

Thursday, 13 October 2022

(10.00 am)

(Proceedings delayed)

(10.45 am)

SIR BRIAN LANGSTAFF: Good morning, Professor Tedder.

THE WITNESS: Good morning, sir.

SIR BRIAN LANGSTAFF: Welcome to the Inquiry. May

I apologise to those who have been waiting here and online for the slight delay there has been this morning.

There are two reasons for it. One is traffic. The second is that some further documents needed to be shown to Professor Tedder because obviously there will be some questions about them and they have recently been disclosed to Core Participants.

We're now in a position to proceed. Let me explain to you the setup. You're talking obviously to the room in front of you and those in front of you are largely Core Participants and participants in the Inquiry. At the back of the room there may be representatives of the press from time to time.

To your left, there are lawyers who represent various of the interests in the Inquiry and, of course, Ms Richards who will be asking you the questions. Behind me over my right shoulder there is Mary who will in a moment or two ask you to take the affirmation. But

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these tiny little agents can do in the human population and if I may be seen to be eloquent about viruses, it's not because I don't recognise the damage, and my sympathy goes to all of those who have seen at first hand family damage and loved people damaged by this virus.

Q. Thank you.

I'm going to start just with a brief overview of your career. You took a degree in zoology and then medicine; is that right?

A. Yes. I started working in zoology before I went up to Cambridge. I was tasked by the late Richard Harrison at London Hospital for dissecting dolphins and porpoises and I decided that, as much as I liked medicine, natural sciences and the advantage of being able to go outside the human species took me into zoology at university rather than medicine, which is what I had been anticipated to do.

Q. You then subsequently qualified as a doctor?

A. Well, ma'am, what happened I was offered the opportunity for a PhD in zoology and I did the first year straining mouse urine and looking for olfactory signals in mouse urine, coming back in the evening smelling of mouse urine, and decided, sort of, two-thirds of the way through that that it would be more sensible and

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let me also tell you that your bigger audience, in terms of numbers, is beyond this room. It will be both in this building but mainly online, either on YouTube or live stream, and that will probably number into three figures. So those are the people to whom you are talking when you give evidence.

Mary.

PROFESSOR THE HONOURABLE RICHARD SETON TEDDER (affirmed)

Questions from MS RICHARDS

SIR BRIAN LANGSTAFF: I should have added that if you wish a break at any time, even at short notice, just please indicate.

A. I have a symbol in my hand agreed if I need to have a break, sir. At my age, I have a --

SIR BRIAN LANGSTAFF: You don't need to explain.

A. An urgency.

SIR BRIAN LANGSTAFF: But if you need a break -- you may need a break, and if you do, you will just have to ask for one.

MS RICHARDS: Professor Tedder, before we start,

I understand there was something you wanted to say.

A. Yes. I may appear as a clinical virologist and an academic interested only in viruses. I am interested in viruses but I am even more interested, and almost at a point of terror sometimes, accepting the damage which

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extending my involvement with animals to move back into humanity and resume my medical training at the end of my first year of a PhD.

Sadly, it's one of the few things which I've ever started and never finished. Maybe, who knows -- I came back into medicine, trained at the Middlesex Hospital, and became a virologist more by accident than anything.

Q. So you're what would be described as a medical or clinical virologist and that to distinguish that from the position of Professor Weiss who was a non-medical virologist?

A. Robin was not medically qualified but he was as concerned as me about the clinical impact of viruses on people. But, yes, I'm a medical virologist and a physician and a member of the Royal College of Physicians.

Q. You tell us in your statement you worked in 1973 as a house physician at the Middlesex Hospital Medical School Department of Virology and you worked under Dr David Dane, and I'm going to come back to Dr David Dane in a few minutes. You then, I think, did a period as a house surgeon in Kettering, Kettering General Hospital; is that right?

A. KGH, yes.

Q. Then you returned in 1975 to the Middlesex Hospital

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1 Medical School. You were an Assistant Lecturer,
2 Honorary SHO, and then Honorary Registrar in the School
3 of Pathology at the Middlesex Hospital Medical School,
4 1975-76; is that right?

5 A. Yes.

6 Q. And then 1977 to '79 you were the Wellcome Research
7 Fellow in the virology section in The Department of
8 Medical Microbiology still at the Middlesex?

9 A. Yes.

10 Q. You then, 1980 to '81, became a lecturer in that
11 department; is that right?

12 A. Yes.

13 Q. And then a senior lecturer and then, over the years,
14 I think the Middlesex Hospital Medical School then
15 became effectively the UCL Medical School?

16 A. Yes. I mean, those were sort of progression of
17 seniority in any sense. It made very little difference
18 to one's day-to-day work. You were still a full-time
19 member of the Department of Virology.

20 Q. And 1982 to 2003, you were head of the Virology
21 Department there?

22 A. Yes, at UCL.

23 Q. You've had a number of other professorships and roles.
24 I'm not going to go through them all but they're listed
25 in your statement. You're a professor of medical

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1 A. Yes, I think it was a general request but I was on the
2 plaintiffs' side rather than on the commercial side.

3 Q. And you gave oral testimony as a deposition over,
4 I think, three separate days?

5 A. Two or three days certainly. It's a long time ago,
6 ma'am, but --

7 Q. Do you have any recollection now of the detail of any of
8 those proceedings or the nature of the evidence in broad
9 terms?

10 A. Well, I think in broad terms it was a question how you
11 get to know your donors, how you select your donors, how
12 you process the material that you have harvested from
13 the donors, how you treat that, how you use it, and how
14 you keep a weather eye on adverse events.

15 Q. We'll touch on all those issues then as we look at your
16 statement and your evidence.

17 It's clear from the documents and your statement
18 that you had a close working relationship with the
19 North London Regional Transfusion Centre. How did that
20 come about?

21 A. Partly because they were close, closer to us -- and
22 I was working at UCL -- but also because I had knowledge
23 of the transfusion service as a whole and I was
24 particularly a good friend of now Professor John
25 Barbara, who was a contemporary of mine, and then

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1 virology and you were also head of the Blood-borne Virus
2 Unit at Public Health England from 2007 to 2018?

3 A. Yes, I was loaned out by UCL initially on a sort of so
4 many hours per week and eventually was asked to take
5 a role in heading up the Blood-borne Virus Unit at CPHL,
6 PHLS Colindale.

7 Q. Then you've been on a range of committees and working
8 groups over the decades. Again, I'm not going to list
9 them all but, for our purposes, that includes: EAGA (the
10 Expert Advisory Group on AIDS); the ACBSB (the Advisory
11 Committee on the Virological Safety of Blood); the
12 Advisory Group on Hepatitis; the Advisory Committee on
13 Dangerous Pathogens are some of the mini-committees that
14 you've sat on over the years?

15 A. Yes, ma'am.

16 Q. Then you provided evidence to the Penrose Inquiry, the
17 Archer Inquiry, and the Lindsay Tribunal in Ireland?

18 A. Yes.

19 Q. Your statement mentions that you have files of
20 a deposition given in American litigation. I'm not
21 going to ask you about the content or detail of that
22 deposition, but is it right to understand you were asked
23 to give evidence for the plaintiff or plaintiffs in
24 a set of American litigation against a pharmaceutical
25 company?

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1 working also in collaboration with Dr Mortimer at the
2 Colindale kept me in the sort of Northwest London
3 precinct, as it were.

4 Q. We'll see from time to time references to meetings and
5 discussions with Dr Barbara (Professor Barbara now),
6 Professor Contreras and others. Did you have any
7 equivalent working relationships or any particular
8 detailed knowledge of what was going on in other
9 regional transfusion centres?

10 A. Well, I think at the various committee meetings and
11 discussion groups there would have been an exchange of
12 ideas/concepts because we tended to work together as
13 a collaborative group rather than the formation of
14 distinct bits within the framework. So there would have
15 been discussion certainly.

16 Q. I want to start now by asking you a little about
17 hepatitis B. If we just put your witness statement up
18 on screen -- Laurence, it's WITN3436003 -- and if we
19 could go to page 8. I just want to ask you a little
20 about what you say in paragraph 20. So you say this:

21 "David Dane was Head of the Department of Virology,
22 having returned from Ireland, where he was working with
23 Professor Dick on the early polio vaccines and their
24 antibody responses. He pioneered the use of the
25 electron-microscope as a diagnostic tool and

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demonstrated its usefulness for diagnosing herpes virus related skin eruptions. His role was research and diagnostics. He would be looking for things like diarrhoeal viruses and keeping a watching eye for electron-microscope diagnostics for blood-borne viruses. It was early horizon scanning, looking out for anything new."

Then you go on to talk specifically about hepatitis B but, before we do that, could you just explain to us this idea of early horizon scanning and what it was that Dr Dane was doing in that regard?

A. Well, David was, I think without question, one of the pre-eminent medical virologists, or virologists generally working within the medical field, not only in this country but globally. He was an amazingly perceptive, intelligent virologist, looking for -- and I think I did provide you here with an electron photomicrograph of hepatitis B to demonstrate how you can actually look for a virus.

I think he would have -- sadly, he passed away before we really got into the depth of the HIV epidemic, or pandemic, and that is to me always a great sadness because he would have brought tremendous wisdom to people's thinking. I use the term "horizon scanning" because he had an open mind and if he saw a disease

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a poxvirus from a herpesvirus from a filovirus. But you've got to demonstrate that in the sample that you've taken from something, whether it's a lesion on somebody or it is a stool sample from a human or an animal, that you can actually see the virus that you are looking for. And I use the word "see" in the sense of visualise it by electron microscopy.

Q. You go on to talk in the next paragraph about Dr Dane's work in relation to hepatitis B. You explain he was working on the epidemiology transmission routes of hepatitis B. He developed assays for the detection of hepatitis B surface antigen.

Then if we go to the top of the next page:

"He confirmed both sexual transmission and parenteral transmission."

Do you have any recollection as to when he was in a position to confirm the sexual and parenteral transmission route?

A. For hepatitis B?

Q. Of hepatitis B, yes.

A. Well, I remember we recognised in a particular group of people that there was sexual transmission. This must have been the very early 1980s, because he retired in '82/'83, so it would have been the beginning of the 1980s. And it was just recognising that there was

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process happening in a population, he would want to know about it, learn about it, and was there a virus involved with it? Let's not predicate just viruses; was there an infectious agent involved in a disease process? And he would have wanted to determine more about it. He would have attempted to rescue the agent, propagate the agent and indeed, as I said in a rather vernacular sense, he would look for it with the electron microscope and ... yes.

Q. In relation to viruses and the spread of viral disease, what in particular could be the role of electron-microscope diagnostics in the 1970s?

A. It is interesting, it has come back into its own with this problem of the virus infection in young men. The skin eruption. Easily diagnosed with an electron microscope. It is a technique that not many people have access to, because you have to be trained how to use an electron microscope, and it is not as easy as a conventional optical microscope, where you have something on the slide, you stain it, and you look at it down the microscope. You have to use an electron microscope and you don't know, when you are looking for something under an electron microscope, what you are going to find. Because a virus has a discrete structure. I can tell a poxvirus -- even I could tell

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transmission of hepatitis across various relationships.

It was looking, in the sense, epidemiologically rather than using an electron microscope to look physically, but obviously he demonstrated with the electron microscope that he could actually see the hepatitis B virus.

Q. In your statement -- it is at paragraph 27, bottom of page 10, please -- you then set out your understanding, in broad terms, in relation to hepatitis B when you joined the Middlesex Hospital Medical School, and you explain, picking it up in the third line:

"... a viral infection that has a different outcome in different people. Infection may cause an acute hepatitis illness in a person; alternatively, the infection may not cause any acute symptoms yet may sometimes be persistent; some persistently infected persons may get the severe illness of liver failure many years in the future. We thus knew that it caused chronic liver disease, acute illness ... and that was transmitted by ..."

The routes you then describe.

So would it be right to understand that in the '70s, at the time you were working at the Middlesex Hospital Medical School, it was understood that hepatitis B was a serious illness?

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1 A. Ma'am, I'm trying to put my mind back to my years as
2 a medical student, because that's when I would have had
3 my first exposure to David Dane, and only because
4 I needed -- he was the only laboratory that was prepared
5 to let me, as a medical student, use a radioactivity
6 gamma counter because of an experiment I'd set up when
7 I was in America and I wanted to continue that.

8 And I began to work there and realised that the
9 virologists were really very interesting people. So
10 this would have been -- I'm not sure when I actually
11 would have had that complete portfolio of views about
12 hepatitis B. But I do remember the early recognition of
13 transmission of acute hepatitis B through
14 non-injecting -- non-sharp transmission, which implied
15 sexual transmission between people.

16 Q. Do you have any recollection, again asking you to cast
17 your mind back to the 1970s --

18 A. Oh, god.

19 Q. -- of how big a public health problem hepatitis B was
20 thought to be?

21 A. Ma'am, that's 50 years ago.

22 Q. I know.

23 A. Give me the decade again you are asking -- this was --

24 Q. The 1970s. So whilst you are working with Dr Dane
25 essentially.

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1 being particularly a disease amongst men who had sex
2 with men, at that time.

3 Q. Just a couple of further questions in relation to
4 hepatitis B. You've referred to the assay being
5 developed in relation to hepatitis B surface antigen.
6 Why was hepatitis B surface antigen the main antigen
7 associated with the detection of the virus?

8 A. Well, I don't know, ma'am, if you have that
9 photomicrograph still, if you can put that on the
10 screen --

11 Q. I don't think we do have it, I'm afraid.

12 A. That is a great pity --

13 Q. We might be able to get it later.

14 A. -- because that would show you the density of the
15 hepatitis B 22 nm form, which is a small particle, which
16 is surface antigen by any other -- Australia antigen if
17 you like. That is the marker, the most common marker in
18 the bloodstream of people who are infected with
19 hepatitis B. And that is, in short, hepatitis B surface
20 antigen. It is abbreviated to HBsAg. HBsAg, we
21 virologists refer to it. Other people call it Australia
22 antigen, but that is historical.

23 That is a marker evident in people's bloodstream the
24 moment they are -- well, within a week or so of
25 infection, within five to ten days, you will have first

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1 A. Well, I would have been a very young -- I would have
2 been a very junior pair of hands in his laboratory and
3 I would have been interested to learn from him that this
4 the -- this was about the time that the Willowbrook's
5 School experiments were conducted, whereby children were
6 inoculated or infected with a short incubation
7 hepatitis, which turned out to be hepatitis A, and
8 a long incubation hepatitis, which was hepatitis B, and
9 the Willowbrook School showed that the two didn't
10 interact, there was no immunity, one transferred to the
11 other.

12 So beginning to recognise this was a transmissible
13 infection, yes, I would have acquired that knowledge
14 from David, and I would have seen that. And the
15 recognition that it was parenterally transmitted through
16 inoculation accidents would have exteriorised, gone into
17 the field of, well, if you are using a large quantity of
18 blood, you are certainly going to get an infection.

19 Q. Was it do you think understood by you and your
20 colleagues, at least at Middlesex, in the 1970s that
21 hepatitis B was -- there was a particular issue of
22 prevalence amongst gay men?

23 A. Well, I am sure if David had been there and -- he would
24 have -- yes, we must have recognised it was
25 transmissible like that, but I was not aware of this

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1 the viral DNA coming into the plasma and then the viral
2 antigen. So within ten days of infection you will be
3 Australia antigen positive or hepatitis B antigen
4 positive in the plasma.

5 Q. Then in terms of the core antigen, HBc, and leaving
6 aside any role that might have in surrogate testing for
7 other conditions, that we will come on to at a rather
8 later stage, what part would that core antigen -- what
9 part did it or could it play in the detection of
10 hepatitis B in the '70s or early '80s?

11 A. Can I just extend that into a description of what
12 happens to the markers in acute hepatitis B because this
13 is relevant. If I was to infect myself now, within
14 5 days to 10 days I would have viral DNA and surface
15 antigen coming into my bloodstream. Within 4 to 6 weeks
16 I would have a liver which is full of hepatitis B virus,
17 which in itself is doing some liver damage, but then my
18 immune system wakes up and says: hey chaps, we've got
19 a virus in these hepatocytes, we're going to take them
20 out. Not realising that if you take out all the
21 virus-infected cells, you're actually putting the person
22 into -- you are putting that liver into incipient
23 hepatic failure. This is when you go yellow.

24 And if you have fulminant hepatitis B, which means
25 that the immune system is over aggressive, it will

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1 probably kill you. It will destroy your liver. And the
2 only way you can save somebody is by transplanting them,
3 and you really don't do that in the acute phase, you
4 haven't -- in those days you don't have time. So you
5 die of fulminant hepatitis.

6 What is more likely, in a significant proportion,
7 the virus actually colonises the liver, doesn't
8 stimulate the immune system other than producing
9 antibody to core antigen, which is anti-HBc, so you then
10 become surface antigen positive in the peripheral blood
11 and you have antibody to the core component, anti-core,
12 in the peripheral blood.

13 Does that answer your question?

14 Q. Yes?

15 A. It gives you a way of defining recency of infection
16 because you can look at the type of antibody that is the
17 anti-core, and in the acute infection you will have
18 a lot of IgM. It's diagnostically useful.

19 Q. Then you have two passages in your statement talking
20 about aspects of HBV that I have been asked to ask you
21 to explain.

22 If we can go back to the statement, Lawrence, and go
23 to page 50. Bottom of the page.

24 It is just picking it up in the last line and then
25 over to the next page, you say:

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1 "... has taught me a lot about the biology of
2 persistent infection, the level of virus replication
3 (inferring the level of infectivity), its variability
4 and the evolution of the virus during its persistence in
5 the host (which is quite a complicated
6 interrelationship)."

7 Again, I have been asked to ask you to explain how
8 the virus evolves during its persistence in the host and
9 what implications that might have for the health of the
10 patient?

