moved on, operations could be done for
 2 these patients. You know, people with haemophilia are
 3 no different to any of us. They can get appendicitis.
 4 They can get things that you need to do an acute
 5 operation on. And having these concentrates absolutely
 6 transformed things because you could do that now.
 7 So I hope that explains things, and why it would not
 8 be sensible or even practical to go on back -- back --
 9 to using cryoprecipitate. It was not a safe product.
 10 **Q.** It was a safer product than factor concentrates,
 11 whether NHS or commercial, was it not?
 12 **A.** Well, it depends how you define "safer".
 13 **Q.** In terms of risks of transmitting hepatitis to start
 14 with.
 15 **A.** In terms of transmitting hepatitis, if -- once you've
 16 got over 300 units, it's almost inevitable you're
 17 going to get it. But, you know, if you're treating
 18 a patient who has bleeding, what is the greater risk?
 19 Do you want somebody with, say, a cerebral haemorrhage
 20 to die because, you know, they've been treated with
 21 ineffective cryoprecipitate that hasn't brought the
 22 level up?
 23 And, you know, if you're operating on somebody,
 24 it's very difficult to plan how many units of
 25 cryoprecipitate you want when you can't even know

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1 what's in the bag. It's just -- it's an extraordinary
 2 idea. And I think you have to balance the risks. And
 3 all you -- and -- sorry, I don't want to be
 4 aggressive -- but all that is being seemingly
 5 considered at the moment is the risk of non-A non-B
 6 hepatitis, which at the time there was very limited
 7 information. We didn't have -- the virus wasn't
 8 identified until 1989 so we didn't have a test. You
 9 are suggesting that it was important to avoid that
 10 risk, and then you expose the patient with the
 11 haemophilia to a much bigger risk. Because if you use
 12 the concentrate, you know what's in the bottle, you
 13 can precisely dose it. It's just a whole safer
 14 procedure.

15 And I think from the quality of life perspective, it
 16 would also be an issue for the individuals with
 17 haemophilia.

18 **Q.** Do you agree or accept that patients with haemophilia
 19 or other bleeding disorders who are going to be
 20 treated potentially with concentrates should be told
 21 that non-A non-B hepatitis was a risk of their
 22 treatment and that it was a serious disease with
 23 long-term consequences? To quote Dr Kernoff.

24 **A.** I think at the time that you're talking about this,
 25 I -- fortunately, maybe, for me, I wasn't in the

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1 position of talking people through their treatment.
 2 I've explained that what I was doing was following up
 3 information that had been acquired from that
 4 treatment.

5 What I do know is that patients -- when the
 6 knowledge evolved, was that patients would be told there
 7 was a possibility of this transaminitis or hepatitis,
 8 but the treater, or Peter I suppose, at that stage,
 9 would have said, "We don't know what the long-term
 10 consequence of this was."

11 And I think I would just go back also to the point
 12 that, for most people, it was an asymptomatic disorder.
 13 So it wasn't an issue, you know. Their priority was to
 14 be treated.

15 But I think it probably -- I don't know, because
 16 I wasn't Dr Peter Kernoff in that period. I was, at
 17 that time, or certainly in the 1980s when I was doing
 18 this research, I was looking at data. I wasn't the
 19 person who was administering the treatment.

20 **Q.** The question I asked, Professor Lee, and I'm not sure
 21 that you've quite answered it, is not what as a matter
 22 of fact patients were told at the Royal Free, do you
 23 accept -- you're free to disagree -- do you accept
 24 that by the late 1970s or early 1980s, patients had
 25 a right to know, should have been told, that the

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1 treatment they were being offered carried a risk of
 2 non-A non-B hepatitis and that, whilst much was still
 3 unknown, non-A non-B hepatitis was a serious condition
 4 with long-term consequences?

5 **A.** I don't agree with that. And, you know, I'm trying to
 6 remember back 37 years, basically. You know, you've
 7 quoted the papers, and what you've quoted is certainly
 8 true. But there was also a great, great unknown. So
 9 I don't agree with the totality of what you said
 10 there.

11 **Q.** Do you disagree with my characterisation of the
 12 condition, or are you disagreeing with the suggestion
 13 that patients should have been given that information?

14 **A.** I don't disagree with patients being given
 15 information. I think all patients should be given
 16 information, and that's all -- the way certainly I've
 17 practiced. But it's very difficult giving information
 18 when the information itself is being debated, and it
 19 is not entirely clear what is happening.

