

1 Thursday, 22nd October 2020
 2 (10.00 am)
 3 SIR BRIAN LANGSTAFF: Today we hear from Dr Tuddenham.
 4 MS RICHARDS: Yes.
 5 SIR BRIAN LANGSTAFF: May Dr Tuddenham be sworn.
 6 PROFESSOR EDWARD GEORGE TUDDENHAM (sworn)
 7 Examined by MS RICHARDS
 8 SIR BRIAN LANGSTAFF: Dr Tuddenham, if at any stage you
 9 want a break, please just let us know, will you?
 10 A. Yes.
 11 MS RICHARDS: Professor Tuddenham, I'm going to start by
 12 asking you just to give us an overview of your career.
 13 Your statement tells us that you were a senior house
 14 officer and registrar in pathology at the United
 15 Liverpool Hospitals, '69-'71.
 16 A. Correct.
 17 Q. And then you moved to the University Hospital, Wales,
 18 in Cardiff, where you worked under Professor Bloom
 19 from March 1972 to the end of 1975?
 20 A. That's right.
 21 Q. And I'll ask you a few questions about that in
 22 a moment. You then moved to the States for a period
 23 of time. You were a research associate at the
 24 University of Connecticut 1976 to 1977?
 25 A. Yes.

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1 Q. What was the work you were undertaking there?
 2 A. I had two projects. One, I was looking at human
 3 endothelial cells, which had recently been established
 4 in culture so one could study how they reacted to
 5 various stimuli and whether they produced Factor VIII
 6 or von Willebrand factor, as we then called it,
 7 Factor VIII-related protein; and the other project was
 8 purifying Factor VIII using immobilised columns of
 9 antibodies raised in rabbits.
 10 Q. And then you returned to the UK and you took a post at
 11 the Royal Free Hospital, at the beginning of 1978.
 12 A. Yes.
 13 Q. That's going to be the focus of most of my questions,
 14 you'll understand but, just to get the dates, you were
 15 for the first half of 1978 appointed I think on
 16 a locum basis?
 17 A. Yes.
 18 Q. And then your role became permanent in around
 19 September 1978 and you were joined in the course of
 20 1978 as a co-director by Dr Peter Kernoff?
 21 A. Yes, that's correct.
 22 Q. You remained in that position until 1986?
 23 A. Yes.
 24 Q. And you were doing work with Speywood during that
 25 period which, again, we'll come on to at a later

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1 stage. Where did you then move on to in 1986?
 2 A. I was able to join the Medical Research Council with
 3 my own Research Council-supported group. They first
 4 sent me to the National Medical Research Centre at
 5 Mill Hill for some retraining in molecular genetics,
 6 and then I moved to Northwick Park, where I set up my
 7 research group recruiting scientists who I knew or had
 8 met while I was at Mill Hill.
 9 Q. And what was the principal focus of your research
 10 there?
 11 A. We were going to use the new tools of molecular
 12 genetics and protein chemistry and structure function
 13 determination to study in more detail the properties
 14 and activities of the various components of the
 15 clotting mechanism, both at the protein structure
 16 function biochemical level and also at the genetic
 17 level, and we were using those tools to discover new
 18 mutations and identify genes that previously were only
 19 known from clinical studies. And we were able to, for
 20 example, establish the cause of some rare genetic
 21 diseases, and use the knowledge we gained from
 22 studying the pathology of abnormal molecules to
 23 understand more about the normal structure and
 24 function of clotting.
 25 Q. And then you took up a post as a Professor of

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1 Haemostasis at Imperial in 1994?
 2 A. Yes, this came about because Northwick Park Research
 3 Centre was closed down, and the MRC dispersed the
 4 groups who were working there, some of them to a new
 5 centre which they set up at the Hammersmith Hospital
 6 site, on Du Cane Road, and I was with one of those
 7 groups that moved to the new centre, and Imperial
 8 College kindly bestowed a professorial chair on me at
 9 that point.
 10 Q. Your role there, did that remain a research and
 11 academic role or did you have clinical
 12 responsibilities at that stage?
 13 A. It remained a research and academic role, although
 14 I did interact more with the Haemophilia Centre there,
 15 Professor Laffan, and provided some advice on cases,
 16 and also was interacting with the clinical teams of
 17 the Haematology Department.
 18 Q. Then you returned to the Royal Free Hospital in
 19 January 2006, in what capacity?
 20 A. I returned there as Professor of Haemophilia. We
 21 established a new chair in the name of
 22 Katharine Dormandy, which had been one of her original
 23 intentions, and I was also a director of the centre,
 24 so that I was clinically in charge of the, by then,
 25 much enlarged Haemophilia Centre and Thrombosis Unit,

1 and my major role, as stated at my interview applying
2 for the post, was that -- if possible, to initiate
3 studies on gene transfer, gene therapy.

4 **Q.** So you took over the role of director on
5 Professor Lee's retirement?

6 **A.** Correct.

7 **Q.** Although director, was your principal work there still
8 the research work?

9 **A.** Actually, no. I'd say I was able to devote about 30%
10 of my time to research. There is a large component,
11 of course, of administration. There was
12 a reorganisation going on for the haemophilia
13 services. The Pan-Thames Haemophilia Consortium was
14 considering the future of the service, and there had
15 been a proposal that it should be privatised, which
16 I resisted vigorously. And of course managing a large
17 clinic, both active for patients with haemophilia but
18 several other conditions, and also a thriving and
19 active women's clinic, which was with colleague --
20 professor now -- Rezan Kadir, an obstetrician, and we
21 were providing an interesting and, I think, very
22 valuable service there.

23 So I was very active clinically, very active in
24 the management issues as well as running the research.

25 **Q.** And that was a place you held until July of 2011?

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1 **A.** Yes.

2 **Q.** And then your statement tells us that your -- you
3 still hold the post of Honorary Consultant
4 Haematologist at the Royal Free. Does that involve
5 any active clinical work or research work or both?

6 **A.** Both. I'm active in several trials of gene transfer,
7 gene therapy, and haemophilia A and B.

8 **Q.** You were a member of UKHCDO during that first period
9 1978 to 1986 and you were one of the Reference Centre
10 Directors, and we'll come back to that. I'm going to
11 ask you some questions about that.

12 You were also on the Medical Advisory Panel of the
13 Haemophilia Society. What did that by and large
14 entail?

15 **A.** Yes, the Haemophilia Society would get an advisory
16 panel together on a regular basis, I think it was
17 three or four times a year. And it was relatively
18 informal, the issues of the day were raised and
19 discussed with the chairman and secretary of the
20 Haemophilia Society. The chairman in those days had
21 one of his -- his son was one of our patients, as it
22 happened. Of course it's very much a family concern,
23 haemophilia.

24 And we would, I would say, debate, discuss, in
25 a sort of fairly relaxed way. But of course the whole

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1 issue of infected blood and AIDS was ever more
2 present, and so there were discussions about such
3 issues, to which I contributed mostly when asked, more
4 about issues of diagnosis and technical aspects of the
5 kinds of assays that we carried out, which were a big
6 focus of my interest. I'd say the more clinical
7 aspects tended to be dealt with more by Peter Kernoff
8 and other colleagues.

9 **Q.** And you also sat for a period of time on the Advisory
10 Committee on the Virological Safety of Blood during
11 your MRC time?

12 **A.** Yes, I was called back in to that committee.

13 **Q.** We'll look at some minutes of decisions of that
14 committee at a later stage of your evidence,
15 Professor.

16 Can I just take you back, then, to the first half
17 of the 70s, '72-'75, when you were in Cardiff working
18 under Professor Bloom. As I understand it, this was
19 when your interest in haemophilia bleeding disorders
20 was particularly sparked?

21 **A.** Yes, I was a lecturer but I was in a training post,
22 and so rotating through the various
23 sub-sub-specialties of haematology, ranging across
24 from management of malignant cases, acute and chronic
25 leukaemia, myeloma, lymphoma, and also laboratory

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1 management, examination of blood films, examination of
2 bone marrow, taking bone marrows, examination of
3 tissue histologies, and so I got a very thorough
4 training in all those aspects.

5 There was active research in that unit, and
6 particularly interesting, it became to me more and
7 more so, was the research that Arthur Bloom was
8 managing, and he became a mentor to me in the studies
9 that he was undertaking into what were then the
10 unclear and even mysterious relationship between the
11 different Factor VIII deficiency disorders,
12 haemophilia A and von Willebrand disease.

13 **Q.** Were there any other particular research projects that
14 you can recall that Professor Bloom was undertaking at
15 that time other than the von Willebrand's research?

16 **A.** They were interested in platelet disorders, as well,
17 and he helped me make a first observation of
18 a complication of a platelet disorder which involved
19 the lung, which often gets quoted, but his interest
20 was mainly around haemophilia A and von Willebrand
21 disease, and he had collected a large cohort of
22 patients and families with those conditions which were
23 studied in parallel, trying to disentangle the
24 relative causation, which became a key to much of my
25 later research.

1 He gave me a couple of other research projects.
 2 They were interested in the time at which Factor VIII
 3 first appears during embryology, they were studying
 4 the distribution of Factor VIII in tissues, its
 5 synthesis. So he had a broad research programme. It
 6 was very active, it was to my mind the best research
 7 programme in the UK at that time on these fundamental
 8 issues.

9 **Q.** To what extent did you have involvement in any of the
 10 clinical practices of Professor Bloom at Cardiff, in
 11 terms of his interactions with and treatment of
 12 patients?

13 **A.** I was -- when the patients came in, as they all did in
 14 those days, for on-demand treatment, I would be
 15 responsible, when I was in that section of my
 16 rotation -- training rotation, for treatment, which of
 17 course we gave as quickly and as efficaciously as we
 18 could.

19 Home treatment wasn't at that time developed in
 20 Wales. I hesitate slightly but I wasn't aware there
 21 was any home treatment at that time.
 22 Katharine Dormandy was a pioneer in introducing home
 23 therapy, in London. So I would be involved with the
 24 immediate treatment.

25 The outpatient clinical work I would sit in with

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1 Professor Bloom when he was seeing patients and
 2 setting up diagnosis and treatment programmes, going
 3 on ward rounds, seeing the patients when they were
 4 admitted. The usual training role of a trainee
 5 haematologist.

6 **Q.** Can you recall whether there were any particular
 7 discussions, within the department, about the risks of
 8 hepatitis at that time?

9 **A.** I've racked my brains over that and I can't recall it
 10 at all. The risk that we particularly looked at and
 11 focused on was inhibitor, the development of antibody
 12 to the Factor VIII, which means the patient becomes
 13 resistant to treatment. Because at that time we had
 14 very few options for treatment for a patient in that
 15 situation.

16 **Q.** We understand from other documents that the Inquiry
 17 has seen that Professor Bloom took a direct and active
 18 role in deciding what concentrates and treatments and
 19 blood products should be used, and had a number of
 20 direct interactions with pharmaceutical companies.
 21 Were you involved in any of that or did you observe
 22 any of that when you were there?

23 **A.** No, I wasn't involved and I didn't observe it.

24 **Q.** Do you know whether blood samples were stored in
 25 Cardiff in the way we know Dr Kernoff stored samples

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1 at the Royal Free?

2 **A.** I'm sure samples were being stored because one would
 3 often need to have a particular sample for
 4 a particular experiment so it's useful to have samples
 5 from a patient with a severe form of haemophilia
 6 because we used them in the one-stage assay. And from
 7 the patients with von Willebrand disease, where one
 8 had several different assays to perform or develop,
 9 looking at different aspects of that condition,
 10 samples would have been stored. I don't remember
 11 there being a plasma bank of any size.

12 **Q.** Can we move on, then, to the Royal Free Hospital and
 13 the Haemophilia Centre there, which you joined in
 14 1978.

15 You were, if you don't mind me saying so,
 16 relatively young at that point in time when you were
 17 appointed, and your clinical practice, in terms of
 18 haematology, had been what you just told us about in
 19 Cardiff?

20 **A.** Yes.

21 **Q.** Dr Kernoff, too, I think, was relatively young at that
 22 time --

23 **A.** Yes.

24 **Q.** -- the time of his appointment. What had his route to
 25 becoming director been? Do you know?

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1 **A.** He'd been doing some research in Oxford, and he went
 2 from there to work with a Dr Hymie Nossel in New York,
 3 and I believe it was there that he became most
 4 interested in the aspect of hepatitis and treatment
 5 with Factor VIII or Factor IX products. And so he was
 6 still working on those projects when he was appointed
 7 as the clinical NHS director, and I'd been appointed
 8 as Katharine's successor to a senior lectureship, so
 9 an academic appointment. So when he eventually came
 10 to join us, we were co-directors, which I think is --
 11 was a unique arrangement and I'm not aware of another
 12 such arrangement in the UK or elsewhere, but we --
 13 because we had parallel but distinct interests, that
 14 worked very well. That I could focus on the academic
 15 and research, and he focused -- also on research, but
 16 mainly on the clinical service.

17 **Q.** And what can you tell us about the facilities at the
 18 Royal Free Haemophilia Centre when you arrived in
 19 1978? What did they comprise?

20 **A.** On day one it was still very minimal, really. We
 21 weren't still using the caravan that had been the
 22 place where Katharine saw patients when she started
 23 her Haemophilia Centre. We were using part of -- the
 24 hospital was newly built, and a purpose-built centre
 25 was ready and empty and waiting for us to move into,

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1 but in the first weeks, before we moved in, we just
2 had couple of offices and a small lab area, and we saw
3 patients in the General Outpatients, and patients who
4 came in and needed to come in, went on to the wards.

5 I moved the centre, once I was appointed, into the
6 new purpose-built area, on two floors on the corner of
7 the hospital, and it was a blank sheet. I had to
8 decide what went where, who did what, and make it up
9 as I went along.

10 **Q.** In terms of where the clinical care was done, the
11 sense we got from Professor Lee's evidence
12 yesterday -- obviously she was describing things when
13 she arrived at the beginning of 1983 -- was that there
14 were an area with a number of rooms but all located
15 together?

16 **A.** Yes.

17 **Q.** And Dr Kernoff was based there.

18 **A.** Yes.

19 **Q.** And that's where patients were seen. That's where
20 Professor Lee was based, the nursing staff and so on.
21 Were you based on the floor above?

22 **A.** Yes. I had my office upstairs near to the lab and my
23 research group.

24 **Q.** Again, Professor Lee described to us from 1983 onwards
25 that there were regular meetings. She talked about

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1 Tuesday meetings and Thursday meetings of the whole
2 department to discuss various different matters. What
3 could you -- what can you recall about those?

4 **A.** Yes, in our multi-disciplinary team meetings, we
5 were -- a whole principle was to bring everybody
6 together so that everybody knew what was going on,
7 including laboratory staff, and -- because a key to
8 running haemophilia care effectively is to have
9 a well-developed laboratory. It's a
10 clinico-laboratory specialty; our excellence, which is
11 one of the things that attracted me to the specialty.
12 So we would also that have the physiotherapists, the
13 psychosocial workers, social worker, and nursing, of
14 course, and medical staff, and we would go through the
15 aspects of clinical care and technical aspects of
16 laboratory observation and monitoring.

17 **Q.** In terms of the treatments policies and practices when
18 you arrived, we've got a description from you in
19 a seminar that you participated in in the 1990s.
20 Could we have RLIT0000022, please, Henry.

21 This is a -- described as a witness seminar,
22 February 1998, "Haemophilia: Recent History of
23 Clinical Management." A number of people
24 participated, including yourself. And if we could go
25 to page -- Henry, if you look in the bottom right-hand

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1 corner, it'll be page 35, but I'm not sure what page
2 that is electronically. It'll be more than 35. So if
3 you could go 10 pages further on.

4 So we can see the description here. We can pick
5 it up with Professor Lee's observation at the top of
6 the page. She says:

7 "In our Centre, we were a bit slow to use large
8 full clotting factor concentrate because it wasn't
9 really until you and Peter Kernoff came that people
10 were started on this treatment, because Katharine had
11 been so taken up with the cryoprecipitate."

12 Then Dr Matthews makes an observation. And then
13 if we can just see what you then talk about. You say:

14 "Katharine had a wonderful relationship with her
15 patients. It was maternal in some ways, because she
16 knew them all very well, and their social
17 circumstances. She put a very great deal of effort
18 into ensuring that they would have the best possible
19 circumstances for home treatment. She was a pioneer
20 in that area and obtained, as you mentioned, money for
21 them to have freezers in their own homes in which they
22 kept cryoprecipitate.

23 "I would say that, to be fair to Katharine, it was
24 difficult, as other speakers have mentioned, to obtain
25 adequate supplies of higher-purity concentrates other

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1 than for surgery, and the Centre's treatment relied
2 very much on cryoprecipitate produced through local
3 Blood Transfusion Centres. Things changed, of course,
4 when Peter Kernoff and I came in after Katharine
5 tragically died, and the concentrates were brought in
6 progressively through battles against the controllers
7 of the finances. Although, to do them justice, they
8 did progressively increase the fraction of local
9 capital that was being expended on imported
10 concentrates until they reached towards the dizzying
11 heights of today. So it was a transitional phase.
12 Katharine was a pioneer and it undoubtedly changed the
13 lives of our patients at that time to have their own
14 freezers filled with locally produced
15 cryoprecipitate".

16 There was a period of time when you first took up
17 your post when Dr Dormandy was still there, not long,
18 I think, before she died, but you did work with her
19 for a short period of time.

20 **A.** Not in the clinic. She had actually become more or
21 less bedridden by the time I arrived and took over, so
22 she was no longer working when I started.

23 **Q.** But that is an accurate description, is it, of what
24 your understanding was of how things had been
25 organised at the Centre under Dr Dormandy?

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1 A. Yes.
 2 Q. So predominantly cryoprecipitate, at least for adults.
 3 Your statement suggests that children may already
 4 have been on NHS concentrates by then. Is that right?
 5 A. That's right, yes. We were treating children with
 6 concentrate. I can't remember giving cryoprecipitate
 7 to a child with severe haemophilia. And ... so, yes,
 8 that's my recall.
 9 Q. And do you know why children in particular were on NHS
 10 concentrate at that point in time; the adults still on
 11 cryo?
 12 A. There's an issue of volume, and the concentrate was --
 13 as the clue is in the name -- it's a much smaller
 14 volume to give, it's easier to give it, and for
 15 children you tend to use very fine needles, especially
 16 the youngest children, and cryoprecipitate doesn't
 17 easily go through a fine needle. It's very -- it's
 18 sticky. It's actually mostly fibrinogen, which is
 19 a big, sticky molecule with a little bit of
 20 Factor VIII. And so the concentrates were a big step
 21 forward for treating small children.
 22 Q. Can you recall the extent to which, at the time you
 23 arrived, there was use of commercial concentrates?
 24 A. We had access to some. It was there in the mix. It
 25 gradually became the case that we used more and more,

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1 as is shown by all the documents you have from Peter
 2 during his time obtaining resources and running the
 3 clinical service.
 4 Q. What else was available for treatment in 1978? Was
 5 DDAVP being used already at that stage at the centre?
 6 A. No. We didn't get -- we did start using DDAVP pretty
 7 soon after Mannucci had described its utility. And
 8 the exact time at which we were using it regularly is
 9 some time after 1980.
 10 Q. And then, in terms of those with haemophilia B -- and
 11 again, I'm just looking at the point in time in 1978
 12 when you and then later Dr Kernoff arrived, was
 13 haemophilia B already being treated with NHS Factor IX
 14 concentrates at that point?
 15 A. Yes, it was. Yes.
 16 Q. And what treatments were being used for those with
 17 inhibitors?
 18 A. Right. Um, for haemophilia A with inhibitors, we
 19 didn't have any resource other than to try giving
 20 a large dose of Factor VIII. The observation that
 21 Factor IX concentrate could be helpful was made by
 22 somebody who accidentally gave Factor IX instead of
 23 Factor VIII. And, in hindsight, the reason that
 24 worked was that the Factor IX concentrates we were
 25 using in those days were a mixture of clotting

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1 factors; some of them already activated. Clotting
 2 factors circulate in our blood in a precursor or
 3 proenzyme form and become activated during the process
 4 of forming a clot. But when purifying Factor IX, you
 5 end up with a mixture of related factors, some of them
 6 active, and so the Factor IX concentrate of the day
 7 was actually quite effective in treating patients with
 8 antibodies to Factor VIII, because the active factors
 9 jumped over the block -- a so-called bypassing
 10 agent -- and then that was formally developed into the
 11 product called Factor VIII inhibitor bypassing agent
 12 fibre which is an activated Factor IX complex
 13 concentrate.
 14 So we were beginning to have some new tools, but
 15 it was a while before we got the activated Factor VII,
 16 NovoSeven. We were struggling with patients with
 17 inhibitors.
 18 Q. So the major change, then, that was instituted under
 19 the new directorship was the shift from
 20 cryoprecipitate for home therapy to concentrates.
 21 A. Yes.
 22 Q. Why was that decision taken?
 23 A. If one makes up cryoprecipitate practically, one soon
 24 encounters the fact that it's a variable product.
 25 It's got to be thawed. It's very -- the amount of

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1 Factor VIII in it varies quite a lot, so you have to
 2 give five or ten bags. You've got to thaw out each
 3 one, draw it up, this gloopy material, through large
 4 diameter needles into syringes over -- it's
 5 time-consuming. And then infusing it is a slow
 6 business because of its viscosity.
 7 To go from that to a little bottle with a defined
 8 amount of Factor VIII in it that you just add the --
 9 usually water for injection to it, it dissolves pretty
 10 quickly; draw it up easily, and give it fairly
 11 quickly. That's obviously a big step forward, and it
 12 was appreciated by everyone, not just the doctors and
 13 nurses; the patients we could say. And the material
 14 can be stored in a domestic refrigerator; doesn't have
 15 to be in a freezer.
 16 So it had many obvious practical advantages, and
 17 also, in the case of requirement to elevate factor
 18 level in the patient up towards or in the normal range
 19 of surgery -- head injury, life threatening
 20 bleeding -- it was much more reliable to achieve that
 21 than the use of cryoprecipitate.
 22 Q. So practical considerations, convenience, efficacy.
 23 What consideration was given to the relative safety of
 24 cryoprecipitate and concentrate?
 25 A. It was pretty early on noticed, by the way, with

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1 cryoprecipitate at first that multiple donor
 2 treatments, for example, 5, 10, 20, 50 bags of cryo
 3 expose you to 50 donors, and within less than a year
 4 of Judith Pool publishing the method for making
 5 cryoprecipitate, the fact that there was an increased
 6 incidence of hepatitis was reported on. So we already
 7 knew that multiple donor exposure enhanced your
 8 chances to -- for blood-borne infection; hepatitis.