11 A. Okay. It is a difficult concept and it is one which
12 I ran into a difficulty of trying to make it clear to
13 people. If I can take the analogy of the Red Queen in
14 Alice in the Looking-Glass. You remember the Red Queen
15 used to run around in circles going nowhere? And this
16 is a concept which I try to apply to hepatitis B: it is
17 continuing evolving but it doesn't actually lead it
18 anywhere. It is just mutational change. Five years'
19 time you will find other mutational changes. And these
20 mutational changes vary in the type of virus persistence
21 infection with hepatitis B.

22 I don't want to lecture but shall I put that in
23 context?

24 Q. Yes.

25 A. When you become persistently infected with hepatitis B,

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1 "As an aside, I should note that we tend not to use
2 the term 'carrier' anymore because it implies the benign
3 'carriage' of the virus which is passively in the host
4 when in fact it has the potential to cause long-term and
5 sometimes severe liver disease in the host."

6 I have been asked to ask you to explain a little
7 more about that.

8 A. "Carriage" generally implies a benign relationship
9 between the carrier and the carried. It doesn't
10 actually give a measure of the fact that the virus is
11 turning over in somebody. It is a persistent infection.
12 You could carry something and be unaffected by it, have
13 it not replicating and it just waiting to replicate and
14 cause disease.

15 That is not how hepatitis B works. Hepatitis B,
16 when it becomes established in the liver, it is
17 a persistent infection. And that is why I tend not --
18 for years, decades, I used the term "carrier" because it
19 meant somebody who is carrying the virus, but it
20 actually demeans the importance of virus persistence
21 rather than virus carriage.

22 Q. Then, paragraph 155, so the next paragraph, you say
23 this:

24 "Over the years working on this virus ..."

25 So we are still talking about hepatitis B here:

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1 the virus is turning over very quickly in your liver and
2 it is producing a component of it called the e antigen,
3 which becomes a marker of high level virus replication.
4 And the e antigen is almost a surrogate for -- it leads
5 the immune system a bit astray.

6 What happens is the virus then evolves and no longer
7 expresses e antigen in the way you would expect. There
8 is a mutational change. But this allows the virus to
9 sit in the liver and continue to replicate and it does
10 so by not allowing bits of itself to be thrown out into
11 the plasma, recognised by the immune system and got at.
12 So it goes into a sort of covert stage but still turns
13 over in the liver, still comes out in the liver, and
14 still is infectious in the blood.

15 During that evolutionary period it is relatively
16 silent until you get into the stage of the immune system
17 suppressing the persistence. And this is -- sorry, this
18 sounds a little bit of a eulogy -- just makes me ...

19 In the early part of the infection, which may be
20 20 or 30 years, you produce e antigen as well as
21 surface antigen. The virus is then suppressed because
22 the immune system sees bits of that. And then, further
23 on, the virus will then change its expression of the
24 e antigen to allow it to continue to replicate without
25 being seen by the host. So the virus comes back and you

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1 progress into chronic liver disease.

2 This evolution, to me, is a very subtle way of
3 the virus being suppressed, escaping, continuing to
4 grow. And you see that there are a range of mutations
5 which are required in the virus in this escape period.

6 Q. Thank you.

7 I'm just going to turn then to non-A, non-B
8 hepatitis, and sticking with the 1970s, to the extent we
9 are able to divorce that from your later knowledge.

10 If we put the statement back on screen, please,
11 Lawrence, and go to page 11, paragraph 28.

12 You say this in paragraph 28:

13 "Non-A, non-B hepatitis ... had a very similar
14 pattern of transmissibility by blood -- components and
15 products -- although one of the bizarre phenomena which
16 impacted our view of the severe and chronic nature of
17 NANB was that acute infection was often very mild
18 clinically such that persistence was not associated at
19 that time with an understanding of its ability to cause
20 severe end-stage liver disease. Post transfusion
21 transaminitis was for some time (wrongly) considered to
22 be 'trivial'."

23 Then you refer to intravenous immunoglobulin
24 preparations.

25 When you talk about this bizarre phenomena impacting

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1 you can see how it would be easy to say, "Well, it has
2 been such a trivial infection now, it is not going to
3 matter, look at hepatitis B doing this and non-A, non-B
4 or hepatitis C doing this, this doesn't matter, this
5 does matter". Which was understandable in some ways but
6 was actually not the case. Because the further out you
7 go, what has been a little ripple on the surface becomes
8 quite a devastating end-stage liver disease.

9 Q. Why was it, do you think, looking back now, that
10 virologists, those in the medical community, as you
11 describe, took the severity of the acute symptoms, if
12 I can put it that way, as the indication of the
13 long-term -- the potential long-term effect of the
14 disease?

15 A. I'm not sure, ma'am, that we did that. I think what --
16 a virologist would always be nervous about anything that
17 is a persistent infection. I think my colleagues in
18 clinical medicine and perhaps gastroenterology would
19 have been less concerned about something which comes in
20 and gives you a tiny little tickle of abnormal LFTs,
21 elevation of liver function tests or below -- above or
22 below the cut off, would consider that to be less
23 damaging than something comes in and says, "Hooray, I'm
24 here, bang". But, of course, with hepatitis B, this
25 means that you are going to get rid of the virus. This

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1 "our view" of the severe and chronic nature of non-A,
2 non-B hepatitis in the '70s, which is what this question
3 is asking you, who is the "our" you are referring to
4 there? Is that the Middlesex Hospital Medical School
5 Virology Department or are you speaking more widely?

6 A. I think it was a wide view of medical virologists,
7 transfusion people, physicians. Looking back on it, the
8 description of mild, transient -- often --
9 transaminitis, that is inflammation of liver, a little
10 bit of liver enzymes coming into the peripheral blood,
11 little bursts of activity, and then settling down and
12 perhaps going along like this, close to the cut off,
13 below the cut off, above the cut off, you know, a little
14 bit of turnover, and thinking that that is trivial.

15 Well, it wasn't trivial. And certainly in
16 retrospect now, if you follow people 20 years through
17 this period, you meet the crunch time when the
18 inflammation which has been going on here has damaged
19 the liver such that the liver is no longer able to
20 sustain the individual. So it is not trivial but
21 I think it was -- the fact that, unlike acute
22 hepatitis B, which could be devastating, it could be
23 fatal, the acute hepatitis B can kill, acute non-A,
24 non-B gives you a little bit of transaminitis. And if
25 you compare those two, you can see how you could be --

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1 coming in with hepatitis B means you are going to get
2 the long-term persistent infection, which is as damaging
3 as the long-term persistent infection of hepatitis C.

4 Q. Then do you have any recollection as to when your
5 understanding of the non-A, non-B hepatitis could indeed
6 be severe and chronic, when that was something you
7 appreciated or began to appreciate?

8 A. I think one was always nervous about it as a clinical
9 virologist, finding somebody with a persistent
10 infection, especially if we haven't seen them before.
11 I think it was when one realised that there were people
12 who were anti-HCV seropositive presenting with end stage
13 liver disease, or severe liver disease, that one was
14 very quickly forced into realising this was not
15 a trivial infection but this was the beginning of
16 something which would then escalate towards severe
17 chronic liver disease.

18 When that happened for me, I don't know. But it
19 would have been a realisation from the
20 gastroenterologists that this virus infection actually
21 mattered a great deal.

22 Q. Now, you talk in the next paragraph -- so if we can have
23 paragraph 29 visible -- about Dr Dane's major concern
24 about the American commercial sector and producers of
25 blood components and fractions recruiting prisoners and

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1 paid donors. You refer elsewhere in your evidence to
 2 that being I think his "red flag", the use of prison
 3 blood and paid donations his red flag, and:
 4 "... his overriding need to 'know your donors' ..."
 5 Can you just -- and this was obviously during the
 6 1970s because that was when you were working with
 7 Dr Dane before his retirement in the early '80s. Can
 8 you just tell us a little more about that and about what
 9 it was that Dr Dane was particularly troubled about in
 10 that regard.
 11 A. I think it was in the scenario of not -- now, I'm not
 12 criticising anybody and I don't want anybody to perceive
 13 that I'm criticising the transfusion service or people
 14 who were dealing with this because, at the end of the
 15 day, you needed to have enough plasma to come through to
 16 sustain the clinical requirements.
 17 And the American approach was that you could
 18 harvest -- I use that term advisedly -- you could
 19 harvest blood more easily from your prison population,
 20 which would tend to be male rather than female, and you
 21 could give an incentive to harvest the blood but you
 22 knew very little about their -- what drove those people,
 23 what took them into prison, why they were in prison, let
 24 alone what they did in prison. And David's view, in as
 25 much as I recall it, and I see it written, and I know he

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1 blood product you're going to give somebody, and I think
 2 in fact many of my colleagues in the transfusion service
 3 in the late '70s and early 1980s would have been exposed
 4 to this question.

5 Q. Now, you've referred in your evidence, in your written
 6 statement, to in particular the concern about the
 7 American commercial sector recruiting prisoners as
 8 donors. Do you recall any discussions, whether with
 9 Dr Dane or others again in the '70s or early '80s, about
 10 the extent to which blood was still being collected from
 11 prisoners in the United Kingdom?

12 A. I don't recall, but I would be very surprised if we had
 13 not -- given everything that I've written, that we had
 14 not discussed it. I'm sure we had discussed it but
 15 I can't give you a time and date, I'm afraid.

16 Q. Then I just want to ask you about something that is in
 17 your evidence to the Archer Inquiry. So if we could
 18 have on screen please, Lawrence, ARCH0000011 and if we
 19 go to ... let's find the beginning of your evidence.
 20 I can't find the first page now but, in any event,
 21 I assure you this is your evidence.

22 If we go to page 171, there is just one passage
 23 here. There's a question from a member of the Archer
 24 panel, Ms Willets at lines 3 to 4, a reference to people
 25 suffering from a mild form of haemophilia and it was

27

1 was always concerned that you must know your donor, you
 2 can't know anything about the -- you can't know anything
 3 about the excipients (and that's things which shouldn't
 4 be in the blood) are in the blood unless you know
 5 something about the donor: who they are, what they do,
 6 where they do it, how often they do it, who they do
 7 whatever it is with whoever they're doing it, in the
 8 very broad vernacular sense.

9 But unless you know your donor you won't know what
 10 transmission of agents they are at risk from, and this
 11 may be something you don't know when they were on
 12 holiday in Guatemala or when they were on holiday in
 13 West Africa. Unless you know your donor, how are you
 14 going to assess malarial risk, how can you assess the
 15 microbiological risk, and indeed sexual transmission or
 16 injecting drug transmission risk. If you don't know
 17 your donor, you're relying entirely on testing.

18 Q. And do you have any sense of how widely Dr Dane's
 19 concern in the 1970s about this (the use of prison
 20 blood, the red flag, the need to know your donor), how
 21 widely that concern was shared?

22 A. He would have certainly been propagating that view in
 23 the late 1970s/early 1980s without a shadow of a doubt
 24 because it was always "know your donor" and know your
 25 donor so that you know what is the blood component or

26

1 clearly preferential that they were receiving
 2 cryoprecipitate, and then I just read out your answer
 3 and just you about that. So you say this:

4 "Can I turn that round: it was obligatory that they
 5 did not receive concentrate. It was the other way
 6 round; people had small requirements for Factor 8
 7 replacement. Certainly in our hospital, under the late
 8 Jimmy Stewart, who was the consultant haematologist, he
 9 maintained, with the agreement and support of David
 10 Dane, on the one [hand] and John Crasse ..."

11 Is that a reference to Dr Craske?

12 A. That -- I'm sorry, ma'am -- is a misspelling. I hadn't
 13 seen that.

14 Q. "... [Dr Craske], on the other, both of whom you will
 15 have heard of, that the policy should be that unless you
 16 had to give a concentrate -- this was in the late 70s
 17 and early '80s -- don't give a concentrate unless you
 18 absolutely had to, maintain people on cryoprecipitate."

19 So is it right to understand that was your
 20 understanding of the policy for the treatment of
 21 haemophiliacs at the Middlesex Hospital in the late
 22 '70s/early '80s?

23 A. It was how you supported the haemophiliac population and
 24 I think the change came when you were giving it on
 25 routine demand, routine exposure, rather than waiting

28

1 for a crisis and this evolved into problems that we had
2 with a busy haematology department where people would
3 come in in what I call a "bleeding crisis" and, in that
4 situation, we always tried to treat with the
5 cryoprecipitates rather than using a concentrate. But
6 obviously if you were faced with a critical situation
7 and you did not get the blood clotting under control,
8 the patient would die, then you have to use concentrate.

9 But I think Jimmy Stewart and David Dane between
10 them tried to make sure that if there was any
11 opportunity of controlling the illness of a patient, it
12 was done on cryoprecipitate, rather than concentrate.
13 But, you know, one had to use concentrate to save a life
14 if it was necessary.

15 Q. And would it be right to understand that what
16 underpinned that approach was the risk of transmission
17 of hepatitis at that point in time? Or that would have
18 been a main, a central part of it?

19 A. That would have been the major concern, until such time
20 as the concentrates became heat-inactivated and there
21 was microbiological control on the concentrates for heat
22 inactivation and then that altered the balance of risk.

23 Q. We can take that down, thank you.

24 Did you have any particular knowledge in the '70s
25 and '80s of the notification mechanisms, such as the

29

1 associated with only one disease which we knew of at the
2 time, which was an adult T cell lymphoma leukaemia later
3 in life which was very difficult to treat. And
4 therefore, as it was a potentially oncogenic human
5 retrovirus, the principle was to stop it being
6 transmitted from mother to infant and that meant, even
7 though we don't do it nowadays in the United Kingdom,
8 you should have screening in the antenatal clinic to
9 identify the infected mum and give her support,
10 counselling, social support, family support, and access
11 to breast milk substitute. It's the same as it should
12 be nowadays.

13 Q. So that was HTLV-I --

14 A. Yes.

15 Q. -- and an understanding of the link with a form of
16 leukaemia.

17 Then how did an understanding of HTLV-II come about?
18 Again, I'm looking at the early 1980s.

19 A. Okay. It's interesting. Am I allowed to use my hands
20 to demonstrate?

21 Q. Yes, of course.

22 A. If you have a population of reactivity in an
23 immunoassay, which if you look at it is like that
24 (*indicated*), and then as you look at it from there, your
25 positives are out here (*indicated*) -- so you've gone

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1 yellow card system, for incidences of viral disease such
2 as hepatitis?

3 A. Well, I was aware of the yellow card system. I was also
4 aware of the desire that there should be feedback to the
5 transfusion service of every adverse outcome because,
6 unless you have that, how do you know to analyse risk
7 and benefit and have a protocol in place to introduce
8 a change to reduce risk, to maintain benefit? It was
9 really important that my colleagues in the transfusion
10 service had a way of getting that information.

11 Q. And was there any sense at the time of the extent to
12 which the yellow card system, or indeed any other
13 systems, were effective?

14 A. I would not have been aware of that, ma'am.

15 Q. Can I then just turn to ask you next a little about
16 HTLV-I and HTLV-II --

17 A. Yes, ma'am.

18 Q. -- before we come on to HTLV-III, as it was initially
19 named, and HIV.

20 In the early 1980s, you were doing work in relation
21 to HTLV-I and II, and I'll ask you about the development
22 of tests a little later. But what's your recollection
23 of what was understood about those two viruses?

24 A. Well, ma'am, it started off with HTLV-I, which we knew
25 then was transmitted from mother to infant, was

30

1 from a high signal to a low signal because you're using
2 a competitive test -- you will have your negative
3 population and your positives there. And if you are
4 a curious virologist, you will see things in the middle,
5 neither positive nor negative, but they're always there
6 and you take them and you repeat them and they're always
7 there. So you say, well, okay, let's get another bleed
8 and you repeat them and they're still there. Then
9 you've got the intellectual exercise of there are your
10 negatives, there are your positives, here are your not
11 negatives, but they're not positive either.

12 But the important way is to think of those as
13 they're not negative. So what are they? And that
14 turned out to be the sister virus of HTLV-I, it turned
15 out to be HTLV-II, and we still don't really know what
16 the long-term sequel to that is -- or I don't. I know
17 HTLV-I has leukaemia, it also has a neurological disease
18 which gives you a tropical spastic paraparesis (which is
19 where your spinal cord gets damaged and your limbs don't
20 work), and other sort of inflammatory association
21 diseases with HTLV-I.

22 HTLV-II is a similar retrovirus and, because I found
23 we had the negative population, the positive population
24 and this population, I wanted to have a test for this.
25 So I replicated what we did for the HTLV-I test with

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1 HTLV-II sera and then I had a test which gave you
2 positives, negatives, and things in the middle. There
3 was the HTLV-I, here was the HTLV-II, and there was the
4 negative population and it taught me a great deal about
5 how to build immunoassays, and these were competitive
6 assays where you looked for the test serum blocking
7 a labelled antibody, which would bind to the solid phase
8 because there was an antigen there, and your patient's
9 sera comes in and if it goes in and stops this coming
10 on, you get a loss of colour. And that's a competitive
11 signal and that tells you your patient has an antibody
12 which blocks that.

13 Q. We will come back to the assays that you then worked on.

14 I want to turn next to ask you about your awareness
15 of AIDS and how you came to have some knowledge in
16 relation to that. Again, if we start by picking it up
17 from your witness statement, if we can have that back on
18 screen, Lawrence, and go to paragraph -- page 12.

19 You say this in paragraph 31, picking it up at the
20 end of the first line:

21 "... it is hard for me to define the individual
22 points at which I became aware of AIDS, its association
23 with blood and/or blood products, and its nature as the
24 outcome of an infection which was most likely to be
25 a virus."

33

1 Public Health Laboratory at Colindale, and I would have
2 been involved in discussing things like such as this.
3 I seem to remember that the striking thing in one of
4 these MMWR reports was the fact that they had also seen
5 this in injecting recreational use of drugs which then,
6 by the time you've got a sexual transmission and an
7 injecting recreational drug transmission, if that's not
8 hepatitis B, it's got to be something very similar to
9 hepatitis B. It's got to be a transmissible,
10 parenterally transmissible, virus infection.