20 **Q.** So this is a hypothetical question because
 21 I understand that you were not at the Royal Free at
 22 this time. But bearing in mind Dr Kernoff's own
 23 characterisation of the condition as a "serious
 24 disease with long-term consequences", is that a piece
 25 of information which, in your view, should have been

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1 given to patients at that time?

2 **A.** Well, I go back to what I said earlier. It was the
 3 knowledge at the time. He qualified it. So I don't
 4 know. I wasn't in the position of giving the
 5 information at that time, to the patient. I don't
 6 know what he told the patient. But when he qualified
 7 that, as far as is known, I'm sure he probably would
 8 have told the patient, "This is a problem". That was
 9 his way. He told patients things. So I don't -- but
 10 I -- again, I think it is inappropriate to ask me what
 11 Dr Peter Kernoff would have told patients.

12 **Q.** That's not the question, Professor Lee.

13 **A.** What is the question?

14 **Q.** The question, I'll say it again. The question is: do
 15 you consider, as at 1979, or 1980, that patients
 16 should have been told that their treatment carried
 17 with it a risk of developing non-A non-B hepatitis
 18 which was believed to be a serious condition with
 19 long-term consequences?

20 **A.** Can I answer that question. It's very difficult for
 21 me to say what people -- what consultants delivering
 22 care at that time should have said. Maybe I can
 23 say -- I never treated one of those patients first
 24 time. Ever. Then.

25 **Q.** In 1979?

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1 A. No. I wasn't there.
 2 Q. Yes. I know. I'm trying to understand the point
 3 you're making, Professor Lee.
 4 A. I didn't. I -- I didn't treat any patient there
 5 until 1987. Okay?
 6 So I've forgotten what the question is. I'm
 7 terribly sorry.
 8 **SIR BRIAN LANGSTAFF:** It's the hypothetical question.
 9 A. Yes, well, what I think I would say is that I can't
 10 project what I would have said then, but what I can
 11 project is what I would have said when I was in the
 12 position that -- if I was in that position -- in fact,
 13 I wasn't in that position -- of giving people
 14 untreated concentrate before 1985, and I'm sure that
 15 what I would have said is that there may be a problem,
 16 but we don't know what it means.
 17 **MS RICHARDS:** Is this your evidence in relation to what is
 18 a matter of fact the position was at the Royal Free,
 19 1983, and --
 20 A. No, it's not a matter of fact because I don't know
 21 what Dr Kernoff said to patients, and I wasn't in the
 22 position to actually give treatment then.
 23 Q. Professor Lee, if you'll let me ask the question,
 24 you'll understand I wasn't suggesting what you think
 25 I may have been suggesting.

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1 As I understand your evidence so far, you're saying:
 2 as a matter of fact, you don't know what was or wasn't
 3 said to patients about non-A non-B hepatitis.
 4 A. Yes, that's right.
 5 Q. Is that not something that you ever discussed with
 6 Dr Kernoff, given that you were researching the
 7 incidence of liver abnormalities in these patients?
 8 A. Can I remind you again that the study I was looking
 9 at, the information, the retrospective information
 10 I was looking at, I started looking at the end of
 11 January 1983, by which time most -- all the patients
 12 had been treated. What -- there was still patients
 13 who were being followed up.
 14 Q. So is the answer to my question that you didn't have
 15 any discussions with Dr Kernoff about the information
 16 that was provided to patients at that time?
 17 A. No. My job was to try to find out more information.
 18 Q. As far as you know from your time at the Royal Free in
 19 1983 and 1984, or indeed anything that you may have
 20 learnt subsequently about that time when you took up
 21 your consultant post there, were any changes made to
 22 treatment policies or practices in response to the
 23 risk of non-A non-B hepatitis?
 24 A. Which period are you talking about?
 25 Q. The first half of the eighties, but in particular '83

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1 and '84.
 2 A. No, I wasn't -- I wasn't in the position to -- that
 3 wasn't my role and it wasn't in my knowledge. And by
 4 the time I was in the position that I was
 5 a consultant, in 1987, the concentrates were all
 6 heated. So the practices were never part of my job.
 7 Q. If we could just look at your evidence to the
 8 Lindsay Inquiry, LIND0000326.
 9 If we could turn, please, to page 15, so the very
 10 bottom of that page, you can see you were asked about
 11 what the practice was in 1983 and you talked there
 12 about a very strict policy about using DDAVP for those
 13 with mild disease. And then if we go over the page,
 14 you say at the top of the page:
 15 "For those who had severe Haemophilia A, there was
 16 not any positive stopping of treatment and people went
 17 on having both National Health Service and commercial
 18 concentrate."
 19 Now the context of that question may have been the
 20 response to the developing knowledge of AIDS, but is it
 21 right to read that as being practices in relation to the
 22 treatment of patients at the Royal Free didn't change in
 23 1983 and '84? That's --
 24 A. I don't know about change, what I -- this evidence
 25 that I gave to the Lindsay Inquiry 20 years ago was