9 The fact that in making concentrate one pools
 10 hundreds to thousands of donations of plasma, very
 11 obviously increases exposure to numbers of donors and,
 12 therefore, to whatever transmissible agents they may
 13 be carrying.

14 I believe that was appreciated, but the extent to
 15 which that was a risk in numerical terms wasn't
 16 sufficiently appreciated, in hindsight. We had
 17 already encountered hepatitis in subjects who'd
 18 received hundreds by the time they'd been on
 19 cryoprecipitate regularly on remand for a year or two
 20 or three. They would have clocked up the number of
 21 exposures to get hepatitis, and so switching to a
 22 product which perhaps in the way -- rather naive way,
 23 we considered it, "Oh, well, they've already been
 24 exposed. This is not going to change that," was,
 25 I think, the kind of appreciation we had at the

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1 beginning.

2 We didn't see a sudden change just by going to
 3 concentrates from cryoprecipitate in the patients we
 4 were treating who we'd already been treating for quite
 5 a while on cryoprecipitate.

6 Of course, that changes when you start giving new
 7 treatments to new, not previously exposed patients,
 8 because instead of their needing to be exposed over
 9 several score or hundreds of bags of cryo, the first
 10 exposure to a bottle of a concentrate made from
 11 hundreds of individuals is going to put the risk
 12 straight up there straight way.

13 **Q.** When did that realisation occur, as far as you can
 14 recall? Was that something known in 1978?

15 **A.** That was something that those who were using the
 16 concentrates had become aware of by 1978. Certainly,
 17 Peter Kernoff was already aware of that from the
 18 research he was doing with Dr Nossel in New York. So
 19 he came in with the knowledge of that and the
 20 intention to study it in detail.

21 **Q.** And the decision to shift away from cryoprecipitate to
 22 concentrates, was that Dr Kernoff's decision alone?
 23 Was that a joint decision; can you recall?

24 **A.** Well, I was there giving concentrates to patients and
 25 aware of the advantages we've just discussed. And it

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1 was the general agreement that we needed to use
 2 concentrates because of the advantages and the fact we
 3 could get better control on haemostasis. And it was
 4 sort of enthusiastically received across the whole
 5 field of haemophilia care that concentrates were the
 6 way to go. And I was, you know, impressed by the same
 7 arguments for the switch.

8 **Q.** In terms of patients who were not severe
 9 haemophiliacs, so mild haemophiliacs, and before you
 10 started using DDAVP regularly, which I think you
 11 suggested was 1980 or thereabouts, so that period, '78
 12 to '80, would mild haemophiliacs have been given
 13 concentrates?

14 **A.** Yes, they might well have been. Yes.

15 **Q.** Just want to look at some of the annual returns with
 16 you. I'm not expecting you to remember the data
 17 that's recorded in them, Professor Tuddenham, but just
 18 so we can see from the returns what products were as a
 19 matter of fact being used. So if we could please
 20 have, Henry, RFLT0000362.

21 The annual return is buried deep in this document.
 22 Before we turn to it, can I just ask you, do you know
 23 what these documents were? We've got a number of
 24 them. It says, "Monthly allocation of Factor VIII."
 25 This one happens to be from September 1979. And we

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1 can see at the bottom it says:

2 "Photocopies to ET [which I presume is you] PK
 3 [which would have been Dr Kernoff] and PL [presumably
 4 the nursing sister]"?

5 **A.** Yes, Patricia Lilley. So that's me, Peter Kernoff,
 6 and the senior nurse on the unit.

7 **Q.** And what is this document? What does it tell us and
 8 what was its purpose at the time; do you know?

9 **A.** These are the beginnings of treatment -- summaries of
 10 treatment records which was, of course, to be
 11 developed far more into the National Haemophilia
 12 Database eventually so we know every product that each
 13 patient has received. So where you've got "GRO-A",
 14 that's a patient's name that's been redacted.

15 **Q.** It is, yes. Yes.

16 **A.** Correct, yes. So we can see what treatment the
 17 patient four down -- and it says, "Allocation". I'm
 18 thinking aloud. Eight. Ten times 245, so that --
 19 yes, those -- 245; that's the number of units. That
 20 must have been concentrate because there's a serial
 21 number for the concentrate batch and the date it was
 22 given.

23 **Q.** If we go on in this document, Henry. It should be,
 24 I hope, page 12?

25 **SIR BRIAN LANGSTAFF:** Just to clarify, the numbers on the

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1 monthly allocation, is that the number of bottles?
 2 **A.** I'm puzzled by that too. I'm just thinking -- if we
 3 look at patient where it says "20", the patients -- in
 4 fact, I think -- you're quite right. Yes. Ten will
 5 be the number of bottles because each bottle had 245,
 6 yes. So the next patient's been allocated 20 but in
 7 fact has used 50 bottles. And so --
 8 **SIR BRIAN LANGSTAFF:** Curiously, one of those bottles has
 9 got 230 in it.
 10 **A.** Yes, it's a different batch. If you look at the batch
 11 number -- (overspeaking) -- it's HL6619.
 12 **SIR BRIAN LANGSTAFF:** Yes, thanks.
 13 **A.** Batch-to batch variation. So I think the allocation
 14 would be a kind of guess at expected usage, and then
 15 what's written in is what they were actually treated
 16 with.
 17 **MS RICHARDS:** Then if we go to page 12, please, Henry, we
 18 have the annual return for 1979. So we can see
 19 towards the top of the page this is for patients
 20 having haemophilia or Christmas Disease, so they're
 21 brought together in one document at this time. Total
 22 number of haemophiliac patients treated during the
 23 year, 130. Number with Factor VIII antibodies, we
 24 seem to have two-numbers there, 14 or 12, but let's
 25 not worry about that. Number of Christmas Disease

25

1 patients treated during the year, 26.
 2 If we go down the page, Henry, we can see there's
 3 usage there of cryoprecipitate and NHS factor
 4 concentrate, and then larger amounts of Profilate and
 5 Factor VIII, so two of the commercial concentrates,
 6 and then an amount of Koate and a smaller amount of
 7 Hyland. We've then got further down bovine and
 8 porcine Factor VIII -- I'll ask you about that
 9 later -- and some FEIBA being used. And then for the
 10 Factor IX column, we can see it's entirely Factor IX,
 11 NHS Factor IX concentrate.
 12 So we can see, by 1979, predominantly
 13 concentrates, and of those concentrates, predominantly
 14 commercial, rather than NHS for haemophilia A.
 15 **A.** Yes.
 16 **Q.** And then if we could go, please, Henry, to page 18 of
 17 this document. This is again part of the annual
 18 returns for 1979. It's one of the standard forms.
 19 Just so we can understand, these were the forms
 20 that were submitted by the Haemophilia Centre to
 21 Oxford --
 22 **A.** Yes.
 23 **Q.** -- for analysis. And so, as well as the summary we've
 24 just looked at, details of every patient, their date
 25 of birth, their base Factor VIII level, whether they

26

1 had inhibitor, whether they'd been jaundiced, whether
 2 they were on home therapy and the type of material,
 3 that would all be sent on an annual basis to Oxford at
 4 this time?
 5 **A.** Yes.
 6 **Q.** Do you know whether patients were aware that data
 7 about them, named data about them, was being sent to
 8 Oxford at that time?
 9 **A.** I don't know. I don't recall any discussion about
 10 that point. I would think that there was some
 11 awareness that the national statistics were being
 12 gathered, which were of course crucial for our
 13 discussions with the Department of Health.
 14 In fact, this is a side comment: the World
 15 Federation of Haemophilia always puts to the
 16 development of better and new programmes in developing
 17 countries. The first thing you need is to gather
 18 statistics, because then you've got some data to
 19 present to your Minister of Health. So whether --
 20 I don't remember having a discussion with any patient
 21 ever at that time about having details about their
 22 treatment sent to a central database.
 23 **Q.** And then if we could look at the returns for 1980.
 24 Henry, that's RFLT0000363. And we can see -- I think
 25 the return's now broken down separately, so the first

27

1 part of it is haemophilia A and carriers of
 2 haemophilia A and von Willebrand, and then there's a
 3 separate return for haemophilia B. So we can see the
 4 numbers treated here: 125 haemophilia A, 4 carriers,
 5 20 of von Willebrand's. Then if we look at the
 6 haemophilia A patients columns, we can see some usage
 7 of cryoprecipitate in hospital; a very modest amount
 8 used for home treatment. NHS factor concentrate:
 9 a small amount used in hospital; a larger amount used
 10 for home treatment.
 11 Would that have reflected predominantly the
 12 treatment that was being given to children?
 13 **A.** I think some of that may have gone to adults, but
 14 probably most of it was to -- for children.
 15 **Q.** Then we can see there's a range of different
 16 commercial products being used so there's some usage
 17 of Profilate, Koate, and Hemofil, and then a much
 18 larger amount of Kryobulin -- nearly a million
 19 units -- and then a still larger amount of
 20 Factor VIII, the Armour product, nearly 2 million
 21 units.
 22 So by this time, we can see here clearly on the
 23 returns that the move that you've described here
 24 towards commercial concentrates is the primary line of
 25 treatment.

28

1 A. Yes.

2 Q. Then if we just look over to the von Willebrand's

3 column, do we see there no home treatment for

4 von Willebrand's patients, so it's all hospital

5 treatment?

6 A. Mm.

7 Q. It's in fact cryoprecipitate being used as the main

8 treatment at that point, some NHS factor concentrate,

9 and a very small amount of commercial concentrates.

10 A. Yes. Cryoprecipitate is rich in von Willebrand

11 factor, and particularly the high-molecular-weight

12 form which is most effective in dealing with the

13 problem you have in von Willebrand disease which needs

14 large molecules in the process of forming the first

15 bit of clot, which is a platelet plug. And so it's

16 a very good treatment for von Willebrand disease.

17 Concentrates have variable amounts of

18 high-molecular-weight von Willebrand factor in them,

19 and it was many years before specific concentrates

20 were developed that were for use in von Willebrand

21 disease. At that time, I see we were -- had issued

22 some of the Factor VIII concentrates, but some of them

23 weren't very effective in those days. The NHS

24 Factor VIII concentrate was pretty effective. So the

25 more you focus on purifying the Factor VIII, the less

29

1 von Willebrand factor activity you have, unless you

2 pay attention to concentrating that as well.

3 Q. If we go on two pages, please, Henry, we can just look

4 at the same return but for haemophilia B. So 25

5 patients with haemophilia B treated during the year

6 1980. And we can see the exclusive treatment, both in

7 hospital and at home, is the NHS Factor IX

8 concentrate?

9 A. Yes.

10 Q. And then just one last set of returns. We don't have,

11 I think, the returns for 1981 or 1982. We've got the

12 '83 returns. Henry, can we have HCDO0000184_006. We

13 can see again the number of patients at the top. 128

14 haemophilia A, 4 carriers, 24 von Willebrand's. Then

15 if we look at the pattern of treatment for

16 haemophilia A patients, we can see a relatively modest

17 amount of cryoprecipitate used for hospital treatment.

18 NHS factor concentrate, we can see there the usage for

19 home treatment is much more extensive than the usage

20 for hospital treatment, 1.2 million units. But then

21 again the bulk of the treatment, the commercial

22 concentrates, so we've got for both home and hospital

23 treatments, over a million units of Factor VIII. And

24 then for Koate, over a million units for home

25 treatment, and over 238,000-odd for hospital

30

1 treatment. And similar amounts, in terms of hospital

2 and home treatment, for Hemofil and Kryobulin. So

3 again, the bulk of the products are commercial.

4 A. I'm intrigued to see that NHS Factor IX concentrate is

5 being used. That must have been for the patients with

6 inhibitors. Because it's in the column of haemophilia

7 A patients.

8 Q. It is. We see there for the first time, I think,

9 there's express reference to DDAVP.

10 A. Yes.

11 Q. As I say, we don't have the returns for '81, '82. Then

12 we can see, for von Willebrand's, it's a mix of

13 cryoprecipitate and NHS Factor VIII concentrate.

14 A. Yes.

15 Q. And then if we go to --

16 **SIR BRIAN LANGSTAFF:** Just before you leave that,

17 underneath the Factor IX concentrate, you have what's

18 described as NHS low hepatitis VIII concentrate. What

19 was the low hepatitis NHS product, as you recall?

20 A. Yes, I was intrigued to see that too. I don't know.

21 I wasn't aware of such an entity.

22 **SIR BRIAN LANGSTAFF:** It suddenly occurred to me, I don't

23 think we've heard anything about that, have we?

24 **MS RICHARDS:** No. We know of the hepatitis-reduced

25 commercial products because we've seen the

31

1 discussions -- UKHCDO Dr Rizza, et cetera -- in

2 relation to those commercial products. We'll need to

3 do some further digging, sir, I think, in relation to

4 NHS low hepatitis.

5 **SIR BRIAN LANGSTAFF:** Please.

6 A. It's possible -- pure speculation now -- that these

7 were concentrates batches that had been shown to have

8 a lower risk of inducing hepatitis in treating

9 previously untreated patients. I'm speculating. If

10 Peter were around, we'd ask him, but I don't know what

11 they were.

12 **MS RICHARDS:** And it's a very small volume usage there.

13 A. Small volume. If David Lane is questioned at any time

14 in this Inquiry, he should know about it. He was

15 director of the UK fractionation at that time, yes.

16 **SIR BRIAN LANGSTAFF:** Yes.

17 A. Yes.

18 **MS RICHARDS:** Then we can look at the haemophilia B return

19 for '83 briefly.

20 HCDO0000184_051, please, Henry.

21 And again -- so we see 31 patients with

22 haemophilia B, one carrier. Apart from a small amount

23 of fresh frozen plasma for carriers, and then what's

24 described as "HB Vax", which I'll ask you about in

25 a moment, we can see again it's exclusively NHS

32

1 Factor IX concentrate. The reference to "HB Vax", is
 2 that to vaccination in relation to hepatitis B?
 3 **A.** Yes, we were vaccinating by then. I was too,
 4 actually. It was the vaccine that was produced from
 5 volunteer donors in the New York gay community, who
 6 had what we then called the Australia antigen, which
 7 was one of the antigens of hepatitis B, and so we were
 8 making sure that all our patients and actually staff
 9 were vaccinated.
 10 **Q.** One further document in terms of product usage.
 11 It's CBLA0001244, please, Henry.
 12 This is a letter from you to Dr Lane at BPL dated
 13 23rd January 1981, and you're providing him with an
 14 analysis of Factor VIII usage at the Royal Free for
 15 the calendar year 1979, and you also refer to the
 16 National Haemophilia Centre returns, which we've
 17 looked at for certain years, and you say:
 18 "I have no doubt that our usage under most
 19 treatment categories has increased in 1980 over 1979.
 20 The total usage figure for 1979 ..."
 21 Was just over 3 million units, and then 1980,
 22 3.4 million units.
 23 "The numbers of patients involved was not I think
 24 significantly different ..."
 25 Then, just so we can see the attachments that

33

1 we've found to this letter, if we could go to the next
 2 few pages, we can see here "Haemophiliacs treated with
 3 human Factor VIII in 1979", and you've set out there
 4 the patient group by reference to: inhibitors, severe,
 5 moderate and mild. And we can see there the relative
 6 usage and then the usage in terms of surgery.
 7 And then just so you can see what else you've
 8 written in closing, Dr Tuddenham, if we look briefly
 9 at the next two pages, there's a table entitled
 10 "Factor VIII Units Used by Haemophilia Centres in
 11 1979", and then the final page, "Haemophilia A
 12 Patients known at Haemophilia Centres on
 13 [31st December 1979]".
 14 Why were you sending this material to Dr Lane; do
 15 you remember?
 16 **A.** No. I'll have to speculate. He was interested in
 17 development of new methods for purification, and
 18 I think he was interested in projecting future need.
 19 But more than that I can't say.
 20 **Q.** If you just go back to the letter, the first page, the
 21 letter tells us that you're using more products for
 22 roughly the same number of patients. Do you know why
 23 that was?
 24 **A.** We were improving the treatment and management of
 25 haemophilia. We got more home therapy so patients

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1 could treat immediately when they felt they had
 2 a bleed, when patients were gaining confidence in
 3 coming in, and having surgeries. It was just --
 4 improving management of haemophilia involves using
 5 larger amounts of replacement therapy.
 6 **Q.** Then could we look at, there's a handful of sets of
 7 minutes I wanted to look at briefly with you,
 8 Professor Tuddenham. The first is CBLA0000383 --
 9 sorry, I think I've written that down wrongly, I
 10 think, Henry. It's CBLA0000838. Thank you.
 11 We can see it's described as a "Third meeting of
 12 directors of haemophilia, associate haemophilia and
 13 blood transfusion centres", for -- and then we can see
 14 the regions there: East Anglia, North West Thames and
 15 North East Thames. And the date of the meeting is
 16 1st September 1978.
 17 If we go to the next page we can see the list of
 18 those attending, so it's what I think was referred to
 19 as a supra-regional meeting, with a number of regions
 20 gathered together, and we can see that you were there,
 21 Dr Kernoff was there, Dr Goldman was there, and
 22 Mrs Britten was there from the Royal Free. And then
 23 a number of others from other hospitals, including
 24 Professor Ingram from St Thomas'.
 25 If we could just turn to the third page, Henry, no

35

1 the fourth page, sorry. You'll see halfway down the
 2 page there's an item in the minutes headed
 3 "Distribution of NHS Factor VIII concentrate", and
 4 there's a reference in the third line to:
 5 "In April 1978 Dr Dormandy, [you], Dr Ardeman,
 6 Dr Davies and Mrs Britten met to try and sort out the
 7 distribution of the 360 bottles per month of NHS
 8 concentrate allowed to the North West Thames, bearing
 9 in mind that the requirements at the region were much
 10 more than this."
 11 I don't need to go into the detail of it with you,
 12 but the source of NHS concentrate for you, did you get
 13 that from the Regional Transfusion Centre or from BPL?
 14 This looks like it's the Regional Transfusion Centre
 15 at that time.
 16 **A.** At that time, it must have been the Regional
 17 Transfusion Centre.
 18 **Q.** We've heard from others or seen reference in other
 19 documents in some regions to there being shortages of
 20 NHS concentrate and specified allocations. Is that
 21 what the position was for the Royal Free at this time?
 22 **A.** Yes, we were in need of more factor concentrates than
 23 the NHS could supply, the NHS concentrate. I do
 24 remember this meeting. It was the last occasion that
 25 Dr Dormandy was involved actively with any such

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1 meetings, and I picked her up and drove with her to
 2 where we held the meeting and took her home
 3 afterwards. It was the last time I saw her, actually.
 4 And so, yes, we were trying to decide on fair
 5 distribution of a limited resource.
 6 **Q.** If we go to the next page, please, there's
 7 a discussion about shortages and Dr Lane's perspective
 8 and so on which I don't need to ask you about, but if
 9 we pick it up in the fourth paragraph, beginning
 10 "Dr Kernoff felt":
 11 "Dr Kernoff felt that this did not solve the
 12 problem ..."
 13 That was an issue about allocation.
 14 "... it merely passed it to someone else; it
 15 increased the Royal Free's use of concentrates and
 16 they were already overrunning their budget. The
 17 problem needed to be dealt with at a regional,
 18 supra-regional and national levels."
 19 Then he says this:
 20 "Only 20% of the Royal Free's requirements were
 21 being met with the NHS concentrate at present.
 22 Despite this, and in accordance with the Reference
 23 Centre Directors' recommendations, it was the
 24 intention to switch home treatment patients from
 25 cryoprecipitate to concentrate."