11 Q. Just for the sake of completeness, I'll put this MMWR up
12 on screen because it's not one we've looked at as
13 frequently in Inquiry hearings as some of the ones from
14 July onwards. It's RLIT0001690:

15 "A cluster of Kaposi's Sarcoma and Pneumocystis
16 carinii Pneumonia among Homosexual Male Residents of
17 Los Angeles and range Counties, California ..."

18 Then there's a reference to reported cases in the
19 first paragraph, data on sexual partners, and then the
20 third paragraph talks about sexual contact in particular
21 areas, in Los Angeles and Orange County, the development
22 of symptoms. Then the fifth paragraph talks about the
23 patients from Los Angeles and Orange Counties being
24 directly linked to other patients and being part of an
25 interconnected series of cases, and then there is

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1 Then you refer to the HTLV virus as being the focus
2 of much of your attention in the early 1980s.

3 Then you have set out in the following paragraphs of
4 your statement references to documents that the Inquiry
5 is familiar with, the MMWR report, the Morbidity and
6 Mortality Weekly Reports. If we just go to the bottom
7 of the page, you say this:

8 "Having reviewed the MMWR reports, I have a distinct
9 recollection of noting the association with the
10 bathhouse arena, which had a similarity to transmission
11 of hepatitis B. While I cannot be sure, I think this
12 means my recollection of first noting AIDS in
13 a significant way was the MMWR report for 18 June 1982."

14 We will look at that in a moment. You refer to it
15 and then you say:

16 "It specifically relates to the homosexual male
17 demographic on the West Coast and has references to
18 bathhouses. I should stress that, while the date of the
19 report is 18 June 1982, I cannot actually be sure at
20 what point I became aware of what was reported."

21 Just in terms of receiving the MMWRs, in 1982 how
22 would you have actually received copies of that report?

23 A. Well, at that time, I would have either been in or --
24 I had a very close relationship still with colleagues at
25 CPHL, the Central Laboratory for Public Health, Central

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1 a reference to locations.

2 Then we have the editorial note which refers to
3 sexual contact and the possibility of -- sorry, and the
4 inter-related sexual contacts between the various cases.

5 Is it right to understand, doing the best you can,
6 you think this is an MMWR which -- I think the way you
7 put it in your statement -- might have been your first
8 noting of the disease in a significant way?

9 A. Yes, ma'am. I think there is also a contemporary for
10 this where they actually show cases arising in those who
11 are using injectable drugs and that, I think -- this was
12 one which makes you think of a transmissible agent but
13 then the moment you've got injecting drug use involved
14 as well, you then have to say, well, it's parenteral as
15 well as sexual.

16 Q. Certainly one of the documents that you've referred to
17 in your statement which refers to drug use is
18 BAYP0000028_011. It's the second page. This is, if we
19 can pick it up at the heading halfway down the page:

20 "(AIDS) in Prison inmates -- New York, New Jersey."

21 We can see this is January 1983. Then there's
22 a reference, I think about five paragraphs down, to ten
23 patients reporting they were heterosexual before
24 imprisonment and then the nine patients with PCP were
25 regular users of intravenous IV drugs.

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1 Then if we go to the next page and just look at the
2 editorial note, which is not quite halfway down, under
3 the italicised bit:

4 "Editorial note: Since male homosexuals and IV drug
5 abusers are known to be at increased risk for AIDS, the
6 occurrence of AIDS among imprisoned members of these
7 groups might have been anticipated. Increasingly,
8 epidemiologic observations suggest that AIDS is caused
9 by an infectious agent transmitted sexually or through
10 exposure to blood or blood products. Because of the
11 difficulties inherent in interviewing prisoners, data
12 elicited in such interviews must be viewed cautiously.
13 Given this caution, the histories obtained from the
14 inmates indicate that all or most of their drug use,
15 and, by inference, their exposure to a blood-borne
16 agent, occurred before confinement."

17 That's one of the other pieces of information you
18 refer to in your statement as giving rise to or helping
19 you form your views about this.

20 **SIR BRIAN LANGSTAFF:** Just before we take this off the
21 screen, if I may, there's a reference to the assertion
22 in the first sentence, first line:

23 "Since male homosexuals and IV drug abusers are
24 known to be at increased risk for AIDS ..."

25 The reference is to the CDC, so that would be the

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1 it into the parenteral agent concept which of course,
2 for my mind, having been brought up with hepatitis B,
3 was yet another footstep: it has to be a transmissible
4 agent.

5 **SIR BRIAN LANGSTAFF:** So it was the same sort of pattern of
6 observation of the disease as you would see with
7 hepatitis B?

8 **A.** Yes.

9 **SIR BRIAN LANGSTAFF:** And that would lead you, would it, to
10 think that you would have transference by needle --

11 that's obviously the IV drug user -- and therefore from
12 transfusions and those who suffer from haemophilia?

13 **A.** I think, sir, it would have led me to look at the causal
14 agent in exactly the same frame, conceptual frame, of
15 looking at hepatitis B and that would lead, as you have
16 suggested, sir, to the progression of persistence
17 disease, transmission, et cetera, but, in this case, an
18 agent that we don't know what it is but we know its
19 behaviour and we have a feel for how it transmits
20 amongst people based on everything that we know about
21 hepatitis B and its transmissions through non-parenteral
22 and parenteral routes.

23 **SIR BRIAN LANGSTAFF:** So your conclusion, from what you're
24 saying and given your background, is that this was
25 something which may be a virus, may not be a virus but

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1 MMWR, update on acquired immuno deficiency syndrome and
2 that's a reference in 1982. It was published in 1982.

3 We know from this, although we haven't put up the
4 particular publication, that IV drug users were known to
5 have AIDS. Can we go back to the RLIT0001690 which we
6 saw a moment or two ago, which was the June 1982 MMWR
7 because I noticed something when it was on screen.
8 RLIT0001690.

9 If we go down to the bottom of the page and the
10 editorial note, the editor there is looking at possible
11 readings of what this might show the world about the
12 origins of AIDS or what caused AIDS and it talks in the
13 last paragraph:

14 "Exposure to some substance (rather than an
15 infectious agent) may eventually lead to
16 immunodeficiency among a subset of the homosexual male
17 population that shares a particular style of life."

18 It refers then to using amyl nitrite as a stimulant.

19 So far as you are aware, that used as a stimulant
20 for sex was unlikely to be a stimulant involved in IV
21 drug use presumably?

22 **A.** That behaviour I can't comment on, sir, but, I mean, I
23 think what this led me to perceive was that there was
24 a commonality of men having sex with men and people who
25 were sharing drug usage, injecting drug usage, which put

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1 it was an infectious agent which could be transmitted by
2 blood.

3 **A.** Yes. Parenterally transmissible; so, by definition,
4 yes.

5 **MS RICHARDS:** The way you put it in your statement, I don't
6 think we need to go back to it, but you describe
7 hepatitis B as the best analogue illness for what we saw
8 in the 18 June MMWR report for AIDS. You say it's that
9 linked to the nature of hepatitis B that made you first
10 think that AIDS could be a virus and associated with
11 exposure to blood. We can take that down. Thank you.

12 It's apparent from your statement that you recall
13 that this in the course of 1982 was something that would
14 be the subject or was being the subject of active
15 discussions with colleagues such as Dr Barbara,
16 Dr Mortimer; is that right?

17 **A.** Yes, it would -- I mean, anybody who had exposure to
18 hepatitis B and working with it in populations and
19 epidemiology would have said this is something -- this
20 has to be something very similar.

21 **Q.** You attended a meeting in Washington. I think you can't
22 date it precisely but -- the evidence you have given
23 both to Penrose and in your statement -- is probably
24 late 1982, early 1983. I think you describe it as the
25 first retrovirus meeting.

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1 First of all, can you just help, when you call
2 something a "retrovirus", what does that mean?
3 **A.** It's a term -- when a virus grows and replicates, that
4 means when it grows in the cell, how does it grow? Most
5 viruses you put in, they unwrap, their genome becomes
6 available and it replicates and makes more, throws more
7 of the virus out, and goes on. That is the conventional
8 virus.

9 A retrovirus is handicapped in a way because its
10 genome -- sorry, this is going to be a wee bit of
11 an explanation, sorry. I don't want to confuse.

12 There are two types of nucleic acid, there is DNA,
13 which is normally what is in our nuclei and is what is
14 passed from population to population, and there is RNA,
15 which is taken -- the message on the DNA is
16 transcribed -- is changed into a message in the RNA, and
17 that is a signal to the cell: make this.

18 So a conventional virus will either be an RNA, "Make
19 this, make more of me", or if it is a DNA virus, in,
20 comes out, "Make more of me", and it makes more.

21 Retroviruses are a little more complex than that,
22 because the nucleic acid is RNA but it comes into the
23 cell and rather than say, "Make me more", it says, "I'm
24 going to take my signal and I'm going to bypass you, I'm
25 going to make it into a DNA signal". And it goes into

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1 about these viruses. Why not have these as a cause of
2 a transmissible retrovirus infection in men who have sex
3 with men and people who share drug injection? This
4 would do. And it would be something like HTLV-I or II,
5 one of those two viruses would be responsible.

6 Working with Robin Weiss at the same time, I had
7 developed serological tests for HTLV-I and HTLV-II, the
8 antibody to the viruses. I can explain how I did that,
9 but it was very simple, and it's what taught me how to
10 do it for HTLV-III when that came along.

11 We had a serological test for HTLV-I, we had
12 a serological test for HTLV-II. Remember the two
13 populations I talked about, where we had a test that put
14 them both into the positive area?

15 And we tested young men and other people who
16 had AIDS and we didn't find a significant level of the
17 virus infection in those who were ill and those that
18 weren't ill. And when he said, "Well, HTLV-I or II is
19 the cause of AIDS because, look, it is a retrovirus and
20 people are dying from a retrovirus infection", I put my
21 hand up in the air and said, "Well, we've looked in" --
22 I can't remember -- "20 or 30 cases of AIDS, and we only
23 found 1% or 2% of these have HTLV-I or II. How are you
24 going to say that something which is down at the
25 fraction of 1% or a couple of per cent of the population

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1 the cell. And then the DNA signal is then used to make
2 more RNA to make more virus.

3 So it has to go this reverse step, from RNA putting
4 it into the normal mechanism, which is DNA, and that is
5 called reverse transcription. Because normally, if you
6 read a book, it is: DNA makes RNA, makes protein. What
7 we are saying here is: this is a RNA virus, which comes
8 in, makes RNA, makes DNA, makes RNA, makes protein. The
9 reverse transcription step is characteristic of
10 retrovirus and is obviously susceptible to certain
11 drugs.

12 **Q.** What can you recall about the meeting in Washington?

13 **A.** It was interesting. It was a lively discussion. And
14 I probably raised a big black by being fairly rude to
15 one of the eminent speakers.

16 **Q.** Who was Dr Gallo?

17 **A.** Bob Gallo, yes.

18 **Q.** What was it that gave rise to what you have termed
19 a brush with Dr Gallo?

20 **A.** Well, he became a drinking companion in later life.
21 I hadn't seen him for decades and I would always --
22 I'll always fondly recall this.

23 He had conceptualised -- he had interpreted the data
24 to say that we have got to have a human retrovirus and
25 why not let's have HTLV-I or HTLV-II. Because we know

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1 of everybody who gets AIDS -- that's not causal. You
2 can't say that something which affects 1 in 50 -- what
3 about the other 49 people who have this dreadful
4 infection? So you need to think again."

5 **Q.** But it was Gallo's thinking, was it -- that is the
6 reason why, at that time and for a further couple of
7 years, it was referred to as HTLV-III?

8 **A.** Ah, well, Bob liked to have viruses in his cluster. So
9 he had HTLV-I and HTLV-II, so having HIV and calling it
10 HTLV-III, it became within his portfolio, bless him.
11 There was nothing -- I mean, there are other HTLVs out
12 there nowadays, in countries in Africa. So the number
13 is going to increase and it is better to have it.

14 **Q.** Sir, I note the time. We started late but we have now
15 been going for an hour and a quarter, which would be
16 when we would normally take a break. I'm in your hands
17 as to when this we break.

18 **SIR BRIAN LANGSTAFF:** Yes, I think for two reasons we will
19 have -- well, three reasons we ought to have a break.
20 The first is we have had an hour and a quarter. The
21 second is, I am sure Professor Tedder could probably do
22 with a break. And thirdly, so could the stenographer.

23 **MS RICHARDS:** Exactly.

24 **SIR BRIAN LANGSTAFF:** So we will take a break and we will
25 come back.

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1 Now if we come back at 12.30 pm we will go on then
 2 until 1.30 pm and then we will have a late lunch at
 3 1.30 pm, if that's all right? I see that those around
 4 me nodding and saying that will allow the appropriate
 5 arrangements to be made. So 12.30 pm.
 6 **MS RICHARDS:** And the normal explanation for Professor
 7 Tedder.
 8 **SIR BRIAN LANGSTAFF:** Yes, I will give that just now.
 9 Professor, you are under oath. The rule is that
 10 anyone who is under oath may not discuss any evidence
 11 they have given or any evidence for that matter they
 12 think they might yet be asked to give, with anyone,
 13 whoever that anyone is, but they can talk about anything
 14 else they like.
 15 **A.** I understand.
 16 **SIR BRIAN LANGSTAFF:** 12.30 pm.
 17 **MS RICHARDS:** Thank you, sir.
 18 **(12.00 pm)**
 19 **(A short break)**
 20 **(12.30 pm)**
 21 **MS RICHARDS:** Professor Tedder, I want to turn to
 22 interactions you had or an interaction you had with the
 23 Department of Health in 1983. I'm going to pick it up,
 24 first of all, with your evidence to the Penrose Inquiry.
 25 So if we could have, Lawrence, PRSE0006049, and if

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1 towers and we were told this was really not any of our
 2 business and it was not going to be a problem and go
 3 away and stop rocking the boat."
 4 Over the page. You say:
 5 "Both Philip and I -- well, I can't speak for
 6 Philip. You would need to ask him. But I was somewhat
 7 taken aback and pretty irritated."
 8 That was your recollection to the Penrose Inquiry.
 9 As I understand your witness statement to this Inquiry,
 10 Professor Tedder, you don't have now particularly
 11 distinct recollections of that meeting?
 12 **A.** I think that's -- I have to say, I think that's right.
 13 You know, a lot of water under the bridge, I'm afraid.
 14 I do remember feeling disappointed that there was not
 15 a willingness to go forward and grab opportunities.
 16 But, you know, that's a sort of colouring of what
 17 I think went on. But if you are asking me who said
 18 what, I can't comment.
 19 **Q.** After that meeting you wrote to Dr Walford. I will come
 20 to that letter in a couple of minutes, but I want to ask
 21 you first about some observations you make in your
 22 statement.
 23 So if we could have WITN3436003 back on screen. If
 24 we could go, please, to page 18.
 25 You say this in paragraph 54:

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1 we go to page 96, please.
 2 If we go to the bottom of the page. You were asked
 3 at line 19 about whether you had met Dr Diana Walford in
 4 connection with the whole AIDS problem. And you
 5 explained you had. You referred to the meeting in
 6 Washington which I was asking you about before the
 7 break. Then you say:
 8 "After that and after the meeting, the NIH meeting,
 9 discussing this, it must have been early 1983, Philip
 10 and I ..."
 11 That is a reference to Dr Philip Mortimer?
 12 **A.** Correct.
 13 **Q.** "... went to DHSS to ask what the plans were for -- what
 14 was ready -- what was going to be the plans for
 15 readiness to deal with what, I think I alluded to
 16 earlier this morning, was a disease or infection which
 17 sounded awfully like Hepatitis B in terms of affecting
 18 the same group, having the same sort of transmissions."
 19 Then you refer to having heard in early '83 or end
 20 of '82 about haemophiliacs also being involved.
 21 Then if we go down to line 19, you say this:
 22 "So we felt empowered to go and ask the DHSS what
 23 could we do to explore this, and it was as cold
 24 a meeting inside the room as it was outside. It was
 25 a sort of cold spring morning up in one of the DHSS

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1 "I was not aware of plans to deal with a new and
 2 emerging infection and cannot comment on what if any
 3 processes were then in place. In the early 1980s,
 4 hepatitis B was a disease which caused a clearly
 5 apparent acute illness presenting as jaundice and
 6 hepatitis in gay men. Had there been appropriate public
 7 health surveillance for this, it would have opened up
 8 the immediate possibility of using the same approach in
 9 the same population looking for the disease of
 10 'gay-related immuno deficiency syndrome', 'GRIDS'. This
 11 would have given the absolute substrate for
 12 investigating the emergence of HIV disease in the same
 13 population."
 14 Two questions arising out of that paragraph,
 15 Professor Tedder. Firstly, what kind of public health
 16 surveillance did you have in mind that could have been
 17 appropriate for hepatitis B?
 18 **A.** I think notification to an organisation who would be
 19 able to look for further transmission of infection from
 20 the infected individual; provide protection and -- to
 21 those who might have been exposed -- if the time was
 22 right, there are options for passive antibody given to
 23 people who have had an exposure to hepatitis B. But
 24 also the opportunity to immunise the at risk population.
 25 I use the "at risk" very specifically in this case, the

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sexual partners of. And hopefully to encourage a degree of behavioural change to prevent onwards transmission of hepatitis B.

All of those could be offered partly from a laboratory who's had the central role in knowing where these acute infections were, relating it to the GUM clinics or the health clinics, and the health clinics and the GUM clinics themselves would have had a role in passing that information back to their patients and people seeing them and trying to suggest that maybe they modify their behaviour.

Q. And there was no such system in place that you were aware of at the time?

A. Well, I think there were but I wasn't aware of it being truly effective. But that's just -- that's me as a clinical virologist.

Q. Then can you assist in understanding the reference in that last sentence to the "absolute substrate". What did you mean by that?