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1 cross-checked with the people who were still -- who
 2 had been working at the Royal Free at that time, and
 3 the records.
 4 Q. So, as you previously indicated, this is the most
 5 reliable evidence you've given on those questions of
 6 fact?
 7 A. This is very reliable evidence, what I've said here,
 8 and, you know, I would remind you again that you're
 9 asking me questions in my memory about things that
 10 happened in 1983, which is 37 years ago. And what
 11 I would say about this evidence is that it is much
 12 more reliable. I'm then the Director and Professor of
 13 Haemophilia at the Royal Free, and more importantly,
 14 I have the experience and I'm able to find or
 15 cross-check the record of what was happening. But at
 16 the time that I was doing the research, or looking at
 17 the information from the patient notes and trying to
 18 work out what had happened when these people had their
 19 first treatment with concentrate, these decisions and
 20 if there were changes, they weren't my remit. All
 21 I can do is provide the evidence that was available.
 22 And I think it's very difficult for me -- you know,
 23 Peter's dead and ceased working in 1991. It's quite
 24 difficult for me to know what rules and changes and
 25 things he made. I don't know.

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1 **MS RICHARDS:** Sir, I note the time. I'm going to move on
 2 to the next topic of questioning to HIV and AIDS.
 3 **SIR BRIAN LANGSTAFF:** Well, let's give the Professor the
 4 opportunity to break now until tomorrow, if you'd
 5 rather.
 6 **PROFESSOR LEE:** I would prefer that. I'm exhausted.
 7 **SIR BRIAN LANGSTAFF:** I thought you might say that.
 8 **PROFESSOR LEE:** Thank you very much.
 9 **SIR BRIAN LANGSTAFF:** It is one of those days, I think.
 10 Shall we meet together then, at ten o'clock tomorrow
 11 morning. The rules that I've mentioned to you apply
 12 overnight as they do at any break.
 13 **PROFESSOR LEE:** So I can't talk to my husband tonight.
 14 **SIR BRIAN LANGSTAFF:** Well, you can talk to him.
 15 I wouldn't ever want to stop that, but not about your
 16 evidence, either what you have said or what you may
 17 yet say.
 18 **(4.20 pm)**
 19 **(The hearing adjourned until 10.00 am the following day)**
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1 I N D E X

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3 PROFESSOR CHRISTINE ANNE LEE, 1

4 affirmed

5 Questioned by MS RICHARDS 1

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<p>DR LEE: [4] 58/21 114/17 114/20 114/22</p> <p>MS RICHARDS: [29] 1/5 1/8 32/19 35/9 35/13 35/17 35/20 36/4 45/13 45/21 46/7 58/6 58/11 58/24 63/4 63/16 70/21 79/11 97/25 98/2 108/8 108/21 115/24 125/16 126/16 128/17 133/19 141/17 145/1</p> <p>PROFESSOR LEE: [8] 35/16 35/19 35/25 36/2 108/5 145/6 145/8 145/13</p> <p>SIR BRIAN LANGSTAFF: [40] 1/3 32/5 32/8 35/8 35/10 35/22 36/1 45/16 45/22 58/4 58/10 58/16 58/19 62/21 63/1 63/14 70/7 79/5 79/10 83/2 97/23 98/1 108/4 108/10 114/15 114/18 114/21 121/19 122/23 124/12 126/15 127/17 128/16 132/22 132/24 141/8 145/3 145/7 145/9 145/14</p> <p>'70 [1] 116/11 '72 [1] 116/12 '73 [1] 89/18 '75 [1] 124/13 '77 [1] 68/2 '78 [1] 12/1 '79 [4] 22/13 79/20 122/18 128/13 '79/'80 [2] 22/13 79/20 '80 [2] 22/13 79/20 '80s [1] 103/25 '83 [6] 12/1 12/23 15/13 64/18 81/18 142/25 '83/'84 [1] 64/18 '84 [5] 26/21 64/18 76/17 143/1 143/23 '87 [1] 25/5 '90s [2] 57/1 120/9 'free' [1] 76/5 'haemophilia [2] 13/23 60/8 'haemophilia/hepatitis ' [1] 13/23 'implicated' 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