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1 So, pausing there, we can see that this wasn't
 2 just a patient-by-patient shift. As it were, there's
 3 a policy decision recorded here from the Royal Free?
 4 **A.** Yes.
 5 **Q.** From you and Dr Kernoff?
 6 **A.** Mm-hm.
 7 **Q.** And then this is said:
 8 "Half the home treatment patients at the
 9 Royal Free were still using cryoprecipitate and this
 10 was felt to be an unacceptable state of affairs."
 11 That's quite a strong way of putting it. Do you
 12 know why Dr Kernoff thought it was unacceptable to be
 13 using cryoprecipitate?
 14 **A.** The short answer is "no", because I didn't discuss
 15 this with him at the time, but I think it's fair to
 16 speculate that that's unacceptable because of the just
 17 practical difficulties of handling, managing, making
 18 up and transfusing this primitive, as it seems by
 19 comparison to the freeze-dried concentrate,
 20 cryoprecipitate material.
 21 **Q.** The minutes continue:
 22 "If NHS concentrate was not available then
 23 commercial concentrate would have to be bought."
 24 And the returns show us that that's exactly what
 25 happened.

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1 Then this:
 2 "... the extra cost might not be very great since
 3 the cost of cryo to the Royal Free was not
 4 inconsiderable and, taking into account the unitage,
 5 it worked out at almost the same price as commercial
 6 concentrates."
 7 I don't think we've seen this elsewhere so far,
 8 Professor Tuddenham. This suggests that the Royal
 9 Free was having, at that time, to actually pay for
 10 cryoprecipitate.
 11 **A.** Yes.
 12 **Q.** Can you recall anything about that?
 13 **A.** No. No. Peter dealt with all of that. But it is
 14 impressive that it's almost the same price. We were
 15 using a lot of cryo.
 16 **Q.** And then there's just one further passage in these
 17 minutes.
 18 If we could go on two pages, please, Henry.
 19 If we look at the paragraph in the bottom half of
 20 the page, it's headed "Possible problems of blood
 21 donations from family members of patients on home
 22 treatment":
 23 "Dr Kernoff mentioned an incident that had taken
 24 place at the Royal Free Hospital where the mother of
 25 a patient on home treatment pricked herself and

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1 subsequently developed hepatitis. Before becoming
 2 ill, she had donated blood which had apparently been
 3 administered to a patient ... The boy himself was
 4 positive to hepatitis B antigen although remained
 5 asymptomatic."
 6 Pausing there, is it correct to read this as the
 7 mother developed hepatitis B?
 8 **A.** Yes.
 9 **Q.** Then this:
 10 "Dr Kernoff pointed out that family members of
 11 patients on home treatment should be considered high
 12 risks for transmission of hepatitis and should not be
 13 allowed to donate blood."
 14 I don't know whether you recall anything about
 15 this particular incident?
 16 **A.** No, but her son clearly was a carrier of hepatitis B,
 17 and handling blood from someone who is a hepatitis B
 18 carrier is a notoriously high risk for transmission.
 19 And as we see happened here.
 20 **MS RICHARDS:** I'm going to turn to some UKHCDO minutes.
 21 Sir, I note the time, it's 11. Is that
 22 a convenient point at which to take the first break?
 23 **SIR BRIAN LANGSTAFF:** Yes, it is.
 24 We have a break every morning for a coffee or
 25 refreshment, and normally it's 45 minutes, so we'll

40

1 take that 45 minutes, and quarter to 12, if you
2 please.
3 **MS RICHARDS:** Sir, if you could explain to
4 Professor Tuddenham the position in relation to
5 discussing evidence.
6 **SIR BRIAN LANGSTAFF:** Yes, I will.
7 Professor, you're giving evidence. You must not
8 talk to anyone, whoever they are -- it includes
9 counsel, those with you, and so on -- about your
10 evidence, either what you have said or what you think
11 you may be asked to say. You can talk about anything
12 else you like.
13 Thank you.

14 (11.02 am)

(A short break)

16 (11.43 am)

17 **MS RICHARDS:** Professor Tuddenham, there's a set of
18 minutes I want to look at briefly with you.
19 It's HSOC0010549, please, Henry.
20 This is minutes of a meeting of the Haemophilia
21 Centre directors, 13th November 1978, so it's the big
22 meeting not the Reference Centre Directors meeting.
23 If we go to the fourth page -- sorry, Henry, my
24 apologies, it should have been the third page -- we
25 can see just above the "Present at Scientific Session

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1 Only" we've got your name. So you were in attendance
2 at the meeting.
3 If we go, please, Henry to page 12, using the
4 numbered pagination at the top of the page.
5 Excellent, thank you.
6 We can see halfway down, just over halfway down
7 there's a heading:
8 "Supplies of Factor VIII concentrates, the DHSS
9 Contract and the Price of Commercial Factor VIII."
10 There's a fairly lengthy discussion which I don't
11 need to trouble you with the detail but if we turn on
12 two more pages -- please, Henry -- we see, picking up
13 on the point we saw being made by Dr Kernoff in that
14 last set of minutes, here, four lines down:
15 "Dr Tuddenham said that the cost of
16 cryoprecipitate to his Centre is purchased from
17 Edgware Blood Transfusion Centre and calculated on
18 their assay of the Factor VIII content worked out at
19 7.5 pence per unit. The cheapest price for commercial
20 concentrate is close to this figure and occasionally
21 below it."
22 So that's your observation.
23 Then:
24 "Dr Wensley ..."
25 I think he was Manchester.

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1 "... on the other hand estimated that the cost of
2 making cryoprecipitate was about one-third of the cost
3 of making concentrates."
4 Was cryoprecipitate an actual hard financial cost
5 to the Royal Free? That's what the minutes seem to be
6 suggesting.
7 **A.** Indeed. Otherwise, I wonder why I would have bothered
8 to work it out. I think it must have been priced per
9 unit. And we were used to paying for blood product
10 pro rata, plasma, fresh frozen plasma, platelets.
11 That's certainly what that implies.
12 **Q.** There seems to be a very stark difference there
13 between the cost that you're experiencing from Edgware
14 Blood Transfusion Centre and what Dr Wensley is
15 describing.
16 **A.** Yes --
17 **Q.** Do you know what -- sorry, carry on.
18 **A.** Yes, I'm just thinking of the cost. You've got to buy
19 the plastic-ware. The donors give their precious
20 blood, from which the plasma is obtained, free. Then
21 you've got to spin it down, put it into a freezer, and
22 then partly thaw it, squeeze off the excess, and
23 freeze it again. So it's quite labour intensive. And
24 you've got your staff equipment and so on. So --
25 however, how Dr Wensley would know the cost of making

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1 it, presumably, he's a transfusionist who was running
2 a centre.
3 **Q.** No, Dr Wensley was the Haemophilia Centre Director at
4 the Manchester Royal Infirmary.
5 **A.** Okay, so he must have talked to the people who were
6 making his cryoprecipitate and worked it out from
7 that. I mean --
8 **Q.** Do you -- I'm sorry --
9 **A.** Well, I suppose if that's the case, they were adding
10 on a percentage amount for profit to pay for other --
11 and it's not -- it was a -- the Edgware Blood
12 Transfusion Centre, of course, is a not for profit
13 operation, within the healthcare service, and, if they
14 chose to make that profit on their cryoprecipitate,
15 that was their commercial decision.
16 **Q.** Do you know whether the relative cost of
17 cryoprecipitate was a factor in Dr Kernoff's decision
18 making about using commercial concentrates more than
19 cryoprecipitate?
20 **A.** I should think it must have entered into it, yes.
21 **Q.** There are some UKHCDO meetings, both Reference Centre
22 Director meetings and the bigger meetings of all
23 directors, in the course of 1981 at which a particular
24 issue was discussed on a number of occasions and
25 concern expressed, about a proposal to take control of

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1 purchasing and supply away from Haemophilia Centre
 2 Directors, and give that control to Regional
 3 Transfusion Centre Directors, or Regional Transfusion
 4 Centres. I can show you the minutes if need be, but
 5 do you recall that debate at all?
 6 **A.** No.
 7 **Q.** Well, let me just show you what Dr Kernoff wrote about
 8 it then, rather than asking you about what was said in
 9 more general terms in the minutes.
 10 If we go to OXUH0000886_002, please, Henry.
 11 This is a letter from Dr Kernoff to
 12 Professor Bloom, 28th September 1983, so this picks up
 13 on the issue of centralised purchasing two years after
 14 it was discussed in strong terms by the Haemophilia
 15 Centre Directors.
 16 And we can see Dr Kernoff saying he's concerned to
 17 hear this idea had been voted again and he was very
 18 much opposed to it.
 19 And then the second paragraph, last sentence, he
 20 says he thinks:
 21 "... that the proposal should be resisted by the
 22 Haemophilia Reference Centre Directors as vociferously
 23 as possible."
 24 I just want to -- he encloses a paper. I just
 25 want to ask you about the paper. So if we go to the

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1 next page we can see he sets out a number of concerns.
 2 And if we look at just four of the points, I think.
 3 Point 4, "Control of usage", he says:
 4 "Responsibility for usage of and expenditure on an
 5 essential drug must lie at the point of consumption -
 6 ie, with Haemophilia Centre Directors. It will be
 7 ethically and legally impossible to restrict usage by
 8 imposition of cash and supply limits ..."
 9 So that's one of the points he makes.
 10 If we then go to point 6 -- just a little bit
 11 below that, please, Henry -- we can see this is
 12 September 1983:
 13 "Increased concern about AIDS/hepatitis requires
 14 central control."
 15 His response is to say:
 16 "Not so. Maximum flexibility and ability to
 17 respond quickly to changing circumstances can only be
 18 achieved if responsibility for selection of type of
 19 material/brand/formulation remains with those who have
 20 most intimate knowledge of the subject."
 21 Then if we go over the page, under the first
 22 paragraph, "Mechanics of Purchasing, he says:
 23 "Tendering and contracting must involve very close
 24 collaboration between Haemophilia Centre Directors,
 25 financial/administrative personnel and the companies."

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1 Then last point before I ask you about this -- if
 2 we go down the page, Henry, towards the second half of
 3 the page, thank you.
 4 If we see the third paragraph down on the screen,
 5 he says, sets out a concern:
 6 "... the supply of Factor VIII may be restricted,
 7 and this will be contrary to the interests of
 8 patients. Haemophilia Centre Directors will not
 9 tolerate interference with supply by the BTS, because
 10 the BTS has no responsibility for patient care."
 11 It's clear this was a matter that Dr Kernoff was
 12 very concerned about. He wanted, for some of the
 13 reasons we see alluded to there, Haemophilia Centre
 14 Directors such as himself to retain control and be
 15 actively involved in purchasing.
 16 Is this something that you recall being discussed
 17 with Dr Kernoff as a particular concern at the time?
 18 **A.** No. I don't recall that at all. Reading these
 19 letters has been quite an eye-opener to me. Nowadays
 20 we do it all centrally but it's done as a billing
 21 process in which we're involved, not just haemophilia
 22 doctors, but patients and the Department of Health,
 23 and subsequently have achieved extremely good pricing.
 24 Best in the world, actually -- I mean lowest. It's
 25 called best, but for product of equal quality. That's

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1 become more complicated, of course, since there's many
 2 more different advanced products now.
 3 But back then, Peter's insistence on local
 4 decision, I can see the force of the arguments he uses
 5 for it. But -- and I wasn't aware of it at the time.
 6 He took care of all that.
 7 **Q.** But that possibly answers my next question but I'll
 8 ask in any event, Professor Tuddenham. We've seen
 9 from other documents, which I won't trouble you with
 10 now, Dr Kernoff being actively involved, consistent
 11 with what he says here, with choosing which particular
 12 pharmaceutical company or companies will receive the
 13 contract for a given year's supply. Did you have any
 14 involvement in that or was that solely the province of
 15 Dr Kernoff?
 16 **A.** That was solely his province.
 17 **Q.** Before I turn to ask you about issues relating to
 18 risks involved in hepatitis and HIV, there's just one
 19 further issue about products I wanted to explore with
 20 you at this stage. Porcine factor, which we've seen
 21 alluded to -- some usage of in the annual returns, and
 22 was something you were quite closely involved with in
 23 the early 1980s?
 24 **A.** Yes.
 25 **Q.** I'm going to ask you to look at one document -- I

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1 think we've got a range of documents from you,
 2 including some published papers on the topic, but
 3 we'll just look at one. It's IPSN0000156_101 -- IPSN,
 4 sorry, IPSN0000156_101. Sorry, Henry.

5 These are some notes of a lecture you gave in
 6 Toronto -- I've got a note it's 1981, which sounds
 7 about right. Do you think that's right? Because the
 8 document itself is undated. I think that's put
 9 together from the reference to the 1976 World
 10 Federation, then "After almost 5 years", so it would
 11 seem to fit being around 1981.

12 **A.** Yes.

13 **Q.** There are two particular issues that you're talking
 14 about in this lecture. One is about a fractionation
 15 process using polyelectrolytes?

16 **A.** Yes.

17 **Q.** And then you talk specifically about porcine
 18 Factor VIII.

19 Before we come on to the latter, could you just
 20 explain briefly, and in terms that those of us who are
 21 not scientists will understand, the issue in relation
 22 to polyelectrolytes as a new method?

23 **A.** Yes, it's a solid phase process where the
 24 polyelectrolyte whose chemistry is described in the
 25 side is packed into a column, through which fluids can

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1 be passed, and the property of the polyelectrolyte
 2 surface is that it exposes a certain charge density.
 3 And the solutes, that is the -- whatever is dissolved
 4 in the fluid you flow over it, be it plasma or
 5 cryoprecipitate, they will differentially absorb onto
 6 the surface depending on the charge and distribution
 7 of charge, and you can then wash, and whatever didn't
 8 absorb gets washed off, so you're left with those that
 9 are absorbed onto the solid polyelectrolytes, and then
 10 you can elute them, wash them off again, with
 11 a different solution, that detaches them
 12 progressively, and you can arrange it to detach some
 13 before other of whatever is absorbed.

14 So this a purification step, a solid phase
 15 purification step, which turned out to be very
 16 attractive for purifying Factor VIII and
 17 von Willebrand factor, because it had the property
 18 that the von Willebrand factor and Factor VIII stuck
 19 together, but you could take off the Factor VIII
 20 leaving the von Willebrand factor behind and make
 21 a good advance in purification of the Factor VIII away
 22 from everything else and von Willebrand factor, which
 23 is its natural carrier in the blood.

24 And that's very advantageous with pig Factor VIII,
 25 which, like human Factor VIII, and like, actually, in

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1 the blood of all vertebrates, down to bony fish, they
 2 circulate together, Factor VIII and von Willebrand
 3 factor, but the pig von Willebrand factor, when you
 4 give it to humans, has an undesirable property that it
 5 causes platelets, these little particles that plug up
 6 wounds, to aggregate in the circulation, and that can
 7 be quite dangerous. So purifying pig Factor VIII
 8 von Willebrand factor complex on these columns
 9 delivers you a highly purified pig Factor VIII without
 10 the undesired pig von Willebrand factor.

11 **Q.** And we've seen reference to the polyelectrolyte
 12 material in correspondence from Speywood. Was this
 13 work that was being undertaken with your assistance by
 14 Speywood at the time?

15 **A.** I was working with them at the time, and they supplied
 16 me, they supplied us with pig Factor VIII, that we
 17 used in -- I think it was a landmark paper, really --
 18 treating patients with inhibitors of Factor VIII, who
 19 make antibody to human Factor VIII but less so towards
 20 animal Factor VIII, and therefore the animal
 21 Factor VIII was able to correct the defect, ie, for
 22 the -- in the haemophilic blood that you couldn't
 23 treat with human Factor VIII, you could treat with pig
 24 Factor VIII.

25 So we had good results with that and some patients

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1 were able to carry on using pig Factor VIII for years.
 2 Others did make an antibody to the animal as well, but
 3 it particularly helped me in my research efforts
 4 purifying human Factor VIII to have, as a first step,
 5 using polyelectrolyte which Speywood supplied to me.

6 **Q.** If we go to the last page of this document, please,
 7 Henry. First paragraph, you say this:

8 "Porcine Factor VIII is, of course, used for the
 9 treatment of inhibitor patients. Thrombocytopenia has
 10 been virtually eliminated as a side effect, and other
 11 adverse reactions are much less severe than with
 12 previous animal preparations. Haemophilia centres
 13 which have used Hyate:C [so that's the porcine
 14 Factor VIII product sold by Speywood, I think] report
 15 dramatic improvements in the lifestyle and morale of
 16 their inhibitor patients."

17 Then you say this:

18 "The possibility of porcine Factor VIII:C being
 19 used for non-inhibitor patients in countries with
 20 a shortfall of human Factor VIII should now be
 21 seriously considered. Of course, viral hepatitis is
 22 not present in porcine plasma, and the product thus
 23 presents no risk of infection."