A. I think what I'm suggesting, if you put that in place, in having a mechanism for surveillance, interaction with the risk populations, this would have given one an opportunity to say: Hey folks -- because we don't want to put a gender on it -- we've have talked to you about hepatitis B, just be careful because there's

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the value of having a good serological test for antibody against an emerging infection which facilitates determining when, where and how a virus may be passing in the host population."

If we go back to the previous page. I'm not going to ask you to talk on any level of detail about your interactions with the Government into Covid -- we are not the Covid Inquiry and there is a Covid Inquiry which has recently begun -- but it is more the reflections that you are able to draw based upon interactions back in the early '80s with the Government in relation to AIDS and then interactions more recently, as you describe here, with the Government in relation to Covid.

Do you have any thoughts or reflections on why there seems to be, as you describe it, a short sightedness about the value of certain kinds of tests and certain kinds of response?

A. I think there is two components in an answer to that. If I can get the trivial component away first, which is: there is a great reliance by DHSC and people in that area of authority to distance themselves from an academic who comes and says, "I have got a damn good test and this will work", because it is not commercial.

And to get a test of the sort of ability that we have, you would have to get it commercialised and -- and

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something out there which we think has a similar role of transmission, and if you can protect yourself by your behaviour from getting hepatitis B, you may also benefit from getting infected by whatever the cause of this new and emerging disease is.

Q. If we can look at the next three paragraphs please. You say this:

"55. Even today with the advent of Covid, when I was able to produce within the first few weeks of the emerging coronavirus epidemic, serological tests which could identify both acute and past infections with Sars CoV 2, and offered these to the Government, they were entirely disregarded.

"56. ... My reflection suggests that the pressure to develop antigen-based and PCR-based diagnostics for detecting the infection in the acute phase distracted people from the value of having serological tests which could be used on a population basis to map the transmission of this virus within the population as a whole.

"57. Interestingly we seem to be running through a similar scenario 36 years later. It was very similar to the response I received when I told DoH in 2020 that what we needed for Covid was an *antibody* test. I think people focus on finding a test to the virus and forget

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length of time, you have to find a partner and so on. But it means that your technology is not absorbed in the response.

Now, partly an antibody test doesn't help you really to make an acute diagnosis unless you have an antibody test that can measure the process of the antibody and the acute infection, which is IgM antibody. And that is what we have for Covid. We have an antibody test which can identify past and acute infections and be delivered by a dried blood spot, all of which enable you to say: Mr Smith, over in Little Whopping on the Lyme or somewhere, I'm going to send you a card, drop two or three drops of blood on there and we will tell you whether you have had Covid", or whatever infection. That, to me, as a virologist and somebody who is an old-fashioned animal who likes to measure antibody, is an alternative to the modern approach, where you have to take a throat swap or nose swab, you have to send it to a laboratory for a PCR.

I am not decrying PCRs because I love PCRs, and we have developed them over the years, but people will forget an antibody will map your transmission of an agent in the community rather than having to get acute infections from everybody. For every acute one infection you have, you may have 15 or 20 people who

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1 have been infected. If you are going to do a population
2 of 500 people, it is much easier to do 500 dry blood
3 spots than 500 PCRs where you each have to go up and
4 take the appropriate sample at the appropriate time.

5 People forget serology. It is a good way of
6 determining the evolution of an epidemic into
7 a population, the distillation of the virus going
8 through the population.

9 **Q.** If we turn back into 1983. Following the meeting that
10 you and Dr Mortimer had with the Department, if we go to
11 the letter that you then wrote to Dr Walford,
12 DHSC0003824_164, it's a letter of 20 May 1983 to
13 Dr Walford and you refer in the first sentence to the
14 meeting:

15 "Thank you for seeing Dr Mortimer and myself last
16 week. I gather Dr Catterall has already written to
17 Dr Graveney, I expect you like I have seen a copy of his
18 letter. It is, I believe a reasonable statement of
19 intent. However as a virologist I should like to make
20 a number of comments on the whole problem of AIDS not
21 merely related to a GUM framework.

22 "This condition is likely to be caused by an
23 infectious agent or agents. Its epidemiology bears
24 a striking similarity to hepatitis B. Since hepatitis B
25 became a growth industry we have gained a great deal of

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1 Ma'am, I should think it is again coming back to the
2 similarity of disease patterns in the population of
3 hepatitis B and what you would -- how you would control
4 hepatitis B is identifying where it is, transmission
5 events, counselling people who have been infected,
6 counselling people who are infected. Hepatitis B, of
7 course, we had a vaccine. For this, even now we don't
8 have a vaccine; so it comes back to counselling people
9 and giving people good advice. That's really
10 ultimately, when you have something new in the
11 community, that's what you have to do.

12 **Q.** Would it be right to understand, because you'd gone to
13 this meeting with Dr Mortimer, and we haven't said who
14 Dr Mortimer was, he was based at PHLS so he would have
15 had access to whatever data PHLS had by this stage about
16 the extent of infection with AIDS?

17 **A.** He would have but don't forget PHLS, like the Department
18 of Health, is split into bits and there may not
19 necessarily be routine transmission of information from
20 one group to another. I mean Philip -- who's still
21 a good friend of mine -- is a medical virologist and we,
22 as virologists, may or may not be privy to what
23 epidemiologists have or want or what clinicians dealing
24 with the patient groups have or want.

25 If one could break it down and get people to talk to

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1 knowledge about the infection and about the illness by
2 study of a small, epidemiologically easily identified
3 patient group, the male homosexual. In the UK where
4 hepatitis B is not a major health problem, it has still
5 proved possible to examine the problem of this disease
6 by examining this group of patients.

7 "AIDS is essentially limited at present to the same,
8 easily identified group. So although AIDS has many
9 wider implications covering for example the fields of
10 blood transfusion and risks to medical staff, it is only
11 by detailed study of the homosexual patient that we will
12 be likely to make [a] significant contribution to an
13 understanding of its aetiology.

14 "The work on AIDS covers three main aspects; to be
15 successful I am certain that a multidisciplinary
16 approach is vital. Also since the evidence is that the
17 disease is becoming established in the UK I think that
18 it is necessary to set up this project now."

19 Now, just pausing there, can you recall -- difficult
20 question, I suspect, so many years after the event --
21 what evidence it was that you had in mind that the
22 disease was becoming established in the UK? What kind
23 of information you might have had which led you to make
24 that observation?

25 **A.** It was 39 years ago. It is a bit difficult to recall.

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1 each other without feeling of, you know, there's
2 a sectarian limit to where I am and somebody else over
3 there will say, "Well, it's all our problem; let's try
4 and solve it for the betterment of people", you need to
5 get talking and you need to break down barriers -- and
6 that's barriers both up to government, down from
7 government, and at the level of people who are dealing
8 with individuals and populations.

9 **Q.** Then turning to the letter, you outlined three areas of
10 work that you thought was important to undertake. I'm
11 not going to read those out but we can see the heading
12 "Patients, immunology, virology."

13 If we go over the page and just pick it up in the
14 third line, you say this:

15 "If there is a single novel aetiological agent
16 causing AIDS and if this agent is present as a viraemia
17 (likely since Factor VIII is implicated) it may well be
18 amenable to the sort of approach [which] identified
19 hepatitis B and the human parvovirus."

20 Pausing there, can you help us understand the
21 statement that it was likely to be viraemia because
22 Factor VIII was implicated?

23 **A.** Well, it feels like -- if you gave the pattern of
24 this -- not the clinical features, but if you gave the
25 pattern of this disease and transmission events and who

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1 it affected and who it didn't, you'd say, well, that's
2 a transmissible agent, sexually transmitted, probably
3 causing persistent infection and persistent infection is
4 leading to disease, and there may be an illness of acute
5 infection which we don't know about. That is how
6 I think a clinical virologist would have thought about
7 that and then, having thought about that, would say,
8 "Well, we need to have a way of testing. We need to
9 develop diagnostic assays" and that includes virus
10 assays and includes looking for virus -- literally
11 looking for virus -- and also antibody tests.

12 **Q.** Then we can see in the next paragraph -- I don't need to
13 read it out -- but you set out the kind of support in
14 terms of funding that you were looking to the Department
15 of Health to provide (inviting the Department of Health
16 to consider providing) to enable the work that you
17 describe there to be undertaken.

18 As I understand it from your statement, although the
19 documents suggest that some funding was received from
20 the Medical -- or may have been received from the
21 Medical Research Council, there was no funding that was
22 provided in response to this by the Department of Health
23 itself?

24 **A.** That's a difficult question for me to reflect on, as
25 I say, nearly 40 years ago.

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1 LAV-I from Montagnier.

2 **Q.** We will come on to that. Just then sticking with the
3 interactions that you had had with the Department of
4 Health, if we go back to your statement, WITN3436003,
5 page 22, you say this in paragraph 69 and 70:

6 "While the wording that was used in the meeting with
7 Dr Walford may not have specifically been 'stop rocking
8 the boat', the sense that I got was that the DHSS did
9 not regard testing as a problem. She indicated that
10 they would not provide the necessary funding.

11 "The issue was that, by early 1983, we knew that we
12 needed to do something quickly. I think this is why
13 I found the response from the DHSS particularly
14 difficult. I felt that we were ready to go and do
15 something to help, but the DHSS was saying that it was
16 not really their business to fund it. It is worth
17 remembering that by this stage, because of my work on
18 HTLV-I and HTLV-II, the modelling indicated that we
19 could easily make an assay for HTLV-III B."

20 Is it right to understand from your evidence, both
21 to Penrose and here, and the fact of the letter that you
22 wrote, that your sense was that the Department was not
23 responding with a sufficient sense of urgency,
24 a sufficient sense of the importance of addressing it?

25 **A.** It's difficult to reflect on that, what I actually felt

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1 I'm not sure. I think we did. We were put forwards
2 with support to the MRC to seek funding with
3 Professor Adler, who was the GUM physician or GUM
4 physician lead in our local clinic.

5 If you're asking me exactly what returns we got, I'm
6 afraid I really can't recall. All I know is we were
7 busy the whole time providing testing for anybody who
8 wanted it. That's all we could do at that time.

9 **Q.** The letter you wrote to Dr Walford was, I think, the
10 same date as the publication by Montagnier in Paris of
11 the LAV 1 data. In relation to that, did you have any
12 knowledge in advance that that was going to be published
13 or any knowledge in advance of what had been found?

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

15 **Q.** Sorry, we can take that down.

16 Do you have any recollection of what your response
17 was and reaction or the reaction of colleagues to the
18 Paris publication?

19 **A.** No because I was a serological -- my activity was
20 a serological component of a response to this new agent.
21 We did not have the facility in the first instance for
22 propagating the virus in tissue culture. We developed
23 that but we certainly never had the expertise to make
24 primary isolates and that was not our remit. That fell
25 to Robin Weiss and his colleagues, and indeed gifted

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1 at the time. I think it's when you have a sense of I've
2 got something which could really be helpful and I'm able
3 to produce this, "Look, I've done this" and you get
4 a feeling of, "Well, that's all right but it's ..." you
5 know. So not exactly "so what" but didn't get a feeling
6 of, "Gosh, that really could be important. Let's take
7 that forward".

8 Now, all I can say Philip and I would have felt
9 disappointed.

10 **Q.** Then, if we go to paragraph 81 of your statement,
11 page 27. You say this:

12 "In respect of funding, I do have a recollection of
13 a meeting with someone from the DHSS sometime later --
14 I think around 1984 when we had serological tests. It
15 might have been at an MRC meeting although I am unsure.
16 I remember there being someone from the Department of
17 Health who said words to the effect of 'haven't we done
18 well'. I recall seeing Professor Weiss bristle at the
19 suggestion. He responded that the Department had done
20 absolutely nothing. I remember the man backing away
21 from Professor Weiss. It was completely incorrect for
22 him to say 'we' as we had essentially been forced to
23 fund the entire programme by other means -- from
24 internal funding, funds to me in my dual post at the
25 time, through the [Health Authority], or possibly

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1 through the MRC."

2 Do you have any further recollection of that later
3 meeting or does that paragraph essentially describe what
4 you can recall?

5 A. I do think you should ask Robin Weiss what his
6 recollection of that is. I have never seen him be so
7 irritated -- in a perfectly gentlemanly manner but just
8 saying, "This is not on, what you're saying. You
9 haven't done anything. How dare you say haven't 'we'
10 done well. You should be saying haven't 'you' done
11 well".

12 Q. Can I just ask you, on the issue of public health
13 funding more generally, to look at something you said to
14 the Archer Inquiry. So ARCH0000011, please, page 160.
15 Now, just to put it in context, this part of your
16 evidence takes place as part of a discussion about
17 self-sufficiency and the upgrading of BPL and the Chair
18 of the Inquiry says this at lines 4 to 9:

19 "I think we are very conscious of the dangerous of
20 hindsight, but what has been suggested is that it was
21 a little late, by 1974, to think about upgrading the
22 facilities for processing this. Elstree, for example,
23 was a long way behind what its capacity could have been
24 if there had been a timely investment.

25 "Answer: I think that's probably fair. I think

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1 sector approach from an academic or group of academics
2 who say they can do something well.

3 I suppose I can understand it but, speaking as
4 somebody who could have done something for SARS-CoV-2,
5 we still have the best tests out there which predicts
6 neutralising antibody and can we find anybody in this
7 country to manufacture it? No. It's sad. I don't
8 think it will make a great deal of difference because
9 the commercial assays are out there now but, you know,
10 we were ready to run with it last year.

11 Q. So would it be right to understand from your evidence
12 that, both then and now, it might be thought that
13 there's an infrastructure problem in terms of what one
14 does and how one makes the best of the developments that
15 scientists can make and how that is then put into
16 practical implementation?

17 A. I mean, that's a difficult question to answer because
18 there is a competitive air in academia. You know,
19 academic centres will always want to see their centre
20 benefiting as opposed to others benefiting. So there
21 is -- it's not exactly a neutral environment in which
22 you come forward and say, "I've got something which
23 actually matters".

24 In generality, it would be nice to feel that if you
25 came up with something which was really good, people

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1 the -- if one blames anybody, it is the financial
2 structures in this country which sometimes don't put
3 money into health service emergencies, and certainly one
4 didn't recognise this as an emergency until much, much
5 later, or it became an emergency because of a failure to
6 invest."

7 Then the Chair's comment:

8 "Of course the time to provide for something is
9 before it becomes an emergency."

10 And you say:

11 "Indeed, yes."

12 Now, I'm not asking you about the issue of funding
13 for the redevelopment of BPL. It's the general
14 observation you make there about the financial
15 structures in this country which sometimes don't put
16 money into health service emergencies or perhaps don't
17 put them in sufficiently far in advance. Again, are
18 there any observations drawing on the many decades in
19 which you've been involved in research and scientific
20 development, any further observations you would have
21 about that?

22 A. No, it feels very reminiscent of what I've currently
23 about the serological diagnostics for SARS-CoV-2. I can
24 understand the reluctance of people in the position of
25 authority to be seen to be favouring an independent

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1 would listen to you. I mean, look what Mitchell had to
2 do with the Spitfire. He had to take it out and fly it
3 and demonstrate it and then its worth was recognised and
4 so one went forwards. That's perhaps a very personal
5 analogy because I'm an aviator.

6 But it would be nice to feel that there is a way of
7 engaging with government, engaging with DHSC, which
8 doesn't fall into "I'm breaching a zone because I want
9 my academia to be recognised above everything else"
10 which is, I think, how many people perceive academics.
11 It's not actually that. Sometimes it's the academic
12 group will have something which really has a benefit for
13 society and it's finding a mechanism to enable that.
14 That sounds awfully pretentious and I'm not trying to
15 lecture people up there how to deal with this, but it
16 just would be nice to have a mechanism where you could
17 have a non-confrontational discussion with DHSC or
18 somebody and say, "Look, actually what about this? This
19 matters".

20 You know, we almost got it right. We have had it
21 right sometimes with people, but it would be nice to
22 have it out in the open and a mechanism for doing that.

23 Q. Can I then ask you to look at a document from October
24 '83. This is moving on or moving away from the
25 interactions with Dr Walford or others. It's

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1 CBLA0001749. These are the minutes of a meeting of the
2 MRC Working Party on AIDS. The date is 10 October 1983
3 and we can see there the list of members, departmental
4 observers and then "by invitation" and you are there
5 identified as being present by invitation.

6 If we could go to page 3, paragraph "(c) Aetiology"
7 says:

8 "The aetiological background to AIDS was considered
9 with passing allusion to the antigen overload
10 hypothesis. An increased microbiological load with
11 multiple infections associated with active virus
12 replication in the host was thought a possible mechanism
13 for immunodeficiency. The more widely held view that
14 AIDS was due to a novel 'AIDS agent' was also
15 discussed."

16 Then there is a further discussion which I'm not
17 going to read out. We see there again the reference to
18 the analogy with hepatitis B, however.

19 Then the next paragraph says:

20 "Retroviruses were considered ... it was noted that
21 HTLV was a possible candidate on the basis of its known
22 tropism for T helper cells. However a critical
23 evaluation of the data led to the view that it was more
24 probably an opportunist was unlikely to be the
25 aetiological agent."

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1 The parasitologists and the bacteriologists will say,
2 "Well, hang on a tick. Okay, we hear what you say but
3 are you sure that it's not a bacterium? Are you sure
4 it's not a parasite or a protozoan?" The answer is no,
5 but one's overall feeling as a virologist is that this
6 fits very well.

7 Then you would need to ask a parasitologist whether
8 this fits well with the parasitological aetiology or
9 bacteriological aetiology. Does that answer your
10 question?

11 Q. Well, I think probably it's best you're able to, given
12 that I was asking whether you had any recollection of
13 from whom the challenge came and 40-odd years later,
14 39 years later that might be a --

15 A. The simple answer, ma'am, is no, I don't recall but
16 I think I can see the reasoning behind it.

17 Q. I'm going to move now to the topic of donor selection.
18 At this point in 1983 there is as yet no test in
19 relation to HTLV-III/HIV. We'll come on shortly to your
20 work in developing a test.