24 And then if we just go to the very bottom of the
 25 page, you talked about various other points, and then

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1 you say:
 2 "We feel a higher purity Factor VIII concentrate
 3 at a yield significantly above the conventional offers
 4 excellent prospects for the treatment of haemophilia
 5 in the 1980s."
 6 Turning back to that first paragraph, we have seen
 7 from the annual returns for the Royal Free porcine
 8 Factor VIII being used in what looks like inhibitor
 9 patients only. Was porcine Factor VIII ever used more
 10 widely in the first part of 1980s for non-inhibitor
 11 patients in the UK?
 12 **A.** No, it wasn't. We had in Oxford a whole period in the
 13 1950s when it was used because there weren't supplies
 14 of human Factor VIII. But it was only used for short
 15 procedures like surgery. So we never did actually
 16 transfer over to using pig Factor VIII against human.
 17 Can I have a short break?
 18 **Q.** Yes, absolutely. I think a five-minute break, sir?
 19 **SIR BRIAN LANGSTAFF:** Yes, absolutely. Would five minutes
 20 be okay?
 21 **(12.01 pm)**
 22 **(A short break)**
 23 **(12.06 pm)**
 24 **MS RICHARDS:** Professor Tuddenham, do you know why porcine
 25 Factor VIII wasn't, following your optimism in 1981,

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1 used other than for patients with inhibitors? Was not
 2 enough of it made, or were there other concerns?
 3 **A.** The concern was that, although some of the patients we
 4 treated who had inhibitors to Factor VIII did not
 5 subsequently develop inhibitor to porcine, most of
 6 them eventually did.
 7 It's still, by the way, used in the rare condition
 8 acquired haemophilia, which is an autoimmune condition
 9 mostly in older patients, people, whose immune system
 10 goes out of regulation and they start making
 11 antibodies to their own Factor VIII. It works very
 12 well there. And it still can be used in some patients
 13 with congenital haemophilia who have antibodies.
 14 But in the general case, it's regarded as --
 15 there's no reason to use it generally in haemophilia A
 16 without inhibitors because we have access to large
 17 amounts of recombinant and plasma-derived safe
 18 product.
 19 At that time, supplies were limited, and I was
 20 thinking of it as a cheaper way to provide treatment
 21 in low and middle-income countries. And originally,
 22 when Macfarlane developed these animal concentrates at
 23 Oxford, the reason was that there was very little
 24 access to human plasma-derived Factor VIII, whereas he
 25 could access huge amounts from normal agricultural

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1 slaughterhouse sources. And so it was a breakthrough
 2 in its day. The further purification made a very
 3 useful product; we now have it in a recombinant form.
 4 But as a treatment, it never really came in as
 5 a general treatment.
 6 It could have been used as a way to spare use of,
 7 at that time, a very risky, dangerous human-derived
 8 factor concentrates, but it never was so used.
 9 **Q.** I wanted to turn then specifically to the risks of
 10 human concentrates and start, first of all, with
 11 hepatitis.
 12 You describe in your statement an early experience
 13 of learning about hepatitis in 1969. Could you just
 14 elaborate upon that? It's paragraph, I think, 24 of
 15 your statement if you need to look back at it.
 16 **A.** Yes. My senior registrar, Dr Brown, had experience
 17 with a patient which was written up, and it's in the
 18 documents available -- it's published in The Lancet --
 19 a patient who'd been treated with a fairly large
 20 amount of cryoprecipitate but then developed
 21 hepatitis B, as became apparent, and he died from it.
 22 So I was introduced to the danger of blood
 23 transmitted infection at the very first stages when
 24 I first came into contact with treating haemophilia.
 25 **Q.** And then the observation you made in your statement

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1 was that non-A, non-B having been detected, you've
 2 said it seemed quite mild compared to hepatitis B
 3 without the dreaded fulminant hepatitis that occurs
 4 with hepatitis B.
 5 What was the basis for the view that non-A, non-B
 6 hepatitis was mild at that time?
 7 **A.** Just that most patients had a transient, as it seemed
 8 then, illness with a modest elevation of the enzymes
 9 we used to track inflammation and damage in the liver,
 10 the so-called transaminases, and then appeared to get
 11 better and had no apparent -- clinically apparent --
 12 problems. It was only when we came to follow them up
 13 carefully over subsequent months and years that we saw
 14 there was ongoing liver damage, and we started to
 15 track that using liver biopsy. And you could see the
 16 effect of the chronic inflammation in the liver
 17 leading to fibrosis and loss of active liver function,
 18 eventually leading to liver failure and liver cancer.
 19 But at the start, it appeared to be mild compared to
 20 hepatitis B, whereas, as we saw, can lead fairly
 21 rapidly to death.
 22 **Q.** As I understand it, the observations of non-A, non-B
 23 being mild was about the acute stage?
 24 **A.** Yes.
 25 **Q.** Comparing the acute stage. But it's also right -- and

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1 indeed Professor Lee referred us to a paper or case
 2 report she had written on it -- you could have
 3 fulminant hepatitis in non-A, non-B hepatitis?
 4 **A.** Yes, you can, but rarely, I gather. You can also
 5 recover from non-A, non-B hepatitis and clear it
 6 naturally, which doesn't happen, I think, with
 7 hepatitis B.
 8 **Q.** Do you recall whether you saw at the time the World in
 9 Action documentary, December 1975, which looked at the
 10 donor pools in the States which were used then to make
 11 the concentrates that were being used for
 12 haemophiliacs?
 13 **A.** In 1975?
 14 **Q.** Yes.
 15 **A.** I didn't see it, no.
 16 **Q.** You didn't see it.
 17 In paragraph 26 of your witness statement, you
 18 said that you knew that commercial donation was the
 19 norm in US products, but you had no idea of the low
 20 standard of screening donors. So the use of paid
 21 commercial donations which resulted in what's
 22 sometimes referred to in contemporaneous documents as
 23 people from skid row, intravenous drug users and so
 24 on, donating blood for money. That was something that
 25 you were unaware of?

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1 **A.** I didn't know that that was how they obtained their
 2 plasma. They certainly didn't admit it or ... in
 3 their literature about what they sourced their product
 4 from. We just didn't know.
 5 **Q.** So you've said your perception of the type of donor
 6 recruited in the US was optimistic, to say the least?
 7 **A.** Absolutely. I just assumed that they had standards
 8 of -- similar to what we would have applied to people
 9 donating plasma in the UK.
 10 **Q.** I have, with a number of the other clinical witnesses,
 11 looked with them at some of the materials from the
 12 mid-1970s about non-A, non-B hepatitis, but given that
 13 you arrived at the Royal Free in 1978, I wondered if
 14 we could just look at the state of knowledge in 1978
 15 with you.
 16 You described in your statement steps being taken
 17 at the Royal Free in terms of liver biopsies.
 18 **A.** Mm.
 19 **Q.** Again, I think that's paragraph 24. And you've
 20 referred to -- picking it up in 1978 and being at the
 21 Royal Free -- an awareness of chronic hepatitis,
 22 monitoring of the severity of the complication, and
 23 then liver biopsies being undertaken in the -- with
 24 advice from the unit established by Sheila Sherlock
 25 who was at the Royal Free --

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1 **A.** Yes.
 2 **Q.** -- until there was, I think, an incident where a --
 3 one particular patient, after a liver biopsy, died.
 4 You go on to say:
 5 "It was clear that the chronic inflammation
 6 associated with non-A, non-B hepatitis was causing
 7 fibrosis and declining function in some patients."
 8 So is it fair to say that, whatever your state of
 9 knowledge in the earlier part of the '70s might have
 10 been, by 1978, you were aware, and your colleague
 11 Dr Kernoff certainly would have been aware because
 12 hepatitis was his particular interest, that non-A,
 13 non-B hepatitis was a clinically significant condition
 14 with potentially serious long-term consequences?
 15 **A.** Yes. Although, as I say, the -- our understanding of
 16 the longer-term consequences evolved over time.
 17 **Q.** Yes. I think, rather than take up your time with lots
 18 of documents, I'll just ask you to look at one with
 19 me, because it's something authored by Dr Kernoff.
 20 Henry, it's BART0002487. You'll see this is
 21 a letter dated 27 April 1979. It's sent by Dr Kernoff
 22 to Dr Colvin. And we just go to the second page. If
 23 you zoom in, Henry, on paragraph 2, "Types of
 24 therapeutic material available", we can see -- it's
 25 about two-thirds of the way through that long

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1 paragraph -- Dr Kernoff describes non-A, non-B
 2 hepatitis in these terms:
 3 "This is a serious disease with long-term
 4 consequences."
 5 Then he goes on to talk about its possible
 6 prevalence in different parts of the world.
 7 By '78/'79, although I appreciate entirely,
 8 Professor Tuddenham, there is still a lot more to
 9 learn about non-A, non-B hepatitis, it was understood
 10 that it was a serious condition.
 11 **A.** Yes.
 12 **Q.** HIV. I just wanted to ask you about your developing
 13 knowledge in relation to AIDS. Again, we've looked in
 14 the Inquiry at a number of documents in relation to
 15 this, so I'm just going to take you to two, rather
 16 than take you to all of the documents we've explored
 17 with others.
 18 Henry, could we have PRSE0002410, please. This is
 19 an article that appears in the New England Journal of
 20 Medicine, January 1983, 13th January 1983, and it's an
 21 article by Jane Desforges. We can see it's "AIDS and
 22 preventative treatment in haemophilia".
 23 She talks about cases -- so if we go down the
 24 page, please, Henry -- she talks, in the paragraph
 25 beginning "The risk":

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1 "The risk associated with exposure to plasma from
2 multiple donors, however, has long been a concern in
3 the care of these patients, primarily because of
4 evidence of virus-induced liver disease."

5 Then talks about hepatitis.

6 Then she goes on in the next paragraph to say:

7 "Now we're becoming aware that treating
8 haemophiliacs with Factor VIII preparations may exact
9 a high cost. Reports in the Centers for Disease
10 Control include three haemophiliacs amongst cases of
11 acquired immunodeficiency syndrome (AIDS)."

12 If we go over to the next page, please, Henry. We
13 can pick it up in the last paragraph of the left-hand
14 column. She says:

15 "The fact that haemophiliacs are at risk for AIDS
16 is becoming clear."

17 Then if we look at the last sentence of that
18 paragraph:

19 "Preventing the complications of the present
20 treatment may have to take precedence over preventing
21 the complications of haemophilia itself."

22 First of all, at this time, early 1983, would you
23 expect to have been reading the New England Journal of
24 Medicine as part of keeping up to date?

25 A. One would certainly wish to be up to date, and the New

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1 England Journal of Medicine is a premier medical
2 journal with the highest impact factor, then and now.

3 This particular opinion, editorial piece, is
4 putting very starkly a balance between which takes
5 precedence: complications of haemophilia, or
6 complications of treatment, which would be a hard
7 thing to do when not knowing the prevalence or -- of
8 the appeared complication of AIDS. But it's
9 prescient, and it certainly brings to attention that
10 choice.

11 Q. And can you recall when you first became aware of the
12 reports of an association between haemophiliacs
13 receiving factor concentrates and AIDS?

14 A. Oh, as soon as it was reported by the Center for
15 Disease Control.

16 Q. So that would have been --

17 A. It was immediately.

18 Q. So that would have been, I think, probably July 1982?

19 A. Yes.

20 Q. The second document I wanted to look at with you,
21 Professor Tuddenham, is at PRSE0002647.

22 These are the notes of a meeting with Immuno at
23 London Airport, 24 January 1983. It's not a meeting
24 which you're recorded as having attended, but if we go
25 to the last page, please, we can see who was present.

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1 You'll see there a list of names, including the
2 Reference Centre Directors -- I think all of them
3 apart from you -- and Dr Kernoff there, presumably
4 representing the Royal Free, and then others. We know
5 that there were representatives of Immuno. We can see
6 Professor Zuckerman was there and a number of
7 directors of non-Reference Centres but of some of the
8 more significant and larger other haemophilia centres.

9 A. Mm.

10 Q. This was a meeting that was discussing the possibility
11 of hepatitis-reduced Factor VIII and Factor IX
12 concentrates, discussing the possibility of trials in
13 relation to that. But there's also a discussion about
14 AIDS.

15 So if we just go to the page before this, please,
16 Henry. We can see, under the heading "Acquired
17 immunodeficiency syndrome", it's reported:

18 "This was discussed in the after-lunch period.
19 Dr Craske summarised the current position."

20 And then if we go towards the last paragraph on
21 that page, we can see that what the summary includes:

22 "Ten haemophiliacs have been in the US have been
23 affected and five have died. The youngest was age 7.
24 All cases have had prolonged treatment with
25 Factor VIII. There's no specific implication of one

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1 particular product or batch. Other cases involving
2 blood and blood product transmission have included
3 platelets transfused in three cases."

4 And then it gives examples of two of those cases:

5 "The second, a 20-month-old child ... who had
6 received several units, including platelets known
7 to have come from a homosexual donor. The child has
8 developed autoimmune haemolytic anaemia and a possible
9 AIDS state".

10 And that's the case referred to in some of the
11 literature subsequently as the San Francisco baby
12 case.

13 Over the page, we can see, fourth paragraph down,
14 the attention of the meeting being expressly drawn to
15 the New England Journal of Medicine from 13 January.

16 I'm conscious this is a meeting that you were not
17 at, Professor Tuddenham, unlike all the Reference
18 Centre Director meetings which you attended.

19 Do you have any recollection of this meeting being
20 raised with you by Dr Kernoff?

21 A. Yes. We ... probably didn't have a long discussion
22 about it because I can't recall it. I do recall the
23 T4/T8 ratio being discussed, and the implication being
24 that cryoprecipitate either had something that
25 maintained a better ratio, and there was something in

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1 the concentrates that changed it. But I don't recall
2 a detailed discussion, no.

3 **Q.** Professor Lee told us yesterday that, whilst she
4 didn't know anything about this meeting, that the
5 question of AIDS was something that, in 1983 and 1984,
6 was -- I'm paraphrasing, not directly quoting -- but
7 something that was very much being discovered within
8 the Centre?

9 **A.** Yes.

10 **Q.** Can you recall any particular discussions, concerns,
11 views, being expressed, whether at the
12 multi-disciplinary team meetings or otherwise, about
13 AIDS and what the Centre's response should be?

14 **A.** We were looking out for it, and signs of it, in our
15 patients. They were aware that it was entering the
16 haemophilia community as a result of the treatment.
17 And the first patients who showed clear signs would
18 have been sometime during 1985, I think, at the
19 Haemophilia Centre.

20 **Q.** In the Royal Free?

21 **A.** At the Royal Free, in our patient group. There'd been
22 a patient earlier in Bristol, the first UK patient.
23 But we had a man who died of chickenpox pneumonia,
24 which is obviously highly atypical in an adult. And
25 soon after that, another patient was developing

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1 progressive neurological problems which ended. And so
2 by the time I left at the end of 1985, we'd actually
3 had two deaths.

4 We also, of course, knew, as soon as we tested
5 everyone, which -- who was positive. But, yes, we
6 were constantly talking about it.

7 **Q.** Am I right in understanding that you attended the
8 World Federation of Haemophilia meeting in Stockholm
9 in 1983?

10 **A.** Yes, I did. Yes.

11 **Q.** And I think we've got a copy of a paper you delivered.
12 It was reproduced in the bulletin. So just to see
13 whether I can prompt your memory if I need to, it's
14 PRSE0000411, please.

15 And if we go -- this is edition number 2 of 1983.
16 If we go, please, Henry, to page 12. We can see there
17 a talk, "Innovative Alternatives to Human Factor VIII"
18 by you. And if we go to the next page, it says --
19 this is at the very bottom:

20 "Abstract number 37 given at the World Federation
21 of Haemophilia Stockholm, 1983."

22 So is this the text of the talk you gave at that
23 Stockholm meeting?

24 **A.** Yes.

25 **Q.** If we go back to the previous page, please, Henry,

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1 right-hand column, about a third of the way down --
2 actually, we'll just pick it up in the beginning
3 because you talk about the process of preparation of
4 concentrates in very stark terms. You say:

5 "Let me begin by describing a process for you, one
6 that's very familiar and one carried out in all
7 developed countries. A heterogenous natural product
8 in liquid form derived from many individual citizens
9 is pooled. Various substances are added and
10 precipitation occurs [etc, etc]. The end product is
11 then widely distributed. Now, what process do you
12 think that might be? Production of Factor VIII
13 concentrate?"

14 If we skip over the picture of you, we can see you
15 say:

16 "No, actually I was describing a sewage plant.
17 The basic principles of sludge separation closely
18 resemble those of fractional precipitation."

19 Then you say:

20 "I submit to you that the technology of
21 Factor VIII concentrate production has got stuck at
22 a point reached by about 1970."

23 You then go on to talk about a number of matters
24 that I don't need to ask you about, but if we look at
25 the right-hand column -- thank you -- third paragraph

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1 down, you say this:

2 "Now, who is to blame for this deplorable
3 situation, the results of which are being discussed in
4 the seminars on hepatitis and AIDS? Frankly, we're
5 all in this together: doctors, patients, national
6 blood centres, commercial fractionators. We must
7 recognise the deficiency and take drastic steps to
8 bring coagulation factor purification into the 1980s.
9 I do not consider that heating and irradiating blood
10 products to remove things that shouldn't be there in
11 the first place is anything other than a temporary
12 measure of desperation."

13 It would seem fairly clear from that that very
14 much on the agenda of the World Federation of
15 Haemophilia were the risks of hepatitis and AIDS.

16 **A.** Yes.

17 **Q.** Do you recall what in particular was being discussed
18 or raised on either of those issues at that meeting?

19 **A.** I was using colourful language to emphasise the
20 inherent risks of pooling blood from thousands of
21 donors. My view, the biochemical one, of let's purify
22 what we really want out of the blood, and eventually,
23 as I say later, let's synthesize it, which we did
24 achieve, but not for quite a long time -- well, not at
25 three -- two years after that -- what was being

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1 developed then was ways of inactivating viruses. The
 2 details of that didn't really get discussed. There
 3 was a lot of commercial secrecy around that. There
 4 was also a problem that the agents at most risk, as it
 5 turned out, of hepatitis C and HIV, human
 6 immunodeficiency virus, HTLV-III, hadn't been isolated
 7 and characterised at that point, let alone assayed.
 8 So it was sort of feeling in the dark, and there
 9 weren't good or a reasonable animal model to look at
 10 transmission, so you're back to clinical trials of
 11 products after you'd treated them in ways that you
 12 hoped would, in some way, inactivate what you weren't
 13 really sure was there in the first place.

14 So, I mean, we were really in the dark, and I was
 15 taking a kind of purist biochemical approach, which
 16 was: let's isolate the thing we want, and that will
 17 get rid of the virus per se. But, yes, everyone was
 18 well aware that there was a life-threatening problem
 19 with our best treatments, and people were trying to
 20 find ways to deal with it. I suggested the way that
 21 came to me, others were working on viral inactivation.

22 They got lucky with that because the viruses that
 23 they had to inactivate had this property that you
 24 could actually inactivate them by rather simple
 25 methods. But it took a while to perfect those; the

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1 early shots at heat treatment weren't effective, and
 2 didn't finally become effective until 1986. And the
 3 sort of steps on that road weren't being widely
 4 publicised; they were being developed in commercial
 5 laboratories.

6 **SIR BRIAN LANGSTAFF:** Are we moving on from this paper
 7 now?

8 **MS RICHARDS:** Yes, we are.

9 **SIR BRIAN LANGSTAFF:** May I just ask you about two things
 10 which you say in the paper, which have struck me just
 11 listening to you. The first is that you make a case
 12 in your paper that the -- nothing much has happened
 13 with the technology of blood production since the
 14 early 1970s, and you're critical of that.

15 The second is that you observed, I suspect
 16 entirely rightly, that there was quite a degree of
 17 commercial secrecy as between the various commercial
 18 firms which were attempting to inactivate viruses.

19 One of the features of what I'm looking at is that
 20 three or four firms, the four major pharmaceutical
 21 producers of Factor VIII perhaps, in the United
 22 States, all, under their own forms of commercial
 23 secrecy -- so presumably not talking to each other,
 24 short of espionage -- were -- on exactly the same
 25 lines and about the same time produced similar

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1 products. There were differences, but there -- as
 2 you'd expect.

3 So could that have been done earlier with a bit of
 4 will?

5 **A.** I believe so, yes. I do believe so.

6 The purification methods for mass separation of
 7 fractions from human plasma were developed during the
 8 Second World War by Cohn, and the so-called cold
 9 ethanol fractionation was in use as the major -- and
 10 parts of that method are still in use today, but they
 11 were -- sort of modifications of those methods were in
 12 use for the Factor VIII concentrates.

13 Further steps were then taken, very empirically,
 14 but a sort of mainstream biochemical approach to
 15 separating took a long time to find its way through.
 16 They had a product which they could sell, and they
 17 did. And the impetus to improve it came rather
 18 slowly, in my view.

19 I guess I'm taking a purist view of that.

20 **SIR BRIAN LANGSTAFF:** Well, it's your view that I was
 21 looking for, because of the two matters I've just
 22 raised with you. Thank you for that.

23 **MS RICHARDS:** Professor Tuddenham, I wanted to ask you
 24 about the Royal Free Centre's response to what, by
 25 this stage, in the early 80s is a known risk of non-A,

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1 non-B hepatitis, and by 1983 is knowledge of, at the
 2 very least, a possible if not likely link between
 3 factor concentrates and AIDS.

4 Professor Lee's evidence, both to the
 5 Lindsay Tribunal and to this Inquiry, was that there
 6 was no change in the treatment policies at the
 7 Royal Free in response to those risks. So throughout
 8 the first part of the 1980s until the end of 1984,
 9 when heat-treated products became available, her
 10 understanding was that the policy of treating children
 11 with NHS concentrate was continued, but other than
 12 that, and other than that it was -- continued
 13 commercial concentrates in the same way as before.

14 I think that's effectively what your statement
 15 also accepts?

16 **A.** Yes, I am stating that.

17 **Q.** And we can see if we look at RFLT0000019 -- please,
 18 Henry -- we can see it's an application for an early
 19 application for ethics approval of research involving
 20 investigations on human subjects. It's submitted by
 21 Dr Kernoff in 1st December 1983, but your name and
 22 Dr Kernoff's is given as the head of section. I know
 23 you've seen this document very recently.

24 There are two parts of what Dr Kernoff was
 25 proposing to study here: the polyelectrolyte

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1 fractionated porcine Factor VIII, which we've already
2 discussed, and then the heat-treated human
3 Factor VIII. And he goes on to say -- if we look
4 under the heading "Background", he says:

5 "The incidence of acute non-A, non-B after a first
6 exposure to routine human Factor VIII concentrates
7 (either NHS or commercial) approaches 100% ... Of
8 particular concern is the high risk of chronic
9 hepatitis following an acute attack."