21 So donor selection was a means of reducing the risk
22 of transmission through blood and so I want to go back
23 to what you said to the Archer Inquiry on this topic,
24 ARCH0000011, and if we go to page 154. It picks up on
25 the evidence you've already given us earlier, professor,

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1 And then this:

2 "The assumption that the agent was necessarily
3 a virus was challenged and the need to keep an open mind
4 on organisms such as protozoa was stressed. Systematic
5 antimicrobial therapy might provide leads on such
6 agents. It was noted that blood product associated
7 cases could enable some of these alternative hypotheses
8 to be tested."

9 Given it's October 1983 by this time, it may be
10 suggested that it's surprising that there is challenge
11 to the assumption that the agent was necessarily
12 a virus. Do you have any recollection now of from whom
13 that challenge came, the list of members if we go back
14 to the first page?

15 A. No, I don't, but looking at it, there is always an
16 interplay between epidemiologists and microbiologists,
17 and there's also an interplay between microbiologists of
18 the larger organisms, the parasitologist, the medium
19 size which are the bacteria, and those who deal with the
20 smaller things which are virologists, and there will
21 always be a discussion with something new.

22 If the pattern of the disease fits with hepatitis B,
23 as I think it did, those of us who are virologists will
24 say, "Well, that feels awfully like something we've seen
25 before in the forms of transmission of hepatitis B".

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1 about Dr Dane in a little more detail. If we pick it up
2 at line 15, and again the context of the discussion had
3 been about self-sufficiency, but you say this at
4 line 15:

5 "Well, I think one of the -- this probably sets me
6 apart from a number of people, but I think the question
7 of blood products and blood safety, one of the most
8 important mantras I still believe, even in this day and
9 age is 'know your donor'. Know your donor and know the
10 infection risks in your donor.

11 "If I can just step sideways from your question for
12 a moment and give you a current example, we have good
13 British donors who go abroad and they go to some area of
14 the world where there is something else out there that
15 we don't know of, for example, malaria, dengue, which is
16 a virus infection, not terribly nice, rabies, we have
17 had transmissions of rabies in Europe and other virus
18 infections."

19 Line 6:

20 "These sorts of issues show that you need to know
21 your donor and you need to know the environment in which
22 your donor is, where they come from, where they are
23 travelling. Obviously it is not xenophobic, we restrict
24 people who have been in areas of the world where these
25 microbial infections are common. That becomes

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1 an extension of the concept to be self sufficient:
 2 "Self-sufficiency was driven not so much -- in my
 3 experience, was not driven by the financial requirements
 4 or ease of manufacture or trying to protect a home
 5 market, it was just merely a principle that it is much
 6 better to take your blood and tissues and organs from
 7 donors whom you know where they have been, they are in
 8 your country and they will not harbour something which
 9 is not enzootic, endemic, whatever, whether it is in
 10 animals or humans, in this country, and they will not
 11 bring something in. That is the principle of
 12 self-sufficiency."

13 Then you tell us in your statement, and you told us
 14 before, this was a view you had effectively inherited
 15 from Dr Dane.

16 Now, in the UK then, even in the UK, so leave aside
 17 the question of importation of concentrates from
 18 America, to "know your donor", would it be right to
 19 understand that there has to be some attempt to assess
 20 and understand the behavioural and travel history of the
 21 donor and questions have to be asked, therefore, of the
 22 donor?

23 A. You've put two things together, travel history and
 24 knowing about -- (overspeaking) --

25 Q. I have.

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1 privately on a document that their blood should not then
 2 be used for transfusion but could be used for research?

3 A. Well, we know, don't we, that not everybody actually got
 4 the questionnaire. So it actually has to be more
 5 proactive than that. It has to be a controlled
 6 environment in which you have a question and answer
 7 session between the examiner and the donor.

8 Q. If we go back to your statement then, please.

9 WITN3436003. Page 36.

10 So bottom of the page 36, paragraph 108, you make
 11 the point that we have just been exploring about being
 12 able to assess behavioural history and travel history:

13 "... central component of blood safety ... all comes
 14 down to - 'do you know your donor; do you trust them,
 15 are they telling you the truth?'"

16 Then if we go over the page, you say this in
 17 paragraph 109:

18 "I did hold this view in the 1970s and 1980s and
 19 I believe that reasonable and sensible efforts were made
 20 to ensure this in the UK ..."

21 And then you say this:

22 "... although my own view, when AIDS emerged, would
 23 have been to seek to exclude from the outset all men who
 24 had sex with men. I do understand why this was not the
 25 initial response based on the information as it was

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1 A. Both. You need to know what behaviour, what travel,
 2 where and why a donor has been in order to have
 3 a reasonable aspiration of what the risks are.

4 Q. Sometimes those might be questions that are easy to ask
 5 in the environment of a donor centre but sometimes they
 6 may be questions that are difficult to ask, in
 7 particular if it brings into play issues about
 8 lifestyle, homosexuality, drug use and so on?

9 A. Yes. I mean, this is one of the difficult issues. And
 10 the most graphic example would be a husband and wife
 11 being bullied by friends to go and give blood. So then
 12 the husband is asked personal questions about sexual
 13 preferences or sexual exposure and it is very
 14 difficult -- you can imagine the situation where
 15 somebody who doesn't disclose a risk to his spouse has
 16 to disclose it or should disclose it to whoever is
 17 asking the question. So therefore you need to have the
 18 question to the donor being given in a controlled
 19 environment without other people listening, including
 20 spousal contact, and that can be difficult.

21 Q. We heard evidence in the Inquiry that within
 22 the North London Regional Transfusion Centre they were
 23 able to develop certain initiatives, in particular
 24 a questionnaire, which would mean someone would still
 25 give their blood but they would be able to indicate

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1 being received from the US where the target for
 2 exclusion was the homosexual man with multiple/many
 3 sexual partners/contacts."

4 Now, I'm not going to take you to the AIDS leaflets.
 5 You have seen them for the purpose of your statement,
 6 and the Inquiry has looked at them on a number of
 7 occasions, but we know that that first AIDS leaflet
 8 sought to discourage people who have, present tense,
 9 many sexual partners. Men who have many sexual partners
 10 with other men.

11 And as I understand it from your statement, your
 12 view was that the better course would have been to
 13 ensure that all those who had or had had sex with a man
 14 at any point in time would be excluded?

15 A. Yes.

16 Q. So although, as I understand it, you are not critical of
 17 the efforts that were made, the initial donor leaflet,
 18 at least viewed in retrospect through your statement, in
 19 your view didn't go far enough?

20 A. I think we had discussions, and if you are asking me
 21 when and where, I can't recall, but we, as a virological
 22 fraternity, talking to the transfusion service, would
 23 have preferred to have any man who has had sex with
 24 another man. Not asking whether it was receptive or
 25 insertive but just if you had had sex with another man,

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1 full stop, we would prefer you to be absent yourself
2 from being a donor. However you do that and however you
3 deliver that policy is open to a lot of discussion, but
4 that is ultimately the end stage. You want that person
5 to not present themselves as a donor. And preferably
6 not present themselves for a donor to be turned away or
7 to have to step down, because that puts a lot of
8 potential strain on the family relationship.

9 **Q.** You referred in your statement to a meeting that you
10 attended with Professor Contreras and Professor Barbara,
11 as they now are, with representatives of the gay
12 community in London, and there was initial concern
13 expressed at what was seen to be potentially
14 discriminatory towards those who were gay. But is it
15 right to understand that, as the matter was talked
16 through, those concerns were able to be addressed and
17 you describe in your statement there being, at least in
18 relation to the North London Regional Transfusion
19 Centre, a constructive relationship with the gay
20 community?

21 **A.** Yes. I wish I could remember the name of the young man
22 who became quite a friend of us at the transfusion
23 service. And it was actually the inception of the
24 Terrence Higgins Trust which became very much
25 a mechanism for interaction between young men who have

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1 **A.** Well, we are in a similar scenario today, where there is
2 not enough blood to supply the needs of the NHS in
3 the UK, and I think there was a concern -- you could
4 interpret counterproductive in two ways, and you are
5 asking me now and I'm not quite sure what you meant by
6 that, I -- there would be the counterproduction of
7 making people not disclose because their family were
8 present and didn't want to disclose that they weren't
9 fit to be donors. So that was one counterproduction of
10 not having the right mechanism for asking.

11 The other is that, as we are at the moment, we have
12 a shortage of blood to supply the requirements of
13 the Health Service in the UK this week and that close
14 questioning might lead people to say, "Oh, you know,
15 I went up to give my blood and I was put in a room and
16 I was questioned for 15 minutes as to whether I was
17 a man who had sex with men, et cetera, or whether I was
18 doing recreational drugs, and I am not going to go back
19 and give blood again". That sort of approach -- that
20 sort of -- I'm not sure it's right to call it
21 "aggressive questioning", but that in-depth questioning
22 in front of other members of the family might mean that
23 your donor panel becomes reduced from -- and you lose
24 people who are really perfectly valid, good donors.

25 It is a question of how you deliver what you think

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1 sex with young men and the community, whichever part of
2 the community, outside. So that was a meaningful and
3 useful interrelationship exchange of views and advice --
4 bilateral advice, how to find the best way forwards.

5 **Q.** Then, if we just look at minutes of a meeting of the
6 working group on AIDS.

7 It is at DHSC0002251_011.

8 These aren't the minutes of a meeting, this is
9 a minute dated 27 November 1984 -- the date is on the
10 second page, we don't need to go to it -- from Emmy
11 Abrams in the Department of Health to Dr Harris, who we
12 know was a deputy CMO. But it refers to a meeting of
13 the Advisory Committee on the National Blood Transfusion
14 Service Working Group on AIDS.

15 In terms of test kits we will come back to that, but
16 I want to pick up what's said at paragraph 1(iv):

17 "They were not in favour of closer questioning of
18 donors to see if they were homosexual etc. They were in
19 favour of a local session leaflet (such as is used now)
20 which gets people to answer a list of questions amongst
21 which are the AIDS questions. There was concern that
22 too close a questioning might be counterproductive."

23 I don't know whether you can help us in
24 understanding the thinking there. Why would too close
25 a questioning be counterproductive?

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1 is safely in a way that is not going to have counter
2 production, not become unsafe in terms of losing too
3 many donors. And you need to explore it with people.
4 We also need to explore it with donors and ask them how
5 would they prefer to be questioned about this. You can
6 give people a leaflet but, as we know, some of the
7 leaflets weren't seen, they weren't interpreted
8 properly, and, at the end of the day, it's got to be
9 safe for the recipients of the blood and blood
10 components. There is no question of that.

11 **Q.** Do you know whether there was ever any systematic
12 attempt to assess or model what might be the effect on
13 the blood supply, or was it really at a level of there
14 just being a general fear that there might be adverse
15 consequences for the blood supply?

16 **A.** If you are asking were there any objective attempts to
17 use different approaches and measure the outcome, I'm
18 not aware of them. I think it was a general concern
19 that, as we see at the moment, it is sometimes difficult
20 to have sufficient donors prepared to come forwards to
21 support the needs of the NHS.

22 You know, loss of 5% of the donors because of
23 taking -- if your approach to donor questioning was
24 unfriendly and aggressive, you can see that donors could
25 take umbrage, you lose 5% of your donor problems, we are

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1 already 17% short of what we need. You know, it is
 2 a risk either way, and you have got to find a way to
 3 protect people. That's what we have to do, in the
 4 broader sense.

5 Q. Just going -- in terms of questioning people in a way
 6 that's aggressive or confrontational, of course it ought
 7 to be perfectly feasible to know your donor, to ask your
 8 donor questions in a way that is friendly,
 9 non-adversarial, and which explains the importance of
 10 why these questions are asked and the importance of
 11 answering them truthfully.

12 A. Whether it is where your recent travel has been or
 13 whatever. And this would be central to David Dane's
 14 mantra: know your donor -- get to know your donor.

15 Q. Just one final document on this topic, which is one of
 16 the documents you saw this morning, Professor Tedder.
 17 It's DHSC0002249_026.

18 And it is a transcript from The World This Weekend
 19 on BBC Radio 4, 18 November 1984. We can see the
 20 trigger for you, and indeed Dr Gunson, then being
 21 interviewed, appears to be the reports from Australia
 22 that there had been the deaths of three babies who had
 23 received transfusions of blood donated by a male
 24 homosexual suspected of suffering from AIDS.

25 If we go over the page, we pick it up halfway down

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1 Your answer:

2 "Yes, I know without doubt that male homosexuals
 3 continue to give blood. It is particularly important
 4 when you have a blood team going to a place of work,
 5 like for example a factory, and you have half a dozen
 6 men coming up to give blood, and they all read the AIDS
 7 leaflet, and if somebody then turns round and walks out
 8 from the public area, all his mates will say, oh, didn't
 9 know about Fred being gay. Now, this is a, this is
 10 a very real problem, and the way the American clinics
 11 have got round this is by having nurse attendants, or
 12 physician attendants, who interview on a one-to-one
 13 basis the donor, and they can ask them in private. And
 14 indeed, in New York, where infected donors are probably
 15 of the greatest prevalence anywhere in the world, they
 16 have enabled the system to work whereby the donor comes
 17 up, gives his blood, and then at the same time as giving
 18 the blood, says whether it is to be used for research
 19 purposes, or whether it can be used for human
 20 therapeutic purposes."

21 Just pausing there. The evidence we have heard,
 22 Professor Tedder, is that that was the system that was
 23 then -- deliberately modeled on the New York system,
 24 that was introduced specifically into the North London
 25 Regional Transfusion Centre.

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1 the page, there is reference to the work that you were
 2 undertaking to establish a test, and then you are asked
 3 whether you felt:

4 "... following events in Australia that the risk
 5 were such that homosexuals in this country should be
 6 banned from becoming blood donors."

7 I want to read what you said, because obviously this
 8 was relatively contemporaneous, this is what you were
 9 saying in November of 1984:

10 "No not a ban so much as a self-inflicted ban,
 11 perhaps, rather than a state-controlled ban. One would
 12 hope that the transfusion centres would educate their
 13 donor panel sufficiently to make it very apparent, and
 14 easily apparent to the donors why they should not give,
 15 and how socially irresponsible it would be of them to
 16 continue giving if they were male homosexuals."

17 Then the question:

18 "So you are saying, then, that no practising
 19 homosexuals in this country should now give blood?"

20 Your answer:

21 "Yes, and this has been the Department of Health's
 22 policy in this country for a number of months now."

23 Question:

24 "Do you suspect, though, that they are still giving
 25 blood?"

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1 Then your answer continues:

2 "This allows the homosexual to have his blood taken
 3 to make some contribution, if you like, towards
 4 research, but marks the serum and the blood product as
 5 not being fit for human consumption."

6 Then you are asked about the leaflet and whether
 7 that is enough and you say this:

8 "Well, at the risk of making myself unpopular with
 9 my colleagues in the blood transfusion service, I think
 10 it is very clear that the exposure of donors to the AIDS
 11 leaflet is insufficient, because I myself have two male
 12 friends, who are not gay, incidentally, but have acted
 13 as blood donors, and in both instances, neither of them
 14 were asked, nor did they see the AIDS leaflet. Now,
 15 that is worrying if that can happen to two friends out
 16 of the small number of blood donors who are my personal
 17 friends."

18 Then, over the page, you were asked your view on the
 19 position in Australia, and you say this:

20 "In the United Kingdom, the proportion of blood
 21 donors who may be infected with the AIDS virus is
 22 vanishingly small. That is true of 1984, whether it
 23 will still be true in 1985 or '86 I think is
 24 questionable. It must be seen only as a matter of time
 25 before British blood products and British donors become

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1 contaminated with the virus."
 2 Then the interview goes on to interview
 3 Dr Harold Gunson.
 4 18 November 1984, you would have in fact known by
 5 this time, because of your testing of Dr Ludlam's
 6 patients, the Edinburgh cohort, that British blood
 7 products had been contaminated with HIV?
 8 **A.** Yes, I mean, I think Professor Ludlam's problem up north
 9 was not -- I don't think any of us anticipated that. He
 10 certainly didn't. His aspiration was to show that his
 11 recipient panel was clean -- clear of HIV infection, and
 12 this did not take into account the high and expanding
 13 frequency of use of -- injectable drug use for
 14 recreational purposes on the east coast of Scotland, to
 15 the east of Edinburgh, where there was quite a body of
 16 recreational drug usage. Which, of course, had been --
 17 I use it in the non-inflammatory sense -- exposed by and
 18 used by HIV to become established in that population.
 19 Exploited.
 20 **Q.** We will come back later no doubt this afternoon to
 21 further issues relating to Professor Ludlam and the
 22 testing.
 23 Sir, I'm going to move now to the development of the
 24 HTLV-III test. Rather than start that with 4 minutes to
 25 go before lunch, shall we break now for lunch and I'll

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1 ones actually generate photons. So it's is just the
 2 signalling is different.
 3 **SIR BRIAN LANGSTAFF:** May I ask if the difference is
 4 essentially in the label which is attached?
 5 **A.** It is. The label is radioactive in one and you measure
 6 gamma radiation. In the other, it's colorimetric and
 7 you measure the colour -- essentially that. Although
 8 those are the simple two extremes, there are some forms
 9 of EIA which actually measure photon emission, which is
 10 very similar to making gamma emission, so they can meet
 11 in the middle.
 12 **SIR BRIAN LANGSTAFF:** Yes.
 13 **MS RICHARDS:** Now you in the early 1980s were working on the
 14 development of a HTLV-I screening test and that was how
 15 you first came into contact with Professor Weiss; is
 16 that right?
 17 **A.** Yes, it would be because I needed to -- I wanted to have
 18 a serological test, therefore I needed to have an
 19 antigen (that's a protein from the virus) and I didn't
 20 have the facilities to grow that virus because we needed
 21 strict containment -- and I got into serious trouble
 22 once because something wasn't contained as it should
 23 have been -- and I needed the virological proteins,
 24 therefore I liaised with Robin Weiss.
 25 **Q.** And you describe in your statement the nature of the

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1 start it after lunch?
 2 **SIR BRIAN LANGSTAFF:** Well, it is quite a big issue, so
 3 let's take a break now shall we until 2.25 pm.
 4 **MS RICHARDS:** Thank you, sir.
 5 **SIR BRIAN LANGSTAFF:** 2.25 pm.
 6 (1.26 pm)
 7 (Luncheon adjournment)
 8 (2.25 pm)
 9 **MS RICHARDS:** Professor Tedder, this afternoon I'm going to
 10 be asking you about the development of the test for HIV
 11 and then its introduction into the transfusion service.
 12 Before I do that, can I ask you to just tell us what
 13 the difference is between an RIA and an ELISA in terms
 14 of the two assays?
 15 **A.** Right. The only difference -- there is actually no
 16 difference between an RIA and an EIA *per se* because the
 17 components of the tests are the same, but the only
 18 difference is that the read-out in a radioimmunoassay is
 19 radioactivity and the read-out in the EIA is
 20 colorimetric. In fact, some EIAs are very much more
 21 like RIAs because the generation system actually
 22 generates photons; so you measure a signal, as you would
 23 with radioactivity which is measuring radiation, and in
 24 EIAs you measure photon emission. The simple EIA is
 25 a system where it changes colour but the more modern

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1 assay that you developed, and you used these terms: it
 2 was a one step simultaneous competitive assay. Can you
 3 just help us understand what that is?
 4 **A.** Right. This is where you really need a board. Okay,
 5 here we have a piece of plastic which is on this side
 6 it's solid and there is a hole in here and this would be
 7 known as a microtitre well, and it's round so you can
 8 put liquid in here, and it's constrained by the plastic.
 9 On the plastic, we have a protein. This is the
 10 protein stuck on the plastic. If I'm making what I call
 11 a competitive EIA, here's the protein, here's the label
 12 that wants to get on there. So if I ask somebody to
 13 come up and block this, they will put their hand on
 14 there. Do you want to do this?
 15 **Q.** No, I think if you just talk us through it it's easier,
 16 otherwise the microphone doesn't pick me up.
 17 **A.** Okay. There is the solid phase with the protein on it.
 18 Here's a label which is going on to there. If somebody
 19 wants to get on there first or is stronger than getting
 20 on this, they block this from going on there. If this
 21 is an antibody that's going on there and it's stronger
 22 than this, this can't get on there so you lose the
 23 signal. So you get a direct competition. You go from
 24 generating signal to completely losing the signal and
 25 that's because of competition.

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1 So does that -- is that -- do people follow that
 2 principle? So it's a competition binding onto there and
 3 it is blocked by an antibody. That is what I call
 4 a competitive immunoassay.
 5 **Q.** You've explained in your statement and, I think,
 6 produced a slide that there are a range of different
 7 assay formats, antibody assay formats. We'll just put
 8 it briefly on screen.
 9 **A.** Yes, please.
 10 **Q.** It's WITN3436004.
 11 **A.** I hope this is going to be the slide -- yes. Okay.
 12 **Q.** So the competitive assay which you were just describing
 13 is the type 3?
 14 **A.** Yes. I mean, I would say, ma'am, that I'm probably one
 15 of the few people who uses type 1, type 2, type 3, type
 16 4. I use it because, as a serologist, it's easier to
 17 say, but basically you can see in the type 3 you've got
 18 one incubation where you incubate the label, antibody
 19 with the red star on it, with an antibody with no star
 20 on it. And if there's a lot of no antibody with no
 21 star, the antigen -- the label doesn't bind and you get
 22 no signal. So you go from having a strong signal, with
 23 the absence of antibody, to no signal with the presence
 24 of antibody.
 25 **Q.** You again explain in your statement that your view was

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1 assay.
 2 **SIR BRIAN LANGSTAFF:** May I ask, the black Ys, horizontal Ys
 3 that we see there, they are the antibodies?
 4 **A.** They are, sir.
 5 **SIR BRIAN LANGSTAFF:** The protein of interest is, what, the
 6 antigen that you suspect might be there, is it?
 7 **A.** Yes. The target protein in the key is whatever virus
 8 you want is the protein that is specific to that virus
 9 or from that virus.
 10 **SIR BRIAN LANGSTAFF:** So when you've got the fluid which
 11 you're testing, the sera, which contains the -- may
 12 contain the protein of interest and may not, when it
 13 goes into the wells on the plate, and the mixture of
 14 sera is passed over it, the antibodies will bind to any
 15 antigen, any protein of interest in the wells. Is that
 16 the position? But if there isn't any antigen, they
 17 won't?
 18 **A.** Broadly speaking, that is correct. The difficulty in
 19 the type 1 assay is if you take that target protein
 20 away -- that's the top left-hand corner where it says
 21 "first incubation" -- you've got the plastic which is
 22 the sheared part, then you've got a face and then you've
 23 got the viral protein.
 24 If you take that viral protein away in type 1
 25 assays, you quite often find there is a significant

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1 that the competitive assay was the most effective?
 2 **A.** I'm not sure that I would use the term "effective". Can
 3 I just explore that for 30 seconds?
 4 **Q.** Yes, absolutely.
 5 **A.** The advantage of the competitive assay is twofold. One
 6 is that you have to have, as you look at that slide --
 7 go across the bottom, the lower antibodies, the
 8 competing antibody, it has to be an effective
 9 competition otherwise you don't get a signal. And if
 10 you have sticky sera, which would give you non-specific
 11 signals in the type 1 assay, which is what manufacturers
 12 make, you would get a signal in the type 1 assay but you
 13 got no signal in the competitive type 3 assay. And when
 14 you are dealing with something which is really
 15 a damaging infection, if you're telling somebody that
 16 you've got antibody, you're infected, you need to be
 17 certain or you need to be as certain as you can of the
 18 specificity because if you get a reputation for having
 19 a bad test, nobody will come forward to be tested and it
 20 and that's damaging to the environment, that's damaging
 21 to people.
 22 So I personally like the type 3 competitive assay,
 23 and I was working on HTLV-I and HTLV-II with a type 3
 24 assay and it was natural to do exactly the same for HIV
 25 and come up with what eventually became the Wellcozyme

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1 antibody binding because the antibody sticks to the
 2 solid phase. This is particularly true in areas where
 3 you have other infections causing an agitation of the
 4 immune system. Malaria is the classic one where type 1
 5 assays are an absolute nightmare in malarial countries,
 6 and they found that currently with the assays for
 7 SARS-CoV-2, that there is so much stickiness, the assays
 8 are non-specific.
 9 That is the great advantage of the competitive test.
 10 You have to have an antibody of sufficient quantity and
 11 sufficient magnitude, which you frequently find in
 12 an infection, to block the specific binding of the label
 13 onto the antigen. And it gives you -- it's a one-step
 14 assay. You put the two components into the well, you
 15 leave it for an hour, maybe an hour and a half, two
 16 hours, then you wash it and develop it. So you don't
 17 have a second incubation. So technically in the
 18 laboratory it's quite easy to do.
 19 **SIR BRIAN LANGSTAFF:** Thank you.
 20 **MS RICHARDS:** So you had used this type of assay to develop
 21 the test for HTLV-I. You then used the same principles
 22 essentially to develop a test for HTLV-II?
 23 **A.** Can I take you back about 30 years?
 24 **Q.** Of course.
 25 **A.** I developed the same protocol for hepatitis B for core

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1 antibody in hepatitis B and it was very easy, having
2 done that. So when a new virus came up, or any virus
3 came up, we could make a competitive assay. I actually
4 played with making one for cytomegalovirus at one stage
5 and then when HTLV-I and II came round, I made
6 competitive assays for those. So when HIV or HTLV-III
7 came round, it was a natural pathway to go down.

8 **Q.** So if we then go to your statement, WITN3436003,
9 page 56, you say this in the paragraph at the bottom of
10 the page, and this is in relation then to HTLV-III:

11 "The matter then became one of waiting for
12 a suitable sample that could be used to develop
13 a working HTLV-III test."

14 So is it right to understand that once you had
15 become aware of HTLV-III, you understood or believed it
16 was a virus. You knew you had this methodology that you
17 describe through the HTLV-I and HTLV-II in your earlier
18 work. Was it the case that you realised fairly quickly
19 that you might well be able to test for this using the
20 competitive assay, and what you needed was then the
21 sample in order to complete that process?

22 **A.** We needed -- how can I -- putting it in the terms that
23 we had the antibody on the solid phase. We had antibody
24 which was labelled in the fluid phase and we needed
25 a supply and when I say "we needed", it was my

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1 for and were provided with a sample, although some
2 difficulty was experienced with the initial delivery.
3 I [don't] recall precisely when I ... became of their
4 work, although I was aware of it when it was published."

5 You refer to meetings, including with Francoise Brun
6 Vezinet. That's the first way in which you put it in
7 your statement.

8 Then paragraph 179, which is page 56 -- so the
9 paragraph we were just looking at -- you refer at the
10 bottom of the page there to a sample from Montagnier
11 going into transit but ending up being lost due to
12 delays and then, finally in this statement,
13 paragraph 459, which is page 138, you say in the third
14 line:

15 "As far as I recall the original sample of the
16 viruses from Paris was safely packaged and sent in the
17 mail but stayed in the post office over the weekend and
18 the cells died."

19 So just in relation to that first sample sent from
20 Paris to the Chester BT laboratory, or Chester BT
21 Institute, what is your best understanding of what
22 happened and when?

23 **A.** It was despatched by Luc Montagnier and his colleagues
24 for Robin and, for some reason, it got caught in the
25 post office over the weekend and was not kept -- I do

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1 laboratory for my research and my diagnostic work
2 locally, I needed a supply of antigen that could go on
3 to the solid phase and then act as a component for an
4 assay.

5 In fact, the easiest way was to have an antibody on
6 the solid phase which would pull the antigen down,
7 stabilise that, and then use that as a solid phase for
8 the competitive assay and it was -- from my point of
9 view, I did not have the facilities in the very early
10 stage to grow up a category 3 component in a safe
11 laboratory without breaching health and safety
12 regulations.

13 **Q.** Now, in terms then of the wait for what you've described
14 there as a suitable sample that could be used, I just
15 want to try and clarify what happened or what may have
16 happened in relation to the offer of a sample from
17 Montagnier's team in Paris.

18 You put it in a handful of different ways in your
19 statement. I do not mean that in a pejorative sense,
20 professor, I just want to look at what you say and try
21 and work out what happened in relation to that and when.

22 If we go, first of all, to paragraph 53, which is
23 page 17, you talk about being aware of the work of
24 Dr Brun Vezinet and Luc Montagnier:

25 "... wished to derive a UK isolate. ... we asked

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1 not know whether it was live and wet at the time it was
2 sent or whether it was frozen and cryo-preserved ready
3 to be revived when it came into Robin's laboratory.
4 Either way, by the time it came into the laboratory, the
5 cells were no longer viable.

6 **Q.** And do you know roughly when that was? Autumn '83 or --
7 I think I've seen a reference somewhere, not necessarily
8 from you --

9 **A.** Well, it would -- without going into the paperwork or
10 asking Robin, I don't know but it was obviously very
11 early on because that was the cell culture from which he
12 was going to deliver us a secure supply of what would
13 have been LAV 1 or LAV-Un.

14 **SIR BRIAN LANGSTAFF:** I think Professor Weiss may say in his
15 statement -- and he ascribes a date of October, I think.

16 **MS RICHARDS:** It's either September or October. It's the
17 autumn of 1982; that's right, sir. Then just if we put
18 up on screen a letter that was sent by Professor Weiss
19 to the MRC in May 1984, JEBA0000148, and we can see the
20 date 11 May and then, if we look at paragraphs 2 and 3
21 in this letter, paragraph 2 refers to collaboration with
22 medical virologists, in particular with you,
23 Professor Tedder, and the development of
24 radioimmunoassays, described there as specific and
25 sensitive to HTLV. Then Professor Weiss says:

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1 "We already have Montagnier's isolate in our
2 laboratory and I hope to have collected Gallo's isolate
3 by the time you receive this letter."

4 Now Professor Weiss's statement indicates that what
5 happened was a second sample was sent over from
6 Montagnier in February 1984, which may explain then the
7 reference to having Montagnier's isolate in the
8 laboratory. Do you have any further knowledge of how
9 Professor Weiss was able to confirm that he had the
10 isolate from Montagnier from this date?

11 **A.** No, I don't because, although I worked closely with
12 Robin and he was a friend and support on this, that was
13 his area of activity, not mine, because, as I say, we
14 did not have at that stage the facilities for growing
15 a category 3 pathogen.

16 **Q.** And just for the benefit of the transcript,
17 Professor Weiss's statement -- we don't need to put it
18 on screen at this stage but it's WITN6868001 -- I don't
19 have the paragraph number to hand but he explains that
20 a second sample was sent in February '84.

21 Now, there's then reference there to a waiting for
22 an isolate from Gallo or expecting one at around this
23 time. What's your recollection of how it was that you
24 eventually --

25 **SIR BRIAN LANGSTAFF:** I'm sorry to stop you there. We've
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1 a cell-line provided by Gallo", and then you refer to
2 something called CBL1.

3 We have got a statement from Professor Weiss but can
4 you just tell us what your recollection is of how it was
5 you ended up, ultimately, with something you could use,
6 and tell us what CBL1 is?

7 **A.** So from the time of receipt of a cell line through to
8 having an antigen I could use for a culture; the first
9 thing I had to do was to improve the security in the
10 small laboratory which I had at Middlesex Hospital
11 Medical School because we had already had a rather
12 unfortunate episode where, from a ventilator, an exhaust
13 should have gone -- went into a safety bottle and then
14 out of the safety bottle and the safety bottle had been
15 left outside the category -- the containment laboratory
16 extraction platform, and that caused a significant
17 amount of grief with the Health and Safety Executive.

18 But we worked round that and eventually agreed to
19 have a -- culture flasks in the laboratory, and we
20 experimented how to get the production of the antigen.

21 And you are going to ask what antigen are and I will
22 try and explain that in a minute, because you had to ...

23 We found out that if you had the cells growing
24 uninfected in a big flask and you inoculated them with
25 the virus, that means so you put the virus in to infect

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1 got a problem, a technical hitch, with the stenographers
2 so we just need to take a quick break to sort that out.

3 **MS RICHARDS:** Okay.

4 **SIR BRIAN LANGSTAFF:** The reason I'm stopping you is because
5 it's on the transcript, the transcript therefore has to
6 record everything and it's not doing at the moment. I'm
7 sorry about that, professor. We'll take a five-minute
8 break.

9 **MS RICHARDS:** Thank you.

10 (A short break)

11 (3.04 pm)

12 **SIR BRIAN LANGSTAFF:** Thank you for your patience.

13 I understand that normal service is resumed.

14 **MS RICHARDS:** It appears to be sir, yes.

15 **SIR BRIAN LANGSTAFF:** Let's try it and see.

16 **MS RICHARDS:** Just to give the reference that I had
17 previously given, I referred to Professor Weiss'
18 statement, and I found the paragraph number in the
19 break. It is paragraph 320 where he says that the
20 second sample from Montagnier was sent at the end of
21 February 1984.

22 If we just go back to your statement in any event
23 Professor Tedder -- so WITN3436003, page 57 -- you
24 explain in the paragraph at the top of the page your
25 recollection that the sample was "derived from

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1 that culture and you get the culture running for a few
2 days, the turnover of the cells would produce into the
3 fluid, but not into the cells, an antigen which we could
4 absorb on a solid phase and make a competitive antibody
5 assay work very well.

6 The road to this was to have a big flask, with cells
7 at a good density, and ready to infect them, and this is
8 what we asked our colleagues in Porton to do and they
9 actually elected to do it in a different way. They
10 elected to take infected cells, put them in and grow
11 them up in a large quantity. And that did not give us
12 the antigen we needed. There was something peculiar --
13 or something unique by having a lot of uninfected cells
14 pulsing the virus in, waiting a short time and taking
15 the supernatant, as opposed to having a small number of
16 infected cells and letting them grew up and take the
17 supernatant. The first method worked, the second method
18 didn't. And it is something to do with you encouraging
19 rapid growth of cells to release virus envelope, which
20 didn't happen if you expanded the cells from the small
21 inoculant ready infected. That's why there was
22 a difficulty in making the antigen. But we eventually
23 got round that.

24 **Q.** Are you able to say whether if you had had access to
25 a suitable sample, from whatever source, Paris, US,

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developed by Professor Weiss, whatever source, if you had that in, say, summer or autumn of 1983, would you have -- would that have meant you would have been able to develop your test earlier than you did? Or were there other constraints?

A. Can I just -- be careful with the word "develop" the test. Because we had the test running on a small amount of virus, grown up in small vessels, to cover the amount of work that we wanted to do both in our GUM clinics and in the Local Health Authority. So we were not constrained for doing work that we wanted to do, the research and development work that we wanted to do.

What we could -- what we were not in a position to influence were those who wanted to grow this up to be able to supply a manufacturer with an antigen which they could use to make a manufactured version of our assay. And that was one of the difficulties, that our colleagues in Porton had to rethink how they were going to grow the antigen. And when they elected to follow our protocol as having the cells grown up, infect the cells as a -- at a point in time and then harvest, then they could come up with an antigen which would work.