10 Then he goes on to say that the Royal Free has
11 been offered two human commercial heat-treated
12 products for clinical assessment, both of which have
13 been granted clinical trials exemption. And he asks
14 for approval for a piece of work. And we know from
15 other documents that I needn't trouble you with that
16 approval was forthcoming.

17 Do you know whether those trials of heat-treated
18 products ever took place at the Centre?

19 **A.** No, No.

20 **Q.** As in you don't know?

21 **A.** No. Unless one can find a publication in which the
22 result of the trial is included, I don't know.

23 **Q.** And your interest in this, as I understand it, was the
24 porcine element of it. Would you have been involved
25 in any clinical trial in relation to the patients

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1 using the heat-treated concentrates if gone ahead?

2 **A.** No, no, but I was involved in the porcine.

3 **Q.** If we go to BART0000676, this now brings us to
4 December 1984. It's a meeting of the Haemophilia
5 Working Party of the North East Thames Region
6 Association of Haematologists, and we can see that
7 Dr Kernoff is there and you're there.

8 If we go to the bottom of the second page, we can
9 see there's reference to "the possibility of BPL
10 heat-treated concentrate ..."

11 And then there's an agreement in the meantime, if
12 we look at (ii), that:

13 "Heat-treated material should be used whenever
14 possible (with the exception of NHS [Factor] IX
15 concentrate ...)"

16 It's said that:

17 "All new patients, and mild haemophiliacs with
18 injuries requiring maintenance of high levels of
19 [Factor] VIII should be treated with heat-treated NHS
20 Factor ... concentrate or small pool Factor ...
21 concentrate *pro tem* if treatment with cryoprecipitate
22 or DDAVP is not possible."

23 Then if we go to the top of the next page and look
24 at the second paragraph:

25 "Elective surgery should be delayed until the

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1 position is clearer and the efficacy of heat treatment
2 proven."

3 Now as far as one can tell from the documents and
4 Professor Lee's evidence, December 1984 was the first
5 time that the Royal Free effectively responded by
6 changing its approach to treatment, and it did so then
7 in two ways: the introduction of heat-treated
8 concentrates and, at that point, December 1984,
9 a decision to delay elective surgery. Is that
10 correct, as far as you're aware?

11 **A.** Yes, yes.

12 **Q.** And then, if we go to CGRA0000560, please, Henry.

13 I just wanted to ask if you're able to assist with
14 what this letter was concerned with. This is
15 a letter, March 1985, addressed to you. Not entirely
16 sure -- so, yes, it's in relation to Koate, and you're
17 being offered unheated Koate to cover the requirements
18 of the Fatimid Foundation. Is this anything to do
19 with treatment at the Royal Free or is this to do with
20 something else entirely?

21 **A.** It's not to do with treatment at the Royal Free. It's
22 to do with treatment at a Haemophilia Centre in
23 Karachi.

24 **Q.** Okay. Then Professor Lee's further evidence to the
25 Lindsay Tribunal and to this Inquiry was that, having

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1 got to this stage in December 1984, there was then
2 a phased introduction of heat-treated concentrates
3 over a three to six-month period.

4 And we can see a letter at BART0000819_002,
5 please, Henry.

6 This a letter, 17th January 1985, so a month after
7 the meeting we just looked at, from Dr Kernoff
8 addressed to patients receiving treatment on
9 Factor VIII and IX concentrates at the Haemophilia
10 Centre.

11 The heading is "Heat-Treated Concentrates", and
12 it's telling patients that:

13 "To reduce the risks of virus transmission, we
14 have decided that all Factor VIII concentrates used at
15 the [Royal Free] will be heat-treated products."

16 No change proposed currently in relation to
17 Factor IX.

18 Then in the second paragraph it says:

19 "For many complex reasons, including the fact that
20 there is at present no heat-treated NHS Factor VIII
21 available, it will not be possible to change everybody
22 ... to heat-treated products immediately, and not
23 everybody will receive the same type of material. In
24 general, patients routinely treated with commercial
25 Factor VIII will be changed to commercial heat-treated

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1 materials. Patients treated with NHS Factor VIII will
 2 either be changed to heat-treated ... products or kept
 3 on standard NHS Factor VIII for a few months longer,
 4 in the hope that small quantities of heat-treated NHS
 5 Factor VIII may soon become available.
 6 "In the longer term, we hope that larger amounts
 7 of heat-treated NHS Factor VIII will be supplied."
 8 So it would appear to be, in part at least,
 9 a supply issue, in terms of not enough heat-treated
 10 concentrates available to switch everyone immediately.
 11 Do you recall whether there was any discussion in the
 12 centre between you and Dr Kernoff or others about what
 13 to do in response to this particular problem, now that
 14 the dangers of unheated concentrates are explicitly
 15 recognised? Was there a discussion that took place at
 16 all?
 17 **A.** No, I don't recall that at all. Reading this --
 18 I mean, it's obvious that he was very much engaged
 19 with this issue, trying to source heat-treated, safer
 20 concentrates, though whether they would be safer from
 21 the point of view of HIV transmission was not going to
 22 be fully apparent for some time. But we didn't talk
 23 about it. And he -- I was very much engaged at that
 24 point with this race to pure Factor VIII and its
 25 immediate sequelae, and we didn't talk about these

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1 other issues. He kept these to himself.
 2 **Q.** If we just look a couple of paragraphs down, it says
 3 first of all:
 4 "The overall objective of our policy is to give
 5 the safest possible treatment to an individual."
 6 Then it says this:
 7 "Home treatment patients should continue to use
 8 their current stocks until they are almost finished,
 9 as at present, then call in personally ... to collect
 10 new supplies."
 11 Now, the effect of that, presumably, is that
 12 patients who have unheated products capable -- it's
 13 believed, and understood at this time to be capable of
 14 transmitting HIV/AIDS, are going to just use up their
 15 supply rather than any step being taken to ask them to
 16 immediately change. Does that cause you concern,
 17 seeing that there?
 18 **A.** Yes, it is obviously illogical. If there's a risk, it
 19 should be met by immediately stopping using the
 20 at-risk product. However, at that point you've then
 21 go to replace it with something else, because the risk
 22 of bleeding continues.
 23 **Q.** And given that at this point in time, whatever the
 24 arguments might have been earlier, you're talking
 25 about treatment for a relatively short period of time,

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1 a matter of months, it's going to be, or, in terms of
 2 supplies, weeks.
 3 **A.** Mmm.
 4 **Q.** Wouldn't cryoprecipitate, for example, have been, at
 5 least as a temporary measure, an obvious alternative?
 6 **A.** It would have been, and I know that some directors
 7 took that decision, and some patients.
 8 **Q.** If we just look, please, at your statement,
 9 paragraph 205 I think. I'll just put it on screen so
 10 others can follow.
 11 It's WITN3435002, please, Henry.
 12 And if we can go to page 16, please. At the top
 13 of the page, paragraph 25, you say this:
 14 "I am not aware of any formal decision-making
 15 structure in place at KDHC during the period 1978
 16 to 1986. If there was one it was in the knowledge and
 17 judgement of my colleagues, especially Peter Kernoff.
 18 He was certainly as well informed as anyone about
 19 these risks through his work on [non-A, non-B]."
 20 Is it fair to understand from that that these were
 21 essentially judgments, decisions that were being left
 22 to the decision-making process of Dr Kernoff on his
 23 own, essentially?
 24 **A.** Yes, that's my inference from all that happened, and
 25 the documents you've brought to my attention.

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1 **Q.** You go on to say this:
 2 "That may have had an inherent misleading bias
 3 when applied to Hepatitis C as contrasted to HIV ..."
 4 And I just wanted to ask you what you meant by
 5 that.
 6 **A.** Well, he would have formed a view about risk based on
 7 his experience with hepatitis C. And as he
 8 demonstrated, and as we saw earlier, all concentrates
 9 containing plasma sourced from more than
 10 100 individuals -- well, certainly more than couple of
 11 hundred individuals, a biostatistical necessity --
 12 will be transmitting hepatitis C. How much safer it
 13 was in relation to HIV would only emerge when the
 14 understanding of that virus and means to test it were
 15 available.
 16 So I'm speculating, of course, about his thinking
 17 process, and it probably seemed to him likely at that
 18 time that the relative greater safety of NHS
 19 concentrate might not be that much better than the
 20 concentrates from elsewhere.
 21 **Q.** And then in paragraph 27, just so that what you say
 22 there can be understood, the question that you were
 23 there answering, if I can find the question ...
 24 Well, I can find it -- but I can paraphrase it.
 25 The question you were being asked, and you answer

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1 there, is about whether there were any decisions or
2 actions taken by the Centre to minimise or reduce the
3 risk of infection. And your answer is:

4 "Other than only giving treatment when it was
5 necessary to stop bleeding, none that I can recall."

6 And then you say this:

7 "The principle was, 'if in doubt as to whether
8 signs and symptoms were due to bleeding or not, treat
9 anyway'."

10 Can you just explain what you mean by that
11 principle.

12 **A.** It's a general principle in haemophilia care that if
13 you have reason to suspect there may be bleeding, give
14 the treatment that will stop the bleeding and then
15 you've taken care of that as a possible explanation
16 for whatever symptoms you're observing. So it was: if
17 in doubt, treat. But it's a safety principle in
18 caring for people who were always at risk of life or
19 limb-threatening bleeding. But of course that comes
20 into this difficult area of doubt, whether treatment
21 you're giving has its own inherent risks, which the
22 whole subject of this Inquiry.

23 **Q.** Professor Tuddenham, I want to come on and ask you
24 about UKHCDO and its role in response in particular to
25 the AIDS crisis. And although, as you've explained,

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1 your interest by this time was essentially
2 research-based, rather than much by way of clinical
3 decision-making, you're one of the few Reference
4 Centre Directors who will be giving evidence, and so
5 these are issues which it's important to just ask you
6 about.

7 Before we look at any individual document, what,
8 if anything, can you tell us about the way in which
9 the UKHCDO operated, and its hierarchy, and the role
10 of the Reference Centre Directors in that period '78
11 to '85?

12 **A.** We were a group of colleagues who were gathered
13 together under the common objective of organising and
14 improving the management of haemophilia, which was and
15 is still very advanced in comparison to what was
16 available in most other even developed countries.
17 There's other sort of shining examples like some of
18 the Scandinavian countries, but we prided ourselves on
19 being the group that was best able to monitor, manage
20 and progress how we managed this group of severe
21 congenital disorders.

22 So we were gathered together to optimise the
23 monitoring of standard of care, gathering data, making
24 representation to the Department of Health for ways to
25 improve. And as problems arose, as they indeed did in

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1 the way we're here to discuss, they were dealt with.
2 It wasn't very highly hierarchical. We were a group
3 of colleagues who respected each other. People would
4 volunteer to take on the roles within the organisation
5 as they do today, and it wasn't often that there was
6 a contentious issue that would give rise to a vote.
7 I mean, agreements were reached over a course of
8 discussion, and people used best efforts to come up
9 with policies over the sort of new problems as and
10 when they arose.

11 So it wasn't a sort of fierce debating society; it
12 was a collegial effort to gather our thoughts and
13 propose solutions as best we could in, as it was then,
14 a rapidly evolving and difficult -- very difficult
15 situation.

16 **Q.** And the Reference Centre Directors certainly seemed to
17 meet annually. Was that the normal pattern, or was it
18 more frequent than that? There were certainly special
19 meetings we see.

20 **A.** I don't remember. I think you're right: it was
21 this -- we were meeting quite more frequently as the
22 need arose.

23 The meetings tended to take place quite often at
24 the Royal Free, which was convenient for me, and
25 sometimes in Oxford. The agenda was devised by

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1 whoever the lead clinician of the day was. And people
2 spoke as they felt moved, according to their
3 experience.

4 We have a system of having committees that would
5 address particular topics, as I think I've answered
6 questions later on, and they would report back after
7 taking further advice from experts, and the reports
8 were considered. The idea was that if there was
9 a particular project, it would be dealt with in
10 a time-limited way. And I would say that, given a
11 kind of national emergency, really, which this
12 situation gave rise to, we did the best we could, but
13 the steps that were going to change the situation,
14 which was developing the assays that enable you to
15 identify exactly where the infection is and who's got
16 it and what to do about it, and the improvement in the
17 virus inactivation and better quality product, were
18 not in our hands.

19 What we had an opportunity to do was choose
20 between different products and policies, but we were
21 left in this between a rock and a hard place, between
22 the fact you have to treat immediate emergency of a
23 bleed, but is the product you've got a safe, effective
24 means of doing that?

25 So I'd say the overall influence that the UKHCDO

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1 could have on this as being, to some extent just
 2 a gathering of colleagues and a talking shop, is
 3 not -- unless a very, very firm line were taken to
 4 pursue a particular policy, we didn't tend to impose
 5 views that necessarily would be just kind of opinions,
 6 really, educated opinions, on the rest of our
 7 colleagues because we didn't have the executive power
 8 to do that.

9 We could make representation to Government. We
 10 could make recommendations to our colleagues. But we
 11 weren't in a position of being able to issue orders
 12 and dictats.

13 **Q.** Would the task of the Reference Centre Directors, in
 14 responding to this national emergency, have been
 15 assisted by guidance or advice or intervention at
 16 a national level by the Chief Medical Officer, for
 17 example, or the Department of Health?

18 **A.** I can only say that, to my recall, they weren't.

19 Well, committees began to be got together of virus
 20 experts, but the UK didn't have a sort of -- well, we
 21 had the fractionators at Oxford, but they weren't
 22 major players, and they weren't running large research
 23 groups, and they weren't, to my knowledge,
 24 collaborating closely with virologists and
 25 biochemists. I mean, it was all a bit semi-amateur,

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1 slightly ad hoc. That's a harsh statement.

2 I mean, looking back, what were they doing? They
 3 were doing their best to produce good quality products
 4 for us to use. They were clearly underfunded in the
 5 ambition to be self-sufficient. Could have used a lot
 6 more funding and a lot more push to do that. Although
 7 it had been declared an ambition, it didn't come to
 8 pass ever. So we were left trying to do the best with
 9 the limited resources that we had, as you can see, and
 10 it was somewhat frustrating, as Peter Kernoff's
 11 letters illustrate.

12 And we were left trying to make the best of what
 13 was certainly, in retrospect and even apparently at
 14 the time, a pretty difficult and unsatisfactory
 15 situation, in regard to supply, resources, and assays.
 16 We -- all those things eventually emerged, but one
 17 could only wish that they would have emerged sooner
 18 with the benefit of the hindsight we now have. At the
 19 time, we were doing the best we could, I think, is all
 20 I could really say about that.

21 **Q.** Okay. We'll look at some documents with you but, it's
 22 just gone one o'clock, sir, so perhaps I can pick that
 23 up too?

24 **SIR BRIAN LANGSTAFF:** Yes. We'll take a break now until
 25 two o'clock, if you please, and then we come back.

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1 (1.02 pm)

2 (Luncheon Adjournment)

3 (1.58 pm)

4 **MS RICHARDS:** Professor Tuddenham, I'm going to ask you to
 5 look with me at some documents which show the response
 6 of UKHCDO to the AIDS crisis in 1983 and 1984. We
 7 won't look at absolutely everything, but just to put
 8 it in its chronological context, the first reference
 9 to AIDS in a Reference Centre Directors meeting was
 10 September 1982, and the request was made at that point
 11 to Dr Craske to look into the matter and report back
 12 to the AGM that was taking place a week later.

13 So I'm not going to show you those but I'm going
 14 to pick matters up in 1983.

15 Could we have HCDO0000411, please, Henry. If we
 16 go to the next page we can see it's the minutes of the
 17 Reference Centre Directors meeting held at the
 18 Royal Free on 4th February 1983, and we can see you
 19 and Dr Kernoff are both in attendance.

20 Henry, if we could go to page 4, please -- sorry,
 21 the next page, my apologies.

22 You'll see there, Professor Tuddenham, under the
 23 paragraph headed "The AIDS Syndrome", Professor Bloom
 24 referred to the Stockholm meeting, there's an update
 25 that the -- reports from the US suggest that the

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1 incidence of AIDS was higher than first thought.

2 There's an expression of concern that the haemophilic
 3 population of the UK who'd received American
 4 concentrates might be at risk. Dr Craske then
 5 summarised latest information: approximately ten cases
 6 thought to have occurred in non-haemophiliacs now in
 7 the UK.

8 Then there's a reference --

9 **SIR BRIAN LANGSTAFF:** I think it may be 12, might it? Ten
 10 in London.

11 **MS RICHARDS:** Oh, yes, I'm sorry, sir, you're absolutely
 12 right. Yes. Ten cases thought to have occurred in
 13 London, one in Glasgow, one -- it may be -- maybe
 14 that's right.

15 Then -- in any event, those are non-haemophilic
 16 cases.

17 Then we see Dr Craske had drawn up a draft form,
 18 there's a lengthy discussion about it, and the
 19 agreement is that Dr Craske will draw up a new form
 20 for the reporting of cases and arrange for it to be
 21 circulated to Haemophilia Centre Directors.

22 Then there's a suggestion of inviting an
 23 immunologist to join the Hepatitis Working Party.

24 First of all, do you have any recollection of that
 25 particular meeting and the discussions about AIDS in

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1 February 1983?

2 **A.** Yes, yes, of course. We were on full alert. Anxious,
3 worried and, like everyone else, still highly puzzled
4 as to what could be causing this syndrome, presumed by
5 now to be transmissible by direct contact means and
6 therefore likely to be a virus, and looking for advice
7 on how to move forward, given that it was clear by
8 then that the haemophilia population was at risk.

9 **Q.** And the action that was agreed at this stage didn't
10 involve any recommendations about any change of
11 approach to treatment; it's a plan to prepare a form
12 so that cases could be reported to the Reference
13 Centre Directors?

14 **A.** Yes, just observation.

15 **Q.** And then we can see what Dr Craske drew up and what
16 was sent out if we look at RFLT0000021, this is the
17 copy that came to Dr Kernoff but we have -- there were
18 copies that went to, we assume, all the Haemophilia
19 Centre Directors.

20 So it's dated 22nd March 1983, and you'll see it
21 refers in the second line to:

22 "... a recent meeting of the Reference Centre
23 Directors ... prompted us to circulate the enclosed
24 paper so that a system for the reporting of possible
25 cases of [AIDS] can be quickly set up ..."

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1 Then, if we go to -- sorry, in fairness, if I go
2 to the third paragraph, we can see that Dr Craske,
3 Dr Rizza and Professor Bloom say:
4 "We do strongly urge you [ie, Directors] to
5 collaborate in reporting cases of this syndrome ..."
6 There were two documents enclosed with this. We
7 will just look briefly at one of them,
8 Professor Tuddenham.
9 HCDO0000517_002, I think.
10 So this was one of the documents sent out to all
11 Directors, and presumably you would have seen it?

12 **A.** Yes.

13 **Q.** It's authored by Dr Craske. This one is dated
14 1st March 1983. There are earlier iterations of it
15 that were shared with Reference Centre Directors in
16 the autumn of '82. But we can see, if we look towards
17 the bottom of this page, here we see the first of two
18 features noted. Here, in the last paragraph, the
19 delay between the occurrence of initial symptoms and
20 diagnosis and an observation that the signs and
21 symptoms were mostly insidious and non-specific.
22 And then we go over the page, we can see
23 underneath the list of symptoms, there's a paragraph
24 that begins "The overall mortality was highest in
25 those with patients with [PCP]", and you'll see there

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1 the mortality rates, which are obviously very high.

2 If we go on to page 3, we can see then under the
3 heading "Aetiology", towards the bottom of the page,
4 Dr Craske advances three theories. The first is about
5 the possibility of the effect of drugs. Would you
6 agree with me he's then discounting that? He says:
7 "This is not a factor as the disease has been
8 described in patients who do not use the drug."
9 Then he talks about the immunosuppressive effect
10 of cytomegalovirus virus infection and says this seems
11 unlikely.

12 Those two theories are put forward but effectively
13 put to one side; would you accept that? For the
14 transcript, Professor Tuddenham, if you wouldn't mind
15 saying "yes" or "no" rather than nodding.

16 **A.** Yes.

17 **Q.** Thank you.

18 Then over on to the next page, he says here then,
19 his third cause is the suggestion of an infectious
20 agent with a similar epidemiology to that of
21 hepatitis B, and then he goes on to say:
22 "If (3) is the most likely cause, then it is
23 possible that such an agent might be present in the
24 plasma pools used to prepare commercial Factor VIII
25 and IX concentrate manufactured from donor plasma

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1 collected in the USA."

2 He then goes on to discuss the three cases where
3 the likeliest mode of transmission has been blood or
4 platelet transfusion, and explains at least ten
5 haemophiliacs -- this is in the States -- have been
6 reported with clinical features of the syndrome. Five
7 have died.

8 Then if we go to the next page, second paragraph,
9 he says:
10 "It is thought likely that batches of Factor VIII
11 concentrate which might contain the AIDS agent came
12 into use since January 1st 1980 in the USA."
13 Now I've obviously not gone through the entirety
14 of the paper with you, Professor Tuddenham, but would
15 you agree that what emerges from that is, although
16 there is still much that is not yet known, it's likely
17 that the route of admission for haemophiliacs is blood
18 products?

19 **A.** Yes.

20 **Q.** And this is a disease understood to have a high
21 mortality rate?

22 **A.** Yes.

23 **Q.** So that's March 1983.

24 We then come on, in terms of the next step taken
25 by UKHCDO, by the Reference Centre Directors, to a

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1 meeting on 13th May of 1983. Now this is one of the
2 few meetings you didn't attend but for the sake of
3 completeness we'll look at it.

4 It's HCDO0000003_008, I think, Henry.

5 So we can see this is a meeting at St Thomas'
6 13th May 1983. You're not there for this meeting,
7 Dr Kernoff is, and it's a special meeting that's been
8 called.

9 If we go to the second page, we can see
10 a discussion in the last paragraph as follows:

11 "With regard to general policy to be followed in
12 the use of Factor VIII concentrates, it was noted that
13 many directors have up until now reserved a supplies
14 of [NHS] concentrates for children and mildly affected
15 haemophiliacs and it was considered that it would be
16 circumspect to continue with that policy. It was also
17 agreed that there was, as yet, insufficient evidence
18 to warrant restriction of the use of imported
19 concentrates in other patients in view of the immense
20 benefits of therapy. The situation shall be kept
21 under constant review."

22 So this would appear to be the first discussion of
23 whether anything should be done in terms of changing
24 the approach to treatment, but would you agree there
25 is no specific recommendation of any change of

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1 approach, it's just circumspect to continue with an
2 existing policy if that is your existing policy; is
3 that a fair characterisation?

4 **A.** Yes.

5 **Q.** Then we'll see the document that was then sent out in
6 light of that meeting.

7 HCDO0000270_004 please, Henry.

8 So this is the letter of 24th June 1983. This is
9 a blank version but we understand, again, it was sent
10 out to Haemophilia Centre Directors.

11 It refers to the special meeting that we've just
12 looked at and says this:

13 "So far one possible case has been reported to our
14 organisation. This patient ... conforms to the
15 definition published by the CDC in Atlanta ... but
16 cannot be considered as a definite case. We are not
17 aware of any other definable patients amongst the UK
18 haemophiliac population."

19 Pausing there for a moment, Professor Tuddenham,
20 we understand that to be a reference to a case in
21 Cardiff of a patient who was under Professor Bloom's
22 care. Do you recall -- and I know in particular
23 Professor Bloom had been -- you described him,
24 I think, as something of a mentor to you -- did you
25 ever discuss that case, that first AIDS case of

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1 a haemophiliac with him at the time?

2 **A.** No, I wasn't in frequent contact with Arthur then,
3 other than at the Reference Centre Directors meetings.
4 The first confirmed case was in Bristol.

5 **Q.** That was the first death, we think.

6 **A.** The first death, yes. If Arthur had a case he
7 suspected in Cardiff, I wasn't aware of it.

8 **SIR BRIAN LANGSTAFF:** Can I just clarify about the
9 information that we have the Bristol case is that it
10 hadn't been reported to the UKHCDO, and that was the
11 subject of some concern later at a meeting in the
12 autumn, because it had happened, it hadn't been
13 reported so somehow the reporting systems missed it.

14 **A.** Yes, that's right, yes.

15 **SIR BRIAN LANGSTAFF:** That now rings a bell, I can see.

16 **A.** It does, yes, yes. It came out of the blue. It was
17 a bit of a shock. I think the then director of the
18 Bristol Centre wasn't kind of prominent at national
19 meetings.

20 **MS RICHARDS:** Was that Dr Daly?

21 **A.** Yes.

22 **Q.** Yes. Then we can see the two recommendations here
23 given on -- are:

24 "1. For mildly affected patients with
25 haemophilia A or von Willebrand's ... and minor

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1 lesions, treatment with DDAVP should be considered.
2 Because of the increased risk of transmitting
3 hepatitis by means of large pool concentrates in such
4 patients, this is in any case the usual practice of
5 many Directors."

6 Then:

7 "2. The treatment of children and mildly affected
8 patients or patients unexposed to imported
9 concentrates, many Directors already reserved supplies
10 of NHS concentrates (cryoprecipitate or freeze-dried)
11 and it will be circumspect to continue this policy."

12 So, again, what this would appear to be is
13 a recommendation for directors to continue with
14 existing policies if they have them in relation to
15 children and mildly affected patients, or previously
16 untreated patients, and a recommendation to consider
17 the use of DDAVP from the categories of patients there
18 identified.

19 It's quite tentative, isn't it? It falls short of
20 any kind of firm steer or recommendation?

21 **A.** Yes, it's just a polite suggestion, with evidence and
22 reasons given, but it's by no means an order and, as
23 I mentioned earlier, we (the UKHCDO) weren't actually
24 in a position to issue orders, just recommendations.

25 **Q.** Yes, no, I accept not in a position to issue orders.

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1 There could be this kind of polite suggestion, as you
 2 characterise it, at one end of a spectrum, an
 3 instruction at the other, and in between there could
 4 be much firmer advice or recommendations than this;
 5 would you accept that?
 6 **A.** I accept that. There can be firmer or there can be
 7 ... clinical advice is usually couched in very polite
 8 terms.
 9 **Q.** Yes, and we'll see later, when we finally get to
 10 December 1984, that there were recommendations that
 11 were put in different terms.
 12 So this was June 1983 arising out of
 13 the 13th May 1983 meeting. I just want to show you
 14 a document from around this time which is
 15 CBLA0000043_040.
 16 I this is a letter dated 9th May 1983, and it's
 17 written by Dr Spence Galbraith, who was at the
 18 Communicable Disease Surveillance Centre in London.
 19 He's addressing it to the Department of Health.
 20 You'll see in the first paragraph he talks about
 21 the case in Cardiff, he actually identifies it as
 22 being a Cardiff case, and explains that it fits the
 23 recognised criteria for the diagnosis of AIDS, and
 24 then refers to some other reports in The Lancet and
 25 other cases.

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1 Then we can see his recommendation in the second
 2 paragraph is:
 3 "I have reviewed the literature and come to the
 4 conclusion that all blood products made from blood
 5 donated in the USA after 1978 should be with withdrawn
 6 from use until the risk of AIDS transmission by these
 7 products has been clarified."
 8 So Dr Spence Galbraith with, presumably, the same
 9 or similar information available to him as would have
 10 been available to the Reference Centre Directors, came
 11 up with a very different recommendation.
 12 Do you recall whether this came to the attention
 13 of the Reference Centre Directors at this time?
 14 **A.** I don't recall it. Until you brought it to my
 15 attention, I've never seen this letter or was aware of
 16 this view having been promoted. Did you say it was
 17 Kenneth Galbraith?
 18 **Q.** Dr Spence Galbraith.
 19 **A.** Spence Galbraith.
 20 **Q.** Who was -- well, public health was his area of
 21 specialty. He was based at the Communicable Disease
 22 Surveillance Centre, so the cases were supposed to be
 23 reported to him.
 24 **A.** In the UK?
 25 **Q.** In the UK.

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1 **A.** Wow. Well, it's -- then it's quite an authoritative
 2 opinion.
 3 **Q.** I don't say this, certainly, as a criticism of you,
 4 Professor Tuddenham, or necessarily of any of the
 5 Reference Centre Directors, but this is the kind of
 6 opinion that should have been shared, should it not,
 7 with the Reference Centre Directors by somebody?
 8 **A.** Somebody. He, himself, might have considered doing
 9 that, but I don't have any recall of it being
 10 proposed. It's a radical proposal, but it didn't make
 11 its way on to my desk.
 12 **Q.** No. If we go to the next page, he sets out a number
 13 of reasons, and I just wanted to go through the
 14 reasons with you.
 15 So the reasons for his recommendations: one, the
 16 AIDS epidemic in the USA is probably due to a
 17 transmissible agent. Would you agree with that?
 18 **A.** Yes.
 19 **Q.** Based upon the knowledge at the time.
 20 **A.** Yes.
 21 **Q.** Two, the agent is probably transmitted by blood and
 22 blood products. Would you agree?
 23 **A.** Yes.
 24 **Q.** Three, and this may be where his public health hat was
 25 significant, he said this:

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1 "Although this number of cases of AIDS associated
 2 with the administration of Factor VIII concentrate is
 3 very small in relation to the number of individuals
 4 receiving the product, this may not indicate that the
 5 risk is small ..." and he goes on to explain why
 6 that is.
 7 Would you accept that as a proposition that could
 8 and should have been understood at the time? That the
 9 number of currently reported cases was not necessarily
 10 the guide to what the true extent of the risk was.
 11 **A.** I agree.
 12 **Q.** And then if we go over the page, please --
 13 **A.** It's a fundamental principle of epidemiology.
 14 **Q.** If we go over the page, please, to point four:
 15 "Factor VIII concentrate (and pooled products)
 16 would appear to have a high risk of being contaminated
 17 with AIDS agent."
 18 And he explains that's because of the donor pool.
 19 Would you agree with that?
 20 **A.** There's a slightly surprising suggestion there that
 21 homosexuals are more frequent blood donors than
 22 others.
 23 **Q.** I think there may have been some evidence available --
 24 that may have been available to Dr Spence Galbraith --
 25 about certain practices and locations in which bloods

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1 were collected for donations in the States, so maybe
 2 it's a reference to that.
 3 **A.** Interesting.
 4 **Q.** But in terms of the donor pool giving rise to a high
 5 risk of contamination, you would accept that as
 6 a statement, as at 1983?
 7 **A.** Yes.
 8 **Q.** And then:
 9 "5. Apparently no known means of ensuring that
 10 blood or blood products are free of the AIDS agent."
 11 That was correct at the time?
 12 **A.** Of course, yes.
 13 **Q.** And then point 6 is the high mortality rate which was
 14 also known at the time.
 15 **A.** Yes.
 16 **Q.** So we have the polite suggestion from the Reference
 17 Centre Directors, and then the rather bolder
 18 suggestion here. We then come on, in terms of the
 19 next Reference Centre Director consideration, to 19
 20 September of this year --
 21 **A.** Excuse me. Could I just ask a question again about --
 22 **Q.** Of course.
 23 **A.** -- Dr Galbraith's letter? Was this published
 24 anywhere, or was this is an internal communication?
 25 **Q.** The letter was addressed to an official within the

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1 Department of Health.
 2 **A.** Right.
 3 **Q.** So it was not, at least at that stage, published.
 4 Whether it was ever published, I'm afraid I don't know
 5 the answer.
 6 **A.** All right. With hindsight, again, appreciate your
 7 comment in the context, but if it had had wider
 8 exposure, I'm sure it would have had some effect.
 9 **Q.** And then if we go to HCDO0000413, please, Henry.
 10 So we can see this is the next meeting of
 11 Reference Centre Directors. It's now
 12 19 September 1983, and you and Dr Kernoff are both in
 13 attendance at this meeting. If we go to page 3, we
 14 can see "current situation regarding AIDS":
 15 "Dr Craske presented a paper ... updating the
 16 current situation."
 17 You'll see there reference to the patient who died
 18 in Bristol about six lines down, Professor Tuddenham.
 19 So I think there was evidence to suggest that death
 20 occurred in August 1983.
 21 And then if we look at what was then discussed, we
 22 can see a little further down -- if we go to "It was
 23 agreed". Dr Craske, having given that update, the
 24 first thing that was agreed was a point about
 25 discouraging manufacturers of concentrates to sell

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1 material to non-haemophilia centres.
 2 So that may or may not have been an issue of some
 3 importance, but would you agree that's not really
 4 dealing with the public health issue and the risk of
 5 AIDS to haemophiliacs?
 6 **A.** No, it isn't. There was some debate still at that
 7 time as between treatment or management of
 8 haemophiliacs at hospitals by individual doctors that
 9 weren't part of a registered Haemophilia Centre or
 10 Reference Centre, and that did continue for some time.
 11 And I think partly it's referring to that possibility,
 12 this kind of unacknowledged, recorded, or regulated
 13 use of those products.
 14 **Q.** Yes. And then we can see there's then a discussion
 15 about blood products being supplied via regional
 16 transfusion centres (and that's the issue that we saw
 17 Dr Kernoff's strong views on this morning) and we can
 18 see, four lines up from the bottom, the Reference
 19 Centre Directors expressing grave misgivings about
 20 that.
 21 Again, that's not really dealing with response to
 22 AIDS, is it?
 23 **A.** No.
 24 **Q.** Then if we go to the next page, we can see here -- and
 25 it touches on some observations you've just made,

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1 Professor Tuddenham, about the Galbraith letter:
 2 "The position regarding the collaboration of the
 3 Haemophilia Centre Directors, Dr Craske, and the
 4 Communicable Disease Surveillance Centre was raised.
 5 Professor Bloom said Dr Galbraith, director of the
 6 CDSC, was somewhat concerned he hadn't heard about the
 7 Bristol case until after the patient's death."
 8 You'll see that there were some interactions
 9 between Dr Galbraith and Dr Craske, and possibly
 10 Professor Bloom. We don't know the full extent of
 11 them.
 12 Then the issue that's there discussed. You'll see
 13 from that paragraph there's an issue about reporting
 14 of cases and whether it should go via Dr Craske or
 15 directly to CDSC. And if we look down the page, we'll
 16 see the agreement, the underlined bit:
 17 "After discussion, it was agreed by a majority
 18 that reporting to CDSC should be through Dr Craske."
 19 And then the discussion moves on to the collection
 20 of epidemiological data.
 21 So would you accept that there are no substantive
 22 recommendations here about changes in policy or
 23 different ways of treating patients?
 24 **A.** Yes, that's -- that is the case.
 25 **Q.** Then the next meeting is 17 October 1983. This is not

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1 of Reference Centre Directors alone; this is all
 2 Directors. It's PRSE0004440, please, Henry.
 3 We can see it's 17 October 1983. It's a long list
 4 of attendees, and they include you,
 5 Professor Tuddenham. And if we go, please, Henry, to
 6 page 10, we can see an issue being raised under the
 7 heading "Any other business":
 8 "Dr Chisholm [who was director in Southampton]
 9 raised the problem of patients refusing to take up
 10 commercial Factor VIII. She wondered, in view of the
 11 worry of patients whether Directors could revert to
 12 using cryoprecipitate for home therapy.
 13 Professor Bloom replied that he felt there was no need
 14 for patients to stop using the commercial concentrates
 15 because at present there was no proof that commercial
 16 concentrates were the cause of AIDS. Dr Chisholm
 17 pointed out there was a further problem in her region
 18 because of problems in getting large amounts of
 19 commercial concentrates, whereas she could get
 20 unlimited supplies of cryoprecipitate. Other
 21 Directors reported they had the same problems. After
 22 discussion, it was agreed that patients should not be
 23 encouraged to go over to cryoprecipitate for home
 24 therapy but should continue to receive the NHS or
 25 commercial concentrates in their usual way."

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1 Do you have any recollection of that meeting or
 2 that debate, Professor Tuddenham?
 3 **A.** I don't remember Dr Chisholm raising this point. It's
 4 kind of poignant, looking back on it. There was all
 5 this cryoprecipitate, and why not use it for home
 6 treatment?
 7 As we discussed earlier, there was a feeling that
 8 that was a step -- well, there was a reason to say
 9 that that was a step back, but then as the threat of
 10 AIDS from commercial concentrate rises and rises,
 11 alternative views are being expressed by the patients,
 12 as well as the centre directors.
 13 **Q.** Can I invite you to consider in particular what's
 14 recorded here as Professor Bloom's statement. He
 15 says:
 16 "There's no need for patients to stop using
 17 commercial concentrates because at present there was
 18 no proof that the commercial concentrates were the
 19 cause of AIDS."
 20 Does that surprise you as a statement, as at
 21 October 1983, that it's being looked at in that way?
 22 **A.** Yes, it depends what your standard of proof is ...
 23 where, I would say, there's very strong circumstantial
 24 evidence that they are transmitting AIDS. Very strong
 25 indeed.

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1 **Q.** Then we can see, in terms of any action to be taken,
 2 on the next page, we see "Current situation regarding
 3 AIDS". There's a presentation by Dr Craske. There's
 4 discussion about cases, and there's a suggestion that
 5 Dr Craske will send out details about proposals with
 6 regard to recommendations for the handling of samples.
 7 So it's very clear that, in October 1983,
 8 directors are not being given any -- they've not
 9 themselves reached any shared view that there should
 10 not be any change at all in the course of treatment.
 11 **A.** That's correct.
 12 **Q.** We then move on almost a year before there's another
 13 meeting of Reference Centre Directors. So if we could
 14 have up on screen, please, Henry, HCDO0000416.
 15 We can see it's now 10 September 1984. This is
 16 a meeting at St Thomas'. You and Dr Kernoff, amongst
 17 others, are present. And if we go to page 8, please,
 18 Henry, we can see under the heading "Current situation
 19 regarding AIDS", there's a presentation of more
 20 information by Dr Craske. He talks about -- he
 21 presents some graphs. He refers to a paper in The
 22 Lancet. He explains that a further 20 patients with
 23 AIDS-related symptoms have been notified to him. Then
 24 there's a discussion about testing and reference,
 25 towards the bottom of the page, to the possibility of

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1 arrangements for HTLV-III testing now being made.
 2 **A.** Yes.
 3 **Q.** Again, I don't know whether you have any recollection
 4 of that meeting?
 5 **A.** Yes, because by then we'd heard about HTLV-III, and it
 6 was apparent that the most likely causative agent had
 7 been identified, and we could test for it. So it was
 8 trying to consider moving forward.
 9 **Q.** Other than testing, which obviously is a substantive
 10 step, there's still, however, no recommendation to
 11 directors to do anything different in terms of
 12 treatment, would you accept --
 13 **A.** No, there wasn't.
 14 **Q.** Then we come finally to the meeting at which that was
 15 discussed, which is 10th December of 1984.
 16 The reference is HCDO0000394_117, please.
 17 We can see this is effectively a special meeting,
 18 it's not the normal Reference Centre Directors
 19 meeting. You weren't, in fact, in attendance, this is
 20 10 December 1984, but Dr Kernoff was, and a number of
 21 others as listed there.
 22 And if we go, please, Henry, to --
 23 Well, I'll just -- it results in recommendations
 24 and I'll show you the recommendations document rather
 25 than pore over the minutes, but there are just two

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1 parts of the meeting where Dr Kernoff makes a comment
2 that I wanted to ask you about.

3 Page 5, please.

4 You'll see, about four paragraphs down -- this in
5 the context of a discussion about testing:

6 "Dr Kernoff commented that as some 70% of
7 haemophiliacs are now [positive], it may be considered
8 irrelevant if one tells or doesn't tell the results of
9 testing."

10 That seems, at first blush, a somewhat surprising
11 statement. Is that something you ever discussed with
12 him?

13 **A.** When I read this, I was very surprised.

14 At the time I wasn't at the meeting, and so
15 I wasn't aware of it, and I didn't discuss it with
16 him. In the event, as you may be coming to, when we
17 did test all the staff and patients of the Royal Free
18 Haemophilia Centre, we conveyed the results pretty
19 much straight away.

20 **Q.** Yes. Well, I will come on to that. We'll just look
21 at the next paragraph which says:

22 "The Chairman summarised by saying that testing
23 should be instituted as soon as possible, and that
24 information on the test results, should not be given
25 automatically but if asked for."

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1 So it appears to be the view expressed there by
2 Professor Bloom as chair also that, rather than
3 a system of telling patients the results, it will be
4 you'll tell them the results if they ask for them.

5 Would you agree that, amongst other things,
6 a patient's got to know they'd been tested in order to
7 be able to ask for the result, as a matter of logic?

8 **A.** Indeed. There's this range of opinion here, kind of
9 extreme, everybody gets tested and told the result,
10 over to what we would do now, which is proper
11 counselling before you even take the sample, in most
12 cases.

13 **Q.** Then if we go to the document that emerged from this
14 meeting, which is HCDO0000270_007, please.