Q. If we go back a little earlier to the point in time -- you tell us in your statement you had a working RIA that you could use for your purposes, and we will look at

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We can see there the date, 1 September 1984. We can see the range of authors. And then if we look down towards the bottom of the page, if we just look at the summary:

"2000 persons in the UK were examined serologically for antibodies to ... HTLV-III. Sera reacting in a membrane immunofluorescence assay (IFA) to HTLV-III were also positive when tested against cells infected with lymphadenopathy virus (LAV 1), and cross-adsorption tests indicated that these retroviruses are probably identical. A competitive radioimmunoassay (RIA), which was wholly concordant with IFA, was used to screen the sera. 30/31 patients with the acquired immunodeficiency syndrome (AIDS) were seropositive, as were 89% patients with persistent generalised lymphadenopathy (PGL), 17% symptomless homosexual men, 34% haemophiliacs receiving pooled clotting factors, and 1.5% intravenous drug abusers. None of more than 1000 unselected blood donors was seropositive. These data confirm the close association between HTLV-III and AIDS and PGL and show that infection with HTLV-III is also prevalent in the populations in whom these syndromes are most likely to develop."

So that's the summary.

Then if we just go over the page, please. Under the

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The Lancet paper which shows how it was being used in a moment, but you had that working RIA by July 1984 or thereabouts, as I understand it.

Would you have been able to get to that stage significantly earlier if you had had the sample significantly earlier? Or is it impossible to say?

A. I am sure if it had been easier and quicker we might have saved a few weeks. But at the end of the day we needed to develop an understanding of how the assay worked, what its advantages were, what its disadvantages were, what its sensitivity was.

And that's sensitivity in two senses. Sensitivity, if you have a population like this room and some people infected, how many of them could we detect. So that is, in clinical use, the sensitivity of the assay. And then, speaking as an old-fashioned virologist, I've got five positive samples and I'm diluting them in negative plasma, how far can I detect them, that is the analytical sensitivity as opposed to the diagnostic sensitivity. And we had to work out both those parameters for the development of this assay.

Q. Can we then look at the September 1984 Lancet publication, just to see where matters had got to by that stage.

It is NHBT0000068_015.

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heading "Materials and Methods", we have got the first subheading, "Subjects". So we can see the groups who were tested. And so we've got: patients with AIDS, patients with PGL, symptomatic homosexual patients, sexual contact of AIDS patients, homosexuals at risk, heterosexual subjects recruited from GUM clinics, intravenous drug abusers being screened for hepatitis B. And then:

"(8) Haemophiliacs undergoing regular clotting factor replacement therapy, sometimes with American commercial factor VIII concentrate."

And then:

"(9) 1000 unselected blood donors."

"The patients were drawn from the Middlesex, St Mary's, and St Stephen's Hospitals. Blood from groups (1)-(6) was collected between June, 1983, and July, 1984, and the sera were stored ... Sera from haemophiliacs had been collected since 1982."

In relation to the sera from haemophiliacs, do you have any knowledge as to where that came from, in the sense of which centres?

A. No, I don't. But these would have almost certainly come through collaboration with the haematology department at the Middlesex and their contacts. Not necessarily samples would have come from the Middlesex but would

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1 have been generated by Professor Machin and other
 2 colleagues.
 3 Q. I think we also see Dr Craske as one of those named as
 4 those involved and it may have been samples through him
 5 as well?
 6 A. Yes.
 7 Q. Then we have the heading "Virus and Cells". Then we are
 8 told:
 9 "HTLV-I, HTLV-II, and HTLV-III were kindly supplied
 10 by ..."
 11 Then we can see the reference to Gallo and
 12 colleague.
 13 Then LAV-I from Montagnier, Paris.
 14 And then:
 15 "HTLV-III was provided as a persistently infected
 16 cell-line HT ..."
 17 I think the first part of that is self explanatory.
 18 Can you just tell us what that means, "HTLV-III provided
 19 as a persistently infected cell-line HT, clone H9"?
 20 A. Well, it is a particular type of cell line. The HT cell
 21 line would be a human T cell line. And clone 9 means
 22 somebody has selected derivatives from the master
 23 culture and each derivative is called a clone. So it
 24 will be clone 8, 9 of human T cells.
 25 Q. Then it continues that the:

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1 and you dried them. And that is then a dried layer of
 2 cells which contain HTLV-III antigen.
 3 You then take your serum from somebody. Known
 4 positive, known negative. You dilute it a little bit in
 5 buffered saline. And then you put it on there and you
 6 leave it for a period of time.
 7 And antibody, if there is antibody in there, will
 8 stick onto the antigen. You then wash it and you say:
 9 okay, is there any IgG bound on that cell by putting in
 10 a fluorescence labelled anti-antibody? So if there is
 11 antibody there, the fluorescent label comes on and sits
 12 on there, so when you hit it with ultraviolet light it
 13 says, "Hey, I have got a bit of conjugate stuck on
 14 here". And when you actually do this, you can see the
 15 pattern of the conjugate sticking onto the infected
 16 cells.
 17 Q. Then if we go to the top of the next column. So same
 18 page, but the right-hand side. We can see the heading,
 19 "Competitive Radioimmunoassay (RIA) for Antibodies to
 20 HTLV-III". That is the assay you have been describing
 21 to us that you developed?
 22 A. Well, the HTLV-I assay was a competitive, pull it down,
 23 come in, then block it. That's just saying, okay, we
 24 have done it with HTLV-I, HTLV-II, here we do it with
 25 HTLV-III.

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1 "LAV-I was provided as a cell-free culture
 2 supernatant ..."
 3 And so on.
 4 Then we have the heading "IFA". So the
 5 immunofluorescence assay.
 6 I won't read it but can you tell us essentially what
 7 that refers to?
 8 A. Okay. This comes back to a question from the chairman
 9 about methods of detecting antibody. EIA, IA,
 10 immunofluorescence or radioimmunoassay. This is
 11 actually using an immunofluorescent antibody directed
 12 against human IgG.
 13 So what you -- in this particular case, you've got
 14 the cell line growing on plastic. You've infected the
 15 cell line with, in this case, HTLV-III. So -- so start
 16 again. They won't have been ready on the cell line. So
 17 you've got infected cells growing in. You've spread
 18 them onto a surface. You've let them dry on the surface
 19 and you have stabilised them.
 20 So there is the plastic. Here are the cells with
 21 the virus on it. So now you turn it down like this. So
 22 you've got the plastic surface or surfaces, and you have
 23 got the cells on there, each of those cells is
 24 expressing HTLV-III as it is growing in those cells.
 25 You've fixed the cells. You basically killed them

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1 Q. Again, I'm not going to read it out but this article
 2 describes the process that was used in the assay. Then,
 3 if we go to the bottom of the page we have got the
 4 heading "Results":
 5 "Comparison of Tests"
 6 If we pick it up in the second paragraph:
 7 "Sera which were reactive by IFA were all positive
 8 with RIA."
 9 Then further detail given.
 10 Can you just explain the significance of that
 11 sentence?
 12 A. It means that there was absolute concordance between
 13 calling samples positive or negative in the two
 14 different assays, by immunofluorescence or by
 15 competitive radioimmunoassay.
 16 Q. Then if we go to the next page, please, and we look
 17 first of all at table -- that is the second table down
 18 on the left-hand side. So it is table 2. So we have
 19 got the results there:
 20 "AIDS patients ... 30/31 ..."
 21 So that gives us the proportion with HTLV-III
 22 antibodies using these two tests. We can see, amongst
 23 others, the:
 24 "Haemophiliacs who have received pooled clotting
 25 factors ... 63/184 ..."

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1 So 34% had HTLV-III antibodies.
 2 Then if we just go to --
 3 **A.** Just before you leave that, people may be noticing that
 4 only 30/31 AIDS patients were antibody positive. The
 5 reason for that is you can get Kaposi sarcoma in people
 6 without having HIV. I think the one seronegative
 7 patient was a young man with Kaposi sarcoma in the
 8 absence of HIV infection.
 9 **Q.** Then if we go to the bottom of this column and we have
 10 the heading "Discussion". It says:
 11 "Two simple, reliable and specific assays for the
 12 detection of antibodies to HTLV-III have been described.
 13 Findings obtained by competitive RIA shows complete
 14 concordance with those obtained by the membrane IFA,
 15 indicating that results obtained by the two assays are
 16 comparable and that the RIA detects antibody and not
 17 antigen. In addition, the assays indicate that HTLV-III
 18 and LAV-I are indistinguishable."
 19 Then there is a discussion which I am not going to
 20 read out about the results by reference to each of the
 21 different cohorts of serum donor.
 22 Would it be right to understand the significance of
 23 what's described in this paper as being confirmation,
 24 first of all, that the assay that you had developed with
 25 Professor Weiss and colleagues worked in terms of

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1 time to make its mind up, so I would suspect this was
 2 submitted to The Lancet in July, August, September,
 3 sometime -- July probably. And it's -- certainly
 4 July '84, early part of July '84 is when we were quite
 5 certain that we had an assay which was sensitive and
 6 specific and stable and reproducible in the form of
 7 a competitive RIA. Because we were -- interestingly,
 8 4 July is the time we had a meeting, coincidentally, to
 9 say that we've a good test.
 10 **SIR BRIAN LANGSTAFF:** So if any point arises out of the
 11 dating of the first test thought to be reliable in
 12 the UK, it would be early to mid-July '84?
 13 **A.** There would have been other tests available. I mean,
 14 people had the immunofluorescence assay. I'm sure my
 15 colleagues in Chester Beatty would have a virus
 16 neutralisation assay. And we were just showing we had
 17 a competitive immunoassay which fitted with the
 18 routine -- if you can call it "standard" -- indirect
 19 immunofluorescence assay.
 20 **SIR BRIAN LANGSTAFF:** So it is right then to say that
 21 various tests, probably, were available by
 22 mid-July 1984?
 23 **A.** Yes.
 24 **SIR BRIAN LANGSTAFF:** Thank you.
 25 **MS RICHARDS:** And the second article in The Lancet, we don't

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1 detecting the virus that caused AIDS?
 2 **A.** I think that's right. It is comforting that
 3 a competitive immunoassay worked as well as an indirect
 4 antibody assay.
 5 **Q.** And secondly it indicated that HTLV-III and LAV-I were
 6 essentially the same thing?
 7 **A.** In terms of acting as a solid phase for an immunoassay,
 8 yes, they were.
 9 **Q.** There is a second paper in The Lancet on that same date.
 10 I don't think we need to go to it --
 11 **SIR BRIAN LANGSTAFF:** Before we go there. May I just ask
 12 because we started this discussion with a question about
 13 the timing of the test. This was a publication in
 14 The Lancet on 1 September. So the presumably it must
 15 have been in press, submitted to The Lancet a little
 16 while before that? Am I right?
 17 **A.** I wouldn't disagree, sir.
 18 **SIR BRIAN LANGSTAFF:** So, either sometime in July or August
 19 it would have been submitted to The Lancet, and the
 20 tests which gave rise to it must therefore have been in
 21 use before that time. Does that help at all with
 22 roughly knowing when the testing was done of these 2,000
 23 samples, by the method you have described, in order for
 24 this article to be authored?
 25 **A.** I mean, The Lancet is -- sometimes takes a little bit of

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1 need to go to, but just for the benefit of the
 2 transcript, PRSE002140.
 3 I just want to ask you about an observation
 4 Professor Weiss makes in his statement. So if we put
 5 Professor Weiss' statement on screen.
 6 Lawrence, it is WITN6868001, and it should be
 7 page 25.
 8 It is the bottom of the page. So this is in the
 9 context of a section of his statement in which he is
 10 discussing The Lancet article we have just been looking
 11 at, Professor Tedder. And then he says this:
 12 "In terms of the overall significance of these
 13 findings, our article included a larger data set on
 14 blood donors and on recipient of blood products than
 15 previously published reports from any country. Perhaps
 16 more important for this Inquiry, the study revealed the
 17 actual rates of HIV infection in North London for donors
 18 and for different 'risk groups' for AIDS and more
 19 broadly in the UK for patients with haemophilia."
 20 Then it is this sentence, really:
 21 "The findings indicated the urgent need for
 22 screening to detect HIV infection even though the
 23 infection rates in healthy donors was currently low."
 24 Would you agree with Professor Weiss' observation in
 25 that paragraph, but particularly in that last sentence?

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1 A. Yes, ma'am. I don't think that necessarily it's
 2 completely linked with the previous data that we were
 3 going over, which was a small subset, but yes, I mean,
 4 the data here would have been in association with our
 5 colleagues in the transfusion service, and ...

6 Q. There had been, as I understand it from The Lancet
 7 article, the study that's written up in The Lancet
 8 article or the results written up include the thousand
 9 donors from the North London Transfusion Service. But
 10 would you agree that it indicated the urgent need for
 11 screening to detect HIV infection?

12 A. Well, yes, because what it's showing is whether one --
 13 however one addressed this, the virus was present in the
 14 UK population and therefore, even though the prevalence
 15 in healthy donors was currently very low, you could not
 16 say how long that was going to retain low because, you
 17 know, once you have introduced an infectious agent into
 18 a population, if that agent is able -- if the
 19 reproductive rate of that agent is greater than 1, one
 20 person will beget two, two will beget four, and you are
 21 off onto an expanding population. So the sooner you can
 22 control it, the better.

23 Q. An issue I've been asked to invite your observation on
 24 is this: could the test that you've just been
 25 describing, and it's described in The Lancet article,

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1 assay was good but competitive assays probably are less
 2 sensitive in end-point dilution from an anti-globulin
 3 assay, but I really don't know.

4 It would have been interesting to do and whether it
 5 would have -- whether a negative would have been valid,
 6 which is what you need to prevent the onward
 7 transmission into risk populations receiving that
 8 plasma, I don't know.

9 Q. Now, if we go back to your statement, WITN3436003,
 10 page 31, we can see from paragraph 92, so the bottom
 11 paragraph on the page, you say around this period, and
 12 you're answering by reference to a question about
 13 1984/85:

14 "I was one of a group of people providing testing as
 15 requested by haemophilia centres or directors. This was
 16 particularly so because the competitive assay was such
 17 an accurate test and therefore was in great demand."

18 We'll look at some examples of documents and, in
 19 particular, I've got some questions to ask you about the
 20 testing of Professor Ludlam's patients.

21 In the autumn of 1984, going into the beginning of
 22 1985, can you recall who else within the United Kingdom
 23 was providing testing?

24 A. Who else?

25 Q. Who else was providing testing?

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1 could it have been used to test plasma pool samples (for
 2 example, from PFC or BPL) or batch samples of
 3 Factor VIII concentrate?

4 A. Sorry? My hearing is not absolutely good. Could you
 5 say that last --

6 Q. Of course. So could the test, the competitive
 7 radioimmunoassay, have been in principle used to test
 8 plasma pool samples (for example, from BPL) or batch
 9 samples of Factor VIII concentrate?

10 A. Well, let's take it from the bottom first. Testing
 11 Factor VIII concentrate would not necessarily have an
 12 adequate level of antibody in it to be valid in any
 13 assay. I mean, it will have some but I don't know what
 14 level of dilution and sensitivity you would lose.

15 In terms of testing individuals going into that
 16 batch -- was that the first question?

17 Q. No. The first part of it was testing plasma pool
 18 samples, so the actual -- you got several thousand
 19 donations in every pool.

20 A. Okay. Then the same question applies. It could have
 21 been but I don't know the sensitivity. Let's say you
 22 have a 1 in 500 donors who are seropositive. You would
 23 have to say: would the test be adequately sensitive to
 24 always detect a 1 in 500 dilution negative plasma of the
 25 positive? And, frankly, I don't know at this time. The

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1 A. CPHL, the virus reference division at Colindale, would
 2 certainly have been.

3 Q. Do you know what tests they would be using? Yours or
 4 something different?

5 A. I think we collaborated with Philip Mortimer and he
 6 would have used at some stage the competitive RIA and we
 7 helped him -- I'm not sure if we helped him manufacture
 8 that or we sent him materials to build it. There would
 9 have been pressure to use the commercial assays which
 10 I think would have -- there would have been an Abbott
 11 anti-globulin assay and I suspect there would have been
 12 an Immuno anti-globulin assay as well.

13 Q. Other than Professor or Dr Mortimer, do you recall who
 14 else, I'm particularly looking here at the autumn of '84
 15 and beginning of '85, can you recall who else, if
 16 anyone, was providing testing facilities?

17 A. Frankly, with the best will in the world, no. I'm sure
 18 there were but I've no idea.

19 Q. Then if we go to HCDO0000270_007 -- this may indicate
 20 that --

21 A. Could I just make an observation on 92 before it
 22 disappears off the screen?

23 Q. Yes.

24 A. We were approached by the haemophilia centre directors
 25 as a group to provide serological testing for them. So

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1 that doesn't necessarily mean nobody else was doing it
 2 but it does mean that we had a very accurate and very
 3 specific assay.
 4 **Q.** I think you'll find the document on screen confirms
 5 that. So the document on screen is the Haemophilia
 6 Centre Directors Organisation AIDS Advisory Document
 7 drawn up after a meeting at Elstree on 10 December 1984,
 8 and we can see it says in point 2:
 9 "Tests for HTLV-III antibody are available for
 10 haemophiliacs via ..."
 11 Then it's Dr Mortimer in Colindale and then you. So
 12 that would be consistent with your recollection.
 13 Can we then just look at BART0000821. This now
 14 moves us to the beginning of January 1985. It's
 15 a meeting at the Middlesex Hospital Medical School on
 16 3 January between you, Dr Mortimer and Dr Craske. Just
 17 on the issue of testing, if we go to the second page,
 18 there is a heading "recommendations". It says this:
 19 "It was therefore decided to propose to the UK
 20 Haemophilia Centre Directors the following strategy for
 21 HTLV-III serology."
 22 Then paragraph (a):
 23 "All patients treated with Factor VIII and Factor IX
 24 concentrate in UK haemophilia centres would be offered
 25 an antibody test for HTLV-III antibody within the period

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1 The Inquiry has seen or heard evidence, in relation
 2 to some haematology centres, of patients not being
 3 tested until later than that -- so rather later than
 4 April 1985. We've seen evidence of patients being
 5 tested in the second half of '85 and indeed even into
 6 '86. Do you know why that was the case? Did you
 7 have -- was it difficulty in keeping up with the demand
 8 or was it simply that Haemophilia Centre Directors
 9 didn't always send the samples to you to ask you to test
 10 them?