15 So this is the -- called "AIDS Advisory Document"
16 drawn up after that meeting.

17 If we go to the second page, we can see towards
18 the bottom of the page, under the heading "Options in
19 probable decreasing order of safety from AIDS for
20 Haemophilia A", there is a list in order of safety,
21 and then a series of recommendations expressed in
22 firmer terms than the earlier material we looked at,
23 so for example:

24 "Use DDAVP in mild Haemophilia A and
25 [von Willebrand's] if possible."

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1 Then go over to the next page, we can see at the
2 top, recommendations for haemophilia A, different
3 categories, and recommendations for haemophilia B.

4 Then if we look at the text just under that, it
5 says:

6 "In individual patients there may need to be
7 a choice. In general heated concentrate appears to be
8 the recommendation of virologists consulted but
9 individual Directors may wish to make up their own
10 minds. This is particularly true of unheated NHS
11 material."

12 So even at this stage, when there are
13 recommendations, Directors are still being told it's
14 a matter ultimately for their individual judgment?

15 **A.** Yes.

16 **Q.** But did that surprise you at that stage, that it's put
17 in those terms?

18 **A.** Not really. There's still some uncertainty as to
19 efficacy of inactivation of the heat treatment. We
20 can see here that it's considered that the heat
21 treatment has inactivated the AIDS agent, HTLV-III as
22 we were calling it then, and -- but not the NANB
23 agent, which it took quite a while to finally isolate
24 as hepatitis C.

25 So there's a range of risk, and the choice is left

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1 to the individual director.

2 **Q.** This is, as I say, December 1984, so that's roughly
3 two-and-a-half years after the first reports from the
4 CDC in the States of cases in haemophiliacs. It's
5 two years from the report of the San Francisco baby
6 case, it's nearly two years from that Immuno London
7 Airport meeting at which the available information was
8 discussed.

9 Looking at that, do you think,
10 Professor Tuddenham, that that was a good enough
11 response by the Reference Centre Directors, that it
12 took that long to produce any kind of recommendations
13 to Directors?

14 **A.** It seems very gradual and cautious, viewed from here.
15 How good was the evidence for each of the different
16 choices? Um ...

17 It's accepted and was correct that UK-sourced
18 material is lower risk; it's not no risk. And we have
19 a treatment that may well be effective against
20 HTLV-III, and a particular recommendation for patients
21 not previously exposed, that they should have the
22 lowest risk material.

23 Although at that point, it's -- well, cryo isn't
24 zero risk, it's low risk. Heated NHS Factor VIII, low
25 risk. There's a dosage phenomenon you have to look at

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1 when you're doing an inactivation, how many logs of
2 inactivation versus how many infectious particles are
3 present, and those are variable.

4 So they're pretty -- I've got to agree that it's
5 taken a while to get to this point and still the
6 advice is pretty vague.

7 **Q.** I want to then move to deal shortly with some
8 questions relating to what happened thereafter at the
9 Royal Free. We've got some documentary evidence,
10 we've heard from Professor Lee, so I think I can take
11 it fairly quickly.

12 The evidence we had from Professor Lee suggested
13 that patients were tested at the Royal Free using the
14 stored samples that Dr Kernoff had started collecting
15 in 1978 and so patients were tested for HTLV-III
16 without knowing they were being tested. Was that
17 something you knew at the time, or was discussed at
18 the time?

19 **A.** It wasn't discussed at the time and -- do you know,
20 I don't think I even queried it at the time. We
21 just -- "Yes, we're going to test everyone", and it
22 happened. I didn't take that decision and I wasn't
23 asked about it before it happened. I was asked if I'd
24 give a sample to be tested, and I did. As did all the
25 nursing and other staff.

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1 **Q.** In terms of patients then being told their test
2 results, Professor Lee had moved on at that stage.
3 Her understanding was that that was something done by
4 Dr Goldman and Riva Miller. Do you know what the
5 arrangements were for patients to be told that they
6 had tested positive for HTLV-III?

7 **A.** Yes, I did know that Eleanor and Riva were going to do
8 that in the context of their sort of family approach
9 to counselling.

10 **Q.** Do you know whether patients were called in for
11 special appointments for whether it was just something
12 that was shared with them at the next scheduled
13 appointment?

14 **A.** I don't actually know which it was. I would think
15 they were pretty much called in, starting with the
16 positives.

17 **Q.** And do you know whether any advance information was
18 given to patients or whether they effectively just
19 turned up, not knowing that they'd been tested, but
20 told by Dr Goldman that they were HTLV-III positive?

21 **A.** I don't know that. But I should think there's a few
22 people around who do remember it pretty well. Well,
23 a lot of people.

24 **Q.** In terms of the staff who were present -- I meant to
25 ask you this earlier, Professor Tuddenham -- the staff

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1 who were working at the centre by then. We know that
2 Dr Goldman was and obviously Riva Miller, the latter
3 being deceased. Dr Kernoff.

4 What other doctors were working in day-to-day
5 clinical work at the centre in 1984/85?

6 **A.** We'd have had rotating trainees, what we then called
7 senior registrars and registrars who were trainee
8 haematologists. Permanent staff, permanent medical
9 staff, other than myself, Dr Kernoff, Dr Lee,
10 Dr Goldman, no, I don't remember if there were any
11 others.

12 **Q.** Okay.

13 Then, if we could have, please, BART0000675.

14 This is a meeting of the Haemophilia Working Party
15 of the North East Thames Region Association of
16 Haematologists, 22nd May 1985. You're not in
17 attendance at this meeting, Dr Kernoff is. Can I ask
18 you to look at the second page, please. It's the top
19 of the page where it said this:

20 "Concern was expressed about the confidentiality
21 of personal details of HTLV-III Ab positive patients.
22 No lists are circulated ..."

23 Then it says this:

24 "All patients will be informed of the result of
25 their HTLV-III antibody test on request and counselled

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1 on the implications of a positive result to themselves
2 and their families."

3 Now, that would suggest that as at May 1985 there
4 are patients who have not been given their results,
5 and that they're to request the result in order to get
6 it. Do you know anything about that?

7 **A.** No, I -- that would be other centres than the
8 Royal Free.

9 **Q.** Okay.

10 **A.** Since, as we've said, I think all the patients at the
11 Royal Free were informed.

12 **Q.** Can I then ask you a little bit about what you say in
13 your statement about research and some of the ethical
14 principles regarding research.

15 Can we have Professor Tuddenham's statement back
16 on the screen, please, Henry. It is WITN3435002. If
17 we go to paragraph 93, page 48.

18 You say this in paragraph 93, at the top of the
19 page:

20 "The first ethical principle of research involving
21 humans is the one we inherit from Hippocrates 'First
22 do no harm'. The second principle is that consent to
23 take part in research must be a voluntary choice of
24 the participant after a full explanation of the risks.
25 These and other principles are well described in the

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1 Helsinki declaration of 1964."
 2 Then you say this:
 3 "It took several decades for a full implementation
 4 of these principles to be instituted through a formal
 5 network of ethics committees and establishment of
 6 local research departments tasked with monitoring the
 7 clinical research undertaken in host institutions."
 8 And you observe that at the beginning of your
 9 career in medical research, no formal procedures had
 10 been established to demonstrate informed consent or
 11 ethical approval.
 12 Why did it take several decades for those
 13 principles that you rightly identify stemming -- or
 14 being set out in 1964, to filter through and be
 15 implemented in the United Kingdom?
 16 **A.** Yes, I've looked at the history of this, including the
 17 documents you've kindly sent me. As a medical student
 18 I was very impressed by a book produced by
 19 Dr Pappworth, titled "Human Guinea Pigs", which was
 20 blowing the whistle on the kind of research and the
 21 low standards of ethics going on at the Hammersmith
 22 Hospital and at the Royal Free Hospital. Those were
 23 the examples he gave.
 24 It certainly got my attention. There was, up to
 25 that point, a kind of old boys' and old girls' network

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1 idea that doctors were all, rather paternalistically,
 2 able to decide what was best for their patients, and
 3 that they wouldn't -- they would follow the
 4 Hippocratic Oath, and they wouldn't carry out research
 5 on patients that didn't meet the standards implied in
 6 that, and in the general contract between doctors and
 7 their patients that the doctors know what best and the
 8 patients trust their doctors.
 9 And to a very considerable extent, that did work,
 10 but it didn't really begin to take hold, and to be
 11 formally instituted by the setting up of research
 12 ethics committees in local hospitals until the
 13 National Institute of Health in the US said that they
 14 weren't going to fund research, clinical research,
 15 that didn't meet fully ethical standards as monitored
 16 by local committees. And then in the UK, a note was
 17 taken of that, and the Royal College of Physicians and
 18 the Department of Health began to work towards the
 19 establishment of those local research ethics
 20 committees. But it wasn't sort of fully and widely
 21 adopted and constituted in that form until the sort of
 22 1970s.
 23 So yes, there was a delay, and these things do
 24 take a while to evolve, and now of course we have
 25 a very elaborate and well-managed and fully applied

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1 standards for clinical research. But it was just kind
 2 of developed in a rather ad hoc kind of way, as I've
 3 mentioned.
 4 So expressing principles in an international
 5 declaration doesn't immediately translate into
 6 activity on the ground, and one could wish that it had
 7 taken place more quickly, but -- so there was a kind
 8 of a period when it was not even clear that it was
 9 necessary to undergo ethical approval for a trial of
 10 a new drug. Which seems surprising now, but that was
 11 the thinking at the time: that if the patient -- if
 12 a doctor had spoken to the patient and the patient had
 13 just agreed to undergo the trial, there was no need
 14 for anything to be formally recorded.
 15 **Q.** You've given in your statement a long list of the
 16 research projects you were involved with. I'm not
 17 going to ask you about the specifics of any of them,
 18 but you talk in some of them, particularly the earlier
 19 ones, about proceeding upon the basis of a concept of
 20 informed consent -- sorry, implied consent.
 21 **A.** Yes.
 22 **Q.** And what was the way in which that was approached by
 23 yourself and others at the time?
 24 **A.** Okay, so there was only two clinical trial projects
 25 involving administration of new drug, blood product

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1 agents. One was the trial of the Hyate:C porcine
 2 Factor VIII polyelectrolyte purified. The report on
 3 that doesn't even contain any reference to ethical
 4 approval. We did discuss with the patients what the
 5 new product was. It had undergone testing for
 6 efficacy and safety in pre-clinical studies in
 7 animals, and we just discussed it with the patients,
 8 told them why we wanted to give it to them, and if
 9 they agreed, we went ahead. That was the standard at
 10 the time.
 11 The other one was where I treated four patients,
 12 three with severe haemophilia A and one with severe
 13 von Willebrand disease, with the human Factor VIII
 14 prepared with polyelectrolyte that Dr Lane had made at
 15 Elstree and, again, we just explained to the patients
 16 why we wanted to do it and they had the infusion.
 17 It was made -- it was high purity, very high
 18 purity, it was made from UK voluntary donor plasma, so
 19 I would say it was low risk. They were all patients
 20 who'd had multiple infusions of multiple donor
 21 concentrates, and again, we just explained why we
 22 wanted to do it, and discussed it, and they had the
 23 infusions and we reported it. And it was the first
 24 formal proof that von Willebrand factor supports
 25 Factor VIII in the circulation, but it was the only

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1 time that that type of concentrate was used, and it
 2 didn't become part of the way that Factor VIII was
 3 purified at Elstree. But, as I say, those are the
 4 only two clinical research trials involving factor
 5 concentrate I was involved with at the Royal Free
 6 during my first period there.

7 **Q.** The practice of building up a bank of stored samples
 8 that we know took place at the Royal Free, was that
 9 Dr Kernoff's idea?

10 **A.** Yes, it was his idea and it was innovative,
 11 forward-looking, and proved to be a resource for very
 12 important research studies.

13 **Q.** Do you know what, if anything, was said to patients
 14 about that, or about the purposes for which any
 15 samples would be stored and used?

16 **A.** No. I mean, Peter told me straight off from the start
 17 why he was doing it.

18 **Q.** Which was?

19 **A.** That it was to track the potential effects of
 20 transmissible agents given to our patients. Because
 21 he also stored a sample bottle from every batch of
 22 concentrate that we used.

23 **Q.** Do you ever use those stored samples for any of your
 24 research?

25 **A.** On a couple of occasions we were contacted by patients

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1 or their relatives -- and I'm talking about the later
 2 period of my time at the Royal Free, from 2006
 3 onwards -- wanted to know if we could get the sample
 4 back out and check when they seroconverted for
 5 hepatitis C and/or HIV. And we'd get requests from
 6 time to time, they were useful in -- usually in cases
 7 of litigation.

8 So those were the only occasions on which I did
 9 use those samples. I don't know if you're coming to
 10 it, but there was a question of using them in relation
 11 to the most recent threat that's been identified in
 12 the blood supply, which is from Prion disease,
 13 variant CJD.

14 **Q.** I was going to ask you about that this afternoon,
 15 absolutely we can come to it now. Professor Lee
 16 referred to it yesterday and we looked at a newspaper
 17 report. You've dealt with the position in your
 18 statement in more detail so could you perhaps explain
 19 to us your involvement in that issue.

20 **A.** Yes, when it became apparent that at least one patient
 21 with haemophilia had been found post-mortem -- he'd
 22 died of other complications of haemophilia -- that the
 23 prion agent was detectable in tissue -- certainly we'd
 24 realised there was a theoretical, more than
 25 theoretical, risk of blood transmission of the protein

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1 agent that causes CJD and which caused spongiform
 2 encephalopathy in the UK cattle herd, to which the
 3 whole population was then subjected, and with some,
 4 fortunately, low level of transmission. When we, as
 5 I say, became aware that blood products could transmit
 6 prion agent, we -- the haemophilia community took this
 7 very seriously and we started looking over all of our
 8 patients who'd received a blood product from an
 9 individual who later developed new variant CJD.

10 And it turned out that the most -- the largest
 11 group of our patients who had received such a product
 12 were in fact patients with Factor XI deficiency, of
 13 which we had the largest number of patients in the UK,
 14 because of the prevalence in the Ashkenazi Jewish
 15 population and our location in North London. And so
 16 we then had to advise those patients that they were
 17 considered at risk for new variant CJD.

18 By the way, the entire population of the UK is so
 19 considered at risk, and our blood is not -- our plasma
 20 is not used for plasma product preparation if we were
 21 eating beef in the relevant period. But we -- so
 22 there was great interest in the -- and concern about
 23 the extent to which haemophilia, our patients, may
 24 have been exposed to these prion agents from UK blood
 25 products, UK-sourced blood products. It's not

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1 considered that blood products made in other countries
 2 were also so at risk. So the stored plasma bank was
 3 of interest, and I was thinking of things to do
 4 with it, just in general terms, being
 5 a research-oriented clinician, and I got talking to
 6 the people at the prion disease unit here in London,
 7 and asked them if they thought this bank could be of
 8 use in their researches.

9 Now at that point there was no established test on
 10 plasma to find prion. The only test we had then was
 11 to look in tissue, and stain for the material that
 12 accumulates, the prion protein. And -- but there was
 13 a hope that such a test could be developed to look in
 14 blood and the conversation had got just about that far
 15 when one of the researchers from the prion disease
 16 unit was at an international meeting and mentioned
 17 that there was a source of stored samples which would
 18 be of interest to look at and so, very prematurely
 19 from my point of view, this became public.

20 I hadn't got to the point of any arrangements,
 21 much less talking to our patients, which of course
 22 would be essential to do, before starting under -- you
 23 know, now -- by now we're talking 2010, I think -- we
 24 certainly would not proceed to do any tests on that
 25 material without consulting with the people from whom

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1 it was taken.

2 So I acknowledged that there was an unfortunate
3 leakage of early stage discussions at that point, and
4 apologise for any concern or worry that may have
5 caused.

6 **Q.** And just whilst we're on the subject of vCJD, I wanted
7 to ask you to look at a letter you wrote. It's
8 HCDO0000835_001. It's a letter from you and from the
9 clinical haemophilia nurse specialist at the
10 Royal Free in December of 2006, addressed to Dr Hill
11 and to Dr Hay, in their capacity at UKHCDO.
12 "Variant CJD and cost of endoscopes". Won't go
13 through the entirety of it, but we can see from the
14 first sentence, you say:

15 "This is an ongoing problem for us ... we have
16 several patients whose treatment has been considerably
17 influenced by the fact that they are on the at 'risk'
18 register because they had concentrate during the
19 relevant period."

20 Then you go on to give details of the first
21 patient and, picking it up about five lines from the
22 bottom of that paragraph:

23 "Our gastroenterologists were very reluctant to
24 proceed with an endoscopic approach and although they
25 claimed this was not because of the inevitable fact

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1 that the instrument would be quarantined, we don't
2 doubt that it entered the decision. He is under
3 consideration for a double balloon push endoscopy at
4 St. Mark's, but the instrument costs £25,000, and one
5 would have to be bought for him."

6 So that was a case of an individual whose
7 treatment was effectively being deferred, or there was
8 a risk it might not take place at all, because of the
9 cost of having to buy the endoscopy specifically for
10 his surgery.

11 **A.** Yes.

12 **Q.** And then the second patient you gave an example of,
13 and this was a Factor XI case:

14 "... not received one of the batches that
15 contained a contribution from a vCJD patient, but is
16 nevertheless on the at 'risk' register."

17 And you're saying you may have to purchase
18 a colonoscope for that purpose. You've assured the
19 patient that the Department of Health have stated no
20 patient's health will suffer.

21 But there was going to be delay, rather than
22 something that could have been done in one procedure.
23 And if we go over the page, in the second paragraph
24 you say:

25 "These are only two out of a large number of

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1 patients potentially affected by the decision" --

2 **SIR BRIAN LANGSTAFF:** Are the -- what's on the screen
3 isn't the second page at the moment. There it is.
4 Thank you.

5 **MS RICHARDS:** Yes.

6 "These are only two out of a large number of
7 patients potentially affected by the decision of the
8 Health Protection Agency and this is a problem that is
9 going to increase steadily, as the large number of
10 patients affected age and increasingly require various
11 kinds of instrumental intervention for diagnostic or
12 therapeutic purposes."

13 So you were raising this concern, and indeed it's
14 been raised by a number of individuals in their
15 evidence to the Inquiry. How, if at all, has it -- or
16 was it resolved during the time that you were at the
17 Royal Free from 2006 to 2011?

18 **A.** Not definitively. We did our best for each patient in
19 each circumstance; found a way around if we couldn't
20 find anyone to use an endoscope. Eventually,
21 endoscopes were purchased, and there's a large store
22 of such endoscopes, each one assigned to one patient,
23 that we have at the Royal Free for our patients.
24 I think time only will eventually resolve this.
25 Happily, the transmissibility appears to be pretty low

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1 with blood product with prion agent, spongiform
2 encephalopathy.

3 We haven't had any more cases, that I'm aware of,
4 but it's an example of how you never know what's going
5 to turn up next in blood, as new agents appear.

6 **MS RICHARDS:** I was going to turn to another topic. Would
7 you like to take the break now?

8 **SIR BRIAN LANGSTAFF:** Yes, that might be a good idea. How
9 long do you think you need?

10 **MS RICHARDS:** I've got a few more questions for
11 Professor Tuddenham of my own; not a huge number, but
12 there needs to be sufficient time for recognised legal
13 representatives to suggest any further questions to me
14 that they want.

15 **SIR BRIAN LANGSTAFF:** How long is that?

16 **MS RICHARDS:** I'm going to suggest 40 minutes, perhaps.

17 **SIR BRIAN LANGSTAFF:** That sounds fine. So quarter to
18 four.

19 **(3.04 pm)**

(A short break)

21 **(3.45 pm)**

22 **MS RICHARDS:** Professor Tuddenham, I just wanted to pick
23 up on the theme of paternalism. You mentioned that
24 earlier in context of the doctor's attitude towards
25 consent in the context of research. I just wanted to

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1 ask you to think about that principle or that concept
 2 when one is talking about treatment decisions.
 3 Would you accept, as a matter of principle, that
 4 patients should have been told about the risks of
 5 non-A, non-B hepatitis?
 6 **A.** Yes.
 7 **Q.** And would you accept again, as a matter of principle,
 8 that they should have been told about the risks of
 9 AIDS?
 10 **A.** Yes.
 11 **Q.** Would you agree that one of the reasons at least why
 12 that's important is because if you've got a balance of
 13 risks, ultimately the judgment as to whether you run
 14 one risk or the other, and expose yourself to that,
 15 it's got to be for the patient?
 16 **A.** In most circumstances, yes.
 17 **Q.** Yes. So there may be firm advice and a firm view
 18 a doctor holds that they can impart to the patient?
 19 **A.** Indeed, they can refuse. If they're Jehovah's
 20 Witnesses, they will have refused completely to have
 21 any blood product at all in that era.
 22 **Q.** Do you know, as a matter of fact, what information was
 23 given by Dr Kernoff or your colleagues to patients in
 24 the 1978 to '85 period about the risks of non-A, non-B
 25 hepatitis or AIDS?