11 **A.** No, I don't. I mean, I think it was an awful
 12 unpleasant opening of an envelope and finding this virus
 13 where you hoped it wouldn't be and, you know, all I can
 14 say, it was, and it still is, devastating to look back
 15 on now and think of the harm which was going to arise
 16 from this.

17 All I know is that we tried to comply with all the
 18 Haemophilia Centre Directors' requirements and, at one
 19 stage, we were doing an awful lot of testing and I would
 20 say to you that the results of this are still -- should
 21 still be available. I left them behind at UCL when
 22 I left and the files should be available to the Inquiry
 23 through approach to virology at UCL.

24 **MS RICHARDS:** Sir, I note the time. Obviously we had the --

25 **SIR BRIAN LANGSTAFF:** Shall we go on until 4 o'clock because

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1 February to April 1985."

2 Then (b) is:

3 "Family contacts of patients. It was also hoped to
 4 offer HTLV-III antibody tests to relatives of patients
 5 who were found to be HTLV-III positive."

6 Then there's a reference to shortage of reagents and
 7 that would be better done by carrying out limited family
 8 studies to determine risk of spreadable infection before
 9 offering a test to all relatives. Then:

10 "(c) follow up of seropositive patients.

11 "(d) future HTLV-III antibody prevalence surveys."

12 Then if we just go to the top of the next page,
 13 paragraph 2 says:

14 "Haemophilia Centre Directors would be offered the
 15 chance of testing as many of their patients as they
 16 wished within the next three months. Haemophilia
 17 Centres would be asked to send sera to either Dr Tedder
 18 or Dr Mortimer for antibody testing."

19 Then there's a reference to copies of the report
 20 then being sent to Dr Craske at PHL Manchester.

21 It would appear from this that you and Dr Mortimer
 22 were effectively proposing offering to the Haemophilia
 23 Centre Directors testing of all patients with the
 24 expectation that would be between February and April
 25 1985 and also some form of testing for family members.

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1 normally we would have a half-hour break in the
 2 afternoon. We were scheduled to go on to 4.30 or
 3 thereabouts. If we go on now until 4 o'clock or
 4 thereabouts, we can have out -- in one sense, we've
 5 already had our break but --

6 **MS RICHARDS:** And then conclude for the afternoon at around
 7 4.00.

8 **SIR BRIAN LANGSTAFF:** At a convenient time immediately or
 9 shortly after 4 o'clock.

10 **MS RICHARDS:** Certainly.

11 So I just want to ask you then next a little about
 12 the testing of Dr Ludlam's patients which was a little
 13 earlier than this. It was in the latter part of 1984.
 14 Before I do that, you referred earlier in your evidence
 15 today to an understanding about an IV drug use in
 16 Edinburgh.

17 In 1983/1984, do you recall there ever being any
 18 discussions about whether there were particular cities
 19 or locations within the UK, such as Edinburgh, which
 20 might, whether through international travel or IV drug
 21 use, become AIDS hot spots?

22 **A.** I don't, and I think that's evidenced by the surprise
 23 and the awful feeling of devastation with the results
 24 from the study we did with Chris Ludlam.

25 **Q.** Do you recall again from this time, '83/'84, any contact

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1 with Dr Ray Brett in Edinburgh?

2 A. Well, the name rings a bell but if you're asking me what
3 the substance of the contact was, no, I'm afraid I can't
4 at this distance.

5 Q. Then can you recollect how it was that you came to test
6 Dr Ludlam's patients? How, by whom and on what basis
7 was an approach made to you?

8 A. My belief -- and I say this as a belief. This is not
9 fact, this is just I feel that it was recognised that
10 the antibody assay that I had and which Philip was using
11 at Colindale was of sufficient sensitivity and
12 specificity to be able to be used to answer a really
13 unpleasant situation of what is the prevalence of this
14 infectious agent in a population, and I think
15 Professor Ludlam realised that we had an assay and that
16 I was amenable, obviously, to help anybody who required
17 or wanted or would benefit from antibody testing.

18 We made that proposal and he was one of the first
19 people to say, "Can you come and help" and we did.

20 Q. You had obviously tested a number of patients as we saw
21 in The Lancet study, so whatever number it was, 180 or
22 so haemophilia patients for the purposes of that study.
23 In terms of post-The Lancet publication, was Dr Ludlam,
24 as far as you can recall, the first Haemophilia Centre
25 Director to ask you to test his patients or do you not

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1 "Excerpt from the transcript of the evidence of
2 Professor Tedder to the Lindsay Tribunal on 9 July
3 2001."

4 Then you were asked about the testing of the
5 Edinburgh patients and your answer, seven or eight lines
6 down from the top, is this -- I'm going to pick it up
7 three lines into the paragraph that begins, "I think it
8 was earlier than that." You say:

9 "I think it must have been in late autumn '84 when
10 we did the first testing for him because it was -- it
11 was certainly -- I will never forget. It was sitting in
12 what used to be David Dane's room at the end of the
13 corridor, looking out on an autumn sun which was a very
14 hot sort of Indian evening, Indian summer evening, which
15 should have been a lovely evening. It was about half
16 past 7, 8 going through this litany of positive,
17 positive, positive and Christopher Ludlam obviously
18 getting more and more pensive and me feeling less and
19 less kind as this evolution of damage done to a cohort
20 evolved. That was the very early testing when he'd sent
21 us cohorts of samples ..."

22 And then you say this:

23 "... which he already had a clinical suspicion that
24 something had occurred and that was the beginning of the
25 evolution of knowledge on the Edinburgh cohort."

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1 know?

2 A. At this distance, ma'am, I'm not sure. Certainly his
3 was one of the more poignant requests for help.

4 Q. And do you have any knowledge of how those patients were
5 selected? So you essentially received a number of
6 samples and performed the tests on --

7 A. They would have -- we would have been told here is
8 a selection of samples from haemophiliacs. Would you
9 please tell us what the prevalent -- tell us the
10 serological status of each individual.

11 Q. Do you have any recollection of your understanding at
12 the time of why Dr Ludlam was approaching you in the
13 autumn of '84?

14 A. I've thought about this considerably and the trouble is,
15 when you start thinking about things from that distance,
16 you're not quite sure whether you're following a pathway
17 of novel thought or actually recording a memory. My
18 feeling was that he would have wished to show how clean
19 his population were from infection because it was all
20 local Factor VIII. It wasn't imported from the USA.
21 I think it was an aspiration to demonstrate cleanliness
22 and in fact, as we know, the opposite was found.

23 Q. If we go to -- there's an extract from your evidence to
24 the Lindsay Tribunal. It's at PRSE0001668. We can see
25 it is entitled:

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1 What you said to the Lindsay Tribunal would appear
2 to be slightly different from what you've just said to
3 us in terms of your understanding of Dr Ludlam's
4 thinking. Here it was a sense that he had some form of
5 suspicion that something had gone wrong?

6 A. I think I was probably wrong. I think the balance of
7 people's views is that it was a desire to demonstrate
8 that something hadn't happened, rather than what has
9 happened, and that that made it all the more devastating
10 that it was an evolution of disaster unfolding rather
11 than no disaster. And I will never forget that evening
12 just talking with him and it was frightful, truly
13 frightful.

14 Q. The Inquiry's heard evidence about a meeting that was
15 then held in December 1984 at which information -- in
16 Edinburgh in which information was provided to patients,
17 including those who had been tested.

18 Did you have any involvement in that at all?

19 A. Not that I recall. I might have been asked as
20 a virologist to give an opinion, I'm sure, but I do not
21 recall specifically.

22 Q. Just, then, going to go back to some issues relating to
23 the development of the test and, before we break for the
24 end of the day, just look at a handful of documents from
25 late 1984.

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1 So, if we start with PRSE0003109.
 2 Now, this is not a document that you would have seen
 3 at the time, Professor Tedder, because it is an internal
 4 Department of Health document. It is from
 5 Dr Alison Smithies, the date is 13 August 1984, and it
 6 is to Dr Harris at the Department of Health. We can see
 7 it is about setting up a working group to consider the
 8 introduction of the screening tests for HTLV-III
 9 antibodies.

10 I just wanted to pick up what Dr Smithies sets out
 11 in paragraph 2:

12 "You will be aware of the recent development by
 13 Dr Weiss and Tedder of a radioimmunoassay for HTLV-III
 14 antibody and the findings that the limited use of this
 15 test has revealed. It is proposed to extend the test to
 16 all blood donors at the North London Regional
 17 Transfusion Centre for a period of at least 3 months."

18 Just pausing there. Is that correct? Was that the
 19 intention, having done the testing on a 1000 there, that
 20 the plan was to then test all donors at North London?

21 **A.** I'm not sure what happened in the long run. Can you
 22 just rephrase your question again, because I was
 23 thinking about --

24 **Q.** Yes, of course. It is whether what Dr Smithies --
 25 whether Dr Smithies' understanding as set out here was

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1 laboratory or a UK isolate yet to be achieved."

2 Then the suggestion is that that information will be
 3 used to base a policy about using the test more widely.

4 **SIR BRIAN LANGSTAFF:** It describes it as a screening test in
 5 three centres.

6 **MS RICHARDS:** Yes. Do you have any recollection of those
 7 plans?

8 **A.** Well, I know there was an intention to run at
 9 North London a period of testing there, and I think we
 10 could have -- they were conversant with using
 11 radioimmunoassay at the time because the hepatitis B
 12 surface antigen test was an RIA, so an RIA for
 13 a competitive RIA would have been doable. I think the
 14 issue is whether this would have been safe to do,
 15 testing in one centre without -- without making sure
 16 that the other centres were aware -- or unaware that
 17 this was being done, because of the danger of drawing
 18 people in who you -- with the best will in the world,
 19 you didn't want to attract people from the risk groups,
 20 on the basis of having a test, when they may not have
 21 a test in one centre but in another centre.

22 **Q.** Then the reference there to this "depending on the
 23 ability to scale up production of reagents for the
 24 test", in terms of scaling up, your statement tells us,
 25 and this is a general question now rather than this

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1 correct at that time. Leave aside whether it happened
 2 or not, was it the case that the plan was to use the
 3 test, yours and Dr Weiss' test, for all blood donors at
 4 the North London centre for three months plus?

5 **A.** I'm not sure how much I would have supported that,
 6 because of the danger of drawing people in on the basis
 7 of one centre having testing therefore all centres
 8 having testing, that "We'll go get our AIDS tests at --
 9 somewhere -- "at Chelmsford", and it wasn't
 10 North London.

11 I know there was an intention to run it at
 12 North London, and it would have had to have been run
 13 covertly for the danger of not wishing to draw people
 14 into the transfusion service to a centre where it wasn't
 15 being done. I'm not quite sure how to answer your
 16 question.

17 **SIR BRIAN LANGSTAFF:** I think it may help if you read on the
 18 next sentence.

19 **MS RICHARDS:** "As the donor population for North London RTC
 20 is drawn from an area where the incidence of AIDS
 21 patients and possibly contacts is currently the highest
 22 in the UK, it is hoped to extend the screening tests to
 23 at least two other RTCs. This, of course, depends on
 24 our ability to scale up production of reagents for the
 25 test, using either the virus isolate from Dr Gallo's

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1 specific point in time, that scaling up would require
 2 access to a sufficient volume of serum and a secure and
 3 steady supply of HIV culture supernatant?

4 **A.** Yes.

5 **Q.** And it is right to understand that it was the latter
 6 that was more problematic than the former?

7 **A.** We had a great deal of voluntary support from young men
 8 in the risk groups to provide their plasma for this
 9 purpose. It was quite a remarkable option to have this
 10 support from -- as I say, it would have been the
 11 beginning of the Terence Higgins Trust, before it was
 12 called such.

13 It would have been interesting to have to do this.
 14 It would have been requiring quite a lot of
 15 radioactivity handling, and that would have been
 16 containable. It was -- looking back on it now, I'm not
 17 sure what the reason for any delay in this would have
 18 been. It would have been the supply of the antigen. It
 19 would have been the radioimmunoassay, it could have been
 20 concern about not bringing people into the transfusion
 21 centre for testing until one had got coherent testing
 22 elsewhere. You know, this -- I have to apologise but,
 23 at this distance in time, I'm not sure which of those
 24 were the reasons for delaying.

25 **Q.** If we perhaps just look at one further document.

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1 So if we move matters on to October 1984, to
2 DHSC0002323_009.

3 This is another internal Department of Health
4 document. It is from Dr Smithies again. It is dated
5 19 October and it is to Dr Alderslade, and we can see it
6 is in response to a request from the Chief Medical
7 Officer. Not a document you would have seen
8 contemporaneously.

9 The answer to question A from Dr Smithies is this:

10 "Only pilot studies have so far been carried out on
11 blood donors at the North London Transfusion Centre
12 which have shown no evidence to antibody to HTLV-III in
13 the 1,004 donors tested."

14 That is presumably a reference to the donors tested
15 as part of the study reported in The Lancet, because
16 the numbers match? Would that be right?

17 **A.** Yes.

18 **Q.** Then it says:

19 "The test is based on HTLV-III antigen acquired in
20 the course of exchanges common to scientists between
21 Dr Gallo and Professor Weiss. Professor Weiss and
22 Dr Tedder, who together developed the test, did not feel
23 that it was appropriate to greatly increase the amount
24 of test reagent available without agreement from the
25 US authorities to the increased use of the antigen.

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1 been held up by the requirements of HSE [that's
2 Health and Safety Executive] and the activity of trade
3 unionists. The laboratory at the Middlesex Hospital is
4 expected to be finally commissioned by the end of this
5 week. It is hoped that sufficient reagent will then be
6 made available by the beginning of November to test all
7 the blood donors at the North London Transfusion
8 Centre."

9 Then we have in brackets the reference to not
10 wanting to make that too public, for the reason you have
11 already outlined.

12 Do you have any recollection now of what was being
13 said here about the HSE and trade unionists?

14 **A.** Yes, I do. It was an entirely avoidable phenomenon.

15 What had happened was the exhaust from the testing and
16 from virus washing goes through dry-out through pump and
17 put into a discard pot, and the discard pot has a vent,
18 and the vent was meant to be connected to a pipe which
19 sat inside a class 1 cabinet. For reasons beyond my
20 knowledge now, the safety pot was not put in the class 1
21 cabinet but was left outside it, and the
22 Health and Safety Executive, understandably, took
23 extreme umbrage to this and declared it as a major
24 exercise, a major contamination, "Everybody has been
25 infected".

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1 The antigen has been licensed to five US pharmaceutical
2 companies for development of tests and a vaccine.

3 Dr Abrams wrote on 10 August to the Assistant Secretary
4 for Health (in the US) requesting permission for the use
5 of the US antigen in order to enable us to use the test
6 more widely. We have had no reply."

7 Before we look at the next paragraph, I think you
8 say in your statement you don't think this is quite
9 right?

10 **A.** What I'm questioning is what the pressure was on to have
11 more antigen for which testing and where. The
12 difficulty -- and I think that the response from the
13 American side was that it was given for research
14 purposes only, not for quasi commercial use.

15 Now, whether you would consider expanding this
16 seroprevalence study as quasi commercial use, I think
17 the Americans would and we would not consider that
18 a commercial exercise, it is just that we needed to have
19 the data.

20 Does that answer your question?

21 **Q.** Yes. You have dealt with this in more detail in your
22 statement, we don't need to put it up on screen, but you
23 comment on this in paragraph 186 of your statement.

24 Then the second paragraph says this:

25 "In the meantime the production of test reagent has

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1 We eventually tested everybody and nobody had been
2 infected, but it was a salutary exercise of just how
3 careful you have to be to maintain people's aspirations
4 of safety. No harm was done because the safety pot was
5 there, but nevertheless, because it wasn't in the right
6 place, we had a -- I don't know what you would call
7 it -- a category 3 style investigation and slapped
8 wrists all round. It was an unpleasant exercise.

9 **MS RICHARDS:** Sir, I think that's probably the right time to
10 pause because I have got a number of further documents
11 to explore with Professor Tedder, just chronologically
12 taking the story through to '85, but we can do that in
13 the morning.

14 **SIR BRIAN LANGSTAFF:** Yes, it is.

15 The one question which arises out of this, there may
16 be an unanswered question in some people's minds as to
17 the activity of trade unionists. Is that the trade
18 unions being concerned about the safety risk posed by
19 the safety bottle, so associated with HSE, or is it
20 something different?

21 **A.** It was the health and safety representatives in the
22 department, who were also trade unionists, but I think
23 that was coincidental, that they were people who were
24 particularly worried about working conditions and
25 colleagues and the safe, and therefore that incorporated

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1 safety. So it is no criticism of trade unionists, it
 2 was actually, I think, an overreaction, but
 3 understandable, by the Health and Safety Executives, who
 4 happened to be trade unionists. But that was
 5 coincidental.

6 **SIR BRIAN LANGSTAFF:** And what excited this activity was --
 7 is it the same incident you have just described?

8 **A.** Sorry?

9 **SIR BRIAN LANGSTAFF:** What gave rise to this activity, this
 10 concern, was the same incident that --

11 **A.** It was recognising the safety bottle was not in the
 12 cabinet, it was outside the cabinet. The fact that it
 13 was collecting anything, and there wasn't anything to
 14 collect anyway, was nevertheless slapped wrist and
 15 justifiable anxiety. And I learnt if you are going to
 16 put a bottle in the safety cabinet, you put it in the
 17 safety cabinet.

18 You know, I don't criticise. It was an error which
 19 was made but was not an accident.

20 **SIR BRIAN LANGSTAFF:** Thank you. On that note, I think we
 21 will end for the day and come back at 10.00 am tomorrow,
 22 if you would. 10.00 am.

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

24 (4.04 pm)

25 (Adjourned until 10.00 am on Friday, 14 October 2022)

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