1 **A.** No. Conversations with patients that I can recall, on
 2 the occasions when that arose, they were clearly aware
 3 that -- to anyone who was reading the newspapers, it
 4 was, you know, these things circulated, and the
 5 patient community were -- it's not like today with the
 6 era, of course, of social media, but back then, people
 7 were in touch with each other and the news circulated.
 8 But I'm not -- I wouldn't know what was said during
 9 annual review consultations.
 10 **Q.** Can I then just come to the question of pharmaceutical
 11 companies and their role, briefly.
 12 You have described for us in your statement your
 13 relationship with Speywood and then later on other
 14 pharmaceutical companies. Can I ask you to look at
 15 a paragraph in your witness statement, paragraph 46 --
 16 again, could we have it on screen, Henry, it's
 17 WITN3435002. If we go to page 20, please.
 18 It's towards -- in paragraph 46, about last three
 19 lines of the page after you refer to there being
 20 a full sense of the risk benefit ratio, you say this:
 21 "Once the demand for factor concentrate
 22 accelerated with more home treatment and some
 23 prophylaxis the commercial incentive to make more and
 24 sell more seems to have overwhelmed the safety
 25 issues."

1 Are you able to expand upon that observation?
 2 **A.** I did slightly couch that in probable terms by putting
 3 "seems" in the middle of the sentence. There was
 4 clearly money to be made by producing factor
 5 concentrate, as more was being used to improve
 6 management of bleeding. Even by today's standards,
 7 it's still not very high, now that we have prophylaxis
 8 aiming at trough levels which eliminate bleeding. But
 9 there was a steady rise in consumption per capita, per
 10 patient.
 11 And it's a valuable drug that sells at a high
 12 price. Currently there's a \$10 billion industry
 13 making Factor VIII. And back then it was smaller, but
 14 there was a demand, and a commercial incentive.
 15 Did it overwhelm the safety issues? Well, when
 16 one looks at the sort of headlong rush to make more
 17 Factor VIII, getting the plasma from wherever or
 18 whoever, in those days of the late 70s, early 80s,
 19 I think it's fair to say that a commercial incentive
 20 did overwhelm the safety issues, yes.
 21 **Q.** And I just want to refer you to the transcript of an
 22 interview you gave in 2016.
 23 It's JEVA0000011, I think.
 24 So this is an interview you gave on
 25 29th September 2016. You watched a film,

1 Bad Blood: A Cautionary Tale, and you were giving
 2 reflections on that. And then I wanted to ask you to
 3 look at some of the observations or comments you made
 4 about the pharmaceutical industry.
 5 So -- if we go to the second page, please,
 6 Henry -- you say this, picking it up at line 13, you
 7 refer to the film and say:
 8 "I think it's a film that should be required
 9 viewing for drug company executives in the field of
 10 blood products ... it's a very important message to
 11 bear that, as doctors, whilst trying to do our best
 12 for patients with our new technologies, there are
 13 increased risks and it should not be forgotten; and
 14 this thing will happen again, but we need to be alert
 15 to the possibility that we're making a mistake and be
 16 ever-vigilant and take the most measures that we
 17 possibly can to be aware of new threats and to keep
 18 safety at the forefront."
 19 Then you go on to say at line 24:
 20 "I think the commercial interests clearly
 21 outweighed best practice in safety."
 22 Which I think is essentially the point you've just
 23 made.
 24 Then if we go to the next page, please -- if we go
 25 to line 15, please, Henry -- you say this:

1 "It is very difficult to be a paid consultant to
 2 a particular drug company and still keep completely
 3 independent in your thought. I know that because
 4 I have done consulting and in many -- in the industry
 5 and the standards now are certainly better for
 6 declaring interest than they used to be. You have to
 7 be completely transparent with the total amount of
 8 money that you receive and the fact that you're on
 9 consultation boards ... it would be unusual for a very
 10 prominent researcher/medical doctor in the field not
 11 to be engaged with the companies who are making the
 12 treatment that we use, even only in an advisory
 13 capacity."
 14 Then you say this:
 15 "So, yes, there can be conscious and unconscious
 16 bias."
 17 Just pausing there before we come on to the next
 18 part, conscious bias is pretty self-evident. What
 19 were you meaning when you talked about there might be
 20 unconscious bias on the part of a clinician?
 21 **A.** I think that the evidence for that comes out of the
 22 amount of money that was being spent by the companies
 23 and on lavish entertainment.
 24 **Q.** And you go on to talk about that as being at the
 25 bottom of the page:

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1 "... it was overwhelmingly lavish at -- at various
 2 stages that I can recall."
 3 And then you say that you weren't so exposed to it
 4 because you took a very academic route:
 5 "... but I can see how it could influence
 6 people ..."
 7 Then you say this:
 8 "... why were they spending that money?"
 9 You mean there the pharmaceutical companies,
 10 I take it, Professor Tuddenham? The answer:
 11 "Because they could gain influence with it."
 12 And that's the purpose, presumably, of the
 13 interactions, the visits from the sales reps, whether
 14 it's the mugs, the funding of booklets or whatever,
 15 pharmaceutical companies want doctors or hospitals to
 16 buy their product.
 17 **A.** Yes.
 18 **Q.** And then you talk about some examples of lavish
 19 hospitality:
 20 "... you would be going to the best -- to
 21 a conference on haemophilia, there would be the very
 22 best restaurants, the river cruises, the -- all the
 23 paraphernalia of marketing products. It didn't go
 24 quite to the heights that it got in some areas with
 25 a bigger turnover like the, let's say, cardiology and

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1 gastrointestinal diseases where people would go on
 2 cruises for so-called -- for educational purposes, and
 3 make hundreds of thousands of pounds out of it, but it
 4 was -- it was remarkably lavish."
 5 That's from your direct knowledge from the way in
 6 which pharmaceutical companies acted, is it?
 7 **A.** Yes.
 8 **Q.** Then there's a number of specific questions raised by
 9 core participants, Professor Tuddenham, on a sort of
 10 range of miscellaneous but important issues.
 11 You told us about the stored samples of sera and
 12 the fact that Dr Kernoff also stored samples of
 13 concentrate. Two questions -- sorry, three questions
 14 arising out of that.
 15 Have those concentrates, to your knowledge, ever
 16 been tested?
 17 **A.** I don't know. And there was boxes and boxes of
 18 bottles of concentrate that came from each batch
 19 sitting in a cold room at the Royal Free when I got
 20 back there in 2006, as were all the plasma and serum
 21 samples sitting in minus 80 refrigerators which kept
 22 breaking down. They were the old ones.
 23 And at a certain point, when we'd had yet another
 24 meltdown of the minus 80 fridges over a long weekend
 25 and they were beginning to smell bad, we destroyed all

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1 the plasma and sera samples because they weren't any
 2 use anymore and they'd become a biohazard.
 3 And I think the concentrate bottles went out at
 4 the same time, and I'm not aware that they had been
 5 tested. They may have been, I just don't know.
 6 **Q.** Did Dr Kernoff store, as well as the samples of
 7 concentrate, any samples of cryoprecipitate that had
 8 been used?
 9 **A.** No.
 10 **Q.** And do you know whether those -- the samples of
 11 plasma, whether they were ever accessed by others, so
 12 not doctors within the Royal Free, but third parties,
 13 other organisations, other clinicians?
 14 **A.** If so, it would only have been done with consent of an
 15 individual. As I mentioned previously, sometimes we
 16 were asked to do a look-back and test samples, and
 17 I suppose that may have been sent out or supplied to
 18 somebody else. Not -- during my time there, if we
 19 were asked to check back, we did the testing.
 20 **Q.** Okay. You have described in your statement your work
 21 with Speywood and we've got various documents, I'm not
 22 going to ask you for the details of that.
 23 Did Speywood products, were they used at the
 24 Royal Free?
 25 **A.** Yes, indeed. The Hyate:C, the high purity pig

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1 Factor VIII, was used in our inhibitor patients for
 2 many years. In fact the very last batch was used on
 3 the patient who'd been treated back in 1986 sometime
 4 in 2010 to cover a hip replacement I think, yes.
 5 **Q.** And I think we know from the ethical approval document
 6 we looked at earlier, there was, or there was intended
 7 to be a trial of Hyate:C -- sorry -- yes, of the
 8 porcine product.
 9 **A.** Yes.
 10 **Q.** And were you directly involved with that?
 11 **A.** Yes. Yes.
 12 **Q.** Did you perceive there to be any conflict of interest
 13 as between the use of the product at the centre for
 14 patients and your own consultancy with the firm?
 15 **A.** No, it was a unique product, and if a patient had had
 16 anti-human Factor VIII but didn't have anti-porcine,
 17 they were automatically highly suited for that
 18 product.
 19 My other involvement with Speywood was in the
 20 project to purify human Factor VIII for analysis and
 21 cloning and so on, yes.
 22 **Q.** Then going back to the treatment policy in the late
 23 1970s/early 1980s introduced by Dr Kernoff, do you
 24 agree that there was a conscious decision to switch
 25 patients to concentrates from cryoprecipitate?

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1 **A.** Yes.
 2 **Q.** That that switch to concentrates included patients
 3 with mild or moderate, as well as severe haemophilia?
 4 **A.** Moderate, yes. If a mild patient was given
 5 a concentrate when there was an alternative -- DDAVP,
 6 cryo -- it should have been a conscious decision that
 7 there was a reason to do that, that the others would
 8 not have been appropriate, after we'd realised the
 9 risks and the advice had come out. But again, as
 10 always, there's a kind of grey period when the risk
 11 wasn't fully appreciated, and somebody might have just
 12 thought, well, in this particular circumstance, let's
 13 give the concentrate.
 14 And there is one case of that which I've given
 15 evidence on to an earlier phase of the Inquiry, where
 16 a patient had particularly resistant bleed and was
 17 given concentrate. But -- so there would be
 18 a decision, and it should, in all instances, have been
 19 considered.
 20 In clinical medicine, things happen at weekends
 21 when people are on call, and who might not be familiar
 22 with the case, and you might get mistakes and I guess
 23 there is going to be such instances. But as a general
 24 principle, by the time it was the case that we knew
 25 that there was more risk with concentrate to patients,

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1 such as mild patients who hadn't previously been
 2 exposed, then there should always have been
 3 a conscious decision and a good reason to give the
 4 concentrate.
 5 **Q.** And would you accept that the risk of transmission of
 6 hepatitis, of non-A, non-B hepatitis, was known,
 7 whatever might have been the view of the precise
 8 severity of it or its long-term consequences, that
 9 concentrates were highly likely if not certain to
 10 transmit non-A, non-B hepatitis was known by the late
 11 1970s?
 12 **A.** Yes.
 13 **Q.** And would you agree that it's reasonable to infer,
 14 therefore, that Dr Kernoff must have been willing to
 15 take that risk?
 16 **A.** Yes.
 17 **Q.** Just on DDAVP, were there ever any problems with
 18 supply of DDAVP that you're aware of?
 19 **A.** Not that I'm aware of.
 20 **Q.** You mentioned in your statement some involvement in
 21 the Penrose Inquiry.
 22 **A.** Yes.
 23 **Q.** We've not currently been able to track down any
 24 documentation about that, and you didn't, I think,
 25 give oral evidence in any of the formal sessions.

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1 Could you just summarise what your involvement
 2 was, how it came about, and what you did?
 3 **A.** I gave a response to their questions during the course
 4 of several hours. General questions about how we
 5 reached decisions to give particular treatments during
 6 the critical period, late '70s to mid-'80s.
 7 If my evidence was not included in the report,
 8 which I think is what you're saying, then I'm not sure
 9 why not, but because I wasn't involved with the
 10 situation in Scotland, I was giving general background
 11 information, I guess, perhaps not of a sufficiently
 12 specific character to merit inclusion in their report.
 13 **Q.** And did you produce anything in writing, a report or
 14 statement, or was it a question of having a meeting
 15 and answering questions in person?
 16 **A.** It was the latter.
 17 **Q.** You mentioned the 'If in doubt, treat' principle.
 18 **A.** (Nods).
 19 **Q.** How would that apply to patients who were previously
 20 untreated patients -- PUPs; virgin haemophiliacs -- or
 21 those who had only received very minimal or infrequent
 22 treatment?
 23 **A.** It would apply in the same way, but perhaps with
 24 a slightly higher bar on whether this was really
 25 likely to be a bleed, given that in mild and moderate

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1 patients, bleeding is less frequent and usually only
 2 happens after significant trauma.
 3 Somebody with mild haemophilia falls two floors
 4 down on to concrete and has a headache, you're going
 5 to treat them -- I mean, I'm thinking of a specific
 6 case -- and he'd gone to the local casualty and been
 7 refused treatment, and his mother fortunately made him
 8 come to see us, and we treated him. But, you know,
 9 without any hesitation. Just like all clinical
 10 decisions, you've got to take account of all the
 11 circumstances.

12 **Q.** Then two final matters, I think, Professor Tuddenham.
 13 Could we have HSOC0029583, please.

14 This is an opinion you gave to the Haemophilia
 15 Society March 1987, and you were, I think, commenting
 16 in response to a request by Mr Watters of the
 17 Haemophilia Society on a -- was it on the general
 18 litigation or on a specific individual's case? Can
 19 you recall?

20 **A.** Yes.

21 **Q.** Was it general? A general observation about the
 22 litigation, or were you commenting on a specific
 23 individual?

24 **A.** Ah. It's a general observation.

25 **Q.** And then you pose a number of questions. You say:

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1 "Was the Government negligent in not accelerating
 2 self-sufficiency of home produced Factor VIII?"
 3 And you set out your opinion:
 4 "[You] believe the Government was negligent in
 5 that regard but, as pointed out this falls within the
 6 area of 'discretion' and alternative supplies were
 7 procured.

8 And by "alternative supplies were procured", you
 9 mean commercial concentrates, presumably?

10 **A.** Yes.

11 **Q.** And then:

12 "Would be provision of home produced concentrate
 13 have reduced the number of HIV infected patients? The
 14 answer here must very clearly be 'yes' despite the
 15 over-cautious remarks of Professor Bloom in his Lancet
 16 editorial of 1984. He would himself now I am sure
 17 agree that we would have half or less of the antibody
 18 positive cases that we have now had UK Factor VIII
 19 sufficiency been reached in 1977 as promised by the
 20 Government of the day. This means that the
 21 bureaucratic discretion of the Government is
 22 responsible for at least half of our antibody positive
 23 cases."

24 Does that remain your view?

25 **A.** Yes.

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1 **Q.** And then you pose a question about do individual
 2 patients have a prospect of proving negligence? And
 3 you say that might depend upon individual cases.

4 And then if we go further down, I don't think
 5 I need to ask you about your comment at the end about
 6 legal aid or being able to afford court costs.

7 Did you have any other involvement in the
 8 litigation that took place in the late 80s, beginning
 9 of the 1990s?

10 **A.** No, I didn't.

11 **Q.** And then, if we could go, please, to RLIT0000022.
 12 Could we go to page 76. So this is the witness
 13 seminar we looked at this morning.

14 If we could go 10 pages further on and if we could
 15 just go to the previous page to check that this is you
 16 speaking. Sorry, previous page still. I think it's
 17 fairly obvious it's you but I just want to put it in
 18 context. If we keep going back. It's obviously
 19 a long intervention of yours. We've gone too far back
 20 now.

21 **SIR BRIAN LANGSTAFF:** It has all the details which
 22 would --

23 **MS RICHARDS:** It does. We'll move forward to 76. It
 24 talks about Speywood, so I'm fairly confident it's
 25 you, Professor Tuddenham.

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1 You say this in the first -- in the second
 2 paragraph, third line:

3 "Everything that we give to a patient has ... to
 4 be subjected to the most intense scrutiny ..."

5 And that's the principle that you then go on to
 6 discuss in the context of recombinant.

7 Would you agree that that should always be, and
 8 have been, a guiding principle when dealing with blood
 9 products, whether now or in the 1970s and 1980s?

10 **A.** Yes, I would. Yes.

11 **MS RICHARDS:** Professor Tuddenham, those are the questions
 12 I have for you.

13 Sir, I don't know whether -- before I ask
 14 Professor Tuddenham if there's anything he wants to
 15 add, whether there's any questions you have.

16 **Questioned by SIR BRIAN LANGSTAFF**

17 **SIR BRIAN LANGSTAFF:** Yes, I do.

18 At the end of this Inquiry, I shall have to
 19 consider making recommendations. That's
 20 recommendations as to what happens in the future.

21 You have said in your evidence -- you may well be
 22 right -- that we just don't know what may be carried
 23 by blood in the future when that blood is transferred
 24 from one person to another person. And you've said
 25 that we ought to assure the safety of it. How would

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1 you suggest that were best achieved?
 2 **A.** Firstly, by continuing careful and, where possible,
 3 intense surveillance of the response to existing and
 4 future products in people who receive them.
 5 We do have good systems for recording issue and
 6 tracing recipients of given blood donations, and that
 7 performed well in the more recent context of the prion
 8 disease where it was possible to track everybody who'd
 9 received particular batches or products even down to
 10 the individual level. That must be continued where we
 11 use blood products.
 12 And in my view, to the extent that we can, we
 13 should find ways to replace blood products with
 14 synthetic alternatives. The biotechnology industry
 15 has developed and advanced to the point where that can
 16 almost universally be applied. There's still a few
 17 examples where it has yet to be so applied, but there
 18 are occasions when there's nothing quite as good as
 19 the blood product itself because it's full of so many
 20 different agents. But we will never know what's
 21 coming along in the way of a future infective agent,
 22 so we have to preserve vigilance but replace, where we
 23 can, with the products of the ingenuity of
 24 biotechnology.
 25 There are some blood products that currently are

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1 not replaceable: red cells, platelets. These are
 2 produced in a phenomenally complex way within our bone
 3 marrows; ways we've only latterly understood and are
 4 certainly not yet in a position to replace. So there
 5 will be a continuing need for such blood products, but
 6 our best way to guard against future risks and -- is
 7 to maintain vigilance.
 8 **SIR BRIAN LANGSTAFF:** Thank you very much.
 9 **MS RICHARDS:** Is there anything that you would wish to
 10 add, Professor Tuddenham?
 11 **PROFESSOR TUDDENHAM:** Only my great regret that during
 12 that period our best efforts to improve the management
 13 of haemophilia should have resulted in this disaster,
 14 and to hope that we do learn from it, to guard against
 15 any similar such catastrophic consequences by, as I've
 16 said, continuing vigilance and always being aware that
 17 we don't know it all and never will know it all, but
 18 we have to keep learning.
 19 **MS RICHARDS:** Thank you.
 20 **SIR BRIAN LANGSTAFF:** Can I thank you very much for the,
 21 if I may say so, clear, considered, thoughtful and
 22 balanced way that you have given your evidence.
 23 You've -- I have to say, you've given me the
 24 impression that you come with no particular agenda to
 25 pursue, other than helping the Inquiry to the best of

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1 your ability, and I would like to pay testament to
 2 that and thank you very much for coming to give your
 3 evidence, and I suspect you probably regard it as your
 4 duty to do so. You've achieved it, and it may well be
 5 that, as I think your counsel may be aware, there may
 6 be some further questions to be addressed in writing
 7 in due course. I hope that you'll help us with that
 8 too.
 9 **PROFESSOR TUDDENHAM:** Yes.
 10 **SIR BRIAN LANGSTAFF:** Thank you.
 11 **MS RICHARDS:** So that's it for hearings this week, and
 12 then we reconvene on Tuesday to look at Birmingham,
 13 there will be a presentation in relation to Birmingham
 14 Children's Hospital, then we'll hear evidence from
 15 Professor Franklin on Tuesday, probably running into
 16 Wednesday, then from Dr Wilde, so still Birmingham,
 17 and then on Thursday from Dr Parapia, Bradford.
 18 **SIR BRIAN LANGSTAFF:** Yes, so ten o'clock on Tuesday for
 19 those of you who are coming back next week.
 20 Stay safe.
 21 **(4.15 pm)**
 22 **(The hearing adjourned until 10.00 am on Tuesday,**
 23 **27th October 2020)**
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